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Antimicrobial resistance in the environment: ethical considerations for policy

Davide Fumagalli



UNIVERSITY OF GOTHENBURG

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To my Mother and my Father

Abstract

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This thesis contributes to the field of public health ethics by examining the ethical challenges posed by antimicrobial resistance (AMR) in the environment, with a particular focus on those that are relevant to policymaking. While ethical discussions of AMR have largely concentrated on human and clinical dimensions, the role of the environment has been underappreciated. Including the environmental dimension in the debate broadens both the ethical analysis and the scope of potential interventions, raising new questions about responsibilities for addressing AMR-related harms and about fairness in implementing AMR policy. This thesis explores how these issues connect the problem of AMR with broader philosophical issues concerning distributive justice, collective harm, the allocation of remedial obligations, and the justification of liberty-limiting state intervention.

The thesis analyses the case of the consumption of meat and dairy from antibiotic-intensive farming as a driver of AMR from the perspective of the harm principle. In particular, the thesis argues that consuming these products meaningfully contributes to AMR and increases related health risks and that this provides sufficient grounds to justify state intervention to limit such consumption.

Moreover, the thesis examines the role of the principle of least restrictiveness in AMR policy and critiques additive interpretations of this principle. Drawing on a pluralistic public health ethics framework, it argues that a policy's restrictiveness should be judged by the depth of its impact on the individuals most affected rather than by the aggregate extent of the restrictions it imposes on everyone in a population.

Additionally, focusing on the case of AMR-driving pharmaceutical pollution from human use, the thesis argues in favour of the introduction of forward-looking considerations when allocating duties to address such pollution. Specifically, it advocates allocating such duties based on how interventions can effectively prevent harm, regardless of various actors' causal contributions to or moral responsibility for the harm in question.

The thesis further examines the market approval process for human pharmaceuticals as a means of mitigating AMR-driving pharmaceutical pollution and, consequently, reducing the related public health risks. It outlines several possible frameworks for integrating environmental considerations into this process, and argues that more stringent oversight is necessary while avoiding the potential downsides of overly restrictive measures.

Finally, the thesis considers AMR as a sustainability challenge, understood as a challenge of intergenerational justice, and proposes adopting a sustainability principle as a normative guide for distributing resources in publicly funded health systems.

Taken together, these arguments show that addressing the environmental aspects of antimicrobial resistance calls for ethically grounded judgment to navigate the competing normative demands that AMR inevitably involves.

List of Papers

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II. Fumagalli D. (2024). Antimicrobial resistance, one health interventions and the least restrictive alternative principle. *Public health ethics*, Volume 17 (1-2), 5–10,

III. Malmqvist, E., Fumagalli, D., Munthe, C., & Larsson, D. G. J. (2023). Pharmaceutical Pollution from Human Use and the Polluter Pays Principle. *Public health ethics*, 16(2), 152–164.

IV. Fumagalli D. (2024) Environmental risk and market approval for human pharmaceuticals. *Monash bioethics review*.

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1. Introduction

Antimicrobials—including antibiotics, antivirals, antifungals, and antiparasitics—are medicines used to prevent and treat infectious diseases in humans, animals, and plants. After prolonged or excessive exposure to antimicrobial substances, bacteria, viruses, fungi, and parasites might no longer respond to these medicines, becoming resistant (World Health Organisation, 2015). This can translate into severe health risks for patients by making certain infections substantially harder to treat, if not untreatable. Additionally, antimicrobial resistance (AMR) makes some medical procedures, such as complex surgeries, or treatments, such as chemotherapy, substantially more dangerous because of potential infections.

As a result, AMR is recognised as a major threat to human health by numerous organisations and researchers (WHO, 2015; 2021; Inter-Agency Coordination Group, 2019; Prestinaci et al., 2015; US Centers for Disease Control and Prevention, 2019). It is estimated that in 2021 alone, 4.71 million deaths were associated with bacterial AMR, with 1.14 million deaths directly attributable to bacterial AMR (Murray et al., 2022). It has been estimated that by 2050, the yearly global mortality burden associated with AMR will be 8.22 million (6.85–9.65), with AMR being directly responsible for 1.91 million deaths (Naghavi et al., 2024).

Traditionally, research on AMR has focused on identifying its drivers and assessing its impact within healthcare and agricultural settings. However, recent developments have drawn increasing attention to its environmental dimensions, highlighting the role of specific environments—such as waterways and sewage systems tied to healthcare facilities, pharmaceutical manufacturing sites, and industrial farms—as key hotspots for the emergence and spread of AMR. I will explore this aspect in greater detail later in this chapter.

Given the scale of AMR-related harms, various interventions have been implemented and proposed, such as targeting the misuse and overprescription of antibiotics in healthcare systems (also called antibiotic stewardship practices), encouraging the innovation and development of new antibiotics, as well as the surveillance of producers and other key actors, such as healthcare providers. Antibiotic stewardship policies, for example, encourage more conservative prescription practices among general practitioners, while other types of

interventions introduced bans on the use of antimicrobials as growth promoters in farming or as a prophylactic, except under very limited circumstances (EC, 1831/2003; EC, 2019/6). Furthermore, other interventions focus on improving antimicrobial availability, where resistance is primarily driven by inadequate access to proper treatment (Karvanen et al., 2024; Lancet, 2024).

Since these interventions often require considerable resources and could significantly impact the everyday lives of patients and other stakeholders, several ethical questions arise. AMR is strongly correlated with antibiotic use; this raises questions about whether and under what conditions it is justifiable for practitioners to withhold antibiotic treatment, particularly if withholding treatment exposes patients to higher health risks. In agriculture, where antibiotics are extensively used to promote animal growth and prevent infection, the transition to AMR-conscious farming practices involves ethical concerns about what interventions can balance public health goals with the interests of producers and consumers (Anomaly, 2009). For instance, introducing a use-based tax on antibiotic use in healthcare systems or taxing meat products has been proposed as a policy tool to reduce antibiotic use (Giubilini, 2019).

AMR also represents a global challenge, with its effects disproportionately affecting low- and middle-income countries (LMICs), where resistance-related deaths are the most prevalent. This raises broader questions of global distributive justice, such as the duties of high-income countries (HICs) in combating AMR on a global scale and how patent regulations for antibiotics might be restructured to improve access in LMICs. Additionally, AMR raises questions of intergenerational justice, given its potential to compromise future generations' access to effective medical treatment. Addressing AMR sustainability requires weighing the interests of current patients, who may face higher health risks or longer recovery times if antibiotic use is restricted, against the needs of future generations (Mendelson et al., 2024).

Beyond these aspects, the ethical considerations related to the environmental aspects of AMR have been under-addressed in AMR ethics. For example, considering how pharmaceutical pollution can drive AMR, what interventions would be justifiable to incentivise more sustainable development and production of pharmaceuticals without unduly jeopardising patients' access to drugs?

This thesis contributes to the field of public health ethics, with a particular focus on the ethics of AMR, by examining the moral responsibilities of various actors in relation to AMR in the environment and assessing the moral justifications

for regulating their behaviour. In doing so, it aims to address gaps in the ethical discourse on AMR, particularly those concerning its environmental drivers.

To address these gaps, the thesis proceeds in five key areas. First, the thesis engages with the discussion on individual consumer responsibility for collective harms, evaluating the moral grounds for potential state intervention targeting individual food consumption choices. Second, it investigates the application of the principle of least restrictiveness in the design of public health policies targeting environmental sources of AMR, a question often overlooked in existing frameworks. Third, the thesis analyses the distribution of responsibility to mitigate the release of pharmaceutical residues (including antimicrobial residues) into the environment through human use, an area where conventional interpretations of the Polluter Pays Principle (PPP) face important limitations. Fourth, it evaluates the ethical justifications for integrating environmental risk considerations into the pharmaceutical market approval process and healthcare resources allocation frameworks. Fifth, it highlights the aspects of AMR that render it a sustainability threat, framing the ethical dimensions of the problem and delineating the range of interests implicated by it.

1.1 Structure of the thesis

Each of the articles included in this thesis addresses one of these issues (Munthe et al., 2021; Fumagalli, 2022; Malmqvist et al., 2023; Fumagalli, 2024a; Fumagalli, 2024b). In addition to the articles, the thesis consists of six chapters that place the articles into context, elaborate specific themes, and discuss the general significance and limitations of their findings. The remainder of this first chapter provides an overview of the issue of AMR, with a focus on its environmental aspects and their impact on public health. It also explains how ethical considerations play a role in addressing AMR in the environment and situates the thesis within broader academic discussions.

The second chapter explores AMR by drawing comparisons to climate change, highlighting the ethical significance of individual actions in cases where no single person's contribution makes a (significant) difference to the overall problem. It specifically examines the justification for restricting individual consumer choices under the harm principle (HP).

The third chapter looks at different interpretations of the idea that public health measures should be minimally restrictive. It discusses how this idea influences

decisions about policies aimed at reducing environmental factors that contribute to AMR.

The fourth chapter examines how responsibility for addressing pharmaceutical pollution from human use and associated harms (including AMR-related ones) should be shared among different actors (pharmaceutical companies, government, water operators, healthcare system actors, and individual patients). In doing so, it critically evaluates the PPP, a common approach to assigning responsibility for environmental harms, and highlights its limitations in tackling AMR.

The fifth chapter considers the issue of sustainable antibiotic use and its relationship to AMR. It argues that sustainable antibiotic use presents a unique challenge, one that is exacerbated by common approaches to allocating medical resources. To address this, the chapter suggests adding a sustainability principle to guide decisions on antibiotic use and distribution, among other things.

Finally, the sixth chapter summarises the main findings of the thesis, explores their implications for public health and AMR policy, and outlines directions for future research. The six chapters are then followed by summaries of the articles included in this thesis.

1.2 Antimicrobial resistance

AMR occurs when microorganisms, such as bacteria, viruses, fungi, and parasites, develop mechanisms that make antimicrobial drugs ineffective. Although resistance can arise naturally over time through genetic changes, its prevalence has been significantly accelerated by human activities, particularly the widespread and often inappropriate use of antimicrobials in healthcare, agriculture, and animal husbandry and pharmaceutical pollution from antimicrobial production and use (Davies & Davies, 2010).

Antimicrobials are compounds that inhibit or kill microbes, including bacteria, fungi, and viruses (Sanderson et al., 2018). Among them, antibiotics are the most widely used, particularly in human and veterinary medicine. In fact, much of the ethical debate I engage with in this thesis uses the term "antibiotic resistance", which refers to the development of resistance to that specific class of antimicrobials. Antibiotics are categorised into different classes based on their mechanisms of action and target bacteria. For instance, beta-lactams, such as penicillins and cephalosporins, disrupt bacterial cell wall synthesis, whereas macrolides, such as erythromycin, inhibit protein synthesis. Beyond antibiotics, other substances also have antimicrobial properties, including alcohol-based

disinfectants, phenols, iodine, chlorine, and certain pharmaceuticals (McDonnell & Russell, 1999; Karkman et al., 2019; dos Santos Ribeiro et al., 2019; Mackul'ak et al., 2019).

Bacteria develop resistance through two primary mechanisms: vertical and horizontal gene transfer. Vertical gene transfer occurs when random mutations arise within a bacterial strain and are then inherited by subsequent generations, leading to increased resistance over time. Horizontal gene transfer, on the other hand, allows bacteria to acquire resistance genes from different species—including both prokaryotic and eukaryotic organisms—through processes such as transformation, conjugation, and transduction (Rogers, 2019). This ability to share genetic material between species and populations enables resistance to spread rapidly, particularly in environments with high exposure to antimicrobial substances.

Hospitals have long been recognised as key settings for the emergence of resistant bacteria, commonly referred to as nosocomial infections, with notable examples including *Acinetobacter baumannii, Klebsiella pneumoniae*, and *Clostridium difficile* (Davies & Davies, 2010). Additionally, in intensive farming and agriculture, antimicrobials have been widely used not only for treating infections but also as prophylactic or for growth promotion. Their routine and repeated subtherapeutic use create selective pressures that promote resistance directly in farms.

More recent research highlights the role of environments surrounding these key hotspots (i.e. healthcare systems, animal farms, and pharmaceutical manufacturing plants) and, in particular, sewage systems, in driving AMR (Finley et al., 2013; Larsson & Flach, 2021). Understanding these mechanisms and the role of different environments in fostering AMR is essential for addressing the growing public health threat it poses.

1.3 AMR in the environment

Three primary pathways for AMR-inducing substances to enter the environment have been identified and pose specific, unaddressed challenges. These pathways allow for pharmaceutical residues, in particular active pharmaceutical ingredients (APIs), as well as antimicrobial compounds and resistant genes, to spread into ecosystems, impacting wildlife and causing contamination in diverse ecological settings, particularly waterways and wastewater systems, through excretions from both animal and human pharmaceutical use (Larsson & Flach, 2021; Munthe & Larsson, 2026).

A first pathway that contributes to the development and spread of resistance via environmental routes is antibiotic use in animal farming, aquaculture, and agriculture.[1] The excretion of antibiotics from animals treated with these substances enters the environment, contaminating surrounding soils and waterways and spreading resistant pathogens or resistance genes (Larsson & Flach, 2022). Although the use of antibiotics as growth promoters has been banned in markets such as the European Union and the United States, the legacy of this practice has already left high levels of resistance in the targeted antibiotic classes. The antibiotics used today for disease prevention or treatment in livestock continue to impact the environment. Although regulation aimed at minimising this use has only recently been introduced in the European Union (EC, 2019/6), making it the global forerunner, there is still much to do. These may undergo zoonotic transmission, allowing them to infect humans (i.e. salmonellosis or bovine tuberculosis) (Morwal & Sharma, 2017). Second, resistance genes that have developed in animal pathogens can be transferred to human pathogens via horizontal gene transfer in shared environmental reservoirs. Both mechanisms represent significant transmission pathways for AMR between animals and humans and have been implicated in the emergence of resistant forms of diseases such as anthrax, brucellosis, listeriosis, leptospirosis, and campylobacteriosis (WHO, 2020).

AMR developing in farm environments can have far-reaching consequences beyond the immediate farming context. Resistant pathogens and genes originating in domestic animals can pose a threat not only to veterinary health systems, as resistant infections in livestock become harder and more expensive to manage, but also—through environmental exposure and potential transmission to human pathogens—to public health. In addition, such resistance can undermine the long-term sustainability of farms, increasing treatment costs, lowering productivity, and threatening the security of food systems. It should also be noted that wild animals, as such, are not particularly threatened by AMR, since they do not depend directly on effective antimicrobials for their health: it is the reliance on such a resource that makes AMR such a challenge (Larsson et al., 2023).

A second environmental pathway for AMR involves pollution resulting from human antibiotic use. Following therapeutic use, both in clinical settings and at the household level, active drug compounds are excreted and enter the sewage system. Whether treated or untreated, wastewater can become a highly favourable

[1] As an example, antimicrobial substances are used for the treatment of household pets or for pest control and plant cloning in agriculture.

environment for the development and spread of AMR. While therapeutic use in humans accounts for less than half of total global antibiotic consumption, the resulting pharmaceutical pollution nonetheless contributes substantially to AMR.

A third pathway is industrial pollution from pharmaceutical manufacturing plants, which occurs through the discharge of pharmaceutical waste into nearby surface waters and sewage. This pharmaceutical waste consists of APIs: any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product (EudraGMDP Glossary). APIs are highly capable of inducing resistance and are chemically stable, meaning that they can persist in the environment for extended periods to create a lasting selection pressure that favours resistant pathogens (Nijsingh et al., 2019; Larsson & Flach, 2021).

1.4 Interventions to manage AMR

AMR is a growing global health challenge that requires a multifaceted approach. Littman (2014) and Littman et al. (2015) describe AMR as a "super-wicked" ethical problem due to its urgency, the entanglement of stakeholders in its causes, the lack of centralised governance, and the human tendency to discount future risks. These complexities highlight the need for a multifaceted approach that can target the many different drivers of AMR, protect human and animal health, and facilitate the production of new antimicrobials, particularly within a One Health framework that considers the interconnectedness of human, animal, and environmental health (Dar et al., 2016; Nathan, 2024). Below, I distinguish between the following interventions and their goals: antibiotic stewardship, emission control, surveillance, and research and development (R&D).

Antibiotic stewardship: Antibiotic stewardship interventions can help reduce the relevance of AMR in human and veterinary healthcare by, broadly speaking, reducing the demand for antimicrobials in the first place: directly preventing people or animals from becoming infected reduces the amount of antimicrobials that will be used and needed. It is possible, for example, to limit the spread of resistant genes by ensuring good hygienic living conditions (i.e. functioning sewage systems, good quality housing, and clean air and water) and ensuring hygiene standards in healthcare systems and farms (Verveij & Bovenkerk, 2016; Fischer & Bild, 2019).

Another type of antibiotic stewardship practice regulates the use and prescription of antibiotics and other antimicrobials, ensuring the reduction of their overprescription in healthcare, or the limiting or banning of the prophylactic use of antibiotics in livestock farming. The European Union and the United States, for example, have already banned the use of antibiotics as growth promoters in agriculture, and recent EU regulations have further restricted their use in veterinary medicine, bringing these policies in line with AMR-related environmental concerns (EU, 2019/6).

Public awareness campaigns can also help prevent AMR by informing patients about its risks and encouraging adherence to stewardship guidelines. Consumer labelling systems indicating antibiotic use in farming could further influence purchasing decisions, thus promoting more responsible agricultural practices, as well as ensuring that patients or farmers do not demand and clinicians and veterinarians do not prescribe antibiotics when they are not needed (O'Neill, 2016).

Emission control: Preventive strategies also extend to the management of pharmaceutical pollution, since that too can be AMR-inducing. Since particular environments, such as sewage systems, act as AMR catalysts, the improvement of filtration systems at wastewater treatment plants, healthcare facilities, and farms has been proposed. Adjusting packaging sizes for antimicrobials to ensure complete treatment courses and reducing pharmaceutical waste can further mitigate AMR risk (O'Neill, 2016). Additionally, sustainable procurement policies for pharmaceuticals and market-entry requirements could incorporate environmental considerations to limit AMR-driven pollution.

Surveillance: Surveillance is essential for monitoring and controlling pharmaceutical emissions and tracking the spread of AMR across various environments. Importantly, it identifies the routes for the spread of resistant bacteria and helps to plan interventions for limiting their impact (Laxminarayan et al., 2013; Bengtsson-Palme et al., 2017). For example, through surveillance, it is possible to gather antibiotic use data in both human and veterinary healthcare settings. This includes clinical prescription rates, over-the-counter use, and use in agriculture and aquaculture. Understanding usage patterns helps explain where resistance pressure is highest and can highlight targets for intervention (O'Neill, 2016). Additionally, surveillance data from clinical and veterinary samples can help monitor which bacteria are resistant to which drugs: this allows for a better depiction of how AMR affects patients and health systems, as well as

clarifying the incidence of cases with resistant infections among the patient population.

Finally, environmental surveillance measures can also include monitoring pharmaceutical manufacturing waste, agricultural runoff, and wastewater to assess the presence of resistant bacteria and antimicrobial residues. Strengthening surveillance efforts also facilitates early detection of emerging resistance patterns, enabling timely policy responses and more effective stewardship programs. Sewage surveillance, for example, allows researchers to gather relevant information by monitoring regional and temporal trends in resistance and could, furthermore, prove effective in LMICs, being less resource-demanding than traditional clinical surveillance systems (Aarestrup & Woolhouse, 2020; Karkman et al., 2020; Larsson & Flach, 2021).

R&D: A critical component of the fight against AMR is the development of new antimicrobials, which can be used in place of older ones that have become ineffective because of resistance. A major challenge in this area is that most of the actors in R&D are private companies, which often lack sufficient commercial incentives to invest in developing new antimicrobials for the following three reasons (O'Neill, 2016; Huemer et al., 2020). First, as resistance develops with use, the effectiveness of any new antibiotic inevitably declines over time, reducing its long-term market value. Second, stewardship policies designed to prolong the efficacy of new antibiotics also reduce their sales, further limiting profitability. Third, efforts to reduce the environmental impact of antimicrobial production may increase manufacturing costs, adding another financial burden to sustainable antibiotic development. Given that any new antibiotic will eventually become outdated, a comprehensive approach is required—one that combines the discovery of novel drugs with strategies for extending their effectiveness. This includes integrating stewardship policies, ensuring responsible antibiotic use in both medical and agricultural settings, and minimising environmental contamination.

When considering how effective an intervention might be, we should keep in mind that the primary contributors to AMR can differ from place to place, and as such, the preventive measures considered should account for that. In HICs and many middle-income countries (MICs), the primary contributors to AMR are the overprescription and misuse of antimicrobials in humans, coupled with the overuse of antibiotics in livestock and fish farming. In contrast, in low-income countries (LICs) and in some MICs, the main factors are poor access to antibiotic treatment (i.e. incomplete or shortened antibiotic treatments in

humans), inadequate infection control in healthcare settings, poor sanitation and hygiene, and insufficient regulation or surveillance of pharmaceutical waste from manufacturing processes (Karvanen et al., 2024). These differences highlight the need for tailored interventions that address the specific causes of AMR within each country's unique socioeconomic context.

All these interventions can have a significant impact on individuals and society, and they would likely necessitate trade-offs between the interests of different stakeholders, raising ethical issues that I will introduce in the next section.

1.5 The ethics of AMR: state of the art

Although the problem of AMR has long being acknowledged in many fields of research (medicine, environmental science, microbiology, and public health), a substantial ethical discussion started developing only in the last 10–15 years, making it a relatively new field (Littman & Viens, 2015; Hoffmann & Outterson, 2015; Munthe et al., 2019; Jamrozik & Selgelid, 2020; Johnson, 2024). This section introduces the debate in AMR ethics, divided into four central themes: (1) AMR as a tragedy of the commons, (2) AMR as collective harm, (3) distributive justice issues related to AMR, and (4) ethical aspects of AMR in the environment. Finally, this section introduces the gaps in the debate that this thesis aims to fill, with particular regard to the last of these themes.

1.5.1 AMR as a tragedy of the commons

Ever since the beginning of the ethical debate in this area, AMR and its ethical challenges have been taken to present a kind of collective action problem (Anomaly, 2010; Littman, 2014), known as the "tragedy of the commons", a term introduced in another context by Hardin (1968). A common is a "depletable resource whose use is shared by several parties" (Johnson, 2003, p. 271), and a "tragedy of the commons" describes situations in which each individual's rational self-interest leads them to overconsume or overuse such a resource, resulting in its depletion, which harms everyone—even though, paradoxically, everyone would be better off if each limited their use. In these situations, each person benefits in the short term from exploiting (or failing to restrain the use of) the resource, while also losing in the long term because everyone else also pursues that benefit. Consuming the resource is rational at the individual level because each individual stands to benefit personally, and nobody can avoid the resource's depletion by refraining on their own. However, on a collective level, the exercise of individual

rationality results in a highly undesirable outcome. This dynamic mirrors other collective action problems, such as the prisoner's dilemma, whereby individual rationality leads to collective irrationality. In practice, in such a situation, even if individuals are planning for the long term, they may still overexploit the resource if they believe others will do the same, making restraint seem disadvantageous. A popular example of a common is a shared pasture, which can be accessed by several farmers (Hardin, 1968). Each of them has a short-term interest in bringing additional animals to the pasture, but if they all did so, the ecosystem would collapse, endangering their livelihoods.[2] The assumption of AMR as a tragedy of the commons is important for this thesis in two ways: First, it connects the ethics of AMR to many environmental problems, which are understood in similar terms. Second, it links the environmental dimensions of AMR to a particular set of ethical tensions and challenges known to afflict tragedy of the commons-type collective action problems, as well as policy responses that seek to address these.

With regard to the specific nature of the tragedy of the commons challenge of AMR, Littman (2014) defined the pool of resources that we are talking about as "antibiotic efficacy". Individual patients have a short-term interest in accessing effective antimicrobials, such as antibiotics, but at the same time, they have a long-term interest in not undermining access to effective antimicrobials as time passes. It should also be noted that, unlike a standard case of tragedy of the commons, individual use of the resource might actually contribute to depleting the resource substantially. Unlike the commonly cited pasture scenario, where adding an extra animal to the herd may not immediately disrupt the ecosystem, each instance of antibiotic use can directly introduce or spread resistant bacteria to the host or the environment. Nevertheless, the problem arises because of the absence of coordination, meaning that individuals have little incentive not to access effective and available antimicrobials.

There are several ways of dealing with a tragedy of the commons; however, the most common solution is to regulate or reduce access to such resources. In the context of AMR, this can be performed via some kind of taxation or user fee, which disincentivises certain uses of the resource, or through stewardship practices, which, in some cases, directly deny access to it. Now, limiting access to goods such as effective drugs or certain foods can be especially problematic and needs justification; this is why the early debate in AMR ethics identified these themes quite rapidly.

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[2] Other real-world examples of tragedy of the commons are the access to sea resources and overfishing, or emission of greenhouse gasses and climate change.

In this regard, the notion of externality can be applied to farming and, in particular, to meat production and consumption; therefore, a debate on the ethical duties of consumers developed (Anomaly, 2009; Giubilini et al., 2017). The ethical considerations of AMR in farming are often based on the notion of harm: this includes harm to animals (through increasingly resistant bacterial strains), threats to farmers' livelihoods and risks to food system stability (via unsustainable market practices), threats to farm-adjacent ecosystems, and, finally, higher health risks for humans in case of zoonosis. These types of harms are often defined as externalities by economists: the effects of the production or consumption of a specific good on unconsenting third parties who are not themselves involved in these activities. Externalities are costs that are unaccounted for in the market (i.e. they happen "outside" the market) and are not reflected in the market price of the good in question (Mankiw, 2004; Varian, 2006).

The core idea behind these arguments is that meat consumers should bear the full costs of their choices—that is, internalise the externalities they impose on society; this is often taken to justify a tax. A tax could help shift consumer behaviour by reflecting the true societal costs of antibiotic-dependent farming. This perspective places responsibility for AMR-related health risks on individual consumers, much like the "carbon footprint" concept, and is also referred to as an "antimicrobial footprint" (Rosenblatt-Farell, 2009; Patrick & Hutchinson, 2009; Schwenkenbecher, 2014, 2020). Similarly, Duckenfield (2013) highlights the ethical concerns surrounding antibiotics as growth promoters in factory farming, noting that US regulatory efforts have been hindered by value conflicts among key stakeholders.[3] A more in-depth discussion of the ethics of antimicrobial use in farming can be found in Anomaly (2020b).

The notion of externalities is also relevant for antibiotic use in humans, especially in healthcare settings. As such, part of the AMR ethics debate identifies "trivial" antibiotic use in healthcare, considering in particular non-life-threatening infections in otherwise healthy individuals. This requires being able to identify and limit the cases of trivial, wasteful, or unnecessary antibiotic use, often focusing on individuals whose choices are suboptimal for conserving antibiotic effectiveness (i.e. consumers and practitioners). In this case, the patient should bear responsibility for "their contribution to the erosion of the common good", that

[3] When the article was published, European legislation already prohibited antibiotic use as growth promoters in farming in 2001 following calls from the WHO, while the US ended up endorsing similar regulation only later in the Summary Report On Antimicrobials Sold or Distributed for Use in Food-Producing Animals (US Food and Drug Administration, 2018).

is, antibiotic efficacy (Giubilini, 2019, p.1; Anomaly, 2013). In practice, this often warrants the introduction of what is called a "user tax" or user fee, which is used to remedy the harm that the user contributed to.

Besides appealing to the notion of harm to others, Giubilini (2013) also grounds his argument in the duty of easy rescue, which he understands along the lines of Scanlon's (1998) definition. When the costs for an individual are not excessively high, that individual has a moral responsibility to bear these costs to benefit others (including by helping to protect them from AMR-related harm). In particular, the idea is that "restrictive policies would be ethically justified because they would coerce individuals into fulfilling a moral obligation they independently have" (Giubilini & Savulescu, 2020, p. 141).[4]

Another established debate in AMR ethics revolves around the responsibilities that a general practitioner has in relation to their patients. Broadly speaking, a doctor's first responsibility is their patients' health. At the same time, given the correlation between antibiotic use and AMR, reducing antibiotic use and prescriptions also reduces the chances of more patients having to battle resistant infections. The notion of good, or not wasteful, antimicrobial use, then, seems to inherently imply a contraposition between individual and societal interests. This same clash is abundantly discussed in other areas of public health ethics (e.g. pandemic preparedness) (Dawson, 2011; Nijsingh et al., 2020; Hays et al., 2022; Savulescu & Giubilini, 2020; Rid et al., 2019). When antibiotics are prescribed or consumed, the immediate benefit is to the individual patient—curing their infection or enabling a necessary medical procedure—and foregoing an antibiotic treatment would in some cases have severe health risks for the patients. Foregoing non-crucial antibiotic use lowers the societal costs tied to AMR spread and reduces a significant challenge for public health systems. Not only would the patient incur potentially severe health risks, for which the practitioner would be responsible, but it may also put them at risk of treatment failure and relapse of the infection (which also implies a higher risk of it being resistant). As such, stewardship practices place a special responsibility on general practitioners and, more structurally, health systems to shift the health risks from the community to the individual.

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[4] A different formulation of the duty of easy rescue can be found in Singer (1972), and it implies that individuals might even have to commit to great sacrifices if the harm prevented is great enough. Needless to say, Scanlon's formulation of easy rescue is less demanding and, in the debate I am discussing here, Giubilini (2019) as well as Giubilini and Savulescu (2020), side with Scanlon.

1.5.2 AMR as a collective harm

The notion of collective harm captures situations where a damaging outcome results from the cumulative effect of many individual actions—none of which, on its own, appears to make a significant difference (Parfit, 1984; Kagan, 2011). This creates a moral tension, as individuals might feel justified in their action because of a perceived insignificance of their single contribution, and at the same time by doing so they make choices that collectively produce harmful consequences. Framing these scenarios as collective harms, rather than individual ones, challenges traditional models of moral responsibility by showing that large-scale harms can emerge from the uncoordinated actions of many, without any single agent being clearly morally liable for the outcome. Importantly, the role and responsibility of individuals in scenarios, such as climate change and carbon emissions, or specific cases of consumer responsibility (i.e. meat) were thoroughly discussed.

According to some authors, such as (Sinnot-Armstrong, 2005; Sandberg, 2011) the role of individuals is so negligible that it would be unjustified to consider individuals blameworthy, others such as Nefsky (2011, 2017; Pinkert, 2015; Broome, 2019) maintain the opposite, to hold them morally accountable for having "contributed" or helped to bring up a harmful consequence. While this type of framing is mostly known in the context of climate change, as seen in Nefsky (2011; 2017), this way of structuring the problem is recurrent in relation of AMR too (Littmann, 2014; Schwenkenbecher, 2020), and it becomes particularly relevant when trying to first identify AMR-related harms in society and successfully allocate and distribute the responsibility to remedy those harms.

1.5.3 AMR and distributive justice

Questions of fair access to effective antibiotics raise questions of justice if we focus on its distribution within a community, which can be local (i.e. within a state) or global, or over time, making it a discussion of intergenerational justice. These concerns increase when considering that the risks of contracting infections are unfairly distributed and can be heavily affected, and then worsened, by ones' economic status (Millar, 2012; Littmann, 2014; Willis & Chandler, 2019). A simple example of this can be found in the debate on stewardship practices that we already mentioned. Strict stewardship practices are more likely to be fair and justified only in certain contexts where the patient that is foregoing treatment can be easily supported: in the other cases, granting more stable access to effective medication might be simply more effective in reducing AMR health-related risks, and making

sure that people that are already worse off are not disproportionately affected by an intervention. The core problem raised by AMR is that worse-off individuals will carry more health risks because they struggle accessing effective treatments and, at the same time, they will be disproportionally affected by being sick (Littman, 2014). If we are considering the introduction of a tax on antibiotic use for otherwise healthy patients, a wealthier individual will generally be in a better position to withstand the effects of foregoing antibiotics and if they decided so, they would also be able to afford the extra cost of the treatment: both these choices would be harder for someone with less financial means which cannot but raise ethical concerns (Giubilini, 2017).

Reid (2020) and Millar (2020) discussed the ethical problems raised on a global level. In particular, the lack of access to effective antimicrobials, as well as other challenges in being able to complete antimicrobial therapy, inherently contributes to global inequalities exacerbating them. AMR disproportionately affects LMICs, where healthcare infrastructure, access to clean water, and infection control are weaker (Karvanen et al., 2024). Not being able to afford newer antibiotics, reliably accessing healthcare, and robust surveillance systems, LMICs face higher mortality rates due to resistant infections. This imbalance in access to effective treatments means that those least responsible for driving AMR often bear its worst consequences. Furthermore, resistant infections increase treatment costs, prolong hospital stays, and require more intensive care, making healthcare even less accessible for economically disadvantaged populations.

AMR threatens future generations and there is a risk that the current generations might exhaust effective medication, without finding new ones to replace them. If current generations leave AMR unaddressed via unsustainable practices, they will substantially undermine health access for future generations, creating a classic case of intergenerational injustice (Millar, 2011; Littman et al., 2015; Littmann et al., 2020; Littmann & Viens, 2015). What makes this such a complicated matter is that not only antibiotic misuse or pharmaceutical pollution drive AMR, but also normal clinical use. As such, slowing down AMR can be done only if the current generation incurs some type of cost, such as not using as much AMR-driving medication, or financing the development of new drugs: reducing AMR necessarily implies a tradeoff between the current and future generations in one form or another.

1.5.4 AMR ethics and the environment

The recognition of the environment as a key driver of AMR is relatively novel and while it has significantly expanded the preexisting ethical debate on AMR, there much more is left unaddressed. Environmental pathways — such as pharmaceutical emissions, agricultural runoff, and wastewater discharges — extend the problem of responsibility beyond the more traditional focus on clinical prescribing or individual misuse, raising questions about the role of actors such as pharmaceutical manufacturers, wastewater treatment facilities, and food producers (Munthe & Larsson, 2026). While the core ethical challenges, including questions of distributive justice, collective harms are not entirely new, the environmental perspective introduces different possible interventions and practical problems that widen the scope of the AMR ethics substantially. This section offers a short overview of the debate that has developed around it.

Interventions that address environmental aspects of AMR — such as stricter production controls, enhanced surveillance systems, or costly infrastructure upgrades — can be particularly challenging to implement on specific industries or communities, particularly in low- and middle-income contexts, which also happen to be the ones hit the hardest by increased rates of AMR (Munthe et al., 2021; Krockow & Tarrant, 2019; Peters et al., 2024; Sariola, 2024). It seems then that those most affected by AMR are often the least equipped to address its causes. Furthermore, if we consider pharmaceutical manufacturing in low- and middle-income countries, the local populations typically do not even directly benefit from the products that increase environmental pollution, while instead they incur in the health risks tied to rising AMR. These circumstances raise important questions about where the remedial responsibilities for addressing the problem should lie. It has been suggested that economically powerful, high-income countries, as major buyers in the global antibiotic market, have a moral responsibility to exert pressure on pharmaceutical producers to ensure greater transparency over supply chains and stricter environmental controls at production sites (Malmqvist & Munthe, 2020).

