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# Green public procurement of pharmaceuticals as a regulatory response to antimicrobial resistance and its compatibility with the WTO Agreement on Government Procurement

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## Abstract

This article examines the compatibility of production-related environmental criteria in green public procurement with international trade law, specifically the World Trade Organization's Agreement on Government Procurement (GPA). In response to the global health and environmental challenge of antimicrobial resistance (AMR), such measures offer extraterritorial regulation by pharmaceutical purchasing countries where domestic regulation is not forthcoming in pharmaceutical producing countries. The article finds that such green public procurement measures may be compatible with the GPA. The general exceptions of the GPA can be invoked to overcome the potential non-adherence of these measures to the principle of non-discrimination between like products (in this case pharmaceuticals) from different importing countries. The provisions of the GPA relating to technical specifications and tender documentation accommodate such green public procurement measures. The provisions relating to conditions for participation in tenders for a public procurement contract and the award criteria for choosing the bidder to whom the contract should be awarded are silent in respect of environmental considerations. However, this may change with the development of domestic regulation on antibiotic effluent and an expansive reading of the term 'public interest' in the GPA. For now, international trade law continues to adopt a limited, accommodationist approach towards non-trade objectives. This approach must be abandoned given the grave implications of failure to address the adverse impacts of global challenges such as AMR. At the same time, compatibility between green public procurement measures and the GPA cannot be taken for granted. The growing interest in domestic or regional drug security, especially in the wake of the COVID-19 pandemic, may expand the geographical range of pharmaceutical manufacturers, with the possibility that such measures, originally intended to achieve non-trade objectives, restrict trade.

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## 1 | INTRODUCTION

Antimicrobial resistance (AMR) refers to the ability of a microorganism (bacteria, virus, fungi or parasite) to resist an antimicrobial drug (antibiotic, antiviral, antifungal or antiparasitic) that was once used to treat an infection by that microorganism.<sup>1</sup> AMR is predicted to cause 10 million deaths a year and a cumulative loss of US\$100 trillion of economic output by 2050 if left unaddressed.<sup>2</sup> AMR poses serious challenges to human beings and the environment in both pharmaceutical producing countries and pharmaceutical purchasing countries. While these challenges are recognised, regulatory solutions are thin on the ground. There is no domestic regulation of the discharge of 'antibiotic effluent'<sup>3</sup> into the environment. As a result, there is the need to explore other regulatory solutions. These solutions include the incorporation of production-related environmental criteria in public procurement processes by pharmaceutical purchasing countries as an extraterritorial regulatory response to the emergence of AMR in the environment in pharmaceutical producing countries. Interestingly, pharmaceuticals represent two sides of the same coin. On the one hand, they are products or goods that contribute to the achievement of trade as well as non-trade (public health) objectives. In fact, international trade law permits measures intended to achieve non-trade objectives subject to the fulfilment of certain conditions. On the other, the pharmaceutical production process may undermine non-trade (environmental and public health) objectives. Considering this dichotomy, this article makes an original contribution by assessing the compatibility of production-related environmental criteria in public procurement with one component of international trade law that deals with government procurement specifically.

Globalisation of the supply chain has allowed major pharmaceutical companies to outsource the production of active pharmaceutical ingredients<sup>4</sup> (APIs) and the processing of APIs into finished drug products or formulations from developed countries to developing countries. The cost of production is low in those developing countries because of weak or non-existent environmental and labour laws and/or their enforcement.<sup>5</sup> As a result, production in developing countries is economically profitable for both pharmaceutical producing countries and pharmaceutical purchasing countries, and the supply

of pharmaceuticals on the global market has increased.<sup>6</sup> At the same time, misuse and overuse of antimicrobials have resulted in the emergence of AMR as a global public health challenge.<sup>7</sup>

The World Health Organization (WHO) recognises the environment as a medium through which drug-resistant bacteria reach human beings and animals. One route for the emergence of AMR in the environment, specifically water bodies, is the discharge of antibiotic effluent from pharmaceutical manufacturing units. Other routes include the use of antimicrobials by humans or in food-producing or domesticated animals and the improper disposal of antimicrobials or human or waste animal waste including antimicrobials into the environment.