In some cases, these pressures might even lead manufacturers to withdraw from antibiotic production altogether, rather than investing in improving environmental practices. As a result, an ethical discussion around the trade-offs between long-term, sustainable access to antibiotics, and maintaining short-term access to healthcare was necessary (Nijsingh, 2019; McKenna, 2010; Morel et al., 2017). In particular, it was suggested that incentive-based strategies are

adopted, rather than strict bans or financial penalties (WHO, 2024b; Bergström, 2011; O'Neill, 2016; Laximanarayan et al., 2013).

An increasingly acknowledged aspect of AMR policy is the need for a One Health perspective, which emphasizes the interconnectedness of human, animal, and environmental health (WHO, 2015; EC, 2017; EC, 2022). The growing recognition of the environment as a driver of AMR has reinforced the relevance of this approach. Although a truly unanimous formulation of the notion of One Health was hardly agreed on, most authors broadly advocate for interdisciplinary cooperation across sectors and species, asserting that effective responses to health threats require collaboration among diverse actors and scientific fields (Coker et al., 2011; Zinsstag et al., 2011; Gibbs & Paul, 2014). In practice, however, implementing prevention strategies within this framework can involve trade-offs between core values—such as public health, environmental protection, privacy, animal welfare, and food safety (Verweij, 2011; Verweij & Van den Hoven, 2012). While it may seem appealing to prioritize safety and risk reduction, responsible policymaking must also recognize that risks cannot be fully eliminated and that precautionary actions often carry costs. As such, adopting a One Health approach while planning for AMR interventions, requires exploring the ethical implications of its principles against more traditional ones from public health ethics (Johnson & Matlock, 2023).

Finally, since one set of interventions relies on surveillance, some concerns related to the inequities in knowledge production and AMR monitoring capacity, especially the global gap in surveillance infrastructure (which can also prove a very effective way to combat the development of AMR). Improved global AMR surveillance, particularly through wastewater monitoring, could enhance local and global responses to AMR while reducing reliance on ethically sensitive personal health data (Peters et al., 2024; Aarestrup & Woolhouse, 2020).

To conclude, incorporating the environmental dimensions into AMR ethics debates allows a more complete representation of the actors involved with the development of AMR, and informs ethical considerations on the tradeoffs required by the necessary interventions. Questions of responsibility, justice, and risk balancing must now be addressed by focusing across complex global supply chains, local infrastructures, and surveillance systems. This means that considering the environmental drivers of AMR allows us to not only develop ethically justified policies, but effective ones.

1.5.5 Gaps in the research

Now that the relevance of environmental considerations to AMR ethics has been introduced, this section highlights some of the gaps in the literature that this thesis aims to fill.

The first contribution of this thesis is the expansion of the ethical discussion of harm and the responsibility of individuals for increasing AMR. As I mentioned earlier, a significant part of the debate on AMR ethics has focused on the nature of harm (Littman, 2014; Giubilini, 2013; Anomaly, 2019). This debate correlates the various uses of antibiotics (e.g. patients, farms) to some level of increased societal harm or risk. However, a crucial objection was left unaddressed. In fact, if it is even remotely possible to say that in collective harm cases, individuals do not contribute to changing any outcome, how could they be harming anybody with their actions? If so, how can state intervention affecting an individual involved in a collective harm case be justified? It should be noted that while I mostly focus on user tax in the case of meat and dairy products, these same arguments can be applied elsewhere in AMR ethics. For example, applying this objection to the AMR case implies that some of the interventions we considered before (taxing antimicrobial use in farming or healthcare) would make them unjustified: if an individual is not single-handedly causing the problem at all, they should not be held accountable for it.

This objection becomes even more problematic if we consider the environmental drivers of AMR, which, causally speaking, further dilute the relevance of each individual's contribution. In Fumagalli (2022), I consider a possible rebuttal to inconsequentialism in the AMR case, arguing that a user tax would be justified in virtue of preventing harm associated with the consumption of meat and dairy products. While the application of the HP (and the notion harm prevention) to this context is not entirely novel (Shwenkenbenker, 2020; Giubilini, 2018; Anomaly, 2019), the article contributes to the debate by offering additional arguments supporting the characterisation of AMR as a collective action problem and by offering additional objections to inconsequentialism (albeit limited to the case of AMR).

A second contribution of the thesis concerns the problem of balancing restrictions and the effectiveness of interventions in relation to the environmental drivers of AMR. Often, there is a claim that policy restrictiveness must be proportionate to its effectiveness. The general argument is that, among equally

effective policies, policymakers should prioritise the least restrictive alternative available.

Considering the environmental drivers of resistance enables the design of policies targeting AMR that can redistribute costs within society in different ways and restrict individual actions while doing so. Evaluating the different ways an intervention affects an individual's life enables planning for fairer AMR policies. For example, a tax on antibiotic use in farms will affect the purchasing power of a consumer, reducing their access to a specific type of food or diet. At the same time, introducing a tax on antibiotic use in healthcare settings will likely curtail access to a much more fundamental need in an already critical moment. Such measures may be more feasible for limiting access to goods like meat and dairy products, as these—while significant—are not as vital as access to healthcare. Missing out on a certain food product is unlikely to threaten someone's existence, whereas restricted access to healthcare can have severe, even life-threatening consequences. Re-evaluating the notion of restrictiveness in relation to the environmental drivers of AMR allows for spreading the costs of an intervention more fairly by allocating responsibilities across multiple layers of society rather than, for example, solely targeting individuals who access antimicrobials or antibiotics in healthcare. Therefore, the restrictiveness of such interventions must be reassessed and re-evaluated to account for a broader and more nuanced understanding of what restrictiveness entails (Fumagalli, 2024a).

A third contribution of the thesis concerns the allocation of remedial responsibility for pharmaceutical emissions from human use (Malmqvist et al., 2023). Pharmaceutical pollution from use is recognised as one of the drivers of AMR in the environment (Munthe & Larsson, 2025). Traditionally, in most pollution scenarios, responsibility for remedying contamination is attributed directly to those actors that contribute the most to the release of pollutants into the environment, following the intuitive PPP. Healthcare systems are among the greatest contributors to AMR in the environment; yet, they also play an essential societal role and may not be the best-positioned actors to reduce that pollution due to the lack of viable alternative medical practices (Malmqvist et al., 2023). Since healthcare institutions often lack realistic alternatives to preventing emissions without compromising patient care, placing full remedial responsibility on them risks eventually imposing ethically disproportionate burdens on the patients.

A fourth contribution of the thesis concerns the integration of environmental concerns—specifically those related to the manufacturing of human medicines—into the regulatory criteria for market approval. This article contributes to the

debate on regulating pharmaceutical manufacturing pollution by drawing on Nijsingh et al. (2020), who categorised possible avenues for pollution control, as well as pointing out the potential ethical trade-offs tied to the interventions. The focus here is to narrow down and highlight potential ethical trade-offs implied by eventual changes to regulation on market access, which is often recognised as one of the most consequential stages at which regulatory intervention can occur. Therefore, this contribution examines existing European pharmaceutical regulations, provides different alternatives to incorporate environmental considerations in the market access step, and, finally, explores their ethical implications.

A fifth and final contribution of the thesis concerns the debate on the sustainability of healthcare resource allocation (Munthe et al., 2020). This article builds on the existing discussion around sustainable antibiotic use (Millar, 2011; Littmann & Viens, 2015) but shifts the focus towards the normative criteria for allocating resources within healthcare systems. In particular, it identifies what are referred to as negative dynamics—long-term, harmful effects that may arise from how traditional allocation principles are applied in practice. Some of these widely used principles, while seemingly fair or efficient in the short term, can, in fact, exacerbate long-term costs and vulnerabilities within healthcare systems.

When applied to the context of AMR, this article argues that these dynamics may unintentionally accelerate resistance development by overlooking sustainability concerns. In response, the article puts forward arguments in favour of incorporating a sustainability principle into allocation frameworks. The aim is to mitigate these negative effects and promote more prudent, long-term planning—particularly in ways that help slow the progression of AMR.

2. AMR, collective harm and inconsequentialism

This chapter focuses on the problem of AMR as a case of collective harm resulting from consumer behaviour. As mentioned in the introductory section, farming and agriculture are among the main drivers for AMR in the environment. The animal industry keeps production costs for dairy and meat products lower by using antibiotics to treat animals, which allows these products to be accessible to more consumers. Two different but closely related questions need to be answered. Considering that each purchase of these products contributes, albeit by a small degree, to a market that progressively drives AMR, can consumers be considered morally accountable for AMR-related harm? How can a state intervention targeting or affecting consumer behaviour be justified? The first question asks whether consumers are responsible for their contributions to AMR, while the second one is about whether the state can justifiably restrict individual consumers' freedom to reduce this contribution.

This section will focus on the second of these two questions. In order to do that effectively, I will introduce the harm principle, explain how it applies to the AMR case, consider a popular objection to it called inconsequentialism, and, finally, respond to that objection.

2.1 The harm principle

There are several justifications for legitimising state intervention; however, the HP is the most widely embraced, or the least controversial, in the liberal tradition. A traditional formulation of HP can be found in J. S. Mill, On Liberty: "the only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others" (Mill, 1963, p. 223).

In this formulation, Mill's HP asserts that individuals are free to act as they wish—even if their actions are self-destructive or offend others—unless their conduct would likely cause substantial injury to someone else who has not agreed to bear that risk. If, for example, A threatens to intentionally physically assault B without their consent (which might be present in some specific cases, such as fighting sports), then, presumably, HP would justify a state imposing some

restrictions on A's action to prevent B from being harmed. Two conditions for applying this liberal principle are that the harm to be prevented is of a relevant enough magnitude and that the restriction of personal freedoms serves the goal of harm prevention sufficiently. Mill's formulation of HP focuses on harm done to others. Critics point out that in a complex society, few actions fail to impact others, making Mill's distinction between self-regarding and other-regarding conduct difficult to operationalise (Hart, 1963). Feinberg develops Mill's version of HP and expands it further by defining harm as "a setback to interests" resulting from wrongful acts, but this raises further questions about how to interpret a person's interests—whether in terms of desire-fulfilment, pleasure and pain, or objective goods (Feinberg, 1984).[5]

Other theorists, notably Raz (1986), propose that harm is best understood as a setback to autonomy, meaning a reduction in a person's prospects or valuable options. Importantly, Edwards (2014) emphasises the need for clarity when invoking the HP, since varying accounts of harm (which refer to interests, autonomy, or suffering, respectively) bring different normative implications and difficulties, such as whether the principle adequately justifies criminalisation or respects individual liberty. This conceptual complexity highlights the importance of clearly establishing that an action is genuinely harmful and that state intervention will be effective before restricting individual liberties in the name of the HP.

An example of how this principle might be applied is intervention around goods that present a risk to society, such as cigarettes or alcohol. In the case of cigarettes, second-hand smoke was identified as a meaningful risk factor for cardiovascular disease (Katz, 1997). The HP would justify interventions to limit second-hand smoke, such as prohibiting smoking in enclosed public spaces (e.g. bars, restaurants, or clubs) to mitigate health risks imposed on third parties without their consent. In the case of alcohol consumption, it notably reduces reflexes and substantially increases the risk of accidents while driving (Elvik, 2013; European Monitoring Centre for Drugs and Drug Addiction, 2012). HP justifies interventions that limit the amount of alcohol that can be consumed before driving to reduce the risk of accidents and possible resulting harm to others.

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[5] Additionally, unlike Mill, Feinberg will also maintain that state intervention can be justified by serious offense to others (Feinberg, 1984, p. 26). For more on what constitutes a setback of interests, see Fletcher (2016). For more on the role of utilitarianism as a grounding theory of value for the Harm principle see Sumner (2004), while objections to this can be found in Petersen (2020).

When operating under the HP, causal contribution is the requirement to justify limiting the consumers' choices. Anomaly (2009) justifies state interventions against individual meat consumers by applying HP and claiming that by purchasing meat, the consumer is contributing to AMR and, as such, to the "unintended suffering and death of thousands of people you'll never know" (Anomaly, 2020a, p.1). A seemingly harmless and possibly mundane action, such as buying some meat for dinner, contributes to harmful AMR-related outcomes simply because of the sheer number of people doing it. On its own, each of these purchases might not induce much of a change; however, if we consider the aggregated demand for cheap meat and dairy products, those small contributions encourage farming practices that induce AMR (Anomaly, 2020a). This type of phenomenon can be described as a case of collective harm (Cripps, 2011).

In the case of AMR and consumer-related harm, each purchase brings about consequences that are small enough to be easily negligible and hardly comparable to more standard cases of harm. In fact, what harm is a single consumer really causally responsible for, and is it enough to justify limiting that behaviour? How plausible is it to say that they harmed someone simply by purchasing some chicken?[6] The harm produced this way seems too small to warrant a state intervention, such as the introduction of a tax. This relatively intuitive claim highlights a philosophical problem called the "inefficacy problem" or inconsequentialism, which I describe in the next section.

2.2 Collective harm and inconsequentialism

Collective harms cases are cases in which people collectively cause a harm, yet each individual action does not, in itself, make a (meaningful) difference to that harm (Nefsky, 2012, p.1). To illustrate what this means, consider Nefsky's (2019) adaptation of Parfit's (1984) famous Harmless Torturers example:

> An electric shock machine with settings s0 to s1000 is hooked up to a thousand victims. At s0, there is no electric current. At s1, there is a non-zero current, but it is too small to be perceived. In general, each setting increases

[6] Several authors have argued that purchasing meat harms or directly contributes to practices that are harmful for non-human animals (Singer, 1975; Engel, 2000; Norcross, 2004; Jones, 2021). Interestingly enough, the relationship between meat consumption and contribution to harm is very tightly wound together; for more on it, consider Budolfson (2015) and Tyler & Sebo (2020). Here, I am mostly keeping an anthropocentric frame of analysis, which I will expand later in Chapter V, and, as such, I am here referring to harm to humans.

> the voltage by a miniscule amount, such that the difference between any two adjacent settings cannot be perceived. But after very many increases the victims would feel some pain, and by s1000 they would be in excruciating pain. The machine is now set to s0. There are a thousand people, each of whom is independently (without communication or coordination) given the opportunity to turn the dial up a single setting in exchange for $500. Suppose, for simplicity, that the dial-turn decisions are executed by the machine simultaneously: until time t-1 all the decisions are registered, and then at t, the settings change in response to these decisions. (Nefsky, 2019, p.6)

In this example, each individual action adds up in the torturing process by negligible, almost imperceptible contributions. If a single individual refused the $500 the final amount of perceived pain would not be different at all, and the victim would experience excruciating pain because of the amount of people who decided to dial up the setting in exchange for money: this makes this a case of collective harm. A real-world example of collective harm is climate change. In this case, each individual contributes to harmful outcomes in many ways such as dietary choices (i.e. eating meat), travel choices(i.e. traveling often by plane), or by simply heating their house (Vanderheiden, 2015; Nefsky, 2012).

It is possible to describe AMR as collective harm too. Anomaly (2009) and Giubilini et al. (2017) focus on the problem of antibiotic use in farming, where each consumer that purchases meat products contributes to a market that riles on unsustainable practices to the respect of AMR. Others such as Nefsky (2019) and Schwenkenbecher (2020) focus AMR as a broader phenomenon where aggregate antibiotic use (and misuse) contributes to reducing antimicrobial efficacy in clinical contexts.

A common observation is that the role of individuals in this type of scenarios is negligible: this is what gives rise to the "inefficacy problem" (Nefsky, 2019) or inconsequentialism (Sandberg, 2011). If an individual action truly makes no difference in changing the final result, and if it doesn't make the harm any worse, then it seems that the agent is not morally blameworthy (Sinot-Armstrong, 2005; Kingston & Sinnot-Armstrong, 2018).[7]As an example, let's consider here Sinnot-

[7] It is worth remembering that the debate on climate change and emissions focuses on the driver's moral responsibility. Since there is no contribution to the final harm (established in counterfactual terms of not making a difference), there cannot be moral responsibility (i.e. individuals have no responsibilities to refrain from any particular set of action that leads to climate change, such as Joyguzzling). My focus in this chapter is simpler. I simply want to ascertain to what degree individuals in collective harm problems contribute to the final harms, and if that can be enough to ground HP, focusing, of course, on AMR-related harm. The assessment of eventual moral responsibilities and, possibly, what duties might derive from them, will come later.

Armstrong's (2005) *Joyguzzling* example about collective harms and carbon emissions:

> It is Sunday, the sun is shining, and you decide to drive up the coast with a very polluting SUV just for the sheer pleasure of enjoying yourself. There is no particular reason to go on this car ride other than the pure pleasure of it (i.e. health or going to work).

Even if you decided to refrain from Joyguzzling, you would not contribute to reducing the harm created by climate change. Conversely, if you do joyguzzle you would not contribute to any harm, and would seem to have no reason to give up on your Sunday drive up the coast.

In the case of AMR, applying HP to consumers faces similar problems. Even if we accept that each individual plays a causal role in a market that drives AMR (and the harms that follow), their contribution is typically too small to be considered morally significant or to have caused any noticeable harm on its own.

It should be note here that the debate about inconsequentialism is largely concerned with the blameworthiness or moral responsibility of individuals involved in producing collective harms, and if they have any duty to refrain from that involvement. This issue should be differentiated from whether or not state intervention can be justified in restricting such behaviour. Notably, the incosequentialist problem arises in both areas, but I am here concerned with the latter. More specifically, HP states that if an individual's contributions are inconsequential to a harm and do not make any difference to it, then a state is not justified in imposing limitations to individual freedoms. In collective harm cases, inconsequentialism claims that individuals do not make a difference. Hence, HP cannot ground a state's limitation on individual freedoms in cases of collective harm cases.[8]

2.3 Answers to inconsequentialism

Following Nefsky (2019), I divide responses to inconsequentialism into two types. The first set of responses includes those that accept that individuals do not make a difference to the final harm but assert that they can still be acting wrongfully and be responsible for it. In other words, they claim that making a difference in the final outcome is not a prerequisite to being held accountable for participating in a

[8] Other principles, such as fairness, might warrant doing that. These will be discussed in the next chapter.

practice that is collectively harmful, even if, individually, they did not harm anybody. The second set of arguments, instead, simply rejects the assumption that individuals do not make a difference to the final harm that is collectively generated.

2.3.1 Wrong without difference-making

This section examines those arguments that claim that individuals can be held accountable even if their actions single-handedly did not make a difference to a specific harmful outcome.

First, Cripps's (2011) formulation is considered. According to this solution of the collective harm problem, an individual can be responsible for harm, even if they themselves do not individually make a difference, when they do the following:

> 1. acted in ways which, in aggregate, caused harm, and which they were aware (or could reasonably be expected to have foreseen) would, in aggregate, cause harm (although each only intentionally performed his own act);
>
> 2. they were all aware (or could reasonably expected to have foreseen) that there were enough others similarly placed (and so similarly motivated to act) for the combined actions to bring about the harm; and
>
> 3. the harm was collectively avoidable: by acting otherwise (which they could reasonably have done), the individuals making up the putative group could between them have avoided the harm (Cripps 2011, p. 174).

In this case, intentionality and awareness as being part of a group or collective play a crucial role in the individuals' accountability, and, as such, this makes things like media or awareness campaigns crucially important. If, on the one hand, individuals bear no responsibility for uninformed actions or outcomes they could not reasonably foresee, on the other hand, they become responsible for collective harmful behaviour if they were sufficiently informed about it. In practice, this can be a hard condition to satisfy, and it applies to all cases of collective harm, such as climate change or cases of consumer choice (e.g. fast fashion and sweatshops; animal products and carbon emissions). This approach accepts the inconsequentialist claim about individual contributions so much that causal responsibility for the harm is also shared. Individuals themselves bear responsibility only as part of the collective that contributed to the harm, not as single agents.

In this context, harm is a result of the collective's action, and as such, the duties to remedy it are also collective and do not fall on the individual per se. Therefore, what becomes relevant in this discussion is the moral responsibility of the

individuals, which can only be present if they are sufficiently aware or informed via information campaigns, for example. What matters most here is the intentionality behind the choice, rather than the effects of individual actions. As such, uninformed individuals cannot be held morally accountable for the harm they contribute to. With respect to AMR, the small contribution a consumer makes to the market by not purchasing a product cannot ground individual responsibility unless they are made aware of AMR's threat and how they would be contributing to it: this can be a hard requirement to fulfil in practice.

To bypass this requirement, Schwenkenbecher (2020) suggests using a more stringent formulation that holds individuals accountable by adopting Lichtenberg's (2010) account of responsibility. In particular, according to Lichtenberg, acting wrongly in collective harm cases can be done by knowingly contributing to set of actions that "depend on the joint effects of many people's actions" (Lichtenberg, 2010, p. 568) and in the "unfairness of acting inconsistently with how one thinks others ought to act" (Lichtenberg, 2010, p. 569). Lichtenberg's perspective emphasises a rule-based approach in which the wrongness of contributing to harm (e.g. AMR) does not depend on knowing whether enough other people are contributing to cause harm collectively. Instead, it is sufficient to know that, collectively, society should adopt a rule prohibiting harmful actions like antimicrobial misuse. As a result, individuals have a moral obligation to avoid such behaviours, even if they do not know for certain whether their own actions will directly cause resistance, because collective adherence to a rule against misuse is necessary to prevent harm at an aggregate level. Applying this to the AMR case means that knowingly overusing and misusing antibiotics whenever we believe that other people should refrain from them would make us part of the collective that is producing harm and should be considered something we ought to abstain from (Schwenkenbecher, 2020).

Second, I consider fairness-based approaches (Baatz, 2014), which claim that individuals in collective harm cases have a duty not to contribute to the emergence of harm by more than a certain share. Overshooting past that threshold is what makes their contribution harmful and morally wrong. In Joyguzzling, then, going on a car ride might not be intrinsically wrong, so long as the individual maintains their total greenhouse gas (GHG) emissions below their fair share. Joyguzzling could, if anything, be ill-advised, but not necessarily immoral: many important human activities need to produce at least a certain degree of GHGs (e.g. cooking, heating, travel to/from work). This means that an individual would be responsible for collectively caused harm only if they were to overshoot their fair share of

emissions. In other words, one could morally joyguzzle every day, provided they perhaps produce fewer emissions in other areas of their life.

Several challenges have been identified in making the notion of fair share operational (Kingston & Sinnot-Armstrong, 2018; Caney, 2012). Baatz (2014, 14; 2019) also recognised that it is not possible to specify "to what level individuals must reduce their emissions". To overcome this empirical challenge, Baatz (2014) suggests that an individual has a duty to generally lower their emissions so long as that is compatible with a decent life, even when a state or institutional regulation that would encourage cooperation is missing. Admittedly, this line of defence is grounded in the moral intuition that contributing to harm by generally producing possibly unnecessary or avoidable emissions is morally objectionable, even if those emissions are hard to track. What makes those emissions truly unnecessary has yet to be specified, especially since a single individual is powerless and cannot avoid them anyway (Sinnot-Armstrong, 2005). Emissions are wrongful not because they harm someone specifically or because they contribute to harm, but because an individual would behave unfairly towards other people.

A third objection to inconsequentialism in collective harm cases comes from virtue theories and other virtue-based approaches. Generally speaking, virtue ethicists rely on the idea that "an act is right if it is what a virtuous agent would do in the circumstances" (Hursthouse, 1991, 225). In that way, duties are not strictly defined as evaluations of an action's consequences but, rather, according to how much they align with a certain code of conduct or set of character traits (Sandler, 2009; Jamieson, 2009). Individuals are under a general obligation not to perform actions that express a vice or act in a manner opposite to virtuously. Therefore, if we consider moderation or respect for nature a virtue, certain acts, such as Joyguzzling or having chicken for dinner, will be considered immoral or vicious. That would reflect the vice of hypocrisy and not the virtue of integrity.The problem with this approach is that the notion of moral requirement that it seems to imply seems rather weak (Sinnot-Armstrong, 2005; Kingston & Sinnot-Armstrong, 2018). Intuitively, failing to perform a morally required action constitutes a moral wrong; however, it seems hard to prove that within virtue ethics, as shown in cases of supererogatory actions. Some acts or character traits may very well be appropriate, good, or ideal, but that does not always imply that failing to perform them constitutes a moral wrong. Consider, for example, the virtue of generosity and the intuition that a virtuous person must be generous and benevolent. In this scenario, a virtuous agent would always spontaneously donate to a charity in need the excess money they have, provided they see no better or

more virtuous use for it. Behaving virtuously implies behaving with benevolence and donating to that charity each time the occasion presents itself; however, this also conflicts with the intuition that this should be supererogatory rather than morally required. Furthermore, if that were true, not donating to a charity once would then be morally blameworthy, which feels counterintuitive. Again, this does not mean or imply that certain behaviours are not good, ideal, or generally desirable. It simply does not prove that they are morally required (Kingston & Sinnot-Armstrong, 2018).

These responses seek to establish that it is wrong to participate in collective harms by simply rejecting the assumption that difference-making is necessary for wrongdoing, arguing that individuals might very well be doing something objectionable despite the lack of immediate negative consequences stemming from their actions. However, this seems insufficient to justify interfering with those actions under HP. Many behaviours can be objectionable even if not particularly damaging to anyone, but this does not imply that states are necessarily justified in intervening against them: to justify interference under HP, we need actually to establish that, through individual contributions, someone will be harmed. The next section will do that.

2.3.2 Affirming difference-making.

There are two ways of framing the inconsequentialist problem (Gunnemyr, 2019). The first claims that, given the scale of the phenomenon, the individual contribution to aggregated harm is non-existent, while the second claims that the contribution is not morally relevant. These types of arguments seem to rely on a very intuitive, yet misguided understanding of causality. In order to apply HP to the problem of AMR, it is necessary to reject both formulations (Fumagalli, 2022).

Typically, the causal responsibility for a problem or harm is given to those actors that were particularly relevant in generating that outcome and, in particular, whose contribution was necessary and sufficient for that outcome. Consider, for example, a scenario where Person A throws a rock at a glass window, breaking it. In this simple experiment, if A did not throw the rock, the window would not break. A's actions are necessary and sufficient for the window to break. This way of reconstructing A's actions is the counterfactual analysis of causation (Lewis, 1973, 2000). In this scenario, it is easy to identify the specific source of the harm; hence, an eventual application of HP to this context is more intuitive. A threw the rock, and they will have to pay for the window that they broke.

There are cases, however, in which the application of a simple counterfactual understanding of causality leads to counterintuitive results because it is a lot harder to identify a clear-cut causal chain that allows the application of the HP. Consider a scenario where A is part of a thirty-person group that, for fun, throws rocks and bricks towards a big window, shattering it. A's contribution in this scenario here is not necessary at all, and they are not going to be able to prevent the window from breaking by simply not throwing their brick. It is true that even if A were to stay their hand, the window would shatter anyway because of the twenty-nine bricks thrown against it. A's throw needs to be necessary and sufficient for the breaking of the window to be considered one of its causes. Even if A did throw a brick against the window, for the simple occurrence of not being alone in doing so, they cannot be considered a cause of the event. This sounds like a counterintuitive result since we are certain of A's course of action.

I have clarified here that it is impossible to say that A is not part of the causal chain leading to an event where their action is redundant, such as collective harms. This argument, then, rejects the first formulation of inconsequentialism; therefore, it also allows us to claim that individuals in collective action scenarios, such as Joyguzzling and the purchase of meat products, should be considered a part of the causal chain that leads to the respective harms (e.g. climate-change-related harms, AMR-related harms). Unfortunately, this leaves inconsequentialism's more complex formulation still unaddressed, but I will go over that in the next section

2.3.3 Accounting for morally meaningful harm.

Even accepting that individuals are causally related to collective harm cases, it might very well be the case that their contributions are insufficient to create meaningful differences in the resulting harm (i.e. intensity or timing, in the case of climate change) (Kingston & Sinnot-Armstrong, 2018). That being the case, individual contributions might not, strictly speaking, be causally absent; however, since they do not make the problem any worse, they are effectively not harming anyone in a way that justifies restricting that behaviour. Going back to the broken window example, the absence of A's actions has to amount to making a difference in the final event for them to be responsible for anything. Perhaps the window would shatter differently and into fewer pieces, or perhaps the rest of the room behind the window would be damaged less. Similarly, for a consumer to be morally responsible and accountable for harm, not purchasing meat as often should lower

the number of animals being butchered or somehow lower the risk of increased AMR.

One way to account for these minute differences is to use the expected utility approach (EUA), which evaluates actions based on the value and probability of their outcomes. Generally speaking, EUA is a consequentialist account that maintains that one should pursue the course of actions that lead to a greater incremental expected utility, trading off even events that produce some negative value so long as the long-term effects are beneficial (Hammond, 1988; Briggs, 2014; Broome, 1991; Kagan, 2011).[9] An advantage of EUA is that, since it considers the expected consequences, it is a better tool for evaluating the complicated group mechanics that come up in collective harm cases: "it is expected good and expected harm, rather than actual good and actual harm, that contribute to determining what you ought to do" (Broome, 2019, p. 115). At the same time, the negative effects of an action are considered more broadly than in other cases. Therefore, for example, EUA, unlike other consequentialist approaches, evaluates not only the risk of possible harms coming from an action but also the severity of the consequences if that risk were to materialise.

In the case of AMR, bacteria qualitatively change, adapting to new environments and medications and increasingly withstanding antibiotics. Even though the odds of such a change are not particularly high or easy to track, I argue that they are meaningful. Once AMR develops, it brings about a new state of things, where even a mundane visit to the dentist can become not only more painful but also dangerous or even life-threatening due to an infection. Even if unlikely, these expected differences allow us to object to the inconsequentialist claims I introduced earlier. In particular, I argue that HP can justify the restriction of individual freedoms through state interventions in virtue of the expected negative consequences of purchasing meat and other animal products (Fumagalli, 2022).

2.4 Conclusions

This chapter introduced the application of HP to the problem of AMR. In order to do that, I needed to overcome the objection of inconsequentialism in cases of

[9] This account can be differentiated from standard consequentialism, which under some conditions can condemn acts that create short term negative disvalue in favour of long-term utility. For a more in-depth discussion of these topics see Kagan (2011), Hammond (1988), Portmore (2008), Morgan-Knapp & Goodman (2015).

collective harm. While one way to overcome this objection is to simply reject the core assumption of HP, i.e., that causing or risking harm is necessary for freedom-limiting state intervention, by appealing to other normative considerations (e.g. collective responsibility, fairness, virtues), I keep that assumption intact. First, I claim that it is implausible to think that individuals causally do not contribute to collective harm cases. Then, I reject the idea that these contributions are meaningless because any increase, or risk of increase, in AMR would substantially harm other people: as such, any risk of increasing it needs to be reduced. Consumers causally contribute to the problem of AMR in the environment via the purchase of animal products and, as such, they contribute to the resulting AMR-related harms.

The gravity of the long-term impacts of AMR development, as analysed through the EUA, supported the argument for individual consumer responsibility for AMR-related harm. A consumer, despite not being the single biggest contributor to AMR in farm environments, is participating in a chain of events that can be considered harmful. As such, applications of HP, similar to those used for cigarettes or alcohol, are justified.

3. Least restrictiveness and public health

As was mentioned in the introductory section, there are several ways in which antibiotic use can contribute to AMR. In the previous chapter, I mentioned how consumption of meat and dairy products, as well as the use of antibiotics in common household prescriptions and in hospitals, can contribute to AMR. The fact that HP can be applied in this context, however, should be taken cautiously. Even considering that HP might justify some intervention, it may very well be possible that further substantial justification would be needed for any particular intervention. For example, if we acknowledge that smoking can be hazardous for others around us (because of second-hand smoke), the HP would certainly justify some intervention. That being said, nothing up to now can inform us on what type of specific intervention would be legitimate and which one would not: intuitively, a state would not be justified in shooting down smokers one by one only to remedy or prevent the harm they contributed to (or health risks they might impose on others). Once we establish that an intervention is needed, we still need to establish what it may entail specifically, as well as what other conditions need to be satisfied, for a Public Health policy to be justified.

3.1 Pluralism in public health

Typically, most authors argue in favour of a pluralist approach, which balances several moral principles against each other in order to guide decision-making in public health interventions (Kass, 2001; Wilkinson & Savulescu, 2018; Persad, 2021).[10] While it is common to use different names to reference these principles, I will use the following ones: effectiveness, fairness, and restrictiveness. Even recognising that one should adopt a pluralist approach, it is possible to rank the

[10] Among many others, see also Denier (2005), Childress and Bernheim (2008), Daniels (2011), and Grill & Dawson (2017). It should be noted that in this extensive debate, all the authors mentioned frame each of these principles differently. My main goal here is simply to introduce the concepts used and what a pluralist approach in Public Health Ethics might imply, as well as presenting some of the most widely endorsed principles.

possible policy alternatives differently, according to which principle is given normative priority. Ranking the effectiveness of an intervention as more relevant than its fairness or its restrictiveness will lead to radically different results. The rest of this section will introduce these concepts, focusing in particular on restrictiveness. First is *effectiveness*. This principle backs up the idea that an intervention needs to bring about an established outcome. An intervention needs to be supported by data and needs to plausibly be effective in bringing about the expected social benefit, or at least bringing society sufficiently closer to the agreed outcome. Therefore, intuitively, for a policy to be justifiable, it is necessary to estimate that it will actually make a difference when it is implemented. The expected differences will define how effective the intervention will be. A large part of the debate attributes *effectiveness*, the highest normative priority, since, intuitively, the reason why Public Health interventions are there in the first place is because they improve a population's health. Granted that a Public Health goal is necessary and deemed relevant, an intervention that would not achieve it or bring society somewhat closer to its target would simply be a bad tool. Secondly comes *fairness*.

A policy needs to be implemented in a procedurally fair way, as well as distributing benefits and burdens fairly in society. This implies that, for example, a policy aiming at increasing water quality will need to do so transversally so that most individuals will be equally affected by it; alternatively, educational programs on cardiac risk need to be set up in such a way that they will not have exclusive targets, leaving out minorities, which would also be at risk.