The discharge of antibiotic effluent into water bodies can lead to adverse impacts on the environment as well as the life and health of individuals and communities who rely on those water bodies for different uses.<sup>8</sup> The adverse impacts on the environment include animal or plant diseases and loss of soil biodiversity.<sup>9</sup> Water pollution (including wastewater containing resistant bacteria) affects the enjoyment of many human rights including the rights to life, health, livelihood, food and water as well as the right to environment.<sup>10</sup> In addition, the spread of AMR within and outside pharmaceutical producing countries poses a serious threat to global human health and the environment.<sup>11</sup>

In response, the WHO has adopted a One Health approach to AMR regulation.<sup>12</sup> One Health has been defined as 'the collaborative effort of multiple health science professions, together with their related disciplines and institutions—working locally, nationally, and globally—to attain optimal health for people, domestic animals, wildlife, plants, and our environment'.<sup>13</sup> The WHO's Global Action Plan on Antimicrobial Resistance as well as national action plans identify regulation as a key response to the AMR challenge. The possibility of local as well as global adverse impacts on the environment means that regulation by pharmaceutical purchasing countries can complement regulation by pharmaceutical producing countries in addressing the emergence of AMR in the environment. One regulatory option is the imposition of import restrictions or prohibitions based on the production process, as proposed in respect of the use of certain antibiotics in animals intended for human consumption.<sup>14</sup> Another option is

<sup>6</sup>Changing Markets Foundation and Ecotorm, 'Impacts of Pharmaceutical Pollution on Communities and Environment in India' (Nordea Asset Management 2016) 4.

<sup>7</sup>WHO (n 1).

<sup>8</sup>DG Joakim Larsson and J Fick, 'Transparency Throughout the Production Chain: A Way to Reduce Pollution from the Manufacturing of Pharmaceuticals?' (2009) 53 Regulatory Toxicology and Pharmacology 161; YF Lagerqvist and A Åkerblom, 'The Health Paradox: Environmental and Human Rights Impacts from Pharmaceutical Production in India and the Need for Supply Chain Transparency' (Swedwatch 2020).

<sup>9</sup>United Nations Environment Programme (UNEP), 'Bracing for Superbugs: Strengthening Environmental Protection in the One Health Response to Antimicrobial Resistance' (UNEP 2023) 1.

<sup>10</sup>See, e.g., United Nations Human Rights Committee, 'Human Rights and the Global Water Crisis: Water Pollution, Water Scarcity and Water-Related Disasters' UN Doc A/HRC/46/28 (19 January 2021) para 30.

<sup>11</sup>Swedwatch (n 8) 10–11; Changing Markets Foundation and Ecotorm (n 6) 5; WHO (n 1).

<sup>12</sup>WHO, 'Global Action Plan on Antimicrobial Resistance' (WHO 2015) 2–3.

<sup>13</sup>One Health Commission, 'What is One Health?' (2018) <[https://www.onehealthcommission.org/en/why\\_one\\_health/what\\_is\\_one\\_health/](https://www.onehealthcommission.org/en/why_one_health/what_is_one_health/)>.

<sup>14</sup>See, e.g., Regulation 2019/4/EU of 11 December 2018 on the manufacture, placing on the market and use of medicated feed [2019] OJ L4/1 para 8; Regulation 2019/6/EU of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2019] OJ L4/43 paras 41–49.

<sup>1</sup>World Health Organization, 'Antimicrobial Resistance' <[www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance](http://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance)>.

<sup>2</sup>See J O'Neill, 'Tackling Drug-Resistant Infections Globally: Final Report and Recommendations' (UK Review on Antimicrobial Resistance 2016). See also CJ Murray et al, 'Global Burden of Bacterial Antimicrobial Resistance in 2019: A Systematic Analysis' (2022) 399 The Lancet 629.

<sup>3</sup>Antimicrobial resistance in the environment can emerge from the discharge of effluent including residues of antimicrobials—antibiotics, antivirals, antiparasitics or antifungals. This article uses the term 'antibiotic effluent' reflecting its extensive use in scholarship.

<sup>4</sup>An API is 'any substance or combination of substances used in a finished product, intended to furnish pharmacological activity or otherwise to have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.' See World Health Organization, 'Forty-third Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations' (WHO 2009) 150.

<sup>5</sup>Changing Markets and Profundo, 'Bad Medicine: How the Pharmaceutical Industry is Contributing to the Global Rise of Antibiotic-Resistant Superbugs' (SumOfUs 2015).

public procurement, a form of market-based regulation that targets the demand for goods and services. Public procurement is defined as the purchase of goods and services by the government to carry out specific functions.<sup>15</sup> Governments procure pharmaceuticals as part of their responsibility to provide health services to the public and to ensure the realisation of citizens' right to health. There is growing recognition,<sup>16</sup> and implementation, for example, in national and joint tenders in Nordic countries,<sup>17</sup> of measures for public procurement of pharmaceuticals that incorporate production-related environmental criteria.

Such public procurement processes fall within the concept of green public procurement, which is defined by the European Commission as a 'process whereby public authorities seek to produce goods, services and works with a reduced environmental impact through their life cycle'.<sup>18</sup> Green public procurement merits attention as a component of the regulatory toolbox comprising domestic and extra-territorial government-led regulation as well as voluntary regulation by the pharmaceutical industry itself. At the same time, this article does not assume that green public procurement is a panacea. There are several issues concerning the concept and its effectiveness in addressing environmental issues,<sup>19</sup> but they are beyond the scope of this article.

Pharmaceutical purchasing countries may be willing to introduce green public procurement measures but could be concerned about the compatibility of such measures with international trade law. Therefore, this article assesses the compatibility of such measures with the World Trade Organization's (WTO) Agreement on Government Procurement (GPA). International trade law scholarship discusses AMR in the context of restrictions on food imports from countries that overuse antibiotics<sup>20</sup> and specific WTO agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).<sup>21</sup> Scholars have examined the legality of green

public procurement within the framework of the WTO's GPA generally,<sup>22</sup> and specifically with reference to climate change and eco-labelling,<sup>23</sup> and human rights.<sup>24</sup> This article thus contributes to the limited scholarship on the complementarity and tension between the regulation of AMR and international trade law.<sup>25</sup>

The rest of this article is structured as follows. Section 2 introduces green public procurement and the problem of AMR in the environment particularly through the discharge of untreated or partly treated antibiotic effluent from pharmaceutical manufacturing units into the environment in producing countries. Section 2 also sets out the rationale for relying on green public procurement measures adopted by pharmaceutical purchasing countries as a form of regulation and production-related environmental criteria that form part of such regulatory measures. Section 3 assesses the compatibility between measures for green public procurement of pharmaceuticals and the WTO's GPA. Section 4 emphasises the need to shift from a limited, accommodationist approach towards non-trade objectives considering global environmental challenges such as AMR. This is followed by concluding remarks in Section 5.

## 2 | GREEN PUBLIC PROCUREMENT OF PHARMACEUTICALS

Green public procurement of pharmaceuticals refers to the incorporation of production-related environmental criteria in government sourcing of medicines. This non-domestic, extraterritorial form of regulation has the potential to be used to address the discharge of antibiotic effluent from pharmaceutical manufacturing units and the emergence of AMR in the environment. This section responds to the following questions: What is the regulatory challenge? What are the reasons for proposing green public procurement by pharmaceutical purchasing countries based on production-related environmental criteria as a regulatory response? What are the production-related environmental criteria that render these measures 'green'? The

<sup>15</sup>S Arrowsmith, 'National and International Perspectives on the Regulation of Public Procurement: Harmony or Conflict?' in S Arrowsmith and A Davies (eds), *Public Procurement: Global Revolution* (Kluwer Law International 1998) 3.

<sup>16</sup>Antimicrobials in Agriculture and the Environment: Reducing Unnecessary Use and Waste, The Review on Antimicrobial Resistance Chaired by Jim O'Neill (December 2015) 23. See also E Bloomer and M McKee, 'Policy Options for Reducing Antibiotics and Antibiotic-Resistant Genes in the Environment' (2018) 39 *Journal of Public Health Policy* 389; E Malmqvist and C Munthe, 'What High-Income States Should Do to Address Industrial Antibiotic Pollution' (2020) 13 *Public Health Ethics* 275, 277.