The final principle is *restrictiveness*. Once established that a policy can achieve its goals and that it can do so fairly, one needs to evaluate its potential costs, drawbacks, and limitations. The policymaker should consider the drawbacks and burdens of the policy, and, once identified, one should consider whether there are any ways to minimise them. Consider the example made before in this section about "reducing" the smoking population. An intervention may very well be incredibly effective, but society may incur an incredibly high cost because of risks to bodily autonomy and self-determination, risks to privacy and confidentiality, or risks to justice, if, for example, public health practitioners propose targeting public health interventions only to certain groups. On the other hand, it is often hard to structure an intervention that is somewhat effective without it impacting populations' lives at least to some degree. Because of these reasons, *restrictiveness* is often evaluated among comparably effective policy alternatives, preferably picking the least intrusive one among these alternatives (Selgelid, 2009). The other side of

the coin is that the harder it is to justify interventions via considerations of fairness or effectiveness, the more restrictive they prove to be.

As an example, consider the Nuffield Council of Bioethics (NBC, 2007) "intervention ladder", a proposed tool for policymakers that facilitates the ranking of different types of policy interventions:

> The first and least-intrusive step on the ladder is to do nothing, or at most monitor the situation. The most intrusive is to legislate in such a way as to restrict freedoms significantly, either for some groups of the population or the population as a whole, in order to achieve gains in population health. The higher the rung on the ladder at which the policy maker intervenes, the stronger the justification has to be. (NCB, 2007, pp. 41-42)

The tool ranks the policy options in order of how restrictive they would be for an individual. Therefore, for example, if two policy alternatives have similar goals of reducing the smoking population, the best policy is the one that will achieve that goal by interfering the least with personal freedoms. Similarly, consider the following quote from Kass (2001, p. 1779):

> As a rule of thumb, the greater the burdens posed by a program—for example, in terms of cost, constraints on liberty, or targeting particular, already vulnerable segments of the population—the stronger the evidence must be to demonstrate that the program will achieve its goals.

3.2 Interpreting restrictiveness

It is possible to interpret the notion of *restrictiveness* in two ways. A standard interpretation of restrictiveness refers to how a policy will impact society on an aggregate level (Denier, 2005). In this consequentialist framing, *restrictiveness* is a function of the amount of people hit by a policy and the gravity of the restriction affecting them (i.e. if a policy requires drastic life changes from the majority of population such as it would be the case for forcible quarantine to prevent spread of a virus). In other words, the level of *restrictiveness* of an intervention depends both on how many people will be affected by it and how much they are affected. This way to frame *restrictiveness* remains very intuitive and valuable, however it is prone to ignore distributive problems since it doesn't consider how some individuals will be disproportionally affected by such a policy.

Alternatively, the *restrictiveness* of a policy can be understood as a function of how deeply it would impact those individuals that would be affected the most by it. By comparison, this framing would evaluate the severity of the impact of an

intervention, or the changes and adaptations it could require from individuals, to be morally relevant whereas the overall amount of people it would target is not.

Notably, which of these two interpretations one prefers will be informed by one's position on the more fundamental normative issue of aggregation (i.e. whether and how we should weigh together benefits or burdens for different individuals). Some philosophers argue that avoiding many small inconveniences to a large number of people can justify imposing a significant burden on a few, while others reject this logic. Those who accept aggregation, typically utilitarians (Chao, 2015), may find more restrictive interventions justified if they reduce overall harm, in line with the first interpretation of restrictiveness, whereas others, including contractualists, stress that serious individual burdens cannot be outweighed by the sum of minor benefits, in line with the second interpretation (Scanlon11 1982, 1998).[11]

Fumagalli (2024a), endorses the second interpretation of restrictiveness, and rejects an argument that assumes the first interpretation. A key reason for favoring the second interpretation of restrictiveness—which focuses on minimizing restrictions for those most burdened by them—is grounded in a fundamental principle often emphasized in public health ethics: fairness. This principle is often understood to prioritize the well-being of the worst off or most vulnerable members of society over aggregate benefits to populations. It reflects the ethical requirement that interventions should not disproportionately impose costs or burdens on individuals, or groups, least able to bear them, thus protecting those who face greater social, economic, or health disadvantages. As such, fairness is often incorporated as foundational principle in public health policies, as a mean to safeguard the interests of marginalized or disadvantaged populations, and counteracting systemic inequities (Kass, 2001; Persad, et al. 2009; Lewis et al., 2023; Pu et al., 2021).

Endorsing a broader interpretation of *restrictiveness* in public health interventions also likely allows to support One Health-type interventions, since they excel in distributing the burdens of an intervention across multiple societal layers: doing so also maintains effectiveness while reducing the weight each restriction will have on the individuals that will be affected the most. For instance, promoting access to clean water, enhancing sewage systems, and educating communities about pathogen transmission are measures that improve public

[11] See also Parfit (2001), Nagel (1987), Kagan (1992), and Rawls (1971) for differing views on balancing competing claims.

health with less societal burden. A One Health framework, when effective, provides flexibility in cost distribution, making it a fairer policymaking option.

4. Remedial responsibilities for AMR in the environment

AMR raises important ethical questions about responsibility—both in terms of how the problem emerged and, crucially, whose responsibility it is to do something about it. The distinction between backwards-looking responsibility, which concerns blame or liability for past actions, and forward-looking responsibility, which focuses on obligations to act going forward, can be particularly useful in this regard (Miller, 2001; Young, 2011; French & Weinstein, 2014). While both notions are relevant to AMR ethics, this chapter focuses on forward-looking responsibility: identifying who holds special responsibilities to mitigate or remedy the harms associated with AMR, particularly in light of the challenges posed by its collective nature. This chapter introduces the notion of forward-looking responsibility and the related debate on climate-change-related harms. Finally, it discusses how remedial responsibilities can be attributed in the AMR context.

4.1 Defining forward looking responsibility

Forward-looking responsibility refers to the duties or obligations that agents—whether individuals, collectives, or institutions—have regarding future actions aimed at preventing harm, rectifying injustices, or promoting beneficial outcomes. Unlike backwards-looking responsibility, which focuses on attributing blame or praise for past actions, forward-looking responsibility emphasises what agents ought to do moving forward (Miller, 2007). Remedial responsibility is a particular type of forward-looking responsibility, which implies that an individual has a "special obligation to put the bad situation right, in other words to be picked out, either individually or along with others, as having a responsibility towards the deprived or suffering party that is not shared equally among all agents" (Miller, 2001, p. 454).

A commonly used principle to allocate remedial responsibility is causal contribution: responsibility to remedy a harm is to be attributed to those actors who had a central role in creating it in the first place. However, several authors highlighted the limits of grounding remedial responsibility solely in causal

contribution, particularly in collective harm scenarios (Miller, 2001, 2007; Isaacs, 2011; Smiley, 2014). The main challenge is identifying to whom to attribute remedial responsibilities: the causal chain may be too complex to single out an individual or group, and the responsible party may lack the means to remedy the harm, or may not even be alive if the harm is actualised only many years after their contribution. These authors have argued for a pluralistic approach, in which different principles—such as causal contribution, moral responsibility, capacity, benefit, and community membership—are weighed together depending on the particular problem at hand. Forward-looking responsibility is thus often conceived as a broad concept, encompassing multiple values and normative considerations.

For example, Isaacs (2011) shows how *causal* responsibility can still play a role without collapsing the distinction between backwards- and forward-looking accounts. Likewise, Smiley (2014) suggests that rather than treating one principle as primary, we should integrate multiple criteria into a pluralist framework for assigning forward-looking collective responsibility. Here, theorists such as Isaacs (2014) have argued that we can assign forward-looking responsibilities based on several principles: *causal* responsibility, *moral* responsibility, *capacity*-based responsibility, *benefit*-based responsibility, and *community*-based responsibility.

As mentioned before, a main advantage of contribution or *causal* responsibility is that it is intuitively appealing that those who caused the problem should help fix it. However, in many collective action problems (like AMR or climate change), causal contribution is diffuse across many actors, making it difficult to assign in practice. In such cases, causal responsibility cannot do all the normative work, but it may still support other principles. For example, Miller (2001) suggests that in some cases, an actor who is causally responsible for a harm might even have a final (i.e. long-term) responsibility to repay those who intervened immediately, prompted by the other principles. The notion of moral responsibility is connected with that of *causal* responsibility. For backwards-looking moral responsibility to be attributed, however, causal contribution by itself is usually considered insufficient. Two further conditions that are typically taken to be necessary are control and awareness. Therefore, for an individual to be morally responsible for a harm, it is not only necessary that they contributed causally to creating it but also that they did so voluntarily while being aware of the consequences of their actions.[12] Once these further conditions are satisfied, an individual may carry forward-looking

[12] For more on the problem of control, voluntariness of action, and moral responsibility see Dennett (1984) and Shepherd (2014). For the debate on awareness and moral responsibility see instead Wieland & Robichaud (2017) and Zimmerman (1997).

remedial responsibility in virtue of having knowingly and voluntarily contributed to the harm.

Besides causal and moral responsibility, a further principle is the capacity or ability to pay. Here, the idea is that those with the power or resources to address harm have strong reasons to act, especially where others cannot. Miller (2001) and Goodin (1998) see capacity as a pragmatic and justice-sensitive principle, particularly in emergencies or urgent crises, by attributing responsibility to those who are particularly well placed to remedy a harm (in some cases, the agent who caused the harm is not the agent who is now able to remedy it in practice). It should be considered that assigning responsibility based solely on capacity risks unfair results, too. Overburdening the capable may deprive them of valuable resources, and it may also fail to discourage reckless behaviours. As such, relying only on someone's ability to pay does not seem to incentivise avoiding unnecessary harm particularly well. Beneficiary pays maintains that even if an actor did not directly cause harm, they might still bear responsibility if they unjustly benefited from harmful practices (Page, 2012). This principle is particularly useful when tracing past advantages derived from systemic injustices or global inequality (e.g. how some nations benefit disproportionately from trade). However, benefit can be hard to measure and, at the same time, may overlap with both causal responsibility (i.e. the cause of harm and the recipient of benefit often align) and capacity (i.e. someone who benefited from a harm may have increased capacity to remedy it). Still, in contexts like historical pollution or pharmaceutical overuse, it can help extend responsibility to actors who might otherwise be excluded.

A community principle introduces a relational dimension to responsibility. It applies when agents share ties, such as national, professional, or institutional, with those harmed. This can explain, for instance, why HICs may have special obligations towards former colonies, why state institutions may have special obligations to citizens, or why healthcare institutions might be required to take on more of the burden in tackling AMR. Often, this principle is used to morally anchor obligations that might seem too demanding under the other three principles (Miller, 2001).

There is an extended debate about how we should weigh the various principles involved in assigning remedial responsibility against each other. This is important since the weight given to each principle can lead to markedly different outcomes.

Another debated issue is the justification of the principles. For instance, Duus-Otterström (2014, pp. 451–452) notes that the ability to pay principle (APP) relies

on contested moral assumptions, such as the idea that the wealthy have a special duty to assist those in need. Additionally, Mintz-Woo (2021) maintains that if an actor's ability to pay increases because of commendable activities (like reducing consumption or production), then those who act responsibly might paradoxically face greater financial burdens. This could unintentionally discourage beneficial behaviours crucial for remedying the problem at hand (e.g. climate change or AMR), complicating the straightforward application of the principle despite its intuitive appeal. Whether one accepts this principle often depends on one's broader view of (global) distributive justice. Those who believe that global justice demands greater equality are more likely to endorse proposals that place the burden of responsibility primarily on the most advantaged, rather than on the world's poorest. For more on this, see Caney (2005, 2010).

Others, like Marion Smiley (2014), argue that a richer pluralist account should take into account not only justice-based but also outcome-based considerations—bridging towards consequentialist justifications for forward-looking responsibility. It has been suggested by Smiley (2014) and Miller (2001) that instead of treating one of them as primary and the others as secondary, we bring all of them together into a pluralistic normative account of forward-looking collective responsibility, adjusting different principles according to the different practical problems and the related necessities.

4.2 Climate change-related harms and remedial responsibilities

Questions of justice regarding remedial duties emerge in climate ethics. Several arguments have been raised against using a sole principle, such as the PPP (which relies on the capacity principle), to allocate those responsibilities: some objections focus on practical challenges to assess who "the polluter" might be, while others focus on denying their moral responsibility. First, some argue it is unfair to hold agents liable for emissions if they were excusably ignorant of their harmful effects—especially in the past (i.e. they do not have remedial responsibilities since, despite being causally responsible, they are not morally responsible). However, this objection weakens over time when we consider historical emissions: for several decades, the consequences of greenhouse gas emissions have been widely known, and claims of ignorance are increasingly implausible (Singer, 2002; Gosseries, 2004).

A second objection points out that many historical emitters are no longer alive. PPP, then, appears to assign responsibility to a large extent to people who cannot take it up because they do not exist. One response is to treat agents as collectives (e.g. states) so that if country X polluted in the past, it should bear the cost now (Neumayer, 2000; Shue, 2014; Gosseries, 2004).

A third concern arises from justice to the global poor. If people must emit to attain a minimally decent standard of living, it may be unjust to make them pay emission costs, particularly when doing so would push them below that threshold (Caney, 2005). This concern has broader implications: if we excuse developing countries today from bearing emission costs due to their poverty, consistency may also require tolerating those emissions produced by now-affluent countries during their earlier stages of development.

As mentioned earlier in this chapter, given the challenges facing the PPP, many argue that it should be supplemented with additional principles. A possible alternative grounds remedial responsibility on the bearer's financial capacity (i.e. the APP): the greater the ability to pay, the greater the share of the burden (Shue, 2014; Moellendorf, 2014). Critics argue that this principle severs the link between payment and responsibility, as it disregards both causal contribution and benefit.

Another such proposal is the Beneficiary Pays Principle, which holds that agents should contribute to remediation because, and to the extent that, they have benefited from emissions-generating activities (Page, 2012). This principle, however, raises important questions. First, its scope is unclear: is it intended only to address cases where the PPP fails, such as historical emissions by deceased agents, or does it apply more broadly (Duus-Otterström, 2014)? If we think that the poor should be exempt from burdens under the PPP to preserve a decent standard of living, the same concern applies here.

These concerns support the pluralistic approach that was highlighted earlier, which maintains that questions of who should pay cannot be separated from broader moral considerations, such as whether individuals have a right to a minimum or equal standard of living, and practical ones, such as how urgent the matters at hand are and what are the most effective solutions available.

4.3 Remedial responsibility in the AMR context

Like climate change, AMR is a complex, collective problem involving many actors across sectors and regions. Different drivers of AMR pose somewhat different questions of remedial responsibility. It is, therefore, useful to distinguish between different drivers to clarify how principles of remedial responsibility might be applied.

First, we consider antibiotic use in healthcare a driver of AMR. Attributing responsibility based solely on contribution—such as the PPP would do—can unfairly burden healthcare providers who, despite their causal role, often lack viable alternatives and may face financial or operational strain if held solely accountable. Attributing responsibility only through PPP risks threatening essential medical services without a broader systemic support, and to reduce that risk, it is justifiable to use other principles. Another example of AMR-driving environments is wastewater. These are known hotspots for the development and spread of resistant bacteria, especially those surrounding healthcare systems or big cities, or households: this is due, among other things, to pharmaceutical pollution related to antibiotic use. Effective mitigation might involve the installation of advanced filtration systems directly adjacent to healthcare structures, the wastewater treatment plants, or stricter controls on hospital and household pharmaceutical discharge (Boxall et al., 2012; Pruden et al., 2013; OECD, 2019; Directive EU, 2024/3019). Different principles might spread the costs for these interventions differently in society, raising the question of who bears a remedial duty for them.

I will now focus on environmental pollution from use as an AMR driver: while healthcare providers, drug manufacturing, and animal farming industry directly relate to pollution generation, states and large companies generally have more financial means to address it. Additionally, a community-based responsibility approach can single out local actors, such as water treatment operators or municipal authorities, who directly manage wastewater and have an interest and duty to protect community health.

Several important actors, including the European Parliament and the European Commission (Directive EU, 2024/3019), have recently endorsed the PPP as the basis for attributing remedial responsibility in this area. This principle mandates that those responsible for pollution bear the costs associated with preventing, controlling, and remedying environmental damage. It aims to internalise environmental costs, ensuring that polluters are held financially

accountable for their actions. In Malmqvist et al. (2023), we argue against the application of the PPP as the sole basis for responsibility in this area, raising four objections: the indeterminacy problem, the costs of avoiding pollution, the inability of polluting actors to behave differently, and excusable ignorance.

The first objection concerns the difficulty of identifying polluters clearly within the complex network of actors involved in healthcare and pharmaceutical production. In the case of pharmaceutical pollution, responsibility is diffused across manufacturers, distributors, regulatory agencies, healthcare systems, prescribers, and patients. This complexity creates serious epistemic and moral uncertainty regarding who should be held accountable. Furthermore, the problem is amplified by the EU's interpretation of the PPP, which includes both active pollution and failure to prevent pollution (Hinteregger, 2008). This extension makes it possible to classify actors such as water treatment operators as polluters by omission. As a result, the PPP struggles to offer clear and fair guidance on assigning responsibility in this highly entangled causal landscape.

The second objection focuses on the principle's insensitivity to the relative costs of pollution mitigation. The PPP assigns burdens solely based on pollution contribution, without regard to how costly it would be for each actor to reduce their impact. However, in practice, interventions vary widely in cost and feasibility. For instance, upgrading wastewater treatment plants may be less burdensome than restricting the use or development of certain drugs—measures that could jeopardise patient health. Furthermore, some actors, such as healthcare systems or economically vulnerable patients, may face competing resource demands that make cost-bearing disproportionate or unjust. These disparities show that the PPP alone may lead to inefficient or ethically problematic management decisions if it ignores comparative cost-effectiveness and ability to pay.

The third argument targeting the fairness of applying the PPP is that it would eventually risk placing a burden on patients, who are excusably unaware of the pollution they contribute to and likely do not have many viable alternatives. Patients typically rely on expert advice when taking medications and cannot be expected to understand or evaluate the environmental impact of their prescriptions. Holding them responsible—whether directly (e.g. by pricing drugs according to their pollution level) or indirectly (e.g. by restricting access due to upstream interventions)—seems unfair given their lack of informed agency. As said before, this objection is less applicable to institutional actors or professionals, like prescribers, but it raises serious ethical concerns about placing burdens on individuals who lack both the knowledge and the power to alter their

contribution to pollution in meaningful ways. As such, the excusable ignorance objection challenges both the direct and indirect imposition of burdens on patients under PPP.

Therefore, these arguments stress that the bulk of the weight of the interventions is not borne by patients but by those with greater resources and institutional capabilities—such as wealthy states or wastewater operators—regardless of their past involvement (Malmqvist et al., 2023). A similar conclusion could also be reached by applying the community principle: e.g. water operators could be argued to have a special pre-existing duty towards the people who use their service to grant them available and safe drinking water and should, therefore, contribute to financing wastewater treatment upgrades.

However, the hybrid ethical framework defended by Malmqvist et al. (2023), which combines the PPP and the APP, also implies that the pharmaceutical industry holds remedial responsibility for pharmaceutical pollution. In Fumagalli (2024b), I discuss one way to operationalise this responsibility, with regard to pollution from both the use and manufacturing of medicines, namely by imposing environmental requirements on pharmaceutical companies during the drug approval process.

However, this approach also comes with its own challenges, relating to fair access to medicines and the effective reduction of health risks, which I also explore. The article critiques the current lack of stringent environmental risk assessment (ERA) requirements for market entry, arguing that stricter ERA integration could help reduce AMR drivers. Currently, producers are not clearly obligated to provide ERAs, and when they are submitted, the standards are vague or insufficient. Strict interventions might prove practically hard to implement and must balance environmental protection with safeguarding patient access. Overly rigid regulations could unintentionally restrict access to essential medicines—including antibiotics—by deterring market participation.

Therefore, interventions for combating AMR need to balance stewardship and sustainability goals with practical obstacles. Gradual regulatory transitions and integrated approaches—rather than abrupt, uncompromising interventions—offer more ethically robust and effective paths forward. The next chapter will expand on how sustainability in antibiotic policy connects with long-term health rights and environmental stewardship.

This approach reflects a broader ethical challenge: how do we implement policies that protect antibiotics as a vital resource for the future without imposing disproportionate burdens on present-day patients and health systems? Addressing

this challenge requires integrating long-term stewardship, equitable access, and environmental responsibility.

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5. AMR, sustainability and intergenerational justice

The concept of sustainability is central to recent ethical and policy debates, particularly those concerning climate change and other environmental problems. In general, sustainability refers to the imperative to manage resources in ways that avoid their depletion, thereby maintaining the stability and functioning of systems, human and ecological, over time. Although the term can be applied in various contexts, such as with respect to economic models, it is most abundantly used in discussions of our obligations to future generations, in particular in relation to global environmental policy, e.g., regarding the management of climate change. A key moment in the institutionalisation of sustainability discourse was the Brundtland Report, which emphasised development that "meets the needs of the present without compromising the ability of future generations to meet their own needs" (Bruntland, 1987). Given that future patients' access to effective medication and treatment can be compromised by high levels of resistance to antibiotics, AMR presents itself as a problem of sustainability.

5.1 Framing sustainability

The notion of sustainability can be understood in two different ways: anthropocentric and ecocentric. These are two examples of ethical frameworks that define what matters morally and how different interests can be justifiably traded off against each other. The former emphasises human well-being and continuity, which it normatively prioritises above other things. In this framework, an intervention is sustainable if it advances or protects future humans' interests, even if, by doing so, it sacrifices a substantial part of the rest of the ecosystem. The latter view claims that the environment should be considered part of the moral circle, that is, something that possesses an inherent value independent of human

interests. Therefore, failing to consider the interests of environmental entities would be unjustified (Taylor, 1986; Schmidt, 2015; Resnik, 2009).[13]

This distinction is relevant because, in practice, endorsing anthropocentric and ecocentric views can inform action and sustainability-focused interventions in radically different ways. For the former, achieving sustainability might likely imply finding ways of satisfying human needs reliably and efficiently over time, while for the latter, it might more likely mean documenting and protecting the health of an ecosystem, even if it means lowering the quality of life for humans or having them bear some cost.

For simplicity, this chapter does not discuss which of these perspectives might be more justified in general but simply assumes a broadly anthropocentric framework. The main rationale behind this choice is that the policy debates on AMR implicitly endorse such a framework already. An additional rationale is that leading experts on the environmental dimension of AMR have pointed out that AMR is not, as such, a threat to the environment, but rather a part of it that becomes a problem via its effects on human health systems (Munthe & Larsson, 2026). Although considering the environment is crucial to understanding AMR and its related ethical problems, in this chapter, environmental factors and effects are, therefore, considered only instrumentally in relation to the aim of achieving sustainable human health. Therefore, I focus on AMR sustainability for humans and public health, analysing its ethical problems and competing interests, interpreting sustainability within a loosely anthropocentric perspective.[14]

The sustainability problem presented by AMR can be conceptualised as a problem of intergenerational distributive justice (Millar, 2011; Littman, 2014). Among other things, intergenerational distributive justice asks whether, and on what grounds, current generations hold obligations to future people—specifically regarding the preservation of conditions that will make life worth living or even possible for them (Steiner 1983; Roberts and Wasserman 2009; Page, 2007, 2008). Rawls (1971) offers a foundational account of intergenerational justice, introducing the "just savings" principle, which seeks to ensure that the needs and

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13 For a more extensive review of how different ethical approaches might inform ethical considerations and policymaking around climate change, environment and health, see Timmerman et al (2024).

14 Admittedly achieving or maintaining human health is truly challenging without considering and including environmental sustainability considerations: for example climate change can severely threaten the quality of life of an individual or undermine their life expectancy directly. For more on the relation between sustainability and public health ethics see Richie (2019; 2021), Verweij & Ossebaard (2024), and Sheather et al. (2023), Munthe (2026).

well-being of future generations are not neglected simply because they do not yet exist. According to this principle, each generation is morally obliged to maintain "the conditions needed to establish and to preserve a just basic structure over time" (Rawls, 2001, p. 159). This entails preserving sufficient societal resources so that future citizens inherit a just society—characterised by institutional stability, basic liberties, fair equality of opportunity, and social cooperation. The concern for justice continues to focus on the least advantaged in the current generation, but Rawls emphasises that distributive (synchronic) and saving (diachronic) aspects are not separate rules; rather, they form a single principle with two interconnected dimensions, guiding continued improvement in the position of the least advantaged (Atta, 2009; Gosseries, 2001). Following Rawls's just savings principle, the debate has evolved to ask the following question: what exactly should be saved or preserved to ensure justice across generations? This question concerns the currency of intergenerational justice—the fundamental good or quality that must be maintained over time (Gosseries, 2024). As in the general debate about distributive justice, different currencies have been proposed, including welfare, resources, and capabilities (Cohen, 1989; Goodin, 1995; Page, 2007).

Aside from what good or "currency" is relevant, another question for theories of intergenerational justice concerns how those goods are to be distributed across time. Three of the most influential distributive principles—egalitarianism, prioritarianism, and sufficientarianism—offer different answers to this question.

Egalitarianism contends that relative differences between persons with respect to the relevant currency (including those between present and future generations) matter morally and ought to be, in principle, eliminated or reduced (Scanlon 2005, 6). For example, presently living people might be said to treat future generations unjustly if their decisions cause future people to experience lower levels of well-being, possess fewer resources, or enjoy fewer capabilities than their own contemporaries. Equal distribution in the currency of justice should seek to diminish or avoid such discrepancies.

Prioritarianism shifts the focus from strict equality to the moral priority of improving the situation of those who are worst off. According to this principle, benefits for the least advantaged—whether within a generation or spanning generations—should be given extra weight in distributive choices (Parfit, 1997, 213; Wolf, 2009, p. 373). Attas (2009) describes Rawls' difference principle as prioritarian in this sense, arguing that distributive and saving aspects of justice constitute "a single trans-generational difference principle" that advances the position of the least advantaged across time. The prioritarian view emphasises that

increasing the well-being of the worst off is more morally important than raising the average or ensuring strict equality within or between generations.

Sufficientarianism introduces the idea of a threshold: what truly matters is not comparative positions or absolute priority but whether each person in each generation enjoys a level of the relevant good above some minimally acceptable standard (Casal, 2007; Shields, 2012, 2016). On this view, justice is achieved when all individuals reach sufficiency—that is, having "enough"—rather than when they have equal amounts of the relevant good or when the worst-off benefit the most. Policies are evaluated not necessarily by how well they reduce disparities, but by the extent to which they ensure everyone, present and future, is not left below an ethically defensible standard.[15]

A particularly influential view is the capability approach, developed by Sen (1980) and expanded by Nussbaum (2006), which combines a sufficientarian distributive principle with the specific currency of capabilities.

This notion emphasises that justice requires ensuring that individuals have sufficient access to the key fundamental freedoms and capabilities needed for their flourishing, including health. Sen's capability approach highlights health as a foundational capability enabling individuals to pursue goals, participate in society, and achieve dignity. Protecting and sustaining health translates to sustaining freedom and real opportunities over time. Therefore, health is both an intrinsic good and an instrumental condition for the exercise of other capabilities necessary for a life of human dignity and flourishing (Sen, 1980). Nussbaum (2006, p. 76) includes health explicitly among her ten central capabilities, emphasising that "being able to live to the end of a human life of normal length; not dying prematurely, or before one's life is so reduced as to be not worth living" is fundamental. Other capabilities—such as practical reason, imagination, emotional attachments, and autonomy—also crucially depend on health since reduced mental or physical functioning can significantly limit them. For example, mental health issues, like dementia or substance abuse, reduce autonomy and practical reasoning ability, which healthcare systems have a responsibility to address. Thus, in this broadly sufficientarian framework, a core obligation of present generations towards future ones is ensuring that future people can reasonably satisfy their

[15] There is significant debate about what, if any, concern remains for those already above it, and whether justice is indifferent to inequalities existing above this minimum. Distinctions also arise between single-threshold models, multiple thresholds (e.g. for basic needs and flourishing), and different criteria for how to distribute resources to those below or near the threshold. For more against the notion of threshold see (Arneson 1999, 2000), and for a rejection of these claims see (Crisp, 2003; Shields 2012).

health needs, and as a result of that, have the required capacity to live meaningful lives, exercise autonomy, and enjoy well-being.

The capability approach is particularly well-suited for addressing AMR because it explicitly frames health as a fundamental currency of justice—crucial both intrinsically and instrumentally for supporting other central human freedoms and opportunities. This framework captures not only the importance of preserving health itself but also the broader implications of health limitations on autonomy, practical reasoning, and social participation. Such dimensions are especially relevant in the context of AMR, since this challenge—as described in section 1.5.3—threatens to undermine a range of social institutions and factors crucial for enabling members of society to live a flourishing life.

That being said, the practical challenges and tensions associated with the requirements of sustainable AMR policy tend to arise regardless of which specific theory of justice is used to analyse what sustainability implies. Promoting sustainability often entails present-day sacrifices, some of which can be substantial, to afford fair conditions for future people. The heart of sustainability debates lies in these trade-offs: how can we justify imposing present-day burdens to secure the health needs of future populations? The more ambitious the commitment to future justice, the more demanding the interventions—raising pressing questions about feasibility and fairness for those who bear their cost (Barry, 2012; Gardiner, 2006; Littmann et al., 2015). Even admitting that future generations have a right to health, to which AMR presents a threat, how can we identify the corresponding duties of present generations, and how far do those duties go? In practice, nothing comes entirely without cost and, while some sustainability measures may be relatively easy to accommodate, others may involve more significant trade-offs.

5.2 Sustainability and AMR

This subsection examines the sustainability challenge presented by AMR more closely. Specifically, it addresses how decisions about distributing limited healthcare resources must now contend not only with immediate patient needs and cost-effectiveness but also with the long-term goal of ensuring that essential services—such as antibiotic therapies—remain available and effective for future generations. The sustainability challenge arises from the tension between meeting

current demands and protecting the capacity to deliver high-value care and safeguard public health over time.[16]

5.2.1 Rational and prudent antibiotic use

Sustaining antibiotic efficacy fundamentally involves managing trade-offs between individual patient benefit and the broader public health goal of preserving antibiotic effectiveness for future generations. Even when antibiotic use is medically justified, it contributes to resistance development, which affects both current and future patients. This introduces ethical challenges for prescribers who must balance the immediate, tangible risks to individual patients against uncertain, long-term societal benefits (Littmann, 2014).

Economic interventions such as increasing antibiotic prices to reduce use or, for that matter, to incentivise more sustainable production practices (Nijsingh et al., 2019), while effective for some resources, present ethical problems in the context of antibiotics. In many countries, healthcare systems bear the cost of medications, and higher prices would increase overall healthcare costs. Moreover, price hikes in low-income regions could unfairly limit access to antibiotics for vulnerable populations that already face financial barriers to care. Due to these complexities, stewardship efforts focus on rational prescribing, primarily avoiding misuse, such as prescribing antibiotics for viral infections, which does not disadvantage patients but contributes to resistance reduction (Littman et al., 2015): for the sake of clarity, this specific case is arguably not a trade-off, since nobody would benefit from being prescribed an antibiotic they do not need.

However, rational use must also include restricting antibiotic use in cases where some small benefit might be realised for the individual patient: these would be mild infections in otherwise healthy individuals and limiting immediate and frequent use of last-resort antibiotics like carbapenems to prevent resistance escalation (Littmann et al., 2015). This inevitably places prescribers in a conflict of interest between the welfare of the present patient and the health of the broader public. Importantly, the cost to the individual denied antibiotics is immediate and often predictable, whereas the benefits to future society are uncertain and diffuse. This ethical dilemma underscores the need for transparency and explicit discussion in antibiotic policy about how to balance these competing interests, acknowledging

[16] The costs of inaction may materialize so rapidly that it will affect current populations—not just future ones. This should severely challenge assumptions that preserving antibiotic efficacy is a matter of distant concern; it becomes instead an urgent ethical imperative within our own lifetimes.

future patients' rights and the societal importance of maintaining antibiotic efficacy (Littmann et al., 2015).

This challenge also extends to antibiotic use in factory farming—a significant contributor to AMR burden. While regulations, such as the recent EU ban on human-relevant antibiotics in farming, address part of the problem, intensive farming conditions often foster frequent illness, inducing the need for recurrent antibiotic cycles. Incentive structures prioritise animal survival over animal health quality, thereby exacerbating antibiotic use without necessarily improving their welfare. When considering sustainability in farming, one should keep in mind that, as it is now, antibiotic efficacy is being risked by maintaining consumption patterns of specific foods like meat and dairy when these practices could threaten human health.

Regarding the meaning of sustainability in relation to antibiotic use, two core considerations emerge. First, sustainable stewardship in human medicine involves solving numerous practical challenges—such as ensuring appropriate use, improving diagnostics, and enhancing access to therapies. This type of intervention would reduce AMR drivers without withholding antibiotics from patients who have a strong need for them. Second, sustainable stewardship may still require foregoing antibiotic courses even when they offer some patient benefit.

Beyond human medicine, antibiotic use in agriculture presents an additional layer of ethical considerations. Sustainable stewardship in farming raises the question of how much risk to public health and antimicrobial effectiveness society is willing to accept to avoid changes in dietary habits. This mirrors the tension in human medicine but highlights the fact that achieving sustainability in antibiotic use requires confronting difficult trade-offs and responsibilities across sectors.

5.2.2 Resource allocation in healthcare

Munthe et al. (2021) examine how pharmaceutical pollution accelerates AMR and how purchasing cheap antibiotics incentivises environmentally harmful production methods. In particular, the article argues that although healthcare systems have strong moral reasons to ensure that the medicines they offer to patients are cost-effective, purchasing the cheapest antibiotics also incentivises producers to pollute substantially. In publicly financed healthcare systems, the principle of equal treatment is one of several ethical principles intended to guide

resource allocation (Bognar & Hirose, 2014). This principle requires that individuals with the same health needs should have access to the same care and, other things being equal, that similarly severe needs are given a similar level of priority. Importantly, this principle assumes that such needs are valid independently of when they arise. If a state has a duty to provide its citizens with appropriate healthcare, that duty is not constrained by short-term considerations; it extends across time, recognising needs as enduring rather than transient.

While this is true in theory, the practical realities of healthcare systems—such as budget cycles, political mandates, and resource constraints—often lead to a strong short-term focus. For this reason, in Munthe et al. (2021), we proposed the introduction of a principle of sustainability in healthcare decision-making: if a resource allocation pattern at time t1 produces negative dynamic effects at time t2, this counts, to some extent, against this pattern at t1, and in favour of resource allocation patterns at t1 with no or weaker negative dynamic effects at t2 (Munthe et al. 2021, p. 93). In this context, a negative dynamic is one that progressively diminishes the resources available for future allocation rounds, as well as the effectiveness in accessing them: AMR is a fitting example of such a dynamic, since, unless precautions are taken against it, fewer (effective) resources will be available in future resource allocation rounds. The sustainability principle we propose helps counteract negative dynamics (e.g. AMR) by increasing the priority allocated to equal treatment in future allocation rounds, which should be equally considered legitimate targets of care and resource allocation.

One might argue that such a principle is redundant because other principles (in particular, equal treatment) already require long-term needs to be considered (Davies, 2021; Vong, 2021). That is admittedly true, but the sustainability principle proposed there serves less as a conceptual distinction and more as a practical tool. Its value lies in making long-term considerations visible and more clearly operational within systems that are otherwise dominated by short-term pressures: by introducing sustainability considerations openly, long-term goals should become harder to shift (Munthe et al., 2022).

5.3 Conclusion

This long-term aspect is not incidental; it is intrinsic to the very nature of AMR. Resistance develops cumulatively, and the rate and distribution with which we consume antibiotics or disperse AMR-driving substances today directly influences

the landscape of available treatment options tomorrow. Therefore, the ethical dimensions of sustainability are not simply an overlay on AMR policy—they are foundational to understanding how the problem is generated and how it ought to be addressed. By explicitly including sustainability in stewardship and healthcare resource allocation decisions, it is possible to ensure that the long-term interests and immediate clinical needs are leveraged in a systematic and transparent way.

6. Concluding remarks

This thesis argues that policymaking on AMR—particularly regarding its environmental drivers—inevitably demands deliberate ethical reflection. The challenge of AMR is shaped by many aspects, such as clinical misuse, the everyday actions of consumers, the structure of our food systems, policy choices, and the behaviour of industrial and pharmaceutical actors. Every significant policy lever addressing AMR requires balancing different ethically relevant considerations, including public health, personal liberty, fair access to medicines, and ecological sustainability. The research presented here unpacks how this balancing plays out when, for instance, we consider restricting access to certain specific goods (e.g. meat or dairy), introducing ERAs at the stage of market approval, or assigning responsibility for pollution in ways that might affect the delivery of care. The thesis highlights how consumer choices interact with environmental AMR risks, how fairness and restrictiveness should be understood in regulatory decisions, and how responsibility should be allocated for pharmaceutical pollution and its remediation. Moreover, the thesis highlights the trade-offs and tensions at play in the pursuit of antibiotic sustainability: any intervention with long-term implications for antibiotic access carries weighty ethical consequences.

By drawing these strands together, the findings of this thesis can hopefully contribute to ethically informed decision-making, which recognises that any genuine effort to tackle the environmental facets of AMR requires openness about the trade-offs involved, clear articulation of values, and a commitment to fairness for both present and future generations.

6.1 Limitations and further research

The thesis's analysis of responsibility for pharmaceutical pollution has largely centred on the PPP, which—although a dominant framework—does not exhaust the possible approaches for distributing remedial duties. Potential in alternative models, such as the Beneficiary Pays Principle and the community principle, remains unexplored (Miller, 2001; Gosseries, 2004;

García-Portela, 2023). The former asks whether those who ultimately benefit from effective antibiotics, lower drug prices, different patent regulations, or market access laws should bear some of the costs for safeguarding this resource. The latter asks how and whether community-based obligations might be used to justify certain remedial allocation duties (i.e. some actors involved with AMR might have special duties to remedy it, simply for being part of a community or state). Further research could clarify the implications and plausibility of these principles, especially as similar debates in climate policy illustrate the complexities of allocating responsibility to beneficiaries and institutional actors.

Moreover, some limitations are also tied to the mostly anthropocentric framework applied in this thesis, which is due to its interest in debates in public health ethics. Admittedly, further work is needed to critically assess whether a shift towards more inclusive non-anthropocentric approaches could offer new ethical insights, given the increasing recognition in policy debates of the interconnected fates of humans, animals, and the environment (Mehager, 2024; Cañada et al., 2022).

A promising direction for future work would be to explore AMR as a "green–green conflict". Green–green tensions and policy dilemmas arise when sustainability goals come into competition with each other (Warren et al. 2005; Eskajer & Horsbol, 2023): this phenomenon can already be seen in cases such as renewable energy and biodiversity (Dulluri & Rat, 2019; Xu et al., 2020), as well as climate infrastructures and ecological conservation (Ruhl & Salzman, 2023). Of relevance for this thesis, sustainability concerns have already been raised in relation to healthcare systems, their use of resources and their emissions, raising substantial questions in public health ethics (Richie, 2022, 2024). The question I raise here is how and whether AMR interventions fit into this domain. Some measures to mitigate AMR may involve CO2 emissions, meaning that preserving antibiotic effectiveness could inadvertently contribute to worsening climate impacts due to, for example, CO2 emissions from wastewater treatment plants (Rizzo et al., 2019). At the same time, sustainable prevention practices may help lower pharmaceutical pollution and reduce emissions associated with waste management (Ali et al., 2025). Understanding how best to balance the imperative to preserve antibiotic effectiveness against potentially competing sustainability goals is a crucial but unresolved challenge for researchers and policymakers alike.

Finally, a significant direction for further research lies in analysing the responsibility for the historical loss of antibiotic effectiveness. This debate mirrors long-standing debates in climate justice concerning responsibility for past

emissions and the obligations of nations or communities to remediate harms caused by those emissions (Gosseries, 2004; Mintz-Woo, 2023), as well as broader debates concerned with historic injustices and their remediation (Butt, 2008; Lu, 2016; Barry & Goodin, 2009). Analogously, the fact that antibiotic efficacy has diminished over the past century due to patterns of overuse in healthcare and agriculture—including the widespread application of antibiotics for growth promotion—raises important questions about whether some countries or communities could be considered remedially responsible for this legacy. The notion of historical responsibility for antibiotic efficacy loss remains largely unexplored in both the ethical and policy literature, making it a promising and natural extension of current research efforts in the field of AMR ethics.

7. Paper summaries

Paper I – Antibiotic Resistance, Meat Consumption and the Harm Principle

The first paper examines the ethical justification for state interventions aimed at reducing meat consumption via a user tax, grounded in the harm principle, in virtue of its contribution to AMR. In order to do that, the paper addresses the "inconsequentialist objection" most commonly used in the debate on collective harm and climate change, which argues that an individual's contribution has either no effect or a negligible one in collective harm cases: in the case of AMR this argument would imply that meat consumption has a negligible impact on AMR and thus doesn't warrant restrictions. The inconsequentialist claim is objected to, by endorsing an expected utility approach (i.e. while individual actions may have minimal effects, their cumulative impact significantly contributes to AMR). After that, the paper faces some of the objections traditionally raised against this type of framework in other collective harm cases such as consumer behavior and its relation to climate change. The paper then argues that the case of consumer choice and AMR drivers can be differentiated from the traditional examples considered in the debate on climate change, lending itself to a more correct application for the harm principle. The paper concludes that state interventions, such as taxes or regulations on products such as meat and dairy, can be justified to mitigate the harm caused by an individual consumer's participation.

Paper II – Antimicrobial Resistance, One Health Interventions and the Least Restrictive Alternative Principle

The second paper, critically examines the ethical justification for One Health interventions addressing AMR, focusing on the notion of the least restrictive alternative principle. In this discussion article I engage directly with arguments claiming that One Health approaches—by targeting multiple sectors such as

human, animal, and environmental health—are inherently more restrictive and thus more ethically burdensome to justify. The paper challenges this claim on two fronts. First, I distinguish between the additive restrictiveness of a policy (i.e. the number of people affected) and its individual restrictiveness (i.e. the degree of constraint on each individual). From this perspective, a policy that affects more people but imposes milder restrictions on each may be less ethically problematic than one that imposes heavy burdens on fewer individuals. Second, the paper objects to the claim that the least restrictive alternative principle, inherently carries a special normative weight. Additionally, it is argued the principle should be balanced alongside other ethical considerations, such as proportionality, effectiveness, and equity. Finally, One Health interventions should not be presumed ethically suspect on the basis of their scope alone, and may in fact be more ethically sound than narrower, more burdensome policies.

Paper III - Pharmaceutical Pollution from Human Use and the Polluter Pays Principle

The third paper examines the ethical and practical challenges of applying the Polluter Pays Principle (PPP) to pollution resulting from human use of pharmaceuticals. The paper highlights that while the PPP is a widely endorsed principle in environmental policy—asserting that those who cause pollution should bear the costs of managing it—its application in the context of pharmaceutical pollution from human use is problematic. Specifically, such a principle would place remedial responsibilities (i.e. the burden of bearing the costs of the interventions needed to reduce the risk of AMR) on actors that often lack the capacity to mitigate their contributions to pollution without compromising services they provide to society.

To address these issues, the paper proposes a hybrid framework that combines the PPP with the Ability to Pay Principle (APP). This approach suggests that while it is important to hold polluters accountable, considerations of effectiveness and practicality call for other actors—such as water operators and taxpayers—to share the burden of managing pharmaceutical pollution.

Paper IV – Environmental Risk and Market Approval for Human Pharmaceuticals

The fourth paper highlights a regulatory inconsistency in how environmental risks are handled during the market approval process for pharmaceuticals in the EU. While current European legislation requires an Environmental Risk Assessment (ERA) as part of the approval process, the results of that assessment do not actually affect whether a drug is approved. This is in contrast to the rules governing veterinary pharmaceuticals, where environmental impact can determine market access. Furthermore, the paper argues that this gap allows for the continued approval of human medicines with potentially serious environmental consequences, particularly in relation to antimicrobial resistance (AMR). Introducing regulation in the market approval step is one of the possible interventions to remedy pharmaceutical pollution, but that would come with several ethical concerns: ensuring access to necessary medications both in the short and long term might become challenging.

To address the issue, the paper outlines seven possible policy models that would integrate environmental considerations into the decision-making process. These models differ in how they weigh environmental protection and long-time interests against the current clinical need, ranging from maintaining the current system to adopting strong regulatory mechanisms that could prevent market approval for drugs with unacceptable environmental risks. Finally, I suggest that while patient access should remain a core concern for the policymaker, a more balanced approach is needed—one that does not simply treat environmental harms as externalities, but as relevant threats to future health needs and that raise regulatory concerns in their own right.

Paper V - Sustainability principle for the ethics of healthcare resource allocation

The fifth paper contributes to the debate on sustainable use of antibiotics and, differently from the preexisting debate, focuses on resource allocation in healthcare. The paper argues that the currently established principles used in resource allocation frameworks for healthcare systems—such as equal treatment, need, prognosis, and cost-effectiveness—can inadvertently lead to "negative dynamics" that progressively diminish their capacity and effectiveness to provide

a service. To address these issues, the paper suggests that sustainability considerations should be incorporated alongside traditional allocation principles. In particular, various formulations of the sustainability principle, including treating it as a side constraint, a factor with gradual weight, or through mechanisms like rational savings and insurance models. By doing so, they aim to balance immediate healthcare needs with the preservation of system integrity over time.

Additionally, the paper engages with potential objections, particularly concerns about conflicts with the principle of equal treatment. We contend that, when properly understood, sustainability considerations can be harmonized with existing ethical frameworks, ensuring that healthcare systems remain effective and equitable in the long term.

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Paper I



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Antibiotic Resistance, Meat Consumption and the Harm Principle

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ABSTRACT

This paper vindicates using the harm principle (HP) to justify restricting consumer's access to meat products in light of the impact that it has on the development of antibiotic resistance (ABR). In particular, the study claims that, since an individual instance of consumption, or purchase of meat, meaningfully contributes to the development of ABR in farming environments, a state intervention limiting consumer freedom would be legitimate. The causal impact of individuals in greater-scale problems has long been debated and dismissed as not relevant. The study analyzed two possible formulations of the inconsequentialist objection. While the first formulation, which maintains that individuals have no impact, can be rejected independently of the context of application, rejecting the second formulation, which maintains that this impact is insufficient to warrant applying HP, is more difficult. In order to successfully respond to this version of inconsequentialism, the paper vindicates the value of considering ABR and ABR-related harm within a more traditional expected utility arguments.

KEYWORDS

Antibiotic resistance; individual harms; collective actions; causality

1. Introduction

This paper investigates the viability of the *harm principle* (HP) to justify restricting consumer freedom regarding the purchase of products, such as meat, that require intense use of antibiotics for their production in light of the antibiotic resistance (ABR) challenge. Such justification is particularly hindered by the so-called *inconsequentialist objection* (Sandler, 2010). This argument claims that individual contributions to complex collective action problems are neither meaningful nor morally relevant to count as the type of harm that HP recognizes as legitimate ground for restricting individual freedom.

The paper is structured as follows. The second section provides relevant information regarding the problem of ABR and its urgency. It also explains the environmental impact related to meat production and ABR. The third section defines the HP-based argument for policies aimed at limiting antibiotics use in meat production in more detail. Thereafter, the fourth section outlines the inconsequentialist objection and distinguishes two ways of understanding it. The fifth provides responses to the first variant of inconsequentialism. The sixth section provides responses to the second interpretation of the inconsequentialist

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objection by applying the expected utility argument to factory farming as a general phenomenon, furthermore it justifies the addition of ABR to the utility calculation.

My discussion is limited in two ways. First, I ignored justifications for regulations that are not based on HP, such as virtue ethics (Knights, 2019) and fairness-based justifications (Baatz, 2014; Caney, 2010; Schwenkenbecher, 2020). Hence, even if harm-based considerations would fail to justify restrictions on consumer freedom such restrictions may be justified in some other way. Nonetheless, I did not consider that possibility here. Secondly, I focus on justifications for regulations based on evaluating the consequences of individual action. As such, I do not consider group-based reasons and justifications for policies related with collective action problems.[1]

2. Background

When antibiotics are used, susceptible bacteria are eliminated, while bacteria that are resistant to antibiotics survive and reproduce. The blunt administration of antibiotics to an environment inhabited by resistant bacteria generates a selective pressure that creates the conditions in which the resistant bacteria can easily reproduce.

Infections from resistant bacteria kill 700,000 people every year, with over 90% of them in low and middle-income countries (Interagency Coordination Group on Antimicrobial Resistance [IAGR], 2019). Furthermore, by 2050, ABR will be responsible for 10 million deaths each year and cause damage to the economy akin to the 2008–2009 global financial crisis (IARG, 2019). For this reason, a battery of measures targeting different practices has been outlined in a World Health Organisation [WHO] (2015) global action plan. Antibiotics are used in many practices – from treating common infections in human healthcare and animal farming to preventing serious complications after surgery or treatments that weaken a patient's immune system, such as chemotherapy for cancer. In the farming sector, antibiotics can be used as growth promoters. The EU, later followed by other countries, such as the US, implemented policies to ban this practice, which, however, is still adopted in other countries (Laxminarayan et al., 2013). Additionally, the prophylactic administration of antibiotics in animal farming is widely used to enable production methods that would otherwise not be economically sustainable due to high infection rates.

Antibiotic-rich environments provide bacteria with a strong selective pressure, inadvertently creating the conditions for them to develop resistant genes that enable them to survive. Because of this, according to WHO, antibiotic use is strongly correlated with the development of resistance in the environments where it is used (WHO, 2001). Not coincidentally, healthcare structures, sewers, and farms are highly populated by resistant bacteria (Woolhouse et al., 2015).

Traditionally, ABR policy discussion has focused on the clinical aspect and antibiotic use in humans in healthcare (Bengtsson-Palme et al., 2018; Berendonk et al., 2015; Wright, 2010). Nonetheless, the relevance of the environmental aspect of resistance was recently highlighted (Finley et al., 2013; Larsson et al., 2018). Avoiding the conditions that select and allow the persistence of resistance and limiting the selective pressure for resistant pathogens is necessary. Consequently, the specific contribution to resistance that comes from animal farming, and the production of meat, eggs, and dairy products, such as milk and cheese, must be considered (Woolhouse et al., 2015).[2] For the purpose of this paper,

I focused solely on meat products, which have greater impact and relevance (Anomaly, 2010, 2019; Mellon et al., 2001; Perez, 2018).

Individual agents who consume meat are involved in developing ABR since they jointly comprise a consumer demand that drives the related farming practices (Schwenkenbecher, 2020). This consideration has led several authors to advocate actions to limit the use of antibiotics that in various ways impose burdens on individuals, such as taxes or fees (Anomaly, 2010, 2020; Giubilini et al., 2017; Giubilini, 2019), regulated use thresholds (Anomaly, 2013), mandatory phasing out of legal antibiotic use in farming (Gorbach, 2001), or even banning factory farming altogether (Anomaly, 2013). Requiring meat-producing farms and other facilities to apply effective waste treatment to impede emissions of antibiotic residue and ABR into the general environment may need to be considered (World Health Organization [WHO], Food and Agriculture Organization [FAO], & World Organization for Animal Health [OIE], 2020). I do not debate which (combinations) of these proposals would be the most effective or the easiest to implement; instead, I argue that HP can justify the burden to individual consumers placed by the suggested reforms (Anomaly, 2009, 2015; Giubilini et al., 2017).[3] Specifically, I suggest that a state is allowed to limit access to products that require a heavy use of antibiotics because consumers meaningfully contribute to the development of ABR and, hence, may be held accountable for the consequences of their choices. Against this premise, the inconsequentialist objection maintains that the alleged contribution of individual consumers is insufficiently causally linked to the general harm created by the production practice to justify the burdens of the suggested ABR policies in terms of financial loss, lack of access to desired products, and general restrictions of freedom. In response, I argue that the HP premise can withstand the inconsequentialist objection and justify policies limiting consumer freedom or placing some degree of burden onto consumers to limit their purchases.

3. The harm-based argument for policies burdening individuals

A significant advantage of using HP to justify a policy is that it has already been extensively used to justify restrictions on individual liberty, for instance, in the case of industrial regulation. HP was originally formulated by J. S. Mill in the 19th century and has continued to occupy a central place in political philosophy since then (Feinberg, 1986). It represents one of the most widely embraced grounds for justifying state interventions against individual behavior; for example, it is used to motivate the taxation of several products, such as tobacco (Wilson & Thomson, 2005), alcohol or guns (Kianpour, 2020) and, more recently, sugar (Bateman-House et al., 2018).

The general idea of HP is readily expressed by Mill's original formulation: 'the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others' (Mill, 2001, p. 11). However, this formulation is too vague and imprecise and generates counterintuitive results in many cases, such as surgical operations. Therefore, several more precise interpretations have been developed (Feinberg, 1984, 1985, 1986, 1990; Joseph, 1986). Given the complexity of this debate, I used the definition of 'harm' that Anomaly, drawing on Feinberg (1985), proposed, which defines harm as a likely and not-agreed-upon setback of somebody's interests:

> *Harm*: Agent A acts in a way that reduces B's welfare, by setting back B's interests, B does not consent to A's action, and harm to B is a predictable consequence of A's action (Anomaly, 2009, pp. 425–426).

Several advocates of ABR-related policy action have adopted this definition of harm to limit consumer access to meat (Anomaly, 2009; Giubilini et al., 2017). The HP-based argument for state interventions to limit access to meat now runs as follows: Consuming meat products is positively correlated with the rise of ABR, which implies a reduced efficacy of antibiotics, through farming practices. Individuals that cannot be treated by effective antibiotics are exposed to a greater health risk; hence, those who consume animal products are violating a prima facie moral duty not to harm others (Anomaly, 2009, 2013). The fact that they are violating this moral duty generates both a prima facie moral duty to abstain from the harmful practice and a duty to compensate those they are harming. Both duties warrant state intervention to enforce adherence. For instance, a tobacco or alcohol tax would require consumers to internalize costs that they would otherwise impose on society, thus limiting the harmful consumption (Giubilini et al., 2017). When applying this principle to ABR, a consumer purchasing animal products is setting back people's welfare by consuming products that require antibiotic use. Moreover, the setback caused by the accumulated consumption is sufficiently serious that its prevention warrants limiting the liberty to consume them or compensating society for the harm done.

Notably, the harm in the meat-ABR case is a result of large-scale collective action. Each instance of meat consumption contributes to increasing the concentration of antibiotics in the environment by only a tiny degree, thus raising the likelihood of increased ABR by only a small amount. However, the argument proceeds, the harm resulting from the practice is so severe that it nevertheless warrants limiting the access to meat for individual consumers (Anomaly, 2009; Giubilini, 2019). The HP argument in favor of imposing restrictions on meat consumption can thus be presented as follows:

> *Contribution to ABR*: Each instance of meat consumption contributes to a small increase in the likelihood of increased ABR.

> *Normative Significance*: Each individual contribution to an increased likelihood of increased ABR is normatively significant due to the substantial harmfulness of ABR.

Therefore, according to HP, it may be justified to enact the following:

(a) compensatory measures to offset the harm caused by the consumption of meat;
(b) preventive measures to reduce the consumption of meat produced with the help of antibiotics;
(c) measures to force meat producers to reduce their contribution to AB, thereby indirectly affecting consumers in the form of higher meat prices.

4. The inconsequentialist objection

The core inconsequentialist objection to applying HP to collective action generated harms is the claim that the consequences deriving from an individual's action are too small to be worth regulating: either each individual does not causally contribute to the collectively

generated harm, or each contribution is too minor to matter causally and ground an ethically significant individual responsibility for the harm. This leaves open the possibility that each behavior has no significant causal link, if any at all, to the collective harm, despite the aggregation of these behaviors having such a link.

In the context of climate change, inconsequentialism has been formulated in two ways. The first variant, defended by Sinnott-Armstrong (2005) and Sandberg (2011), maintains that an individual is not causally responsible for climate change since it would happen independently of an agent.[4] Since an individual's contribution is not necessary for the development of climate change, they are not causally responsible for it. This first formulation defines a cause of an event as necessary for its effect to occur. Since it is unavoidable and relentless, an individual plays no causal role in climate change. Later in the paper, I go over why this can be problematic, independently of whether the context for this first formulation is the debate on climate change or ABR.

The second formulation of inconsequentialism does not deny that individuals have a causal relation with climate change but maintain that this relation is too weak to be morally meaningful. This means that the causal contribution does not cause a significant enough harm, that is, a serious enough *predictable* and *unconsented* setback of *interests*. This formulation does present a stronger case for inconsequentialism, and it has been a recurring theme in critical debates on climate change policy (Kingston & Sinnott-Armstrong, 2018; Nefsky, 2019). Since the mentioned HP-based arguments for ABR policies related to meat production are structurally very similar to the HP suggestions for climate change policies targeted by the inconsequentialist objections, these objections would also apply to the argument regarding meat production and ABR.

The two interpretations of the inconsequentialist objection to using the HP argument for justifying policies targeting meat consumption due to ABR can thus be presented as follows:

IO-1. A single instance of meat consumption does not cause the development of ABR or ABR-related harm.

IO-2. The contribution of a single instance of meat consumption to ABR or ABR-related harm is too insignificant to be normatively meaningful.

IO-1 is based on a metaphysical criticism concerning what type of causal relation can be established between an event (a case of meat consumption) and its alleged effect (ABR) or harm. In particular, Kingston and Sinnott-Armstrong (2018) criticized HP arguments in the context of climate policy by contesting that the total amount of climate-related effects or harms would increase due to single minor individual behaviors. Applied to the argument in Section 3, this amounts to rejecting the *contribution* premise. If *contribution* is rejected, linking individual behaviors to ABR or ABR-related harm is impossible. IO-1 thus focuses on what can be legitimately considered a cause of some event, maintaining that, in cases such as climate change or ABR, individual contributions does not qualify, albeit contributing to causing the relevant effects and harms. Actions such as 'joyguzzling' or having a steak for dinner will not make any causal difference to the end result of all joint actions of this kind. Similarly, ABR or climate change continues to develop regardless of a supposedly virtuous action of a single consumer to abstain from the steak or the car ride; hence, that consumer is not causally contributing to any of the two problems or making them worse (Cripps, 2013; Kingston & Sinnott-Armstrong, 2018; Sandberg, 2011).

In contrast, IO-2 does not target the *contribution* premise but attacks the notion that any link between individual behavior and the overall harm would be too weak to carry any normative significance. Specifically, it rests on the claim that a single meat purchase does not impact how ABR or ABR-related harms develops. This point does not question the existence of the consequences of an action but simply their moral weight. As discussed below, how a supporter of IO-2 attempts to establish that claim may vary. As this variant of the inconsequentialist objection regards normative rather than metaphysical matters, IO-2 needs to be assessed on other grounds than IO-1. I now proceed to respond first to IO-1 (Section 5), then to IO-2 (Section 6).

5. Why individual meat consumers contribute to AMR and AMR-related harm

IO-1 has two main limits. First, it relies on a questionable theory of causality that should be rejected on grounds other than the matter discussed here. Second, less implausible theories of causality cannot ground the IO-1 attack on the *contribution* premise, at least not while still acknowledging the generally accepted claim that collective antibiotics consumption serves to explain ABR (Gunnemyr, 2019).

One of the most common points made by IO-1 advocates is that individuals cannot be causally responsible for the considered event (e.g. climate change) because their contribution is not necessary for the event to happen (Sandberg, 2011). Related to the argument in Section 3, the corresponding claim in support of IO-1 is that ABR would increase independently of an individual's meat consumption. This reasoning is based on a simple counterfactual theory of causation (Lewis, 1973), of which I accept the definition provided by Gunnemyr:

> *Simple*: C causes E if and only if it is the case that if C had not occurred, E would not have occurred (Gunnemyr, 2019, p. 401).

According to Lewis (1973), causation is a transitive process, which also the ancestral of counterfactual dependance, where an event C causes event E if and only if there is a chain of causal dependencies is running from C to E. According to *Simple*, for an event C to be considered a cause of a later event, E, the occurrence of C has to be counterfactually necessary for E's occurrence.

For the case at hand, a person's single case of consumption of meat produced from a farm that uses antibiotics can be said to have caused of an increase in the use of antibiotics, of ABR or ABR-related harm if and only if the increase of ABR or of the harm caused by ABR-related harm would not have occurred had that single person refrained from buying meat. Since antibiotic use in farming and ABR and ABR-related harm increases over time regardless of the single action of a single consumer, purchasing meat should not be considered to cause the increased use of antibiotics, increased ABR, or ABR-related harm.

Simple is often considered problematic because it tends to give counterintuitive results in cases of preemption and overdetermination (Lewis, 2004). Consider, for example, an event E with two potential causes, one of which caused E, while the other is a preempted alternative backup that happens slightly later (e.g. a failsafe device of an electric installation kicking in just in case fuses do not work). In the case of the preempting cause, we can see

that it is not a necessary condition since the backup then intervenes to produce the same outcome regardless. None of the two events we would intuitively define as causes are necessary for the event to happen. Lewis defines cases where 'the preempting cause is not a condition without which the effect would have been absent, yet it is a cause' (Lewis, 2000, p. 182) as scenarios of *asymmetrical redundant causation*. Consider now Lewis' example:

> *Billy and Suzy*: Billy and Suzy throw rocks at a bottle. Suzy throws first, or maybe she throws harder. Her rock arrives first. The bottle shatters. When Billy's rock gets to where the bottle used to be, there is nothing there but flying shards of glass. Without Suzy's throw, the impact of Billy's rock on the intact bottle would have been one of the final steps in the causal chain from Billy's throw to the shattering of the bottle. But, thanks to Suzy's preempting throw, that impact never happens (Lewis, 2000, p. 184).

Some of the difficulties thus illustrated can arguably be bypassed using a more elaborated version of the counterfactual theory from Lewis, better suited to deal with the problematic cases of overdetermination and preemption using a notion of individuating similar events (Lewis, 2000). Looking back at the Billy and Suzy example, without Suzy's throw, the bottle would have shuttered anyway due to Billy's throw. However, this event would have been a different case of shattering than what would have happened had Suzy thrown the bottle. The alterations of the (true) description of how an event comes to occur to some extent determine *what* event is occurring. The degree of alteration between the 'ifs' and 'hows' that an event can bear without being considered a different event altogether is defined as *frailty* in Lewis' terminology. If an event is extremely frail, the following happens:

> It would take only a very slight difference to destroy that event altogether, and put a different substitute event in its place [. . .] How much delay or change do we think it takes to replace an event by an altogether different event, and not just by a different version of the same event (Lewis, 2000, pp. 185–186).

In the example above, if we wanted to say that Suzy's throw caused the shattering, we would also have to maintain that the shattering of the bottle is a frail event. This means that we also have to maintain that, if Billy's case of shattering happened, it would be sufficiently delayed and different. Reformulating *Simple* into *Elaborated* is possible thanks to a slightly modified account of causality that is described as *influence*.[5] The more fine-grained notion of causation as influence allows to consider different degrees of causal influence that an event C might have over another one and describe an event more realistically, allowing to deal with complex cases of overdetermination and preemption. In particular, event C causes an event E only if a chain of dependencies runs from C to E.

Here, I consider Gunnemyr's rephrasing of Lewis' formulation of *Elaborated* counterfactual:

> *Elaborated*: C influences E if and only if how, when or whether C occurs makes enough of a difference for how, when or whether E occurs (2019, p. 410).

If we relate this to the case of meat consumption and ABR, individual meat consumption influences antibiotics use in farming, ABR, and ABR-related harms to the extent that facts about how, when, or whether the consumption occurs affect how, when, or whether antibiotic use, ABR, or ABR-related harm occurs. The scale of events matters, and some events contribute more significantly than others. The real problem is how to draw the line

between cases of antibiotic consumption that have too little influence to be counted as causes and those with a sufficiently large influence (Gunnemyr, 2019).

Even assuming *Elaborated*, the influence exerted by a single purchase may still be insufficient to induce additional levels of resistance or make ABR-related harm more likely.

This leads to a number of specific issues regarding the nature of ABR. How can the increase of resistance be tracked properly? The spread of an already resistant bacteria can increase, new strains can be selected, or resistant genes can spread to new bacterial populations: how should we account for or measure these events? While the answers to these questions are mostly of an empirical nature (and beyond the scope of this paper), the possibility that even a single act of meat purchasing risks contributing somewhat to ABR and ABR-related harm is still open. Notwithstanding, *Elaborated* also suggests that meat consumption may not make any difference at all.

To solve this analytical stalemate, we may use Gunnemyr's (2019) observation that certain collective harms are extremely hard, if not impossible, to explain unless we maintain that they are caused by aggregations of tiny contributions. Unless we consider tiny contributions, the phenomena of climate change would lack a causal explanation. For example, in the case of joyguzzling, if we disregard each individual drive as a cause of global warming, we cannot fully explain what caused it. Consequently, this example differs from other often used examples, such as Sinnott-Armstrong's *Flood* example:

> *Flood*: Global warming is more like a river that is going to flood downstream because of torrential rains. I pour a quart into the river upstream (maybe just because I do not want to carry it.) My act of pouring the quart into the river is not a cause of the flood. Analogously, my act of driving for fun is not a cause of global warming (2005, p. 299).

While the flood in the example can be explained by the torrential rains, phenomena such as global warming would be hard to explain without considering the small contributions of events such as joyguzzling on a Sunday afternoon.

Similarly, if the influences on ABR from the consumption of meat were not causally relevant, the ABR challenge, especially the emergence of resistant bacteria in the environments surrounding farms, would be almost impossible to explain. Seen in this light, a case of meat consumption would have to be recognized as a causal factor for the development of ABR; otherwise, scientific facts about how ABR emerges and is transmitted in the environment would be impossible to acknowledge. Given that the consumption of meat incentivizes farming methods that rely on the abundant use of antibiotics and that such use of antibiotics is the most likely explanation for higher ABR around farming areas, the purchase of meat is probably a cause of the rise of ABR.

To summarize, there seem to be good reasons to think that individuals contribute to ABR. In particular, the first formulation of inconsequentialism can be rejected because it relies heavily on *Simple*, which can often lead to counterintuitive results. Transitioning to more nuanced causal theories, such as *Elaborated*, helps describe complex phenomena such as ABR more correctly. Finally, considering *Elaborated* and the necessity for causally explaining the emergence of resistance around farms, individual contributions through meat purchase can be considered salient causes of ABR.

6. Why individual consumers' contributions to ABR are normatively significant

The fact that IO-1 has been disproven and that a case of meat consumption can be plausibly claimed to cause ABR and ABR-related harm is consistent with IO-2. That is, this causal influence may still not normatively justify state intervention under HP. Because, causally speaking, a single case of meat consumption could be said to contribute to an incredibly small degree of likely increase in ABR, how can that legitimize restrictive measures toward individuals? Another variant of this notion is that, since the harmful effect of a single case is practically imperceptible both for the victim of ABR and for the consumer, this agent cannot plausibly be held responsible for it.

I respond to IO-2 by using a development of the expected utility account. This account has been presented by several authors (Kagan, 2011; Norcross, 2004; Parfit, 1988; Singer, 1980) and maintains that even tiny individual contributions are morally meaningful because they still contribute to harms on a large scale. This type of solution to collective actions issues argues that, even if some negative outcomes are extremely unlikely, they would be extremely dramatic if they occurred. There are good reasons to want to minimize their occurrence in order to prevent negative outcome.

Consider the example, found in both Singer (1980, pp. 335–336) and Kagan (2011, p. 124), presented here using Budolfson's (2019) version:

> *The Chicken Order*: We know that there is some triggering number, T (more or less), such that every Tth purchase (more or less) triggers the order of another T chickens I don't have any idea what that number is, but I do know that whatever it is, I have a 1 in T chance (more or less) of triggering the suffering of another T chickens (more or less).

In this case, the risk is that the consumer would trigger the suffering of an additional group of chickens by causing another order of chickens from the retail shop to the farm.

According to Budolfson's (2019) and Nefsky (2019), this account poses three problems. First, the authors maintain that the market does not behave as described in the example. In particular, the food production market is structured not to have to adapt to a single consumer's choice. The argument presented by Singer and Kagan is built on imaginary 'triggering' cases, which do not accurately depict how things work, and depicting *The Chicken Order* as a threshold case is an overstatement. Producers seldom accommodate for variations in goods demand with market buffers or other methods and, big producers in particular, will not modify their behavior according to the purchases of a single customer; therefore, threshold scenarios do not exist in this context. If the market mechanics reconstruction that Budolfson supplies applies in *Chicken Order*, then it will also apply in the ABR case. If the number of animals being raised its independent from the decision of a single consumer because of market buffers, then so will be the amount of antibiotics being used in farms.

Second, even if constructing *The Chicken Order* as a threshold case was correct, the chance of making a difference through a single case of consumption may be so minute as to be negligible; it would be the equivalent of 'casting a decisive vote in a large-scale election' (Budolfson, 2019, pp. 1717–1718). Holding a single individual causally responsible for the election's result seems counterintuitive.

Third, even ignoring the first two issues, the calculation of expected utility does not guarantee that it would favor not buying the chicken: it may be the case that, given the small chance of affecting the chickens' suffering, more expected utility may be produced by buying the chicken and enjoying it (Budolfson, 2019). The next paragraphs address three aforementioned objections.