<sup>17</sup>See, e.g., Upphandlingsmyndigheten (National Public Procurement Agency), 'Find Sustainability Criteria – Medicinal Products' <[www.upphandlingsmyndigheten.se/en/criteria/nursing-and-care/medicinal-products/](http://www.upphandlingsmyndigheten.se/en/criteria/nursing-and-care/medicinal-products/)>; Sykehusinnkjøp HF (Norwegian Hospital Procurement Trust), Experience Report – Environment, Environmental Requirements for Pharmaceutical Procurements 2020-2022 (February 2022) <[www.sykehusinnkjop.no/siteassets/dokumenter/legemidler/miljorapport/erfaringsrapport-miljo\\_en.pdf](http://www.sykehusinnkjop.no/siteassets/dokumenter/legemidler/miljorapport/erfaringsrapport-miljo_en.pdf)>; Sykehusinnkjøp HF (Norwegian Hospital Procurement Trust), Second Joint Nordic Tendering Procedure for Medicines completed (27 January 2022) <<https://www.sykehusinnkjop.no/nyheter/nyheter-2022/second-joint-nordic-tendering-procedure-for-medicines-completed/>>.

<sup>18</sup>Commission (EU) 'Public Procurement for a Better Environment' (Communication) COM (2008) 400 final, 16 July 2008, 4.

<sup>19</sup>See, e.g., S Lundberg et al, 'Is Environmental Policy by Public Procurement Effective?' (2015) 44 *Public Finance Review* 478; KM Halonen, 'Is Public Procurement Fit for Reaching Sustainability Goals? A Law and Economics Approach to Green Public Procurement' (2021) 28 *Maastricht Journal of European and Comparative Law* 535.

<sup>20</sup>See A George, 'Antimicrobial Resistance (AMR) in the Food Chain: Trade, One Health and Codex' (2019) 4 *Tropical Medicine and Infectious Disease* 54.

<sup>21</sup>See K Outtersson, 'The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law' (2005) 67 *University of Pittsburgh Law Review* 67.

<sup>22</sup>See P Kunzlik, 'Environmental Issues in International Procurement' in Arrowsmith and Davies (n 15) 199; G Van Calster, 'Green Procurement and the WTO – Shades of Grey' (2002) 11 *Review of European Community and International Environmental Law* 298; MA Corvaglia, 'Public Procurement and Private Standards: Ensuring Sustainability under the WTO Agreement on Government Procurement' (2016) 19 *Journal of International Economic Law* 607; R Koch, *Green Public Procurement under WTO Law: Experience of the EU and Prospects for Switzerland* (Springer 2020).

<sup>23</sup>See H van Asselt et al, 'Greener Public Purchasing: Opportunities for Climate-Friendly Government Procurement Under WTO and EU Rules' (2006) 6 *Climate Policy* 217; B Neamtu and DC Dragos, 'Sustainable Public Procurement: The Use of Eco-Labels' (2015) 10 *European Procurement and Public Private Partnership Law Review* 92.

<sup>24</sup>O Martin-Ortega and CM O'Brien (eds), *Public Procurement and Human Rights: Opportunities, Risks and Dilemmas for the State as Buyer* (Edward Elgar 2019); EA Rossi, 'Human Rights Clauses in Public Procurement: A New Tool to Promote Human Rights in (States') Business Activities' in M Buscemi et al (eds), *Legal Sources in Business and Human Rights: Evolving Dynamics in International and European Law* (Brill 2020).

<sup>25</sup>See SJ Hoffman et al, 'International Law Has a Role to Play in Addressing Antibiotic Resistance' (2015) 43 *Journal of Law, Medicine and Ethics* 65; SR Van Katwyn et al, 'Making Use of Existing International Legal Mechanisms to Manage the Global Antimicrobial Commons: Identifying Legal Hooks and Institutional Mandates' (2020) *Health Care Analysis Article* 3565; D Wenli et al, 'A 'Whole of United Nations Approach' to Tackle Antimicrobial Resistance? A Mapping of the Mandate and Activities of International Organisations' (2022) 7 *BMJ Global Health* e008181.

responses set the stage for an enquiry into the compatibility of such measures with international trade law in the next section.