The first objection is based on the empirical analysis related to the meat production market. Unless individual purchases impact ABR and antibiotic use in farms differently than they do with *Chicken Order*, then the first objection still applies. A single decision not to purchase meat products is not going to drive a producer toward different farming methods or make it inconvenient for them to raise the same number of animals. In a similar way, it would be reasonable to expect farms to keep using the same amount of antibiotics. I am conceding this point to Budolfson, but these considerations are limited to evaluating the direct impact of a single purchase on the producer via the market. Some authors suggest that there are indirect, or social, consequences that an action can have, which can effectively bypass market buffers. For example, purchasing a product signals to the society around us that we might deem certain practices acceptable (Lane, 2018; Lawford-smith, 2015). Similarly, never purchasing a product can at least give the impression that we find something about it to be problematic. This is obviously far from provoking a guaranteed change in our social circle's consumption habits, but it still might encourage similar behavior or transition to different habits and hence diminish the consumers' demand on an aggregate level.

Through indirect contribution, a single actor can have an impact on its close social reality and encourage a greater amount of people starts to imitate their purchasing behavior. An individual purchasing act makes a possibly small or unlikely contribution to the overall demand for meat, and a change in this overall demand can be sufficiently large to overcome buffers.[6] This first objection is then relevant, but since it neglects the social dimension of causality, its strength is limited.

My response to the first of Budolfson's objections still leaves room for the second one. It might still be the case that the impact of a single instance of meat consumption is negligible due to a very uncertain or small probability of triggering a resistance development or transmission. Consumers causally contribute to developing resistant bacteria by a very small amount. Wondering whether this amount is sufficient to grant an application of the harm principle seems reasonable.

Two points can be raised against this objection from an expected utility perspective. Firstly, as previously argued, when considering the expected utility of an action we should factor not only the direct impact on the market a purchase has, but also its social implications. Secondly, we should consider that inconsequentialist arguments are typically applied and considered in relation to single, discrete problems (i.e. CC or *animal suffering or* ABR) despite the fact that all of them are collective action issues related with the topic of industrial meat production. An argument should be made in favor of measuring the expected utility of consumers action in a more complete scheme that includes all these aspects together, as well as the social aspects related with indirect causation that were just mentioned. The addition of ABR to this calculation might seem a minor one, but it is needed nonetheless. To this regard, consider a difference that sets ABR and animal suffering apart from each other. Unlike animal suffering, ABR can harm more generations than one and hence can contribute to greater harm. Once a strain of bacteria becomes

resistant to an antibiotic there are no chances of treating that type of infections reliably and efficiently. Moreover, it is extremely unlikely that a strain of bacteria will lose those genes that confer them evolutionary advantage. In other words, ABR is not reversible. In fact, adding up all the supposedly not meaningful consequences related with meat production and consumption would more likely lead to a substantial negative expected utility.

The third objection maintains that 'non-cooperation'—in this case, buying meat – might be the option with the greatest expected value because the pleasure derived from it would not outweigh the odds of triggering grave consequences. On the one hand, this objection rests on the idea that consuming meat correlates with high amounts of value and personal pleasure. This argument overlooks that it may be feasible to 'produce' similar levels of pleasure by consuming other types of food without risking consequences such as the development of ABR. To support this objection, one would have to value meat products more than all other alternatives. At the same time, one would have to downplay the fact that those alternatives would entail lesser related health risks for future generations to the regards of GHG emissions and ABR. The expected value approach may well mandate choosing a possibly less pleasurable food option if that resulted in safer food production environments. The addition of ABR (with its intergenerational implications) to the utility calculus makes it significantly less likely that buying the meat is the advisable option.

In addition to these objections, a final one might maintain that, if a consumer was not aware of the existing link between meat consumption, animal farming, and ABR, a state's intervention would be unjust. The state would only be legitimized in curtailing consumers' freedoms if the consumers were willfully choosing to increase ABR through the purchase of meat.

There are two reasons to disregard this concern. First, from a pragmatic point of view, an information campaign, coupled perhaps with a label system, would allow to reasonably inform consumers about the impact of their choices. Once this is done, a consumer could be held accountable by the state for their choice to buy meat products that require substantial antibiotics use.

Second, one of the advantages of using HP is precisely that it does not require knowledge on the perpetrator's part to be applied. Considering the example of the alcohol or sugar taxes that were mentioned earlier in the paper, HP could be applied regardless of whether consumers knew about the consequences of their choices and without implying moral responsibility. Whether an agent is aware of the consequences their actions and whether those actions are intentional matter in establishing moral responsibility. However, this paper aimed to justify state intervention, which, according to HP, could be made even in the absence of moral responsibility.

7. Conclusions

This paper focused on the role of individual consumers in inducing ABR by purchasing meat products. Given the big scale and complexity of the issue, one might be tempted, as often happens in the climate change debate, to downplay the moral relevance of such small individual contributions. The paper explored two ways in which this concern could be formulated and rejected both for different reasons. The first formulation, IO-1 claims that a single instance of meat consumption does not cause the development of ABR or ABR-related harm, is false both in the context of climate change and ABR: either

phenomenon could not be explained unless we supposed that individual actors causally contributed to them to some extent.

The second formulation, IO-2 claims that a contribution of a single instance of meat consumption to ABR or ABR-related harm is too insignificant to be normatively meaningful, and it presented a greater challenge.

When calculating the expected utilities of one single purchase of meat one should focus on two issues. Firstly, individuals can have an indirect impact on the demand for meat, and hence on related use of antibiotics, by influencing people close to them. Considering this broader causal chain allows to circle around Budolfson's objection. Secondly, the expected utility of purchasing meat is, in practice, often related with more than one collective action problem. In particular, relevant GHG emissions, as well as chicken suffering cases with *Chicken Order*, and ABR are all stemming from industrial farms and the market supporting them. An argument can be made to add up all the small negative utilities that single individual produces in all these settings with a single action. Arguably, if we consider all possible contributions and negative expected utilities, it is more reasonable to reject the second version of inconsequentialism.

By providing reasons to reject both versions of inconsequentialism in this context, this paper claims that a state can reasonably intervene on a consumer's freedom to purchase meat products in virtue of related harm that might result from its production.

As the focus of this paper is trying to withstand the inconsequentialist objection, many questions remain unanswered regarding the practical aspects of any resulting policy. In the clinical context, Giubilini (2019) argued that taxing antibiotics would also be ethically justifiable even though it might introduce inequalities in the access to healthcare. In the context of meat and dairy production, introducing taxation may lead to a rise in prices, making healthier and more sustainable products only accessible to a fraction of the population. The specific question concerning the fairness of access to food needs to be investigated further.

Notes

1. See for instance as Parfit (1988), Killoren and Williams (2013) and Dietz (2016).
2. Do note that any farming practice, not only animal related ones, links to ABR, as resistant bacteria and resistance genes are environmentally transmitted via soil, waterways and manure (Larsson et al., 2018). The related antibiotic footprint and impact will be different in entity, type and size of the contribution (Hollis & Maybarduk, 2015). Each farming sector uses different types of antibiotic, according to what animal is being bred, and it is possible to notice that the bacterial population adapted accordingly in each environment (Samanta & Bandyopadhyay, 2020).
3. Regarding the general evaluation of interventions in response to antibiotic resistance, see Nijsingh et al. (2020) or Littmann et al. (2019).
4. There presented with a variety of labels, such as Inefficacy problem (Nefsky, 2019), no-effect-view (Sinnott-Armstrong, 2005).
5. 'Where C and E are distinct actual events, let us say that C *influences* E if and only if there is a substantial range C_1, C_2. . .of different not-too-distant alterations of C (including the actual alteration of C) and there is a range E_1, E_2. . .of alterations of E, at least some of which differ, such that if C_1 had occurred, E_1 would have occurred, and if C_2 had occurred, E_2 would have occurred, and so on' (Lewis, 2000, p. 190).

6. A third way consumption behavior can be considered as socially relevant is by indirectly influencing policymakers. A politician that is informed on the citizen's preferences might be reluctant in applying regulation that goes against them such as, for example, ones that limit antibiotic use. For further debate on the indirect relation between citizens and policymakers see Johnson (2003), Sinnott-Armstrong (2005) and Baatz and Voget-Kleschin (2019).

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Paper II

Antimicrobial Resistance, One Health Interventions and the Least Restrictive Alternative Principle

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Antimicrobial resistance (AMR) is increasingly recognised as a threat to human, animal and environmental health. In an effort to counter this threat, several intervention plans have been proposed and implemented by states and organisations such as the WHO. A One Health policy approach, which targets multiple domains (healthcare, animal husbandry and the environment), has been identified as useful for curbing AMR. Johnson and Matlock have recently argued that One Health policies in the AMR context require special ethical justification because of the so-called *least restrictive alternative principle*. This article analyses and rejects two assumptions that this argument relies on. The first assumption is that One Health policies are generally more restrictive than their alternatives because they target more domains and impact more people. The second assumption is that the least restrictive alternative principle has a special normative importance in that it establishes a systematic presumption in favour of the least restrictive policy options. Once these assumptions are rejected, the use of One Health policies on AMR can be justified more easily than Johnson and Matlock argue.

Introduction

Antimicrobial resistance (AMR) is a phenomenon consisting of the emergence and spread of microorganisms capable of resisting the effects of antimicrobial substances, such as antibiotics. This phenomenon causes the currently available antibiotics to be increasingly ineffective, eventually making bacterial infections more dangerous and many medical treatments relying on antibiotics (including most surgeries) riskier. AMR poses a very urgent challenge to human health and society and can endanger wildlife and the environment (Nuffield Council, 2007; IACG, 2019; WHO, 2021). The WHO and others have called for coordinated actions regarding the development of new classes of antibiotics as well as several preventive, stewardship and surveillance measures (Hoffman and Outterson, 2015; WHO, 2015; Van Katwyk et al., 2019; Jamrozik and Selgelid, 2020).

Recent research highlights the important role of the environment in driving AMR (Larsson and Flach, 2021). In certain environments such as pharmaceutical manufacturing plants, healthcare facilities and industrial farms, and in wastewater from these sources, there is a strong selective pressure that makes it more likely for bacterial populations to develop or acquire antibiotic-resistant genes (Forsberg et al., 2012). Prevention measures against the spread of antibiotic-resistant bacteria, resistance genes and antibiotic residues in the environment must therefore involve environmental considerations (Finley et al., 2013; Bengtsson-Palme et al., 2018).

It is widely recognised that battling AMR effectively requires policymakers to consider and address the environmental dimensions of this problem (Pruden et al., 2013; WHO, 2015, 2021). One salient approach is the One Health policy framework, which seeks to target not only human, animal or environmental sources of AMR in a piecemeal fashion, but also several of these domains at once. In the context of farming, for example, a One Health policy could aim at reducing not only antibiotic use in animals but also environmental pollution resulting from that use.

Any type of public health intervention against AMR, including One Health interventions, is going to need some

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ethical justification (Nijsigh et al., 2020). A traditional principle used in the justification of public health interventions is the *least restrictive alternative principle*, which mandates that 'public health agents should seek to minimize the infringement of general moral considerations' (Childress et al., 2002).[1] This implies that if a decision maker is to decide between two public health policies, they should prioritise the alternative that would pose fewer restrictions to other relevant moral considerations, such as autonomy and privacy, other things being equal.

In a recent article, Johnson and Matlock (2022) claim that One Health AMR policies would typically be more restrictive than their alternative since they target more domains. Therefore, they argue, One Health AMR policies need special justification because of the least restrictive alternative principle. Their article then provides two arguments in favour of using One Health interventions to combat AMR, despite their being more restrictive, one appealing to the potentially greater effectiveness of such interventions, the other appealing to their capacity to accurately track moral responsibility. In this article, I will provide a critique of two assumptions underlying these arguments. Firstly, I criticise the additive notion of restrictiveness that Johnson and Matlock must assume to ground the idea that a One Health policy option would often be more restrictive than its alternatives. Secondly, I reject the idea that the least restrictive alternative principle plays a special normative role by establishing a systematic presumption in favour of the least restrictive policy option. I conclude that One Health policies addressing AMR, do not bear a special justificatory burden against the *least restrictive alternative principle*. Therefore, such policies can be more easily justified than Johnson and Matlock assume.

Justifying the More Restrictive Alternative

In motivating their discussion of One Health AMR policies, Johnson and Matlock make two basic claims. Firstly, they argue that One Health AMR policies are often more restrictive because by targeting several domains at once, they potentially impact a wider selection of stakeholders and levels of society.[2] Secondly, they argue that in virtue of being typically more restrictive, One Health AMR policies are in special need of ethical justification. They write:

> Policies that take a 'One Health' approach deal with this cross-reservoir spread, but are often more restrictive concerning human actions than policies that focus on a single reservoir. As such, the burden of justification lies with these more restrictive policies. (Johnson and Matlock, 2022: 1)

Based on these assumptions, Johnson and Matlock provide one justification based on *effectiveness* and another one based on *moral responsibility tracking*. Firstly, they claim that policymakers have reason to choose the policy that will more effectively prevent the most harm and suffering to humans, animals and the environment. Therefore, they argue that a policy could be justified despite being more restrictive if it is more effective than its alternatives. Secondly, they argue that One Health policies can hold actors *accountable* for past AMR-related harms and identify those who are capable of *preventing* them more accurately than alternative policies (Johnson and Matlock, 2022).

In short, Johnson and Matlock conclude that One Health policies in the field of AMR may be justified despite being more restrictive if one or several of the following conditions are met: (i) they are proven to be more effective than single-domain policies, (ii) they can be more effective at assigning accountability for past actions, or (iii) they would be more effective at reducing future risk of harmful behaviour. In order to establish if these conditions hold, they argue, it is crucial to rely on empirical evidence.

Johnson and Matlock successfully identify AMR as a pressing issue and highlight the role of the environment as a driver of resistance. Moreover, their article contributes to the as yet very limited public health ethics literature highlighting ethical aspects of AMR in the environment and related policies (Nijsingh et al., 2019, 2020; Malmqvist and Munthe, 2020; Munthe et al., 2021; Malmqvist et al., 2023). Importantly, the authors make the case for the inclusion of more multidisciplinary considerations in normative policymaking and the need for further empirical research on which specific interventions could be the most effective. Despite these advantages, Johnson and Matlock's argument rests on two basic assumptions that I will argue are implausible.

The Restrictiveness of One Health Policies

This section will challenge the assumption that One Health policies, by targeting more domains, are typically more restrictive than alternative policies targeting single domains—the assumption that motivates the need for special justification in light of the *least restrictive alternative principle*. Two examples in public health policy will

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support my claim that One Health policies can only really be considered generally more restrictive if we are relying on an implausible interpretation of restrictiveness.

As already mentioned, Johnson and Matlock argue that One Health policies are typically more restrictive because of their expansiveness, because they typically target more societal levels and stakeholders than single-domain policies. Considering One Health policies more restrictive simply in virtue of this expansiveness, however, relies on an implausible interpretation of the notion of restrictiveness, which I will call *additive restrictiveness*. On this interpretation, the restrictiveness of a policy is determined by adding together all the individual instances of restriction that affect a population. Restrictiveness is considered as a function of the number of individuals hit by the intervention and the impact those interventions have on them. When operating with this interpretation of restrictiveness, the *least restrictive alternative principle* is likely to call for special justification of policies that affect a larger amount of people or a wider set of domains.

In contrast, *individual restrictiveness* evaluates the restrictiveness of a policy in virtue of how much that policy affects the individuals that are impacted the most. This means that restrictiveness is a function of the restrictions a policy imposes on single individuals, irrespectively of how many are targeted by the intervention. When operating with this interpretation of restrictiveness, the *least restrictive alternative principle* will mandate the policy that is least restrictive for the individual who is restricted the most by that policy.

Operating with the notion of *additive restrictiveness* in the context of public health leads to counterintuitive results. Consider the following two examples. The first is the case of an intervention that aims at reducing the spread of a dangerous infectious disease. Suppose that one could intervene on this issue by making it compulsory to wear a mask on public transport. An equally effective alternative policy would instead mandate coercive isolation of a few infected individuals. These interventions would definitely restrict people's lives differently. The first policy would impact a very large number of people to a small degree, while leaving many aspects of their lives unchanged. The second policy would have a much more severe impact on each isolated individual but affect very few people. Comparing these two options, the first one would be the most restrictive if we applied the notion of additive restrictiveness, while the second would be the most restrictive if we were operating with the notion of individual restrictiveness. Clearly, in this case, it makes more sense to understand restrictiveness in an *individual* not *additive* sense, such that the coercive isolation policy is the most restrictive one.

The second example is the case of AMR arising in wastewater as a result of pharmaceutical use by human patients. Suppose one could intervene with a preventive non-One Health approach which significantly reduces medically indicated antibiotic prescriptions for a limited patient population. This solution would likely limit patients' access to medicines, potentially lowering the quality of treatment they receive. Patients would struggle with infection longer and face an increased risk of related complications. Alternatively, one could intervene with a multiple-domain approach, requiring water service providers to upgrade wastewater treatment plants to better remove pharmaceutical residues, incentivizing the pharmaceutical industry to invest in long-term research and development on less polluting antibiotics and making some changes in prescription practices but more modest ones than on the first alternative. The first approach would be the more restrictive one from an individual point of view, whereas the second one would be more restrictive in an additive sense because it would be financially costly necessitating increased water fees or taxes imposing a small but notable economic burden on very many people. Intuitively, the first option clearly seems more restrictive in the sense relevant to the *least restrictive alternative principle*.

These two examples suggest that the restrictiveness of a policy cannot be simply estimated by adding together the individual instances of restriction that the policy imposes across domains. The assumption of *additive restrictiveness* is too insensitive to how each specific individual is affected. Hence, I reject Johnson and Matlock's assumption that the expansiveness of One Health policies is likely to make them more restrictive in a sense relevant to a plausible interpretation of the *least restrictive alternative principle*. In fact, considering the specific case of AMR, the second example suggests that One Health policies may typically be *less* restrictive than single-domain policies because they distribute the burden of policies across more people.

The Role of the Least Restrictive Alternative Principle

This section challenges the normative role that Johnson and Matlock assign to the *least restrictive alternative principle*. They write:

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> We accept an initial presumption in favor of the least restrictive alternative among the policies available, and as such, that the burden of justification for ethically preferring a more restrictive policy lies squarely with that more restrictive policy and the other moral concepts that might, together, justify preferring it instead. (Johnson and Matlock, 2022: 3)

Johnson and Matlock here appear to assume that when evaluating policy alternatives, the least restrictive alternative principle has a special role compared to other moral principles. More precisely, it establishes, at the outset of the analysis, a presumption against whatever policy alternative is more restrictive than the least restrictive one. This places the burden of proof (or burden of justification) on proponents of the more restrictive alternative to point to other moral considerations (e.g. effectiveness) that must be weighty enough to justify overturning the starting presumption. However, if these considerations are not sufficiently compelling, the presumption stands and policymakers must choose the least restrictive option.

This interpretation of the *least restrictive alternative principle* contrasts with how the principle is commonly understood in authoritative sources. For instance, Childress and colleagues write:

> Even when a proposed policy satisfies the first three justificatory conditions—that is, it is effective, proportionate, and essential in realizing the goal of public health—public health agents should seek to minimize the infringement of general moral considerations. (Childress et al., 2002: 173)

In this interpretation, the *least restrictive alternative principle* is used to choose between similarly effective, proportionate and essential alternatives, which carry different risks of infringing on personal liberties to promote public health. Given two alternative policies that are similarly effective in achieving their goal, proportionate regarding their imposed burdens and benefits, and where either one or the other must be applied to reach the goal, the preferable option is the one that is less intrusive and infringes less on individual autonomy. As a second example consider Kass:

> If 2 options exist to address a public health problem, we are required, ethically, to choose the approach that poses fewer risks to other moral claims, such as liberty, privacy, opportunity, and justice, assuming benefits are not significantly reduced. (Kass, 2001: 1780)

Finally, consider a similar formulation of the principle, provided by Persad:

> A state or local public health agency shall employ the least restrictive alternative in the exercise of its authorities or powers, especially compulsory powers. This means that where the agency may exercise one or more of its authorities or powers to accomplish essential public health services and functions, it shall, to the extent possible, employ the policy or practice that least infringes on the rights or interests of individuals. Employing the least restrictive alternative does not require the agency to adopt policies or programs that are less effective in protecting the public's health or safety. (Persad, 2021: 182)

In these sources, the function of the *least restrictive alternative principle* is not to establish an initial presumption. Rather, it plays a more modest checks-and-balances role, guiding choices between options that are comparable or similar with respect to other moral considerations (e.g. effectiveness). By contrast, Johnson and Matlock's talk of a presumption suggests that they assign greater normative importance to the principle.

However, the idea of a presumption can be interpreted in different ways. In one interpretation, which is common in legal contexts, the standards of evidence that must be satisfied to establish a presumption are lower than the standards of evidence that must be satisfied to overturn it (Koplin and Selgelid, 2015). So, in the case under discussion, proponents of the least restrictive policy alternative would not need as compelling evidence to support their case as proponents of a more restrictive but more effective policy. The more restrictive alternative would systematically be harder to justify (in terms of producing evidence), despite it being more effective. Such asymmetrical standards of evidence make sense in criminal law because they track an underlying normative asymmetry. The notion 'innocent until proven guilty' expresses an asymmetry in standards of evidence that reflects the recognition that punishing the innocent is normally morally worse than failing to punish culpable offenders. However, it is unclear whether similar underlying normative asymmetries are present in the context of public health, including AMR policy (cf. Koplin and Selgelid, 2015). It is unclear that protecting personal freedoms is systematically more important than protecting people from drug-resistant infections in a way that justifies holding those who defend any AMR policy that is more restrictive than the least restrictive one to higher standards of evidence than those who oppose it. At the very least, establishing such an underlying normative

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asymmetry would require some principled argument that Johnson and Matlock do not provide.

But perhaps this is not what Johnson and Matlock have in mind when they talk of a presumption. In an earlier section of the article, they write:

> We hold to a pluralist approach (Dawson, 2016), claiming that which policy is ethically preferable will depend on a number of different factors, such as how restrictive it is, how effective it is, whether it is proportionate, whether it distributes burdens in an acceptable way etc. What's more, these values may trade off against each other[…]. (Johnson and Matlock, 2022: 1)

This appears to suggest that public health policies should be evaluated based on several different ethical considerations, where each has *pro tanto* weight but none plays a special role in decision-making. This view is consistent with only an implausibly weak interpretation of the idea of a presumption in favour of the least restrictive alternative. It does imply that other things being equal, one should choose the least restrictive policy available. But it also implies that other things being equal, one should choose the most effective policy, or the one that distributes burdens most equitably. Since all plausible moral principles play the same role on this approach, it is potentially misleading to single out any particular principle (e.g. the least restrictive alternative principle) as establishing a presumption.

So, depending on how we understand it, the notion of a presumption in favour of the least restrictive alternative seems either inappropriate in the context of AMR policy or potentially misleading.

Conclusion

I have challenged Johnson and Matlock's claim that One Health policies on AMR need special justification against the *least restrictive alternative principle* in two ways. Firstly, I have questioned the implicit assumption of additive restrictiveness, which is assumed by their claim that the expansive nature of One Health policies typically makes them more restrictive. I have argued that an individual notion of restrictiveness is more suitable for evaluating the degree of restrictiveness of public health policies and that One Health policies are not typically more restrictive in this sense.

Secondly, I have questioned Johnson and Matlock's suggestion that the *least restrictive alternative principle* has special normative importance in a way that justifies a systematic presumption in favour of the least restrictive policy option. It is more plausible to think of the principle as one among several prima facie principles that policymakers must balance against each other case by case when determining what to do.

In conclusion, justifying the use of One Health policies in the AMR context is considerably easier than Johnson and Matlock argue.

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Notes

1 This principle has also been referred to as the *least infringement principle* (Childress et al., 2002), *minimisation of burden principle* (Kass, 2001) and *least restrictive alternative principle* (Persad, 2021).

2 It should be noted here that the authors are aware that in some cases One Health policies are less restrictive than their alternatives and, in such cases, 'the ethical justification may be less necessary, as there is less of a presumption against One Health policies to begin with' (Johnson and Matlock, 2022: 4). Even with this caveat the principal assumption they rely on is that, typically, a One Health-type policy is going to be more restrictive than its alternatives.

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Paper III

Pharmaceutical Pollution from Human Use and the Polluter Pays Principle

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Human consumption of pharmaceuticals often leads to environmental release of residues via urine and faeces, creating environmental and public health risks. Policy responses must consider the normative question how responsibilities for managing such risks, and costs and burdens associated with that management, should be distributed between actors. Recently, the Polluter Pays Principle (PPP) has been advanced as rationale for such distribution. While recognizing some advantages of PPP, we highlight important ethical and practical limitations with applying it in this context: PPP gives ambiguous and arbitrary guidance due to difficulties in identifying the salient polluter. Moreover, when PPP does identify responsible actors, these may be unable to avoid or mitigate their contribution to the pollution, only able to avoid/mitigate it at excessive cost to themselves or others, or excusably ignorant of contributing. These limitations motivate a hybrid framework where PPP, which emphasizes holding those causing large-scale problems accountable, is balanced by the Ability to Pay Principle (APP), which emphasizes efficiently managing such problems. In this framework, improving wastewater treatment and distributing associated financial costs across water consumers or taxpayers stand out as promising responses to pharmaceutical pollution from human use. However, sound policy depends on empirical considerations requiring further study.

Introduction

While pharmaceuticals are essential to human and animal well-being, their release into the environment is a source of growing concern. Emissions of pharmaceutical residues may occur during drug manufacturing, via urine and faeces following use in humans or domestic animals, in some cases via use on plants, and through inappropriate disposal of unused drugs (Boxall et al., 2012). The great majority of active pharmaceutical ingredients (APIs) are designed to interact already at low concentrations with target molecules in humans

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or pathogens, molecules that are often well conserved across a range of different non-target organisms (Gunnarsson et al., 2008). Accordingly, there is a growing body of evidence for effects on wildlife associated with exposure to various APIs, including reproductive disturbances, behavioural changes and disruption of organ development (Oaks et al., 2004; Kidd et al., 2007; Brodin et al., 2013; Näslund et al., 2017). Environmental emissions of antibiotics are particularly worrisome from a human health perspective because they can create a selection pressure favouring resistant bacterial strains (Bengtsson-Palme et al., 2018; Larsson and Flach, 2022), potentially exacerbating antimicrobial resistance, a major global threat to public health and economic development (WHO, 2015; World Bank, 2017). These concerns have recently led key international actors to emphasize the need for policy measures tackling pharmaceutical pollution (European Commission, 2019, 2022; OECD, 2019; European Parliament, 2020, 2021; WHO/FAO/OIE, 2020).

This paper contributes to the development of feasible and ethically justifiable action in this area, focusing on pollution from human use of pharmaceuticals via household and hospital wastewater.[1] Specifically, we consider the *allocation of responsibility* between key actors for managing this problem. Many different management options exist (Boxall et al., 2012; Pruden et al., 2013; OECD, 2019). *Source-directed* measures mainly target pharmaceutical companies and concern the development of drugs that are environmentally 'benign by design'. *Use-orientated* measures mainly target health professionals and patients and seek to reduce consumption indirectly limiting the subsequent environmental release of residues. *End-of-pipe* measures aim at removing pharmaceutical residues close to the point of entry into the environment, e.g., through waste collection or wastewater treatment. Specifically, while existing wastewater treatment plants (WWTPs) are not typically equipped to effectively capture and remove pharmaceutical residues, some European countries and regions have recently started adapting them for this purpose (Margot et al., 2013; Rizzo et al., 2019). These different types of measures will engage different actors, and impose economic costs, risks and other burdens on them and others in complex ways (Kirschke and Kosow, 2022). Justifying the choice and design of measures therefore requires considering the normative questions of how such costs, risks and burdens should be distributed, and on what grounds.

Previous research has considered the allocation of responsibilities for managing several other pressing environmental and public health challenges, including climate change (Caney, 2010; Knight, 2011; Moellendorf, 2012; Page, 2012), ecosystem conservation (Armstrong, 2018), lack of access to medicines in the developing world (Barry and Raworth, 2002; Malmqvist, 2016) and pollution from drug manufacturing (Nijsingh et al., 2019; Malmqvist and Munthe, 2020). By contrast, how responsibilities for managing pharmaceutical pollution from human use should be allocated remains an unexplored yet critical issue (Larsson et al., 2018).

The present paper seeks to fill this gap. Specifically, we examine the proposal—recently advanced by the European Federation of National Associations of Water Services (EurEau) (EurEau, 2019a,b, 2020; Deloitte, 2020) and endorsed by the European Parliament (2020) and Commission (2022)—that responsibilities for addressing pharmaceutical pollution from human use should be allocated using the Polluter Pays Principle (PPP). We challenge the suitability of PPP as sole rationale for allocating responsibility in this area, propose a more plausible rationale combining PPP with the Ability to Pay Principle (APP) and explore the practical implications of this shift in rationale.

The next section specifies the question under discussion as one concerning the distribution of 'remedial responsibility'. The subsequent section analyses the role of PPP as the default framework for such distribution in recent European policy conversations concerning pharmaceutical pollution. Thereafter (in 'Limitations of PPP') we raise four challenges to PPP in this context. Meeting these challenges, we then argue (in 'The way forward'), requires a hybrid framework where the backward-looking considerations of accountability and blame captured by PPP are tempered by the forward-looking considerations of efficiency captured by APP. Such a framework makes sound policy dependent on empirical considerations that require further study, which we conclude by briefly highlighting.

Four remarks on scope and method: First, while pharmaceutical pollution is a global concern, we focus on the European context. This is because, as mentioned, key European actors have recently proposed applying PPP to this problem, and because this principle is influential in European environmental regulation. While some of our findings may apply more broadly, the justifiability and feasibility of management options likely vary considerably in a global perspective.

Second, to focus specifically on responsibilities for managing pharmaceutical pollution from human use, we set aside other sources of pharmaceutical pollution, including animal use, pollution from manufacturing

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and inappropriate disposal of unused drugs. We also set aside pollution from medically inappropriate or excessive human use, e.g. self-medication with antibiotics and other prescription drugs (Grigoryan et al., 2019). While such use may contribute to an environmental impact, there are strong independent reasons to curb it (namely, patient safety and the need to preserve antimicrobial effectiveness). Managing pollution from appropriate human consumption may remain important in contexts where these other factors are already satisfactorily controlled (e.g. through effective antibiotic stewardship and pharmaceutical waste disposal). Thus, the allocation of responsibility for that management warrants consideration in its own right.

Third, our primary focus is the *rationale* (or justification) for allocating responsibility, i.e. the reasons or principles that make such allocation defensible. Such a rationale is necessary to identify responsible actors, but not sufficient. Empirical evidence is needed too, the nature of which depends on the chosen rationale. Thus, while some relevant evidence may presently be unavailable, the choice of rationale is important because it helps determine what evidence should be produced.

Fourth, we distinguish between two different ways in which the rationales under consideration (PPP and APP) can be used: (i) to justify the *choice of management option(s)* and (ii) to justify the distribution of *costs of management*. When used in the first way, they identify actors responsible for taking action to manage pharmaceutical pollution from human use. In effect, this amounts to choosing between source-directed, use-orientated and end-of-pipe measures since different measures engage different actors. When used in the second way, the rationales identify actors responsible for paying financially for the selected measure(s). While easily conflated, these uses should be carefully distinguished. It may well be that one actor (or group of actors) should do the management, whereas other actors should help bear the economic costs involved.

Allocating Responsibility

The problem of pharmaceutical pollution from human use structurally resembles other pressing societal challenges, e.g. climate change. There is an undesirable situation (here, the presence in water bodies of pharmacologically active substances at potentially harmful levels) that needs to be addressed. However, it is unclear which among several actors (here, drug producers, health professionals, patients, WWTP operators, etc.) should address it. Thus, it needs to be determined who ought to shoulder this burden, and why.[2]

Philosophically, the problem concerns the distribution of *remedial responsibility* (Miller, 2001). Such responsibilities are defined by certain features: they are (a) *special*, i.e. not borne equally by all actors, (b) *normative*, i.e. they give rise to requirements to act and (c) *forward-looking*, i.e. geared towards producing an outcome, towards putting some 'bad situation right' (Miller, 2001: 454). Thus, to assign remedial responsibility for a 'bad situation' to an actor is to single out that actor from others as being required to engage in efforts to improve that situation.[3]

Since such efforts are costly or burdensome, some justification is needed for requiring actors to engage in them. Standard reasons used for this justification refer to moral responsibility, causal contribution, community and capacity (Miller, 2001; Björnsson and Brülde, 2016). That is, I may be required to improve some bad situation because its occurrence is my fault (moral responsibility), because I innocently played a role in causing it (causal contribution), because I have some special pre-existing responsibility or relationship to those affected by it (community) or because I am especially capable of improving it (capacity).[4]

These general grounds of responsibility find specific expression in environmental law and policy. PPP states that the cost of addressing damages caused by pollution should be distributed to actors in proportion to how much they pollute, thus appealing to *moral responsibility* and/or *causal contribution*, whereas APP states that such costs should be distributed in proportion to actors' ability to pay, linking to considerations of *capacity* (Caney, 2010; Moellendorf, 2012).

The next section outlines PPP's central role in recent European conversations about the allocation of responsibilities to address pharmaceutical pollution from human use. Thereafter we first highlight important limitations of PPP when applied to this case and then discuss how these limitations can be overcome by a hybrid rationale combining PPP and APP.

PPP and Pharmaceutical Pollution from Human Use

PPP is invoked as rationale for allocating responsibilities for waste and wastewater management in several binding policy documents within the EU. For instance, the Water Framework Directive states that 'environmental damage should, as a priority, be rectified at source and

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that the polluter should pay' (2000/60/EC, preamble §11), whereas Directive 2018/851 amending the Waste Framework Directive (2008/98/EC) states that '[i]n accordance with the polluter-pays principle, the costs of waste management, including for the necessary infrastructure and its operation, shall be borne by the original waste producer or by the current or previous waste holders' (Article 14). Together, these statements locate responsibility (for paying the costs and organizing necessary actions and facilities) for waste management as closely as possible to the source of the waste producing chain. In addition, both documents refer to the *Extended Producer Responsibility Principle* (EPR): 'producers of products bear financial or financial and organizational responsibility for the management of the waste stage of a product's life cycle including separate collection, sorting and treatment operations' (Ibid, preamble §14). EPR legally operationalizes PPP in a way that allows control of the whole life cycle of a product by pressure on *producers*, via the basic accountability of *polluters* implied by PPP. In this way, PPP provides a framework of legal accountability through the imposition of financial and organizational responsibilities to prevent and mitigate environmental damage across the EU.

Recently, PPP and EPR have figured prominently in European policymaking related specifically to pharmaceutical pollution. In 2019, the European Commission (2019) set out to explore the potential role of the EPR framework for addressing this problem. The 2020 European Parliament resolution on a strategic approach to pharmaceuticals in the environment stresses PPP and EPR as instruments for addressing pollution from both manufacturing and use of pharmaceuticals (European Parliament 2020: §5), a stance repeated in the 2021 resolution on a pharmaceutical strategy for Europe (European Parliament, 2021: §157). And in October 2022, the Commission (2022) proposed revising the Urban Wastewater Treatment Directive (91/271/EEC) to, *inter alia*, require member states to ensure that pharmaceutical and cosmetic residues are removed at urban WWTPs (Article 8) and that costs for necessary WWTP upgrades are borne by pharmaceutical and cosmetic producers under EPR (Article 9).

The most developed case for applying PPP to pharmaceutical pollution from human use has been presented by EurEau, which represents European national WWTP operators. EurEau draws extensively on PPP to argue that the primary responsibility to manage this problem and bear associated costs falls on polluting actors—pharmaceutical producers, regulators, healthcare providers and patients—not on WWTP operators (EurEau, 2019a,b, 2020; Deloitte, 2020). In effect, EurEau uses PPP to advocate priority to management options that engage these actors, i.e. source-directed and use-orientated measures, citing a recent OECD (2019) report that makes similar recommendations. This stance has later been echoed by some European national water service providers (e.g. Svenskt Vatten, 2021). While EurEau acknowledges that end-of-pipe solutions in the form of improved treatment at WWTPs may have some role to play (EurEau, 2019b), these are characterized as 'a means of last resort' (EurEau, 2019a: 3), whereas 'control-at-source measures should have absolute priority' (EurEau, 2020: 8).

In addition to citing PPP to establish that end-of-pipe solutions are of secondary importance, EurEau (2019b, 2020) draws on PPP to argue that, insofar as such solutions are necessary, the cost for them should mainly be borne by the pharmaceutical industry. Upgrading WWTPs to remove pharmaceutical residues will generate financial costs, the magnitude of which is contested (Naturvårdsverket, 2017; Svenskt Vatten, 2021) and varies between techniques used (Rizzo et al., 2019). EurEau advocates applying EPR (hence by extension PPP) to allocate these costs to 'those producing or making available on the market products that emit micropollutants and microplastics' (EurEau, 2020: 6) rather than to water operators or water consumers.

EurEau thus uses PPP in both ways distinguished in the introduction: to support the choice of 'upstream' over 'downstream' management options, and to justify allocating the cost for necessary downstream solutions (WWTP upgrades) mainly to pharmaceutical producers. They characterize this application of PPP both as *fair*, because it assigns responsibility where it is due (to the polluters), and as *effective*, because it encourages upstream actors to avoid or reduce polluting behaviour (e.g. by developing 'green' pharmaceuticals and adopting sustainable drug prescription, consumption and disposal practices) (Deloitte, 2020; EurEau, 2020). This echoes two widely acknowledged general advantages of PPP and the underlying moral responsibility principle (Miller, 2001; Moellendorf, 2012; Armstrong, 2018). First, PPP is sensitive to how harms that need to be addressed come about, reflecting a 'you broke it, you fix it' logic that is intuitively appealing and familiar from various moral and legal practices. Second, by holding those causing harm responsible, it potentially disincentivizes harmful or reckless behaviour. While these are genuine advantages, PPP also has important disadvantages which, we argue, motivate giving it a more

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limited role than its proponents in the present discussion suggest.

Limitations of PPP

We will highlight four significant ethical and practical challenges to the application of PPP to pharmaceutical pollution from human use: the indeterminacy problem, costs of avoiding pollution, the inability of polluting actors and excusable ignorance. Taken together, these challenges make PPP unsuitable as sole rationale for allocating responsibility in this area, calling for a reconsideration of European water operators' PPP-based case for prioritizing upstream action and allocating costs of downstream action to putative polluters.

The Indeterminacy Problem

The indeterminacy problem arises due to difficulties in establishing the causal chain of events producing harms that need to be addressed (Miller, 2001; Caney, 2010). According to PPP, responsibility is borne by polluters, in proportion to how much they pollute. To apply PPP, we therefore must trace different actors' contributions to the pollution and assess their relative magnitude or importance. In the case of pharmaceutical pollution from human use, this means accounting for the behaviour of a multitude of actors, including, among others, manufacturers, distributors, authorization agencies, healthcare providers, physicians and patients. This is empirically challenging because many of the contributions are likely difficult to measure. However, the problem goes deeper: even with accurate and complete empirical information, it needs to be determined which contributions should count in the first place and how to individuate and compare them. A difficulty here is that different contributions to pharmaceutical pollution from human use are highly interdependent. A patient's excretion of drug residues presupposes that a manufacturer produces the drug, that an authorization agency approves it, and (often) that a healthcare system procures/subsidizes it and that a physician prescribes it. Conversely, these other actors do not contribute to pollution (via excretion) unless the patient ingests the drug. This makes it difficult to disentangle different actors' contributions in the way necessary for applying PPP, leaving it indeterminate where responsibility should lie.

This indeterminacy is compounded by the fact that omissions to act are sometimes considered causes for purposes of attributing moral and legal responsibility (Miller, 2001). Specifically, the EU understanding of PPP considers both 'active' polluting practices and failures to take action to mitigate pollution as falling under the principle (Hinteregger, 2008). In effect, not only manufacturers, authorization agencies, healthcare providers, physicians and patients may count as polluters. A WWTP operator that fails to take steps to improve the removal of pharmaceutical residues from wastewater may *also* qualify as polluter, but by omission,[5] and thus, under PPP, be required to take such steps or help fund them.

Admittedly, omissions are not always considered causes of relevance for attributing (moral or legal) responsibility, but mostly count as such when they represent a failure to fulfil some prior obligation, i.e. in cases of culpable negligence (Miller, 2001). However, WWTP operators are arguably under such an obligation, since their socially sanctioned task is to help secure clean waterways. A failure to contribute to this task by taking steps to mitigate pharmaceutical pollution may thus be construed as a relevant cause of the pollution.

The indeterminacy problem challenges PPP in two related ways. First, if we cannot identify some actors as more salient polluters than others, we cannot proportionately assign responsibility. This makes PPP hard to apply, limiting its capacity to guide action. Second, and more fundamentally, distributing responsibility based on actors' contributions to a problem seems *arbitrary* absent a clear picture of the relative magnitude or importance of these contributions. Actors who are assigned larger responsibilities may object, not unreasonably, that they are required to carry greater burdens than others without proper justification.

In response, some might dismiss indeterminacy as a mere theoretical worry because, in practice, EPR specifies PPP by unambiguously assigning responsibility to producers. This response meets the first of the challenges because EPR does single out some polluters as particularly salient. However, it does not meet the second, more fundamental challenge. We still need to ask why pharmaceutical producers rather than other putative polluters *should* be singled out given the complexity of interdependent contributions highlighted above, i.e. what justifies specifying PPP in this way. Here, appealing to EPR clearly begs the question.

The indeterminacy problem challenges PPP both as justification for the choice of management options and as rationale for allocating associated costs. If the most salient polluters cannot be singled out it cannot be determined what actors are mainly responsible for implementing mitigation measures, nor how large costs each actor should bear. Proportionally allocating costs

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for WWTP upgrades is particularly difficult given that such upgrades would simultaneously remove many pollutants, which reach WWTPs via partly distinct causal pathways involving distinct actors. Performing accurate, quantitative comparisons of the environmental impact associated with each pollutant is exceptionally challenging.

Costs of Avoiding Pollution

This challenge links to a common (moral and legal) notion that there are limits to what actors may reasonably be expected to do to avoid causing harm or mitigate harm they cause (Caney, 2010). This concerns both costs or burdens to the actor herself and indirect costs of her action to others. The options that contributors to pharmaceutical pollution from human use have for avoiding or reducing their contribution normally involve costs of either or both kinds. Just like other APIs, those associated with environmental risk are also important for clinical practice and public health. This means that the indirect costs would be high if drug manufacturers were to avoid pollution from use by reducing or even ending production of such APIs. This is not usually considered an option precisely because of the steep potential burden on patients: lack of access to needed medicines. Perhaps more realistically, drug companies could invest in developing new APIs that are 'benign by design', i.e. pose less environmental health risks. However, while this could help phase out potentially polluting drugs in the long term, it will likely play at most a minor role in the nearest decades given the time frame and scientific challenges of bringing new APIs to market.[6] In the short-to-medium term, it is sometimes possible to substitute an active ingredient associated with high environmental risk with a clinically equivalent alternative posing lower risk. For example, diclofenac, which can affect the kidneys in vultures and fish (Oaks et al., 2004; Näslund et al., 2017), may sometimes be replaced with another similarly acting anti-inflammatory drug that is less toxic to fish (Näslund et al., 2020). Substitution could also involve different administration forms where e.g. gels for topical applications could lead to higher environmental releases than pills containing the same active substance (Bielfeldt et al., 2022). However, for the great majority of situations, changing the active ingredient or the administration form comes with a differential risk of side effects and/or differential opportunities to achieve the desired effect in the patient. In these cases, the options for avoiding or reducing pollution (bracketing improper prescription, use and disposal of drugs; see 'Introduction') are to rely on a clinically inferior alternative or abstain from using the polluting drug—both of which are clearly burdensome to patients.

Of course, substantial cost is not necessarily a reason against taking action to avoid or mitigate harm, since alternative mitigation approaches may be equally or more costly. The point is that since PPP assigns responsibility exclusively based on contributions to pollution, it is insensitive to such costs. PPP does not consider the comparative costliness of options available to different polluters when selecting among these options, nor the possibility that options available to non-polluters may involve lower cost than any of these. PPP does not, for instance, allow us to compare the potential health burdens of different actions targeting drug development, prescription and use to each other, nor to the monetary costs of upgrading WWTPs to address pharmaceutical pollution end-of-pipe, when determining how to address this problem. However, such comparisons seem vital for selecting justifiable action in this area.

The cost challenge affects the use of PPP to select management options, since the options currently available to upstream polluting actors would potentially impose substantial health burdens on patients. Potentially the challenge also concerns the use of PPP to justify allocating economic costs to these actors, but it seems less pressing here. Some such actors (e.g. healthcare systems or financially insecure patients) may face powerful competing demands on their resources making them unable to bear costs proportional to how much they pollute without foregoing other important expenses. However, other potentially polluting actors (e.g. financially secure patients) may be so numerous and contribute so little individually to the pollution that each can bear proportional costs without incurring significant burdens.

Inability of Polluters

The cost challenge leads naturally over to another challenge to PPP. Many authors have noted that PPP (or the underlying causal contribution or moral responsibility principles) is susceptible to allocating responsibility to actors that, though they have (culpably) polluted or otherwise caused harm, are unable to address that harm (Miller, 2001; Caney, 2010; Young, 2011). In consequence, the harm will remain unaddressed, compromising the purpose of assigning responsibility in the first place (Miller, 2001). Of course, mere *reluctance* among polluters to engage in pollution control is no justification for failing to do so. However, in some cases the option to avoid or reduce pollution may simply not exist, e.g.

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when a pharmaceutical producer cannot switch from a conventional drug to a 'green' alternative because no such alternative has yet been developed. In other cases, the option may exist but be effectively blocked by other actors. For instance, the costlier reducing the use of polluting drugs is for patients (see 'Costs of Avoiding Pollution') the likelier are they and their treating physicians to resist such reductions, potentially making it infeasible for healthcare decision-makers to implement them even if they are formally decided. Thus, in a context where drugs are largely properly prescribed, used and disposed of, there are likely limits to how far healthcare institutions can go towards reducing use-related pharmaceutical pollution.

Of course, the observation that some of polluters' options are infeasible does not show that all of them are. Rather, the point is this: the feasibility of such options lacks relevance for PPP due to its exclusive concern with contributions to pollution, which limits its ability to allocate responsibility in a way that ensures the pollution is effectively addressed.

The inability challenge mainly affects PPP as a justification for the choice of management options, as key polluters may lack realistic ways of implementing the necessary changes. However, as with the cost challenge, it seems less as damaging to PPP as rationale for allocating economic costs. Some polluters (e.g. healthcare institutions and financially insecure patients) may face financial constraints that make it not only burdensome but infeasible to proportionally pay for pollution control, whereas this is less plausible for polluters who are better off and whose individual contributions are small.

Excusable Ignorance

The excusable ignorance objection to PPP maintains that it is unfair to allocate the burdens of pollution control to polluters if they are unaware, and could not reasonably be expected to be aware, of causing the pollution. More fundamentally, causal contribution to a problem is in most cases considered insufficient grounds for responsibility to address that problem; knowledge or culpable ignorance of the contribution is needed too (Miller, 2001).

Now many contributors to pharmaceutical pollution from human use are or should be aware of their contribution, and so cannot plausibly appeal to excusable ignorance to refuse bearing the burdens of pollution control. Certainly, it should be evident to drug producers that a variety of the APIs they produce risk causing harm when released into waterways. Similarly, regulators and healthcare providers know or can reasonably be expected to know about such risks and their role in creating them. WWTP operators, too, clearly seem aware of these risks, given the recent attention that organizations representing them have devoted to this issue (EurEau, 2019a,b, 2020; Deloitte, 2020; Svenskt Vatten, 2021). The same arguably goes for individual prescribing physicians, but this is less obvious as they may not have been educated about such risks and may have limited opportunities to learn about them in their professional roles.

While the excusable ignorance objection cannot plausibly be raised on behalf of these actors (possibly excluding physicians), it is forceful when raised on behalf of patients. This is because patients cannot reasonably be expected to be aware of risks associated with use-related pharmaceutical pollution as they generally and quite appropriately rely on public agencies' and healthcare providers' expertise concerning the drugs they consume. Given their excusable ignorance, it seems unfair to apply PPP to allocate the burdens of pollution control to them. Such allocation would be *direct* if patients were expected to bear management responsibility by choosing less over more polluting alternatives when purchasing medicines,[7] or assigned economic costs by having to pay more for the latter. More importantly, however, measures taken by *other* putative polluters will typically *indirectly* impose burdens on patients. Avoiding or reducing the production, approval or prescription of medically indicated but potentially polluting drugs will—as highlighted above (see 'Costs of Avoiding Pollution')—potentially negatively affect patients' health.[8] The excusable ignorance objection challenges both the direct and indirect imposition of burdens on patients under PPP.

There are two ways of sidestepping this objection, defending the imposition of burdens on patients despite their ignorance. The first is to interpret PPP as based on causal contribution alone, rather than causal contribution combined with knowledge or culpable ignorance. PPP would then be understood as a *strict liability* principle: 'if people engage in activities which jeopardize other people's fundamental interests [then] they should bear the costs of their actions even if they were excusably ignorant of the effects of their actions' (Caney, 2010: 208; cf. Shue, 1999). However, while strict liability has legal precedent in certain specific contexts, it is often considered unfair as a general moral principle because it holds people responsible for outcomes they cannot predict or avoid (Caney, 2010; Moellendorf, 2012). The second approach would be to inform patients about use-related pharmaceutical pollution and their role in

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it. Effective and accessible information campaigns could ensure that patients are either aware of this problem or no longer *excusably* ignorant since the relevant information is easily and widely available. This might be feasible in the case of *directly* allocating management responsibility or economic costs to patients purchasing medicines since the information could be included in product leaflets or supplied by pharmacists. However, it seems much harder to ensure that patients *indirectly* affected by measures taken by other actors to reduce the production, approval or prescription of polluting drugs are adequately informed. Thus, the excusable ignorance objection remains a challenge to PPP as rationale for the choice of such management options even granted the possibility of informational efforts.

Summing-up

We have highlighted four challenges to PPP as sole rationale for distributing responsibility for managing pharmaceutical pollution from human use. First, difficulties in determining who the relevant polluters are in this case make PPP hard to apply non-arbitrarily. Moreover, PPP is susceptible to allocating responsibility to actors who are unable to address the harm they cause, who can only address it at excessive cost to themselves or others, or who are excusably ignorant of causing it. All four challenges apply to the use of PPP as guide to selecting management options, whereas the use of PPP as justification for allocating economic costs is mainly vulnerable to the first one. This suggests that European water operators' appeal to PPP requires significant modification, especially as justification for prioritizing source-directed and use-orientated measures but also as rationale for allocating costs of end-of-pipe action to upstream actors.

More fundamentally, these challenges arise because PPP assigns responsibility exclusively on *retrospective* grounds, by asking who caused or is causing a problem. This provides reason to include *prospective* considerations when assigning responsibility in this area, asking who is best placed to solve or mitigate the problem. This is our task in the next section.

The Way Forward

Given the limitations of a purely retrospective approach, it is worth starting by considering a purely prospective alternative, which, in the context of environmental law and policy, is represented by APP. As noted above (see 'Allocating Responsibility'), APP is the expression of a more fundamental capacity principle, according to which the responsibility to address a problem should be allocated to the actor(s) who are able to address it (most) efficiently (Miller, 2001; Gosseries, 2004). Once APP is understood in this way, it becomes clear that its name may be somewhat misleading. An actor's capacity to address a problem has two dimensions: *effectiveness* (the likelihood of having an impact, and the magnitude of that impact) and *cost* (the burden the actor incurs or imposes on others by addressing the problem) (Miller, 2001). Thus, the 'pay' in APP should be understood as including not only (direct and indirect) financial costs, but also other burdens to the actor and other parties, whereas 'ability' includes both the ability to shoulder these burdens and the ability to accomplish effective management.

APP is attractive in that it prioritizes ensuring that 'bad situations' are actually improved, independently of how they come about, reflecting the overarching purpose of allocating responsibility. This represents an advantage over PPP, which, as argued in the preceding section, lacks precisely this feature. Also, APP has a certain egalitarian appeal as it tends to assign greater burdens to the better off than to the worse off (Armstrong, 2018). On the other hand, APP lacks the features that make PPP attractive. Since it is insensitive to how harms that need to be addressed happen, it finds no support in the intuitively plausible 'you broke it, you fix it' logic underpinning PPP and does not disincentivize harmful or reckless behaviour.

Since both PPP and APP have notable strength and weakness, and since their respective strengths and weaknesses mirror each other, it is plausible to consider them as complementary rather than rival principles (cf. Miller, 2001). Consequently, hybrid or pluralist views—which are concerned *both* with how problems that need to be addressed come about (reflecting PPP) and with how to address them most efficiently (reflecting APP), and perhaps with further considerations—are widely endorsed by theorists and policymakers, in the climate change context (e.g. United Nations, 1992; Caney, 2010; Knight, 2011) and elsewhere (Armstrong, 2018). Similarly, we contend that a hybrid approach combining PPP and APP provides a better rationale for distributing responsibilities than PPP alone in the case of pharmaceutical pollution from human use too.

While APP and PPP can be combined in different ways, we will briefly sketch a framework specifically designed to overcome the limitations highlighted above. In this framework, APP is used to (i) *specify*, (ii) *constrain*, (iii) *complement* and (iv) *override* the

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recommendations provided by PPP. Consider each function in turn:

(i) While contributions to pollution remain relevant in a hybrid framework, we have seen that this consideration alone yields indeterminate guidance because different contributions cannot be readily disentangled and because their relative magnitude and importance are hard to assess. A hybrid framework overcomes this indeterminacy problem by using PPP to demarcate the broader class of candidates for responsibility assignment (all polluters, including polluters by omission; see 'The Indeterminacy Problem'), and then applying APP to discriminate within that class. That is, APP is used to single out, from among the polluters, those who can contribute to reducing or mitigating the pollution most efficiently. There is thus no need to determine just how much each polluter contributes (as would be necessary under PPP alone).

(ii) Singling out capable polluting actors also addresses the cost challenge, by taking the burdens on the actor and others into account when assigning responsibility, and the inability challenge, by considering whether actors are capable of having a meaningful impact. Here APP constrains PPP, ruling out responsibility assignments that impose excessive burdens (cf. Caney, 2010; Armstrong, 2018) or are practically ineffective.

(iii) If capable polluting actors cannot be clearly identified, a hybrid framework licenses assigning responsibility to other actors based on capacity alone. Here PPP lacks traction and APP is used as an alternative rationale in its own right, addressing the inability problem (cf. Caney, 2010; Armstrong, 2018).

(iv) If capable polluters can be identified, but their options for addressing the pollution are considerably less feasible or more (directly or indirectly) burdensome than options available to other actors, a hybrid approach again licenses assigning responsibility to these latter actors based on capacity alone. Here PPP remains applicable but is outweighed by the concern for efficiency captured by APP, again addressing the cost and inability challenges.

In this way, attractive features of PPP are preserved, while the indeterminacy, cost and inability challenges to PPP are addressed. The excusable ignorance objection is not fully defused, though, since excusably ignorant polluters could be assigned burdens also under a hybrid framework. However, the problem is significantly less pressing in this framework, partly because the constraining function helps limiting these burdens, and partly because the complementing and overriding functions ensure that the main rationale for assigning them will often not be contribution but capacity—a rationale that is not susceptible to this objection (Moellendorf, 2012).

Consider how this approach applies to the case at hand. As regards the choice of management options, we have seen that the most salient upstream approaches either have limited feasibility (e.g. developing 'green' pharmaceuticals), or potentially impose considerable health costs on patients (e.g. reducing medically indicated drug prescription and use when no clinically equivalent alternatives exist). On a hybrid view, these are weighty drawbacks. Moreover, on this view, who contribute most to a problem is not decisive for determining who ought to manage it. Taken together, these considerations make the option of upgrading WWTPs to better remove pharmaceutical residues downstream a strong candidate. Such upgrades, which are already being implemented in parts of Europe (Margot et al., 2013; Rizzo et al., 2019), would avoid the potential health burdens associated with upstream approaches. Also supporting this option is the potential 'collateral benefit' of improved removal of various non-pharmaceutical pollutants (Larsson and Flach, 2022). While a conclusive case for prioritizing WWTP upgrades must rely on empirical evidence (more on this below), the hybrid approach sketched here lends it tentative support.

This prompts the question who should bear the financial costs of such upgrades. The answer here is less straightforward. On the one hand, like PPP, a hybrid framework gives weight to whether actors contribute to pollution, consistent with the proposal that drug producers pay (EurEau, 2019b, 2020; Svenskt Vatten, 2021; European Commission, 2022). Assigning costs to producers has two potential advantages in this framework. First, it could incentivize investment in developing 'green' APIs. Second, the intuitive appeal and legal precedents of having producers pay for pollution control may help ensure social legitimacy and political feasibility.

On the other hand, unlike PPP, a hybrid framework only assigns the cost of pollution control to polluters if they can absorb it without excessive setback to their own or other actors' interests. It is unclear that having drug producers pay meets this condition. The crux is not primarily the *direct* costs to producers, but the *indirect* burdens on health systems and patients that these costs may generate. Drug producers are for-profit enterprises

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operating in a market setting, so having them pay for WWTP upgrades will incentivize them to recoup their increased costs through higher drug prices or to leave markets where such requests are made (Nijsingh et al., 2019). This could potentially limit patients' access to medicines. Even if a drug is publicly subsidized, a higher price may affect access to *that* drug by reducing society's willingness to pay for it or access to *other* drugs since subsidizing it would claim a larger share of society's pharmaceutical budget. Societies could of course decide to refuse price increases driven by producers' costs for WWTP upgrades, but this would again risk access by discouraging producers from selling polluting drugs on national or regional markets. Given the clinical importance of these drugs, diminished access to them may have real health impact. Diminished access may also result, though more directly, if patients or health systems are assigned the cost of WWTP upgrades through fees or taxes on polluting drugs.

Though not conclusively ruling out having drug producers, patients or health systems (partially) bear the cost of WWTP upgrades, these considerations support looking beyond putative polluters when allocating these costs. One option is to offer water operators state subsidies funded through general taxation or other economic incentives for undertaking such upgrades,[9] another is to have water consumers pay through increased water fees. Both options avoid the potential health consequences of targeting putative polluters and limit the burden on each individual by widely dispersing the costs.

This discussion shows how shifting the rationale for allocating responsibility also shifts what options for addressing pharmaceutical pollution from human use warrant consideration. In a hybrid framework, upgrading WWTPs to manage the problem end-of-pipe and distributing associated costs across taxpayers or water consumers stand out as promising approaches. These suggestions remain preliminary, though, and further analysis requires attention to empirical matters. These include the effectiveness of different techniques for removing pharmaceutical residues at WWTPs (Margot et al., 2013; Rizzo et al., 2019), economic costs of implementing these in different settings (Naturvårdsverket, 2017; Rizzo et al., 2019; Svenskt Vatten, 2021), appropriate ways of incentivizing water operators to take action (cf. Nijsing et al., 2019; Malmqvist and Munthe, 2020), the ability of different actors to shoulder costs of WWTP upgrades without sacrificing other important interests, and the feasibility and social legitimacy of allocating these costs to them. Moreover, potential side effects of WWTP upgrades should be considered, including the 'collateral benefit' of improved removal of non-pharmaceutical pollutants (Larsson and Flach, 2022) and potentially increased energy use and CO_2 emissions (Rizzo et al., 2019). While assessing these issues is beyond the scope of this paper, we have hopefully provided a plausible rationale for analysing them further and for identifying further areas of empirical inquiry.

Conclusions

Policymakers must consider how responsibilities for managing risks created by pharmaceutical pollution from human use should be distributed between actors. We have assessed whether PPP is a suitable basis for such distribution, as recently suggested by European water operators and the European Parliament and Commission. While recognizing that PPP has notable advantages, we have highlighted four challenges with applying it to this case. First, since it is unclear who the most salient polluters are, PPP fails to unambiguously assign responsibility. Second, insofar as PPP does identify responsible actors, these may be unable to avoid or mitigate their contribution or, third, only able to do so at excessive cost to themselves or others. Fourth, PPP is susceptible to assigning burdens to actors who cannot fairly be held responsible due to excusable ignorance. These limitations motivate a hybrid framework where PPP, which emphasizes holding those causing large-scale problems to account, is balanced by APP, which emphasizes the efficient management of such problems. While sound policy in this area depends on empirical issues calling for further study, this framework tentatively supports managing pharmaceutical pollution from human use by improving wastewater treatment. The allocation of associated costs remains to some extent an open question, but the importance of preserving access to clinically important medicines supports distributing these across water consumers or taxpayers.

Two final caveats: First, the challenges we have raised for PPP concern its role as rationale for policy on pharmaceutical pollution from human use, not its suitability in other areas, e.g. climate change or pollution from drug manufacturing. Second, some readers may disagree with (aspects of) the hybrid framework we have sketched or some practical suggestions we have made. However, even these readers should recognize the insufficiency of PPP as guide for policy in this area and the need to supplement or amend it, albeit perhaps in other ways.

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Conflict of Interest

The authors declare that they have no conflict of interests.

Notes

1 Globally, other pathways for pharmaceutical pollution from human use are common, e.g. open defecation and pit latrines. However, given our European focus (see below) we set these aside, focusing on the wastewater pathway that predominates in this context.
2 Not all undesirable situations require improvement efforts necessitating the allocation of associated burdens. However, consistent with recent policy discussions in this area, we assume that pharmaceutical pollution from human use does require such efforts.
3 Unless otherwise stated, we intend the terms 'responsibility' and 'responsible' to refer to this kind of responsibility.
4 The *structure* of remedial responsibilities should be distinguished from their *grounds*. While their structure is prospective (they aim at producing an outcome), the grounds or rationale for assigning them to actors may be retrospective (such as what the actors have done). The concerns about PPP elaborated below arise because PPP assigns such responsibilities on purely retrospective grounds.
5 Indeed, any action may be truthfully described as an omission of other, alternative actions, and any omission can be truthfully described in terms of an action that could have been performed instead (Woollard and Snyder, 2021).
6 Innovative drugs approved in the USA between 2010 and 2020 had spent 5–20 (median 8.3) years in clinical development (Brown et al., 2022), which, in the case of new APIs, is preceded by several years of discovery and preclinical research. As an extreme example of slow and challenging drug development, no new antibiotic class targeting Gram-negative bacteria has been approved in several decades, despite great efforts (Kingwell, 2018).
7 Such choices do not impose health burdens if the options are clinically equivalent. However, clinically equivalent alternatives do not exist for many polluting drugs (see 'Costs of Avoiding Pollution').
8 Again, we assume that such measures are implemented in a context where drugs are appropriately prescribed, consumed and disposed of (see 'Introduction').
9 Compare discussions about incentivizing pharmaceutical companies to address pollution from drug manufacturing (Nijsingh et al., 2019; Malmqvist and Munthe, 2020).

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Paper IV

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ORIGINAL ARTICLE

Environmental risk and market approval for human pharmaceuticals

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Abstract
This paper contributes to the growing discussion about how to mitigate pharmaceutical pollution, which is a threat to human, animal, and environmental health as well as a potential driver of antimicrobial resistance. It identifies market approval of pharmaceuticals as one of the most powerful ways to shape producer behavior and highlights that applying this tool raises ethical issues given that it might impact patients' access to medicines. The paper identifies seven different policy options that progressively give environmental considerations increased priority in the approval process, identifies ethically relevant interests affected by such policies, and makes explicit tensions and necessary tradeoffs between these interests. While arguing that the current European regulation gives insufficient weight to environmental considerations, the paper highlights concerns with the strongest policy options, on the grounds that these may very well endanger patients' access to effective medication.

Keywords Environmental policy · Pharmaceutical pollution · Antibiotics · Antimicrobial resistance · Ethics

1 Introduction

Institutions and researchers have recently identified environmental pollution from the use and production of medicines as a threat to human and environmental health (Beek et al. 2016; Mackuľak et al. 2019; UNEP 2019; European Commission 2020; European Parliament 2020; WHO/FAO/IOE 2020). For instance, studies have demonstrated that the release of Diclofenac is harmful to aquatic ecosystems, potentially resulting in adverse effects on wildlife. These effects include organ damage and diminished hatching success in fish, neurotoxicity and oxidative stress in molluscs,

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and hormonal disruptions in frogs (Islas-Flores et al. 2019). Moreover, the release of antibiotics in the environment may increase the selection pressure on bacteria which promotes the mobilization and horizontal transfer of resistance genes (Larsson and Flach 2021) in bacteria. This phenomenon contributes significantly to the problem of antimicrobial (AMR) resistance, which represents a gradual erosion of the efficacy of antimicrobial drugs. Effective antibiotics are indispensable for the treatment of bacterial infections and are fundamental for numerous medical interventions, particularly surgical procedures, which in many cases would become substantially more dangerous without access to antibiotic treatment (Laxminarayan et al. 2013; O'Neill 2016).

These concerns emphasize the necessity of regulating and reducing environmental pollution caused by pharmaceuticals, addressing the potential hazards that it poses to human, animal and environmental health. Various approaches can be employed to achieve this goal, involving different actors and stakeholders (Nijsingh et al. 2019; Malmqvist et al. 2023). Malmqvist and Munthe (2020) have identified four areas where new regulations can be introduced to encourage the pharmaceutical industry to adopt more sustainable practices in drug production and development: authorization, procurement, public subsidy, and generic substitution of drugs. In light of recent initiatives within the EU to enhance the consideration of environmental risk at the authorization level (European Parliament 2019; European Commission 2023), this paper will explore various approaches in this area and analyze the tradeoffs between different normatively significant interests that these require.[1] Interventions that regulate the market approval process can be extremely impactful, as the threat of rejection of the application can be used to apply substantial pressure on the industry, however, it also carries exceptional risk of endangering access to new medication (Nijsingh et al. 2019). For these reasons, a good deal of precaution is necessary (Malmqvist and Munthe 2020).

Against this background, the present paper will address the following question: How should the consideration for environmental risk affect the market authorization process for human pharmaceuticals? The paper is organized as follows. Section 2 outlines the current legislation for the drug approval process for the EU market, highlighting the asymmetries between the requirements for human and veterinary pharmaceuticals. Section 3 makes a normative case in favour of the introduction of environmental concerns in the market approval process for human pharmaceuticals, identifies ethically relevant but potentially conflicting interests that would be affected by changes in the approval process and presents alternative policy models that balance these interests in different ways. Section 4 discusses which model or models represent an ethically defensible trade-off between the competing interests.

[1] In this context, the terms 'environmental risk' and 'environmental impact' connote any risk to or impact on human health caused by a chemical substance or a pollutant released in the environment.

2 Current legislation

Currently, the requirements for market authorization for human and animal pharmaceuticals are outlined in several directives.[2] These directives require an Environmental Risk Assessment (ERA) as a part of the market application for a product. An ERA comprises a series of increasingly detailed and tiered tests which assess the potential impact that a drug could have on the environment and its potential risks (Lee and Choi 2019). The assessment of the quality of the data submitted by the producers is carried out by the Committee for Medicinal Products for Human Use (CHMP), a subsidiary of the European Medicines Agency (EMA). Alternative tests may be accepted, provided that they are appropriately justified in the ERA report and that testing methods are deemed fit for the purpose.

While major awareness of pharmaceutical pollution was already present in the 2001's Directive, it is more strongly emphasized in the recent European Union's Strategic Approach to Pharmaceuticals in the Environment, which aims to address the problem more concretely (European Parliament and Council of the European Union 2019b/6; European Parliament and Council of the European Union 2020/741). The European Commission is currently working on a new directive that targets, among other things, the quality and consistency of assessment of the environmental risks of human pharmaceuticals (European Commission 2023).

2.1 Human pharmaceuticals

The EMA released some guidelines in 2006 (European Medicines Agency 2006), which build on the 2001 Directive. According to the guidelines and the 2001 Directive, for a medicine to be accepted on the market, the producer needs to submit a clinical benefit-risk assessment (BRA) that demonstrates that the benefits of the drug for patients outweigh the risks to their health. The approval of an application depends only on the clinical benefit-risk evaluation and not on the ERA. Thus, the main aspect that is analysed when determining whether to approve a medicine is its impact on patients in the target population and not on its potential broader environmental impact (or related indirect consequences for other patients).

EMA writes:

> Evaluation of the potential environmental risks posed by the medicinal product. This impact shall be assessed and, on a case-by-case basis, specific arrangements to limit it shall be envisaged. In any event this impact should not

[2] Directive 2001/84/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use(European Parliament and Council of the European Union 2001); Directive 92/18/EEC of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the texting of veterinary medicinal products; Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

> constitute a criterion for refusal of a marketing authorization (European Medicines Agency 2006, p. 3).