## 2.1 | AMR in the environment as a regulatory challenge

Over 2000 APIs are being administered worldwide in prescription medicines, over-the-counter therapeutic drugs and veterinary drugs.<sup>26</sup> However, API manufacturing capacity is largely concentrated in two countries. China is the world's largest producer, with an estimated 40% share of global production.<sup>27</sup> India, the world's largest provider of generic medicines, that is, medicines that contain the same APIs as the brand-name medicine, procures almost 70% of its APIs from China.<sup>28</sup> In India, the discharge of antibiotic effluent from pharmaceutical manufacturing units into the environment has led to the emergence of AMR in the environment and its transfer to human beings.<sup>29</sup> The consequences are violations of the rights to life and health as well as the rights to livelihood, food, water and the environment of individuals and communities who reside near polluted water bodies or rely on them for food and livelihood.<sup>30</sup>

The lack of regulation to address AMR in the environment represents a major challenge. Nevertheless, WHO guidance on water and wastewater management in pharmaceutical manufacturing with emphasis on antibiotic production is under development.<sup>31</sup> Further, a few antibiotics are included on the watch list of the European Union's Water Framework Directive,<sup>32</sup> and China has issued the 'Notice on the Reform Implementation Plan for Hazardous Waste Management Supervision and Utilization Capacity' to improve the management and supervision of hazardous wastes including solid waste from antibiotics.<sup>33</sup> However, there are no specific standards on safe

concentrations of antibiotic effluent discharged into the natural environment from pharmaceutical manufacturing units in any part of the world, including in the environmental laws of China and India.<sup>34</sup> Further, none of the domestic laws impose an obligation on pharmaceutical manufacturing units to share information about their discharge levels.<sup>35</sup> In January 2020, the Government of India released draft standards for the concentration of 121 antibiotic residues in the treated effluent of bulk drug and formulation industry as a proposed amendment to the domestic environmental law.<sup>36</sup> However, several pharmaceutical industry associations made representations to the government against the adoption of this proposal, including on the ground that the proposed concentration of antibiotics is lower than that proposed by the AMR Industry Alliance (see Section 2.3).<sup>37</sup> Ultimately, instead of notifying the above-mentioned draft standards for the discharge of antibiotic effluent, the government dropped them.<sup>38</sup>

In any case, the adoption of binding standards is not enough. Governments in producing countries must be able to enforce them.<sup>39</sup> Studies have highlighted the limited capacity (technical, financial and personnel) of statutory authorities in India to enforce pollution-related laws.<sup>40</sup> In addition, there is lack of transparency about the supply chain including information about the identity and geographical location of sub-contracted API producers.<sup>41</sup> What then is the alternative? The next sub-section explores the rationale for adopting production-related environmental criteria in public procurement to address AMR.

<sup>26</sup>EE Burns et al, 'Application of Prioritization Approaches to Optimize Environmental Monitoring and Testing of Pharmaceuticals' (2018) 21 *Journal of Toxicology and Environmental Health Part B* 115.

<sup>27</sup>R Horner, 'The World Needs Pharmaceuticals from China and India to Beat Coronavirus' (The Conversation, 25 May 2020).

<sup>28</sup>P Chatterjee, 'Indian Pharma Threatened by COVID-19 Shutdowns in China' (2020) 395 *The Lancet* 675.

<sup>29</sup>DGJ Larsson et al, 'Effluent from Drug Manufactures Contains Extremely High Levels of Pharmaceuticals' (2007) 148 *Journal of Hazardous Materials* 751; J Fick et al, 'Contamination of Surface, Ground, and Drinking Water From Pharmaceutical Production' (2009) 28 *Environment Toxicology and Chemistry* 2522; Swedwatch (n 8) 22; Changing Markets Foundation, Hyderabad's Pharmaceutical Pollution Crisis: Heavy Metal and Solvent Contamination at Factories in a Major Indian Drug Manufacturing Hub (Nordea Asset Management and Changing Markets Foundation 2018); Changing Markets and Ecstrom (n 6) 13–24.

<sup>30</sup>See P Cullet and L Bhullar, 'The Regulation of Planetary Health Challenges: A Co-Benefits Approach for AMR and WASH' (2022) 52 *Environmental Policy and Law* 289.

<sup>31</sup>World Health Organization, 'WHO Guidance on Water and Wastewater Management in Pharmaceutical Manufacturing with Emphasis on Antibiotic Production', Draft for Public Consultation (WHO 2023).