While the environmental impact of pharmaceuticals is clearly acknowledged already in the 2001's Directive, market approval is never conditional to it. Rather, any environmental side effect of a drug are to be handled after approval, for instance by taking precautions when disposing of unused medicines or medical waste (EMA 2006). Additionally, the European Parliament and Council suggested preventive measures such as increased awareness, promotion of prudent use of pharmaceuticals, and increased transparency during the manufacturing process (European Commission and Council of the European Union 2019/6). These measures attempt to limit pharmaceutical pollution in the environment, without fundamentally changing the market access conditions. The new Directive proposal currently under examination significantly increases the importance assigned to environmental risk by requiring a complete ERA along with a list of possible risk mitigation measures targeting harms identified in the ERA:

> (70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated when new data or knowledge about relevant risks becomes available (European Commission 2023, pp. 30–31).

That said, within the legislation currently in place, the environmental impact of a human pharmaceutical does not affect its approval, and any environment-related risk is handled by preventive or remedial practices after the drug is approved.[3] Normatively speaking, the clinical benefit-risk analysis is the only aspect that is relevant for market applications for human pharmaceuticals.

2.2 Veterinary pharmaceuticals

The European Parliament and European Council adopted the current Regulation in December 2018 and it took effect on 28 January 2022 as Regulation EU/6 (European Parliament and of the Council of the European Union 2018).[4]

In the Regulation's *Article 4, Definitions*, the notion of 'benefit-risk balance' is given a broader definition than in the case of human pharmaceuticals. Specifically,

[3] These might include careful waste and disposal handling of the pharmaceuticals, the reduction and change of packaging, or particular attention to wastewater treatment (Ågerstrand et al. 2015).

[4] Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (European Parliament and Council of the European Union 2019a).

the risks that are relevant are of three kinds (European Parliament and Council of the European Union 2019b, p. 5):

> (a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;
> (b) any risk of undesirable effects on the environment;
> (c) any risk relating to the development of resistance;

Moreover, according to *Article 37,* it is possible to deny the market authorization if (European Parliament and Council of the European Union 2019b, pp. 26–27):

> (b) benefit-risk balance of the veterinary product is negative.
> […]
> (f) risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health;
> (i) risks to public or animal health or to the environment is not sufficiently addressed

By contrast to the case of human-use pharmaceuticals, the approval of a veterinary drug is thus not simply determined by the clinical benefit-risk assessment. A drug might safely and effectively treat, say, an infection in a farm animal, but its approval could be denied because of its environmental effects such as driving antimicrobial resistance.

2.3 Comparison of legislation for human and veterinary pharmaceuticals

There is thus a conspicuous asymmetry regarding the relevance of pharmaceutical pollution for the approval of human and veterinary pharmaceuticals. Awareness about the risks posed by such pollution has had a significant impact on veterinary regulation, but less so in the case of human pharmaceuticals. In no circumstances can market authorization for a human drug be denied on the base of its environmental impact. For human drugs, any level of environmental risk is justified if the use of a pharmaceutical provides a sufficiently high benefit-to-risk ratio for a human patient. In practice, this entails that the interests of patients in the target population are given a higher priority than other interests affected by the drug approval process, be they related to the environment, animal health, public health, or future patients. This enables the approval of clinically safe and effective, but potentially extremely environmentally hazardous human drugs, and only allows action to be taken to address such hazards once a drug is on the market. The directive for human pharmaceuticals being currently discussed (European Commission 2023) would simply refuse the market application of a similar product, whenever the mitigation measures would prove insufficient. As for veterinary medicines, approval can be denied in order to prevent danger to human health or interests, for instance in the form of antiparasitic or antimicrobial resistance. In this context then, the interest of animals in a drug's target population can be subordinated to the protection of human or environmental health. This is indicative of different levels of normative priority assigned

to patients' access to pharmaceuticals and protection from environmental risk. The following section will make the case for including consideration of environmental risk in the approval process of human pharmaceuticals, outline alternative policy options for doing so, along with an analysis of how they would impact different morally relevant interests.

3 Including consideration of environmental risk in the approval process for human pharmaceuticals

As shown in the preceding section, the environmental risk of a human pharmaceutical has no relevance to its approval on the market. This can lead to the approval of drugs that are extremely polluting and contribute to other drugs losing their efficacy, as in the case of AMR. This is potentially problematic because such pollution can have a significant impact on human health, as well as wildlife and the environment.

Several prima facie ethical reasons can be given in favour of the introduction of environmental considerations in the market approval process for human pharmaceuticals. The first reason is preventing direct potential harm to human health stemming from pharmaceutical pollution (European Commission 2019; Mackuľak et al. 2019; Batucan et al. 2022). Pharmaceuticals contain active pharmaceutical ingredients (APIs), which have stable molecular structures making them particularly resilient in the environment. APIs can stay in the environment for a long time, and have in some cases been shown to induce serious biological changes in local fauna, particularly in certain environments e.g. close to pharmaceuticals manufacturing sites, sewage and water treatment plants, and aquaculture sites (Love et al. 2011; Gaw et al. 2014; Lonappan et al. 2016; Sathishkumar et al. 2020). There is a concern that the release of APIs and pharmaceutical byproducts of the manufacturing process might have similar impact on human beings. In particular, Okeke et al. (2022) have highlighted the risk of bioaccumulation of pharmaceutical through drinking water or food(i.e. fish, vegetables, fruits), endangering in particular already immunocompromised individuals, by inducing metabolic disorders or cancer.

A second prima facie reason is prevention of indirect harm resulting from pharmaceutical pollution-induced AMR, which represents a substantial threat to the functioning of healthcare systems (Littmann and Viens 2015; Walsh et al. 2023). Recent research pointed out the specific role of antibiotic use, production and excretion in driving resistance by increasing the selection pressure for relevant groups of bacteria in selected environments such as wastewater treatment plants (Larsson and Flach 2021). Higher levels of AMR mean that antimicrobial drugs are becoming less effective which in turn implies that untreated infections become substantially more threatening. One should not disregard that antibiotics have a key role in enabling safe and more complex medical interventions like surgeries or chemotherapy and staving off neonatal infections (Russell et al. 2023).

A third, related reason is that AMR threatens long-term access to effective medications for future generations, making it a problem of intergenerational justice (Barry 1997; Green 1977) and sustainability (Munthe et al. 2021).

Finally, a fourth reason concerns intragenerational justice related to unequal healthcare access (Sen 2002; Temkin 2000, 2003; Reid 2020). In particular, researchers have highlighted how poor and vulnerable populations are disproportionally threatened by AMR because of limited access to medicines and greater susceptibility to infections with resistant bacteria (Selgelid 2007). Additionally, inequality in healthcare access may compound AMR since poorly treated infections may contribute to the selection of resistance genes (Millar 2020).

Preventing pharmaceutical pollution through the market approval process specifically (rather than through other interventions) can be justified by appealing to effectiveness: since authorization agencies can determine what drugs can be sold on a market, they have significant power to influence pharmaceutical companies' behavior (Nijsingh et al. 2020). That being said, given the wide impact that such an intervention might have in terms of, for example, what type of drugs will be produced, and how fast will they be produced, balancing out the effectiveness of the intervention against the needs of patients to access effective mediation becomes crucial.

The remainder of this section outlines different options for including environmental concerns in the approval process of human pharmaceuticals, focusing on policies that are currently being introduced in the EU or that have been suggested in recent academic literature. As will become clear, such policies face a fundamental tension between individual and collective interest of the sort that is familiar from debates in public health ethics and political philosophy.[5] Specifically, they require tradeoffs between long-term public health considerations and short-term clinical ethical considerations regarding benefits and safety for patients in care (Nijsingh et al. 2019).

Nijsingh et al. (2019) have identified many different stakeholders whose interests may be affected by attempts to address pharmaceutical pollution (including drug companies, physicians and other healthcare staff, as well as patients, animals and the environment). I will focus on those interests that are already of central concern in the market approval process, namely, human health-related ones. In this strongly anthropocentric context, the presumption is that protecting and promoting such interests is the main reason to even have pharmaceutical regulation and risk assessment in the first place. From a normative standpoint in the legislative framework I am considering, the interests of other kinds, such as animals or the environment, are not considered in their own right but only insofar as they indirectly impact human health interests. Undoubtedly lowering pharmaceutical pollution may potentially positively impact wild animals and environmental entities such as ecosystems. However, given that the amount of normative weight that ought to be assigned to the interests of non-human animals and environmental entities is highly controversial I will not focus on them here (Singer 1990; O'Neill 1997; Kamenshchikova et al. 2021;). For example then, the acknowledged environmental impact of drugs like

[5] In the context of AMR, see Giubilini (2017) and (Anomaly 2009). In the context of disease control and justifications for compulsory interventions, see Verweij (2011) and Carlsson et al. (2019). For more general discussions about distributive justice and individual rights in public health scenarios, including for example mandatory treatment and screening, see Persad (2019), Kass (2001) and Dawson (2011).

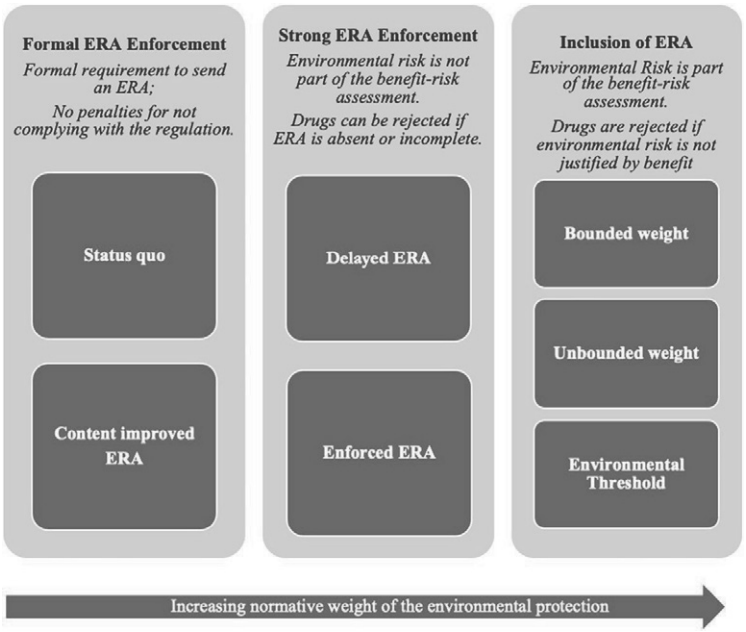


Fig. 1 The figure graphically presents the three categories of policy models. From left to right, the priority given to environmental protection gets increasingly stronger and related requirements get increasingly stricter

Diclofenac is only to be considered as long as it is potentially harmful to human health (Sathishkumar et al. 2020; Batucan et al. 2022).

Among human health-related interests, three types stand out as significant:

The interest of individuals whose direct access to medication would be hampered in case a drug was rejected or delayed in production for environmental reasons. I will refer to this interest using the term *direct patient access*.

The interest of individuals whose health would be endangered by the approval of environmentally hazardous drugs. This group of people includes patients who could experience increased health risk, healthy people which might become ill because of environmental pollution, and patients negatively affected by environmentally-driven drug resistance. I will refer to this interest using the term *environmental protection*.

The interest of individuals whose health may be endangered because of market changes, such as increased price, because of new regulation. I will refer to this interest using the term *indirect patient access*.

For the sake of clarity, the remainder of this section will present different policy options that represent different priorities between the first two of these interests, direct patient access and environmental protection, whereas the third kind of interests, indirect patient access, will be analysed separately at the end of this section. I will draw on recent policy suggestions and the literature on pharmaceutical pollution

to distinguish seven normatively different models that can be grouped into three categories (See Fig. 1). The models are ordered by how they assign progressively more priority to environmental protection. The first category does not consider the ERA, nor its content, to be relevant to whether a drug is approved; the models included in this category are *Status quo* and *Content improved ERA*. The second category introduces strict and enforced requirements regarding the submission of the ERA, but not its content; this includes *Delayed ERA* and *Enforced ERA*. The third category considers the submission of the ERA strictly compulsory and considers the level of environmental risk posed by a drug as potentially relevant for approval (Malmqvist and Munthe 2020); this includes the *Bounded weight*, *Unbounded weight* and the *Environmental Threshold* model. Under no condition will the first four frameworks make it possible to refuse a market application or argue for market withdrawal only on the basis of high environmental risk. The last three, on the other hand, will allow the rejection of a market application although in different ways and in different circumstances.

3.1 Formal ERA enforcement

3.1.1 Status quo

This model is the one currently in use in the EU. Formally it requires a producer to include an ERA when submitting a market application for a drug. In accordance with Directive 2001/83/EC as amended, the 'environmental impact should be assessed, and on a case-by-case basis, specific arrangements to limit the impact should be considered'. However, in any event, 'this impact should not constitute a criterion for refusal of a marketing authorization for medicinal products for human use' (EMA 2006, p. 3).

Caneva et al. (2014) point out that the absence of penalties for not complying with the regulation makes it possible to receive market access without submitting an ERA. Moreover, even when the ERA is submitted, they highlight how the requested studies were either 'missing or of unsatisfactory quality for 83%' of the total (Caneva et al. 2014, p. 314).

As it currently stands, this framework does present a strong issue of compliance and enforcement, as it leaves the option of not submitting an ERA open in practice, limiting the opportunity to address environmental risk after a drug is approved. As such, this framework is the one that prioritizes environmental health the least of the ones I consider here.

3.1.2 Content improved ERA

This framework introduces additional components to the content of the ERA, whilst not making its submission any more compulsory or introducing any time constraint. As an example, Ågerstrand et al. (2015) recommend improving EMA's control over the environmental risk assessment of pharmaceuticals for human use by including more detailed information, for instance by indicating the risk for the development of

antibiotic resistance or including an ecotoxicological assessment. An additional suggestion is the inclusion of data relative to the production of active pharmaceutical ingredients(API) for the medicine. Similar suggestions are made by Lee and Choi (2019). These solutions would in theory allow to increase transparency, and gain important data regarding pharmaceutical pollution, which in the long term can help to establish new more effective risk mitigation practices.

Regardless of which specific content the ERA will require in the renewed legislation, however, the previous considerations regarding compliance and enforcement will remain. Thus, while mandating a more complete ERA would likely serve environmental protection slightly more than in *Status Quo*, patient access would still likely be normatively more relevant.

3.2 Increased requirements for the submission of the ERA

3.2.1 Delayed ERA

A first, not very stringent, requirement can be introduced by requiring an ERA but allowing delayed submission of it. As such, the authorization assessment can start in the absence of an ERA, but will not be concluded without it. Approving a safe and effective but highly polluting drug will still be possible, but at least there will be more awareness and transparency about the environmental impact.

The main advantage of this solution consists in providing additional time for producers to provide the ERA without causing a delay in access that would hinder timely patient access. Doing this makes it possible to have a more complete picture of the environmental impact related to drug manufacturing thanks to ERAs, as well as to give valuable data for the environmental research (O'Neill 2016), keeping priority on patient access. Like with the currently used framework, any meaningful environmental side effect would be handled case-by-case by measures applied after approval. The degree to which environmental pollution would be mitigated would depend on what these measures are.

This option imposes stricter requirements for the recording of environmental risks than the previously outlined frameworks. As such, it does protect environmental health more effectively than the *Status quo* and *Content improved ERA* frameworks, but to a lesser extent than the options I will examine next.

3.2.2 Enforced ERA

A second, more constraining approach is to make the submission of an ERA compulsory for approval on the market; with this model, the option of noncompliance regarding the submission of the ERA is removed. This type of solution was already adopted in Sweden (Strategi för Sveriges arbete för en giftfri miljö 2012), and further suggested by Ågerstrand et al. (2015). This solution could have a positive effect of encouraging transparency related to the manufacturing process and facilitating any post-approval mitigation measures. As seen above, such effects can also be secured by additional rules on what type of information the ERA should contain

(*Content improved ERA*), and the two models may well be combined. Note that in this framework, the specific content of the ERA would still not impact whether the drug is approved. It would be possible to accept on the market an extremely environmentally harmful drug, so long as the ERA study was submitted.

In this scenario, the ERA's content itself is still not considered sufficient to refuse a market application. However, improved transparency and labelling could incentivize the pharmaceutical industry to ensure stronger control of pollution from their production (O'Neill 2016).

Unlike in the previous framework, in this case, there would be no conditional approval. The submission of the ERA would be necessary at the time of approval and follow a hard deadline. By introducing the presence of an ERA as a stringent condition for market access, this framework would make available additional environmental data which could be valuable for developing more effective post-approval remedial actions. However, such a requirement would also require producers to invest more time and resources in the application for market approval than at present, which could potentially slow down the introduction of new drugs on the market, as well as possibly scaring producers off the market. This means that of the first three frameworks presented, this one prioritizes direct patient access the least and environmental health the most.

3.3 Environmental risk as a factor for market approval

3.3.1 Bounded weight

This framework represents the first, cautious, way to include the environmental risk of a pharmaceutical in the benefit-risk assessment of human medicines. Whether or not a drug is accepted on the market will, in certain cases, depend on how the environmental impact of the drug and clinical efficacy will compare to each other. This approach has been proposed by Ågerstrand et al. (2015, p. 5341):

> The ERA should be included in the risk-benefit analysis, but…[t]he possibility to consider the environmental aspects in the authorization should only aim at denying further approvals of products containing a known problematic API when there are already products on the market that cover the specific medical need to the same extent though associated with a lower environmental risk.

This model offers the first example of a scenario where the rejection of a drug could be motivated by its environmental impact. With this framework, it would be possible to refuse a market application if the new product has a worse environmental impact than an already marketed drug that addresses a similar clinical need. In theory, this model forces the market to produce drugs that are more environmentally sustainable than the ones already in use, without critically hampering patient access to more effective drugs.

However, this framework might not be easily applicable in many situations. Suppose that two drugs, x and y, have different APIs. From a clinical point of view, it is unlikely that x and y will have identical clinical effects for identical patient

populations. They will likely vary at least somewhat with respect to effect and side-effects or be indicated for at least somewhat different populations. Hence, it is going to be quite hard to find two clinically equivalent drugs with different APIs that address the exact same medical need (Meredith 2009; Tothfalusi 2008). So long as a drug targets a slightly different patient population or has slightly greater effect or lower risk for an identical population than a drug already on the market, it would be possible for it to gain market access independently of environmental concerns.

In practice, the performance of this model would largely depend on how the relevant medical needs are defined. If they are defined narrowly, it will not be possible to deny authorization very often, as already noted. But in cases where market authorization *is* denied there would presumably be no negative health impact on patients, whose needs are already fulfilled. On the contrary, if the need is defined more broadly, it will be easier to find scenarios where comparable drugs can be already found on the market. This would mean that refusing market access on grounds of environmental risk would be more common, but the risk of at least marginally sacrificing patients' interest in safe and effective medicines would be greater.[6] Thus, the interests of environmental health will receive higher priority the more loosely the relevant needs are defined.

Whichever of the two interpretations is applied, this framework allows refusing a market application on an environmental basis, albeit in a limited number of cases. As such, this framework prioritizes the interests of environmental health more than the previous three frameworks I have considered.

3.3.2 Unbounded weight model

This framework is similar to the previous one because it relies on including the environmental impact of a human pharmaceutical in the benefit-risk assessment. In this model, the refusal of an application on an environmental basis can be justified, even in absence of the availability of another clinically equally good drug. This would be possible when the environmental risk (together with clinical risks) are taken to outweigh the clinical benefits. However, this scenario would leave open the possibility of ensuring patient access to clinically valuable drugs despite adverse environmental effects. The impact of this model will depend on *how much* weight is given to clinical risk, clinical benefit, and environmental risk, respectively (Nijsingh et al. 2019; Malmqvist & Munthe 2020). However, it would in principle prioritize environmental protection more strongly than the previously considered models by, for example, allowing the rejection of a drug that would significantly drive AMR.

3.3.3 Environmental threshold

In the last scenario, a clinically effective drug is rejected if its environmental impact is above a certain threshold. Within this framework, it will be possible to reject a

[6] A similar objection is standardly raised against Cost minimization analysis in pharmacoeconomics (Rai and Goyal 2018).

market application solely by virtue of its environmental effects, even in cases where it might offer revolutionary therapeutical solutions. This is the most drastic option of the ones mentioned until now.

This framework sets a very strict and specific limit to what degree of environmental risk would be tolerable. The implication is that a clinically safe and effective drug might be denied market access because of the set threshold. In theory, this option allows prioritizing the interests of environmental health the most, but this all depends on how much environmental risk is actually tolerated. Some qualifications should be made. On the one hand, if the tolerated environmental impact was very high, even a strict threshold framework might be incapable of refusing market access to very polluting drugs. In this case, patient access would have a higher normative priority. On the other hand, if the tolerated environmental impact was very low, it would be possible to refuse market access even to drugs that have a more average environmental impact. In this case, normative priority would be assigned differently and undeniably to environmental health, at the expense of patient access.

A variant of this *Threshold* framework can be identified in the directive proposed by the European Commission, which introduces a stronger requirement for the submission of a complete ERA, as well as the possibility of refusing a market application if the applicant fails to "propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment" (European Commission 2023, p. 32). Despite not openly referencing the notion of an environmental risk threshold, the new directive operates under the assumption that certain levels of environmental risk are not tolerable, and either a drug has an acceptable environmental impact or the producer needs to present sufficient risk mitigation measures.

Both versions of the *Environmental Threshold* model would prioritize the interests of environmental health more than all the options we considered in this section. Compared to the *Bounded* and *Unbounded Weight* framework, this framework is more rigid, and it sets a strict threshold, which in principle provides a powerful instrument for preventing environmental risk but also potentially requires foregoing significant clinical benefits (Nijsingh et al. 2019; Malmqvist & Munthe 2020) by potentially reducing patient access or scaring producers off the market. That said, the tradeoffs between these interests will vary substantially depending on where the threshold is set and how easy it is for producers to comply. It should be noted that in practice there is a limited understanding of what specific set of environmental circumstances enable the emergence of resistance inclinically important bacteria (Larsson and Flach 2021), and of the relevant environmental pathways for the pharmaceuticals or their impact on human health (Wuijts et al. 2017). As such, understanding precisely how and where to set the thresholds for the ERA remains a hard epistemic challenge.

3.4 Indirect patient access and market dynamics

The third interest is represented by individuals whose health may be endangered because of indirect market changes, for instance patients with health conditions that receive fewer resources because of increased drug prices. The reason for discussing

this separately is that overall this group has a relatively stable interest in avoiding the introduction of new regulations. New regulations and potentially environmentally safer drugs would likely come with very complex consequences of which three should be noted in particular. The more demanding the new regulation will be, the higher is the chance that these consequences will ensue.

Firstly, environmental concerns might cause fewer drugs to be approved, which in turn might mean less competition on the market and potentially higher prices for medicines. Supposing a fixed budget for a healthcare system, this could reduce the resources available for purchasing medicines and more generally for maintaining equally good care.

Secondly, the new requirements related to production could introduce new costs for manufacturers. The reasons could be different but could be due to delayed sales because of necessary testing or forced internalization of environmental externalities. This would likely imply that the price of medicines for healthcare systems and private use would go up (Nijsingh et al. 2019), presenting a scenario similar to the one mentioned above.

Thirdly, if the regulation's requirements are perceived to be too harsh or economically unpalatable, the producers might stop producing certain drugs, compromising access to medicines.

That said, indirect patient access could also benefit from increased weight given environmental concerns. Firstly, the more demanding and presumably effective the criteria for market access are, the stronger the prevention of environmental hazards, which in turn will reduce the number of resources spent on dealing with the consequences of those environmental side effects in healthcare. This could lead to reduced demand for healthcare, meaning that more rather than less resources per health need would be available, again assuming a fixed budget. Secondly, framework options like *Compulsory ERA* would allow the gathering of environmental data and expedite research on pollution levels, which could meaningfully impact indirect patient access as well.

3.5 Conclusion

This section has made explicit how addressing environmental pharmaceutical pollution within the drug approval process will require trade-offs between direct patient access to drugs, the prevention of harm to humans caused by environmental pollution, and indirect patient access to drugs. The seven frameworks presented assign different priorities to these different interests. Specifically, while *Status Quo* assigns the highest priority to direct and indirect patient access, the other models allow assigning progressively more and more priority to environmental protection.

4 Discussion and conclusion

The second section of this paper outlined the current EU legislation for the market approval process and highlighted the differences between the requirements for human and veterinary pharmaceuticals. The third section of this paper presented the ethical arguments in favour of introducing environmental concerns in market

approval process of human pharmaceuticals, and presented alternative policy frameworks that balance different morally relevant interests in different ways. This section will discuss which framework or frameworks represent the best trade-off or balance between these interests. It is useful to distinguish two extremes in the prioritization between interests, one strongly favoring the current patients' access to healthcare or people whose health might be endangered because of potential market changes, and the other one strongly prioritizing prevention of pharmaceutical pollution and long-term access to effective medication.

The first extreme is represented by the current regulatory framework, which gives the highest priority to direct and indirect patient access, with no meaningful concern for environmental protection. The effort put into measures of active prevention against environmentally induced health harm is substantially lower than the one dedicated to direct patient access. Such a difference in priority seems hard to justify for two reasons.

The first reason is the precautionary principle (Gardiner 2006; Manson 2002; Sandin 2004). The precautionary principle, despite having different formulations and interpretations, generally mandates engaging in preventive actions to avoid a future, yet uncertain, serious risk or harm. Pharmaceutical API's are chemically very stable substances, which means that once dispersed in the environment they are not going to effectively contaminate it for a long time. While the specific risks related to each API are not entirely clear, they may in certain cases prove disruptive. Additionally, in the case of antibiotics being released in the environment, there is a meaningful risk of effectively, and irreversibly, selecting for resistant genes. As noted already, this could contribute significantly to the serious public health threat of AMR.. The current legislation effectively encourages polluting behaviour, since it doesn't even penalize producers for not submitting an ERA. As such, *Status Quo*, penalizes those producers that engage in time-demanding testing necessary to submit a complete and detailed ERA for their products.

The second reason is about fairness in right to healthcare. Several authors pointed out the role of fairness in the healthcare allocation context (Selgelid 2009; Kass 2001). In this context, if we are assuming health interests to be equal, there would be no proper reason to treat differently the various groups of patients that this paper identified. Treating the groups of health interests differently would then be unfair.

The other extreme is represented by directly including environmental risk in the benefit-risk analysis, as in the last three frameworks outlined in Sect. 3. Intuitively, this can ensure that environmental protection is more equally considered than it currently is. However, these frameworks come with their own limits and drawbacks. Three main reasons can be identified against using this type of framework.

The first reason is the unfair imposition of risk (Cai 2021) on current patients. This objection grounds itself on the well-known epistemic problem of precisely estimating how pharmaceutically induced environmental pollution will translate to future clinical risk (Levy 1998). It would be practically very hard to establish what specific requirement the ERA should have because it is unclear how and which type of pollution will meaningfully impact human health in the long term and how. In other words, some environmental side effects are hard, if not impossible, to predict and it makes more practical sense to address them once

they materialize by, for example, intervening on wastewater treatment plants rather than on market approval processes (Larsson et al. 2018). Additionally, the production chain is almost oblivious to these issues and any strict changes in the market access requirements will be very demanding to adapt to. This uncertain long-term benefit, obtained by preventing pollution and eventual resulting health risks, is to be contrasted with the clear and established health benefits for current patients, resulting from the standardized methodology for the evaluation of clinical risk in the current legislation. In essence the current patients would be directly paying the price of precaution, for a risk that has not verified yet, and that its particularly hard to pinpoint.

The second reason is the avoidance of harm resulting from pharmaceutical pollution and, specifically, from the intrinsic challenge posed by AMR (Littmann and Viens 2015). Consistent patient access to antibiotics, through use and production, is in itself one of the biggest drivers for bacteria becoming resistant. In other words, the mere fact that antibiotics are used now diminishes the effectiveness of future medication with that same class of antibiotics. Any patient at risk of bacterial infections or in need of a medical procedure presupposing antibiotics has a strong interest in accessing to these drugs. Changing the market approval process will likely slow down the introduction of new antibiotics on the market, in exchange for AMR rising more slowly in the long run. A regulation that prioritizes antibiotic efficacy in the long term with such a strong intervention, carries a strong risk of compromising the current access to effective drugs.

The third reason against this type of intervention is the prevention of harm (Kass 2008) caused by lack of access to new or effective medication. As mentioned in Sect. 3.4, including environmental risk in the benefit-risk analysis is one of the strongest and most impactful ways to affect producer behavior. However, such interventions may also have dynamic effects in the form of slower drug development and increased costs of production resulting in higher drug prices and potentially even in producers leaving the market. Compared to the other frameworks, the introduction of environmental risk directly in the benefit-risk analysis carries a greater risk of such effects because this type of regulation is particularly costly or demanding to comply with. These effects make this type of intervention riskier from the point of view of securing patients' access to effective medication.

That said, these considerations ignore phenomena such as cross-resistance, extended cross-resistance, and co-resistance.[7] These mechanisms might speed up the spread of resistant genes and diffuse resistance to more than one antibiotic class. Additionally, recent research suggests that some pharmaceuticals, and not only antibiotics, might effectively select resistant bacteria(Wang et al. 2020) in the

[7] Cross-resistance is resistance to all the antibiotics belonging to the same class. Drugs assigned to the same class have the same target of action in the cell, and as such can encourage cross-resistance. Extended Cross-resistance is a type of cross-resistance that can confer resistance to more than one drug class. In practice, a class of antibiotics can select for resistance to other drug classes. This phenomenon occurs even with non-medical products such as the increasingly used household detergents, which can select for multiresistant bacteria. Co-resistance occurs when the member of one drug class co-selects resistance to another class of antibiotics with a totally distinct mode of action (Périchon et al. 2019).

environment. This would be extremely problematic as it would spread resistance substantially faster and more diffusely. Monitoring and perhaps limiting the development of cross and co-resistance would be an efficient way to prioritize the long-term availability of antibiotics more fairly, without prejudicing current patient access excessively.

Good reasons can be given in favor of abandoning the current policy model in order to protect environmental health to a greater degree. However, it should be noted that the policy options that giving the greatest importance to such protection, in particular the *Environmental Threshold* model, could have a disruptive impact on direct and indirect patient access to medicines. The goal of protecting long-term human health by addressing environmental risk in the market approval process can be advanced in less disruptive ways by implementing more moderate interventions such as *Delayed ERA* and *Enforced ERA*.

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Declarations

Conflict of interest The author has no conflict of interest to declare.

Ethical statements I hereby declare that this manuscript is the result of my independent creation under the reviewers' comment. Except for the quoted contents, this manuscript does not contain any research achievement that have been published or written by other individuals or groups. I am the only author of this manuscript. The legal responsibility of this statement shall be borne by me.

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Paper V

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Sustainability principle for the ethics of healthcare resource allocation

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ABSTRACT

We propose a principle of sustainability to complement established principles used for justifying healthcare resource allocation. We argue that the application of established principles of equal treatment, need, prognosis and cost-effectiveness gives rise to what we call negative dynamics: a gradual depletion of the value possible to generate through healthcare. These principles should therefore be complemented by a sustainability principle, making the prospect of negative dynamics a further factor to consider, and possibly outweigh considerations highlighted by the other principles. We demonstrate how this principle may take different forms, and show that a commitment to sustainability is supported by considerations internal to the ethical principles already guiding healthcare resource allocation. We also consider two objections. The first of these, we argue, is either based on implausible assumptions or begs the question, whereas the second can be adequately accommodated by the principle we propose.

INTRODUCTION

We propose a principle of sustainability to complement established normative principles used for justifying resource allocation in healthcare. We use three distinct cases to illustrate the need for such a complementary principle, one regarding the cost dynamics of drug procurement, one regarding the environmental dimension of antibiotic resistance and one regarding drug shortages. We start by mapping a general structure for how the normative justification of resource allocation decisions is commonly institutionalised, and use this model to formulate a general argument for sustainability as a core concern in the justification of healthcare resource allocation. The three cases are brought in to illustrate how such a principle is essential to counteract what we term *negative dynamics* that would undermine values backing up the other normative considerations used to justify healthcare resource allocation. We end by considering some basic ethical perspectives that may be used to question the addition of a sustainability principle, arguing that these are either unable to support the other normative considerations used for healthcare resource allocation, or, if adjusted to accommodate these considerations, compatible with a sustainability principle.

JUSTIFICATION OF RESOURCE ALLOCATION DECISIONS IN HEALTHCARE

All healthcare systems need to allocate scarce resources, and the justification of such allocation needs to be based on normative principles. Drawing on general moral and political philosophy, ethicists have debated what such normative principles may be justified and how. Nevertheless, in practice, the operational norms that guide actual decision-making in this area tend to be similar across health systems,[1] and usually include the following principles:

- Need: greater need of care justifies allocating more resources to help the patient group in question (and vice versa).
- Prognosis: greater expected health effect of an intervention justifies allocating more resources to this intervention (and vice versa).[i]
- Equal treatment: equal claims based on need and prognosis justify equal priority for resource allocation (including the balancing of benefits against costs).
- Cost-effectiveness: meeting a prioritised need with a prioritised intervention should not spend more resources than necessary.[ii]

There are well-known disagreements on and differences between countries and regions regarding how these principles are operationalised, and how they should be balanced or traded off in cases of conflict. For instance, while the Swedish regulation on healthcare priority setting is written to exclude instrumental effects on other aspects than the individual patient's health or collective evaluation of the need and prognosis aspects, the UK system for priority setting and health economic evaluation allows wider room for collectivist or economic arguments for recommended resource allocation, for example, that a condition is widespread. In addition, although these principles express a widely recognised ideal, it is also well known that the *realpolitik* of healthcare resource allocation often results in having certain groups of patients win the attention of decision-makers on other grounds than

[i]The need and prognosis principles necessitate assessment of the quality of evidence supposed to demonstrate the nature of patient needs, and the expected value of interventions. This could be added as a separate principle, but for simplicity's sake we here treat is as implicit in the stated principles. Of course, differences between the way that health systems apply and balance the operational norms may also regard what role and weight is given to the assessment of underlying evidence.

[ii]In conjunction, the need, prognosis and equal treatment principles also imply a principle that may be called 'horizontal cost-effectiveness', that is, a principle saying that resources should be systematically allocated to patient groups and intervention types in proportion to the reasons in terms of need and prognosis. As in the case of the need to assess evidence mentioned in the previous footnote, we treat this principle as implicitly assumed in the present context.