<sup>32</sup>See Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy [2000] OJ L327/1; Commission Implementing Decision 2022/1307/EU of 22 July 2022 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council, C/2022/5098.

<sup>33</sup>Access to Medicine Foundation, 'Methods Matter: What Steps are Companies Taking to Help Curb AMR by Manufacturing Responsibly?' (Access to Medicine Foundation 2023).

<sup>34</sup>See DGJ Larsson, 'Pollution from Drug Manufacturing: Review and Perspectives' (2014) 369 *Philosophical Transactions of the Royal Society of London B Biological Sciences* 20130571; A Kotwani et al, 'Pharmaceutical Effluent: A Critical Link in The Interconnected Ecosystem Promoting Antimicrobial Resistance' (2021) 28 *Environmental Science and Pollution Research* 32111.

<sup>35</sup>See, e.g., A Pruden et al, 'Management Options for Reducing the Release of Antibiotics and Antibiotic Resistance Genes to the Environment' (2013) 121 *Environmental Health Perspectives* 878, 881; I Chaturvedi and N Kavalakatt, 'A Case for the Global Governance of AMR by Regulating the Pharmaceutical Supply Chain' in O Rubin et al (eds), *Steering Against Superbugs: The Global Governance of Antimicrobial Resistance* (Oxford University Press 2023) 239.

<sup>36</sup>Government of India, Ministry of Environment, Forest and Climate Change, Draft Environment Protection (Amendment) Rules 2019, GSR44(E) dated 23 January 2020. See also L Leo, 'Check Effluents for Antibiotic Residue: Government to Pharma Firms' (Livemint 2019).

<sup>37</sup>See L Yadav, 'Environment Ministry's Decision to Shelve Antibiotic Residue Effluent Limits Brings Respite to Drug Industry' ([Pharmabiz.com](https://pharmabiz.com), 18 August 2021).

<sup>38</sup>See Government of India, Ministry of Environment, Forest and Climate Change, Environment (Protection) Second Amendment Rules, 2021, GSR541(E) dated 6 August 2021. See also A Vishnoi, 'Green Ministry Drops Antibiotic Effluent Limits from New Rules' (Economic Times, 13 August 2021).

<sup>39</sup>J Bengtsson-Palme, L Gunnarsson and DGJ Larsson, 'Can Branding and Price of Pharmaceuticals Guide Informed Choices Towards Improved Pollution Control During Manufacturing?' (2018) 171 *Journal of Cleaner Production* 137.

<sup>40</sup>See, e.g., S Ghosh et al, The State of India's Pollution Control Boards, Working Paper Series, Centre for Policy Research (October 2022) <<https://cprindia.org/workingpapers/the-state-of-indias-pollution-control-boards/>>.

<sup>41</sup>N Nijssingh, C Munthe and DGJ Larsson, 'Managing Pollution from Antibiotics Manufacturing: Charting Actors, Incentives and Disincentives' (2019) 18 *Environmental Health* 7; Malmqvist and Munthe (n 16) 275; C Årdal et al, 'Supply Chain Transparency and the Availability of Essential Medicines' (2021) 99 *Bulletin of World Health Organization* 319–320. See also Larsson and Fick (n 8); DGJ Larsson, 'Release of Active Pharmaceutical Ingredients from Manufacturing Sites - Need for New Management Strategies' (2010) 6 *Integrated Environmental Assessment and Management* 84.

## 2.2 | Rationale for adopting production-related environmental criteria in public procurement to combat AMR

Public sector spending averages 13% to 20% of the gross domestic product (GDP) in most countries, accounting for annual global expenditures of approximately US\$9.5 trillion.<sup>42</sup> In the EU, public procurement represents 14% of GDP or €1.8 trillion each year.<sup>43</sup> The substantial scale of government spending within the national economy means that public procurement can be used to promote objectives (e.g., environmental and social objectives) that are not inherently necessary to achieve the procurement's functional objective (e.g., ensuring public health, in the case of pharmaceuticals).<sup>44</sup> More specifically, the term 'green public procurement' is used to describe public procurement for environmental objectives. The rationale is that the purchasing power of the public sector in certain countries can be used to achieve environmental objectives.<sup>45</sup>

Most of the medicinal products available on the market in developed countries are produced there. However, research-based pharmaceutical companies, generic companies and parallel importers based in developed countries outsource production of APIs for those products to subcontractors in developing countries. For example, in the EU, 90% of APIs for generic medicines are sourced from China and India.<sup>46</sup> Some of the buyers and consumers of the finished drug products are based in pharmaceutical producing countries while others are based in high-income countries with publicly funded health systems, for example, the National Health Service (NHS) in England, Scotland and Wales.