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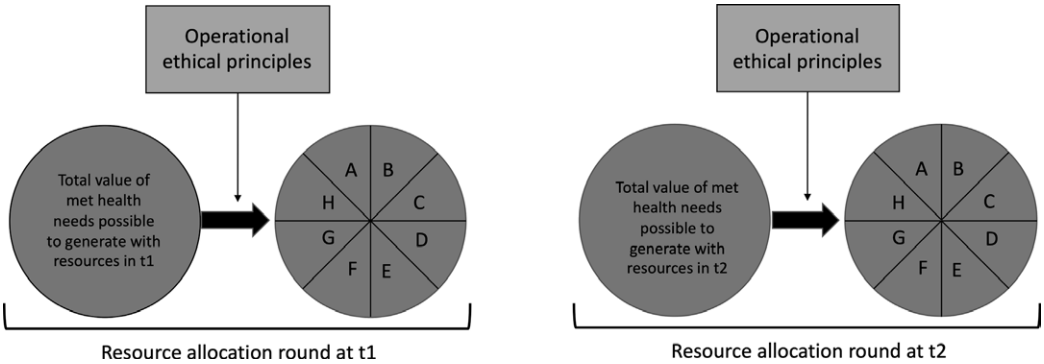


Figure 1 The temporal structure of operational healthcare resource allocation.

those specified in terms of need and prognosis, a recent example being the UK cancer fund.[2 3iii]

In moral philosophy and ethics, debates are ongoing on how this set of principles may be justified, what more exact variants appear as more viable in that light and what practical conclusions may in fact be deduced from such theoretical explorations.[4 5] At this level, there are, of course, long-standing disagreements between utilitarian-oriented consequentialists, egalitarians, desert theorists, Kantians, and so on. In this paper we will, however, for the most part keep these debates in the background. We will, however, return to them in the fifth section, when exploring the prospect of justifying our suggestion of adding a sustainability principle to the set of operational principles.

The justification of healthcare resource allocation decisions thus makes use of (some variant of) the set of operational principles above. However, this set is also used in a particular way, determined by the way that new resources in practice become available within a health system. Typically, this follows some variant of a fiscal year pattern, where resource allocation decisions are made relative to a certain, time-limited 'pie' of resources that needs to be 'sliced' in appropriate pieces (to be handed to appropriate receiving parties). The set of principles above is in practice used to justify this particular slicing pattern—if it conforms to the principles it is justified. This holds regardless of what particular variant of the set is applied (regarding interpretation of the principles, and determination of their role and relative weight). The justification holds until it is time for a new pie to be sliced (eg, the next fiscal year). Thus, besides the operational principles, the actual practice of justifying resource allocation in healthcare also includes a temporal structure, illustrated in figure 1.

THE SUSTAINABILITY PROBLEM OF (JUSTIFIED) HEALTHCARE RESOURCE ALLOCATION

From a standard healthcare ethical standpoint, the question of what is a justified resource allocation will be answered once a 'pie' of resources has been 'sliced' according to a pattern supported by the operational principles. However, this notion of justified resource allocation is complicated by a phenomenon that we will call *negative dynamics*. Negative dynamics enter the reality of justifying healthcare resource allocation due to its temporal structure. Since decision-makers are never in a position to evaluate how to allocate the sum total of available resources across time, but only 'time sliced pies', a particular allocation decision may impact on the conditions for future allocation decisions in ethically relevant ways. Such impact may be both positive and negative.

To present this problem succinctly, it is useful to specify the ethically relevant 'currency' in which the justification of healthcare resources should be formulated. Clearly, the ethically relevant way of conceiving what makes up the 'pie' to be 'sliced' is not the amount of money, time, infrastructure or something like that (although this is what is being allocated in practice). What needs justification is the distribution of value achieved by spending money, time or use of infrastructure in one way rather than another. If no such value resulted, the use of the resource would be obviously unjustified, as would the very enterprise of healthcare. The type of value concerned is, in turn, indicated by the operational principles. More positive value results when more reduction of more severe needs on equal conditions results from a distribution pattern. Therefore, henceforth, when we speak about justifying the 'slicing' of a 'pie' and the 'size' of this pie, this should be understood in terms of the value possible to generate by a round of resource allocation. Based on this notion, let us now present the phenomenon of resource allocation dynamics more closely.

A well-known positive example of such dynamics is when healthcare resources are allocated so that a decrease of the future need of healthcare results. This is the typical idea behind vaccination programmes, where the main benefit takes the form of future absence of disease in the population. Due to the investment in a successful vaccination programme, there will be more healthcare resources available per healthcare need in the

[iii] A major theme in the healthcare ethical discussion regards the role of desert and 'individual responsibility' for health when prioritising healthcare needs.[33] Such considerations are typically absent in the operational systems that have been formulated in different countries, but there may, of course, be different background assumptions about the allocation of responsibility between health systems, professionals within them and patients when healthcare interventions are discharged and effects evaluated (eg, in terms of adherence to prescribed treatment plans and how to respond to that). While this phenomenon is surely worth more philosophical and ethical analysis,[34 35] we here exclude it from the list of *operational* principle. We will, however, discuss considerations of this type in the fifth section, when exploring the philosophical justification of our proposed sustainability principle.

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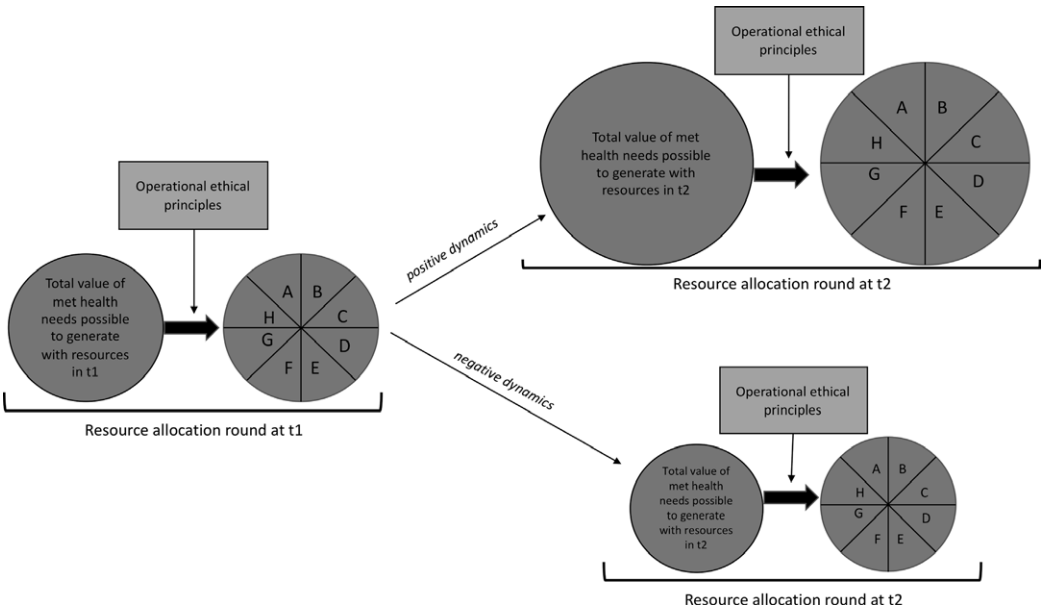


Figure 2 Positive and negative temporal dynamics of operational healthcare resource allocation.

future, and these needs can be better met than if they had been forced to 'compete' with the healthcare needs avoided due to the programme. Another example is when the overall effects of healthcare boost the future income of the healthcare system, so that more resources become available in the future than what would otherwise have been the case, for example, by enabling people who would otherwise have been on sick leave to return to work and pay income tax. It is common to appeal to such dynamics to help justify allocation of resources by pointing to costs of an intervention being offset by future cost reductions or income increases for healthcare.[iv]

Both of these are examples of *positive* dynamics of a resource allocation: more resources per health need become available for future allocations. There are also other examples than these two, but the defining characteristic here is that a resource allocation according to the operational principles positively affects the available outcome value possible to generate through a future resource allocation that uses these principles. *Negative* dynamics, in contrast, occur when the opposite ensues between two temporally separated resource allocation rounds. That is, a justified (according to the operational principles) resource allocation has the effect that less value can be generated through a future justified resource allocation. The structure of both the positive and the negative dynamics is illustrated in figure 2, where the size of the 'pie' sliced by an allocation represents the value possible to generate through this allocation.

Whereas positive dynamics are already taken into account in present applications of the operational principles, as indicated above, negative dynamics are not. We provide three examples that illustrate this omission. The first concerns a presently widely discussed development in the expected health effect of new drugs related to cost per health effect unit of these drugs (however that is measured; eg, quality-adjusted life-year). An increasing number of new drugs targeting very serious conditions have very modest or very uncertain clinical effects (sometimes only effects on biomedical markers of uncertain clinical relevance) but are nevertheless listed at high, sometimes very high, prices.[6 7] Many healthcare systems use the operational principles to prioritise these drugs due to the severity of the condition, and allocate resources for buying them in spite of the weak prognosis. As a result, when these resources are spent, much less healthcare need is met than if the resources had been allocated to drugs with better or more certain effects.[3 8] This 'negative balance' of unmet healthcare need that could have been met with another resource allocation is transferred into the next round, and generates a larger total of unmet healthcare needs for which to allocate resources. If the amount of resources available remains the same, this means that the 'pie' of value possible to generate through this allocation shrinks: there are less resources available per unit of healthcare need. In the next round, this effect will accumulate, resulting in an even smaller pie of value to generate in the following round—and so on. Of course, this negative dynamic may be initially neutralised by increasing the amount of available resources at each temporal stage. However, these resources have to be taken from somewhere else, and if the dynamic continues, this response will become impossible (to justify) at some point. Negative dynamics thereby continuously undermine the economic basis of the healthcare system, as more and more resources are allocated to generate less and less satisfaction of healthcare need. At some point, the economic

[iv] It may be asked whether or not positive dynamics should, in addition, be given a more immediately forceful role as a bona fide *health benefit* in healthcare resource allocation, at least when the dynamic is discharged via the reduction of future healthcare needs (primary prevention), and whether or not that might motivate other additions to the operational principles or not. However, this issue lies outside the scope of the present article.

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basis of the healthcare system will collapse, and hardly generate any value, in spite of costing enormous amounts of money. The basic problem here is a lack of economic sustainability of the justified resource allocations resulting from application of the operational principles.

Another example of negative dynamics comes from the fact that the production of antibiotics (which are essential for all modern healthcare systems) has been found to emit vast amounts of resistance-driving residue.[9] This pollution is contributing to the massive global health challenge of antibiotic resistance,[10 11] the backbone of which can be described in terms of a drastic reduction of healthcare needs that can be met by the system. Growing antibiotic resistance thereby systematically reduces the size of the 'pie' of value available for allocation in the future, and this process is fuelled by the way in which antibiotics are produced. Producers have no reason to change these production practices, however, as procurement of the drugs they produce (based on the operational principles for healthcare resource allocation) is made independently of any environmental externality. As healthcare systems find reason to prioritise clinically equivalent drugs that cost less, a producer will generate a better yield through offering a lower price for an equivalent (antibiotics) product by cheaper production practices that allow pollution. Thus, in this situation, the operational principles will favour a cheaper equivalent drug regardless of their gradual contribution to the antibiotic resistance problem, as this will generate more healthcare need fulfilment per available resource unit in this round. Likewise, they will disfavour any producer that improves the environmental aspects of production and compensates for the cost with a higher price. For each round of justified resource allocation on this premise, resources will be channelled into the hands of producers that contribute to the antibiotic resistance problem, and the future accumulated effect is that this problem increases, thus gradually undermining the effectiveness of healthcare, and shrinking the potential for meeting future healthcare needs. The basic problem here is a lack of environmental (health) sustainability of the justified resource allocations resulting from application of the operational principles.

A recent contribution[12] describes how high-income healthcare systems could act to respond to antibiotics pollution by taking environmental considerations into account in the resource allocation linked to antibiotics procurement. Such a move brings some ethical challenges, and some delicate questions of the exact design of the relevant incentive structures, but a strong case in favour of this kind of solution can be mounted[13] and actions of this sort have recently been jointly advocated by leading global organisations in the area.[14] However, the operational principles in existing healthcare resource allocation systems do not support such considerations, as the immediate effect in the present round (eg, a fiscal year) would be that less healthcare need can be met. The upside of taking environmental production externalities into account, in terms of preventing impaired ability to meet healthcare need due to increased antibiotic resistance, would materialise in the future, not in the present round of resource allocation. The situation thus resembles the shrinking economic room for meeting healthcare needs in the first example: the relevant effect resides in the future, and is not a health effect in the present round of allocation.

A third example of negative dynamics is related to drug shortages, which is a persistent problem in both developed and developing societies and the object of growing attention from governments, scholars and non-governmental organisations.[15–17] A shortage means that a drug becomes unavailable, implying that patients may have to resort to a less effective, more risky and/or more expensive treatment, or see their treatment need go unfulfilled.[15] Antibiotics are particularly affected due to fragmented supply chains and low profit margins, and shortages in this area are especially disconcerting since they compound the antibiotic resistance problem.[16] Though the causes of shortages are complex, at bottom there is a lack of incentive for drug manufacturers to ensure supply reliability.[17] Since the market does not reward supply reliability above the minimum level demanded by regulators and procurers, companies do not invest more than needed in this light.[16] By systematically procuring and subsidising the cheapest among interchangeable drugs without strict expectations related to supply reliability, societies effectively reward manufacturers who keep prices down by minimising spending to that effect. Here, the application of the operational principles maximises the fulfilment of health needs per unit of resources spent in the short term. But at the same time, this creates a systematically increasing risk of future shortages resulting in unmet health needs over time, which reduce the size of the 'pie' of available value in terms of met health needs in the long term. Since these costs arise in the future, they are not accounted for in the allocation round where the principles are applied. Hence, a similar kind of negative dynamic as in the other examples results.[v]

Sustainability is about the ability of a system or an operational pattern to continue to function over time without loss of value. An added principle of sustainability would therefore support taking into consideration the negative dynamics in each of the cases, and allow support of resource allocations that would avoid or mitigate such destructive structural effects. In the next section, we state such a principle, discuss different ways of specifying it and strengthen the case for its inclusion among the operational principles for healthcare resource allocation. In the subsequent section, we will then consider objections against including the principle.

A SUSTAINABILITY PRINCIPLE STATED AND DEFENDED

As a starting point, we will formulate a generic principle of sustainability, which may be made more precise and specific in various respects:

- Sustainability: if a resource allocation pattern at time t1 produces negative dynamic effects at time t2, this to some extent counts against this pattern at t1, and in favour of resource allocation patterns at t1 with no or weaker negative dynamic effects at t2.[vi]

This idea may be varied in a number of ways to be discussed below, for example, regarding strength of the reason against a resource allocation pattern producing negative dynamics, and how that reason can be related to the other operational

[v] In the ongoing COVID-19 pandemic, shortage of healthcare material other than drugs has been highlighted as a major resource allocation challenge.[36 37] Insofar as these shortages are due to procurement patterns that follow the same operational principles as drug procurement, they illustrate the same kind of negative dynamics and further strengthen the case for a sustainability principle.

[vi] Note that the sustainability principle only requires accounting for negative dynamics resulting from the particular allocation pattern under consideration. The future may, of course, hold many other changes of circumstances (eg, pandemics, financial crises, governance reforms) that impact on the resources available for allocation and the pervasiveness and severity of different health needs. However, we set aside such independent changes since they do not, in our view, pose the same principled challenge to existing operational principles as negative dynamics do.

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principles. But before that, it should be noted that any such more normatively precise variant may also be discharged in different specific forms in a resource allocation system.

1. Side constraint: the principle functions like the equal treatment or cost-effectiveness principles, implying limitations to what actions could be justified by the other principles. Just as these two principles rule out allocations leading to unequal consideration of similar need and prognosis claims, or wasteful spending of resources to meet prioritised healthcare needs, the principle of sustainability rules out (excessively) unsustainable allocations.
2. Gradual weight: the principle functions as another relevant variable, besides the ones implied by the need and prognosis principles. These are all capable of producing reasons that could be balanced against the reasons produced by the other two principles to effect an all things considered judgement on what allocation should be favoured (within the limits set by the equal treatment and cost-effectiveness principles).

   In both of these specifications, the principle of sustainability is fully integrated among the operational principles. But the specific discharge of the principle may also take other forms, for instance:
3. Rational savings: rather than producing a reason for what patient groups and healthcare interventions to prioritise in the allocation round at hand, the principle here supports the administrative manoeuvre to withdraw some of the resources from this allocation round, and save them for future use to compensate for the loss of value due to negative dynamics. The principle here operates on a metalevel that relates different allocation rounds to each other and produces reasons for saving resources for the future, as well as for determining how much to save.
4. Insurance: again, this variant of the principle does not produce reasons for or against particular allocations, but rather operates across allocation rounds. In this case, the principle produces reasons for linking the resource allocation system to an insurance scheme that pays out future compensation for negative dynamics, and for paying and designing the premium.

We will in the following initially keep it undecided exactly what variant of these forms fits best to different specific kinds of allocation decisions and sustainability problems. Likewise, we will initially hold open all further normative details about the weight of the reason for sustainability, and initially assume only that there is *some* such reason.

The most obvious argument for the inclusion of a sustainability principle is that it would counteract the negative dynamics described in the previous section, avoiding or mitigating the considerable long-term costs that these generate. Such a principle would, for instance, make room for avoiding or reforming patterns of procurement, subsidy and prioritisation that are justified when assessed by the operational principles applied to each specific allocation round, but that pose a long-term economic threat to the efficiency of a healthcare system or systematically favour polluting or fragile pharmaceutical supply chains over cleaner or more secure ones.

The support for sustainability in healthcare resource allocation is furthermore grounded in normative ideals internal to the operational principles that already guide such allocation. Thus, insofar as healthcare systems attach weight to these principles, they should also adopt some version of the sustainability principle. This is perhaps most clearly seen in the case of equal treatment. This principle demands, positively, that patients who are equally situated with respect to relevant considerations (eg, need, prognosis) receive equal shares of resources and, negatively, that nobody is denied an equal share based on any *other*—arbitrary—consideration. The negative dynamics described in the previous section undermine the application of this normative ideal. This is because they generate a gradual depletion of resources available for meeting health needs and/or a gradual increase of needs to be met over time. At some point, a situation will arise where patients who at time t1 would have received some resource based on their need, prognosis, and so on, will be denied this resource at t2, since the resources available must be devoted to more serious or urgent needs. Patients at t1 and t2 will then have been treated unequally, despite being equal with respect to all relevant considerations. The only difference between them is that they happen to be affected by decisions taken at different times, but, by itself, this temporal distance is morally arbitrary.

A similar point applies to need. This principle is typically interpreted as expressing a prioritarian normative ideal: the worse off a person is, the stronger her claim on some resource that could benefit her, other things being equal.[18 19] The negative dynamics we have described threaten the application of this principle (thus interpreted) too. When some resource is gradually depleted or the needs for that resource gradually increase, a situation will eventually arise where patients at t2 will be denied some resource available to patients at t1, even though the needs of the patients at t2 are somewhat greater than those of the patients at t1. Better off patients (ie, patients with lesser need) will then have taken precedence over worse off patients (ie, patients with greater need), in opposition to the prioritarian spirit of the need principle.

The normative ideal underlying the cost-effectiveness principle might not be vulnerable to negative dynamics in the same way. After all, cost-effectiveness primarily rests on a commitment to avoid waste: it is exclusively concerned with maximising the output generated by the use of some resource, however large or small that resource may be. The mere fact that the resource shrinks, or that claims on it grow, does not make allocations of that resource less cost-effective. However, the importance of not wasting resources is purely instrumental and relative to some idea of what resources should be used for. Societies care about cost-effectiveness not for the sake of cost-effectiveness, but because they are committed to some other value—here, the fulfilment of health needs—that can be realised in greater measure by more rather than less cost-effective allocations. If *this* concern is applied across time, it clearly seems threatened by negative dynamics, because these diminish the amount of the relevant value that can be realised.

Thus, the application of standard operational principles over time is prone to generate outcomes that undermine the normative ideals on which these very principles are based, and the sustainability principle seeks to counteract this effect. On a more abstract level, many ethical theories underlying these ideals could also support the addition of such a principle, although perhaps in different specific variants. Many such theories are future oriented, and as such they can value the dynamic effects of temporally limited resource allocations. These perspectives include (different brands of) consequentialism, harm-oriented rights theories, social contract theories of justice, and so on. Variation with regard to what variants of the sustainability principle could gain such support may regard, for instance, what determines the gravity of a case of unsustainability, or how much it counts against a resource allocation in view of the other principles. But these theories would still provide support for the general idea of a sustainability principle. That is, they could

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motivate *some* version of the principle in the same way as they motivate variants of the other operational principles.

Two related variations in this regard warrant mentioning. The first concerns time frame: *how far* into the future should we look when determining whether a resource allocation decision would be (sufficiently) sustainable? At first glance, answering this question may seem difficult in view of thorny issues discussed in population ethics and intergenerational justice debates concerning the justifiability of discounting the value of future events.[20] The second concerns what *kind* of future scenarios should be taken into account (within a given time frame). Should all possible changes to the need panorama and resource situation be considered? If not, which to include and which to exclude? A possible worry here is that an overly inclusive approach would make the principle impracticable due to difficulties in predicting future outcomes.

We believe that mundane considerations on an operational level make it possible to sketch a preliminary approach to these issues, despite the theoretical complications. First, note that the sustainability principle only regards negative dynamics arising from a resource allocation decision, that is, parts of the future changed by this decision, not wholly unrelated scenarios. Second, the increasing uncertainty regarding the presence and nature of such negative dynamics the farther we gaze into the future means that, in practice, a systemic mechanism substantiating the reality of the negative dynamic needs to be demonstrated. Such mechanisms are present in all three cases presented earlier. Absent some such mechanism, the worry about negative dynamics becomes merely one of many possible scenarios for the future. This goes to show that, just as with the other operational principles, the impact of the sustainability principle, and what requirements it will issue regarding how to assess an allocation proposal, will be dependent on underlying evidence.

OBJECTIONS TO SUSTAINABILITY IN HEALTHCARE RESOURCE ALLOCATION

The support for an operative sustainability principle assumes a concern for how health needs are met in the future (beyond a particular resource allocation round) that recognises the significance of negative dynamics and the call for avoiding it. But some ethical theories are admittedly either not future oriented at all, or not future oriented in a way that would view these dynamics as morally relevant. One obvious example with clear relevance for resource allocation is desert theories of justice.[21 22] These theories share the idea that a justified allocation of goods depends entirely on facts about the past, such as the effort people have made or their contribution to society.[23] The future interests that the sustainability principle is meant to care for are not recognised as valid grounds for justifying any distribution of any kind of goods.

Another example is libertarian theories, which also espouse principles of justice that are purely historical, though in a different sense. Nozick[24] argued that any distribution is legitimate as long as it has arisen through voluntary exchanges of goods that were justly acquired to begin with. On this view, the fact that there will be less goods available in the future or greater need for them has no bearing on whether or not they are legitimately distributed.

Yet another example is strict egalitarianism, according to which each person should have an equal share of whatever good(s) distributive justice is concerned with.[23] On this view, changes to the *amount* of goods available for distribution are not relevant to evaluations of justice; a pattern of equal distribution is all that matters, independent of the long-term availability of the goods in question. Thus, the depletion of goods or the proliferation of claims on them is of no concern, as long as the goods that *are* available are divided equally among those with valid claims.

All of these 'pure' theories are known to face serious objections, and are often modified using elements from future-oriented theories in order to accommodate these. For instance, it is common for theorists with egalitarian sympathies to mix a concern for equal distribution with other concerns in order to avoid powerful objections to strict egalitarianism, such as the levelling down objection.[18] Similarly, many supporters of the moral importance of desert would be willing to pay attention also to other considerations in order to avoid counterexamples, such as when a distribution of goods only according to desert would undermine social stability or basic needs, or drain future resources.[25–28] Thus, whereas certain 'pure' theories may in themselves be unable to support the sustainability principle, the considerations that they are often combined with in order to increase plausibility (eg, concern for social stability or priority to the worst off) include the sort of future orientation which may support the importance of sustainable resource allocation.

At a less theoretical level, we may also note that these 'pure' theories sit uneasily with not only the sustainability principle, but with the already established operational principles of healthcare resource allocation, and the broader ethos supporting them. For instance, desert is either given a very limited role or is rejected altogether as basis for resource allocation in most publicly funded healthcare systems.[1] Another, very salient example regards libertarian ideals of justice, as these famously object to the very idea of a central public agent legitimately assembling goods from individuals and redistributing these, for instance, by funding a public healthcare system.[24] Since the issue of healthcare resource allocation addressed by the operational principles presupposes such a system, libertarians would likely reject *any* such allocation in favour of some market-based scheme (where resources are distributed according to principles of supply and demand). Thus, it seems that reigning approaches to resource allocation in publicly funded healthcare systems must, at least partly, be based on other theoretical perspectives than libertarianism or desert theory perspectives, perspectives likely to be friendlier to considerations of sustainability. The objections from desert and libertarianism challenge not so much the inclusion of a sustainability principle among the operational principles as the basic normative framework of which these principles form part. We can therefore set these objections aside for the purposes of this paper.

A possibly more damaging objection appeals to considerations internal to the established operational principles for healthcare resource allocation. We argued above that such considerations, properly understood, support the addition of a sustainability principle. However, they could also be invoked to challenge this idea. The most forceful objection of this kind is based on equal treatment. Suppose a healthcare system has to prioritise between two equally needy patient groups for whom there exist equally effective treatments. Suppose also that the treatment needed by one of the groups (but not the other) raises sustainability issues; it might, for instance, be an antibiotic the production of which is known to cause significant pollution. If sustainability considerations are included in allocation decisions, it seems that the latter group of patients would take precedence over the former, even though they are equally positioned with respect to need and prognosis. It might be argued that this violates the equal treatment principle, or the normative perspective expressed by it, since the only difference between the groups has nothing to

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do with facts about *them* and so does not constitute a legitimate basis for unequal treatment. Another way to put the challenge is this: including sustainability considerations in order to secure equal treatment *across* allocation rounds may objectionably sacrifice equal treatment *within* such a round.

We have three responses. First, note that the objection does not challenge all forms of the sustainability principle listed in the fourth section, but only side constraint and gradual weight. Since these introduce sustainability considerations into specific allocation decisions, they could indeed in certain cases advocate unequal treatment of groups with equally strong claims from the viewpoint of the other operational principles. However, in the forms of rational savings or insurance, sustainability considerations operate independently of such decisions and thus do not compete with standard operational principles in this way. Since these considerations come into play *before* resources are allocated to patients or interventions, they will not imply unequal allocation in a given allocation round. The objection can thus be sidestepped by having the principle take either of these two forms.

Second, even focusing on side constraint and gradual weight, the unequal treatment involved may not be of a kind that the equal treatment principle, properly understood, rejects. This principle rests on the view that just institutions should not give people unequal prospects based on factors that are, as Rawls[29] (Section 12) puts it, 'arbitrary from a moral point of view'. While Rawls himself had contingencies in the natural and social lotteries in mind, it remains debated just what factors are properly considered morally arbitrary. On one view, any factor outside a person's choice or control is arbitrary.[30] However, this cannot be the view assumed by the equal treatment principle for healthcare resource allocation, since this principle permits prioritising patients with different needs and/or prognosis differently, even though these factors are typically not within people's control. A better suggestion (for present purposes) is the idea that whether some factor is arbitrary depends on the justification of the particular institution in question.[31] For instance, merit is plausibly a non-arbitrary basis for unequal rewards on the labour market but an arbitrary one in the legal system because only the former institution is justified by efficiency considerations. Applying this idea to the case at hand, it seems that sustainability considerations may well qualify as non-arbitrary. Healthcare is plausibly understood to properly aim at mitigating social inequalities,[32] or at least at meeting a population's health needs on equal terms. Functioning in accordance with such a justification over time requires counteracting negative dynamics, for reasons already given. If unequal allocation to patient groups or interventions that other operational principles consider equal is a necessary or effective way of achieving this, then this could be seen as an instance of unequal treatment based on relevant, that is, non-arbitrary, grounds.

Third, even if these lines of reasoning fail, and unequal allocation based on sustainability remains suspect, we must not forget that *failure* to apply a sustainability principle *also* involves an objectionable form of unequal treatment. Absent such a principle, patients' prospects will (as argued above) arbitrarily worsen over time due to negative dynamics. Thus, two egalitarian commitments, one present focused and the other future oriented, pull in different directions, and it cannot be assumed that the former should always take precedence. Rather, how to balance them in a given case remains an open question.

These responses reinforce what we have said from the start: adding a sustainability principle necessitates decisions regarding its more exact form and weight for resource allocation decision-making.[vii] In some application areas, say drug procurement by hospitals, rational savings or insurance may be easier to accept than designs that compete directly with the other operational principles *within* the same budget. Such a design would then also make salient the need to formulate how much of a sustainability threat is needed to trigger a budget adjustment. In other areas, however, allowing sustainability to immediately compete with the other operational principles (side constraint or gradual weight) may be less problematic. For instance, when society decides on subsidy for two clinically equivalent drugs, one of which poses an environmental sustainability problem, it would not disturb standard healthcare ethical thinking to have a sustainability principle motivating that subsidy should be denied to the environmentally problematic drug while granted for the other one. Again, this still leaves many questions open regarding the exact formulation of the sustainability principle, but the examples illustrate how it may be varied to fit important healthcare resource allocation decisions, and be adjusted to a wide variety of views regarding the other operational principles.

CONCLUSION

We have presented a sustainability problem afflicting widely embraced models of public healthcare resource allocation, and illustrated it with regard to drug procurement costs, industrial antibiotics pollution and fragile supply chains for pharmaceuticals. We have formulated a sustainability principle that we propose should be added to standard operational principles for public healthcare resource allocation, and described different forms it may take and how its normative importance may vary. We have defended this proposal by demonstrating how it could fix the identified sustainability problem, and by appealing to normative assumptions supporting standard operational healthcare allocation principles and underlying ethical theories. We have also considered two potential objections, arguing that the first of these rests on highly controversial theoretical assumptions and is irrelevant in the present context because it rejects the basic normative framework underpinning established healthcare resource allocation regimes. However, allowing sustainability to influence healthcare resource allocation does make the ethics of this area more complex, and the second objection considered illustrates that adding a sustainability principle necessitates specifying its role, function and importance in different areas of resource allocation.

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[vii] For similar observations, see ref 38 39.

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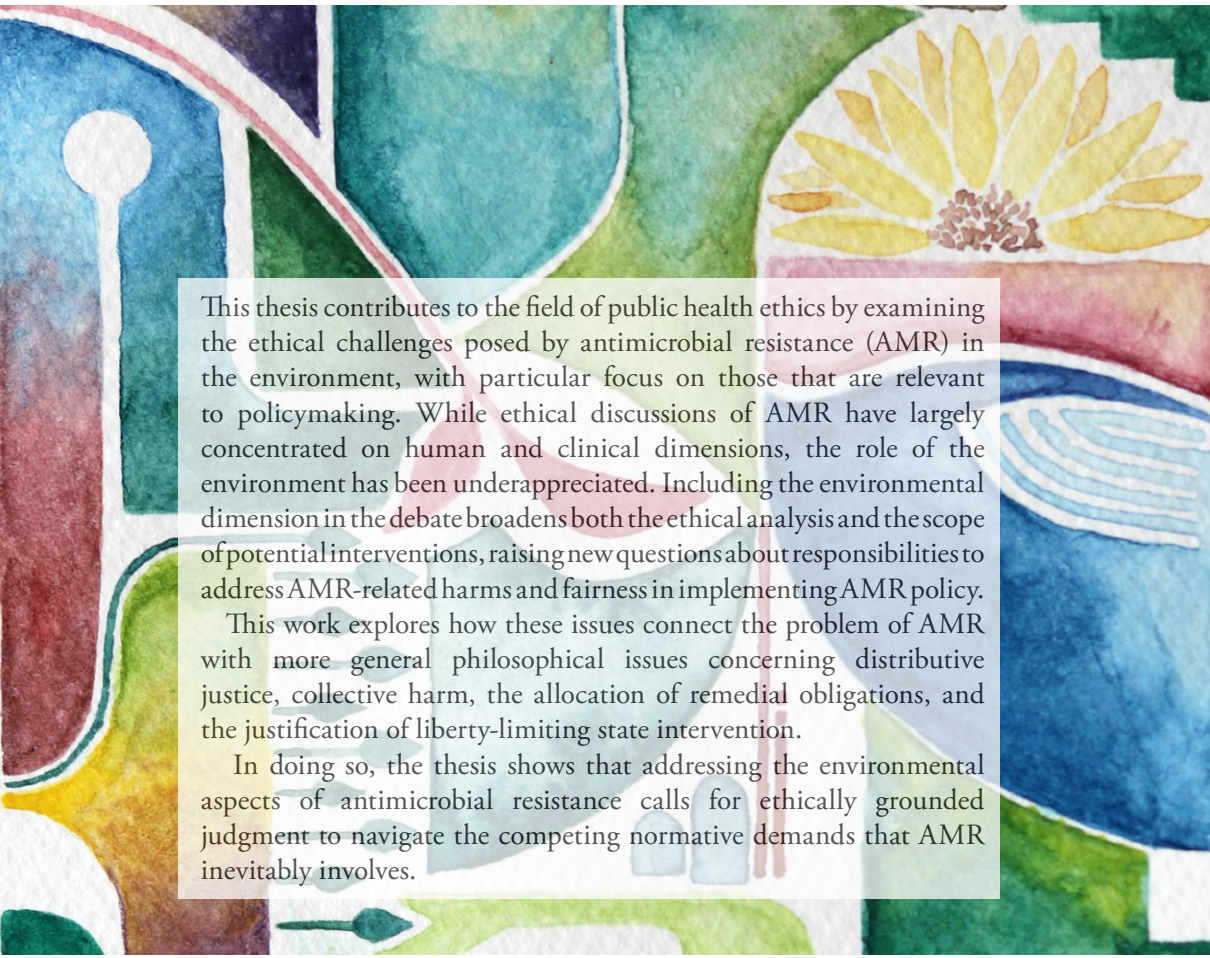
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This thesis contributes to the field of public health ethics by examining the ethical challenges posed by antimicrobial resistance (AMR) in the environment, with particular focus on those that are relevant to policymaking. While ethical discussions of AMR have largely concentrated on human and clinical dimensions, the role of the environment has been underappreciated. Including the environmental dimension in the debate broadens both the ethical analysis and the scope of potential interventions, raising new questions about responsibilities to address AMR-related harms and fairness in implementing AMR policy.

This work explores how these issues connect the problem of AMR with more general philosophical issues concerning distributive justice, collective harm, the allocation of remedial obligations, and the justification of liberty-limiting state intervention.

In doing so, the thesis shows that addressing the environmental aspects of antimicrobial resistance calls for ethically grounded judgment to navigate the competing normative demands that AMR inevitably involves.



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