Malmqvist and Munthe rely on three principles—capacity, responsibility and community—to justify the role of high-income consumer countries in addressing AMR in the environment in pharmaceutical producing countries.<sup>47</sup> In terms of capacity, institutional frameworks in pharmaceutical purchasing countries can create an incentive for the prevention or control of environmental pollution generated by pharmaceutical manufacturing units.<sup>48</sup> Turning to responsibility, the siting of pharmaceutical manufacturing units in developing countries benefits suppliers, buyers and consumers around the world. Cost-effectiveness is the primary reason for outsourcing pharmaceutical production and pharmaceutical pollution to countries like China and India. The pharmaceutical manufacturing units do not pay for environmental pollution; instead, this cost is outsourced to individuals and communities in the areas surrounding the polluted environment.

<sup>42</sup>World Bank, 'Global Public Procurement Database: Share, Compare, Improve!' <[www.worldbank.org/en/news/feature/2020/03/23/global-public-procurement-database-share-compare-improve](http://www.worldbank.org/en/news/feature/2020/03/23/global-public-procurement-database-share-compare-improve)>.

<sup>43</sup>European Commission, 'Public Procurement' <[https://single-market-economy.ec.europa.eu/single-market/public-procurement\\_en](https://single-market-economy.ec.europa.eu/single-market/public-procurement_en)>.

<sup>44</sup>S Arrowsmith and P Kunzlik, 'Public Procurement and Horizontal Policies in EC Law: General Principles' in S Arrowsmith and P Kunzlik (eds), *Social and Environmental Policies in EC Procurement Law* (Cambridge University Press 2009) 9, 12.

<sup>45</sup>S Lundberg et al, 'Using Public Procurement to Implement Environmental Policy: An Empirical Analysis' (2015) 17 *Environmental Economics and Policy Studies* 487, 488.

<sup>46</sup>European Parliament, 'Addressing Shortages of Medicines' (2020) <[www.europarl.europa.eu/RegData/etudes/BRIE/2020/649402/EPRS\\_BRI\(2020\)649402\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/BRIE/2020/649402/EPRS_BRI(2020)649402_EN.pdf)>.

<sup>47</sup>Malmqvist and Munthe (n 16) 276. See also Pruden (n 35) 882.

<sup>48</sup>Nijssingh et al (n 41).

Purchasing countries have a greater interest in procuring pharmaceuticals at low cost to achieve the objective of provision of healthcare for their public than in protecting the environment in pharmaceutical producing countries.<sup>49</sup> However, cost-effectiveness and environmental protection are not mutually exclusive goals if we stop discounting the future and adopt a long-term community perspective. In the short to medium term, the adverse impacts of the discharge of antibiotic effluent from pharmaceutical manufacturing units into the environment may adversely affect the rights of individuals and communities and the environment surrounding the affected water bodies. However, AMR does not respect borders.<sup>50</sup> The WHO acknowledges the influence of trade, travel and both human and animal migration on the transmission of drug-resistant bacteria.<sup>51</sup> As a result, in the long term, AMR poses a serious threat to the environment including in the pharmaceutical purchasing countries.<sup>52</sup> The next sub-section identifies the production-related environmental criteria relating to the discharge of antibiotic effluent in the environment, which can form a part of public procurement of pharmaceuticals.

## 2.3 | Production-related environmental criteria

There is growing recognition, at different levels, of the need to regulate AMR in the environment by incorporating production-related environmental criteria in measures for public procurement of pharmaceuticals. The United Nations informal Interagency Task Team on Sustainable Procurement in the Health Sector engages with suppliers and manufacturers to promote environmentally responsible procurement of health commodities and promotes the use of environmental criteria in pharmaceutical procurement.<sup>53</sup> The Organisation for Economic Co-operation and Development (OECD) identifies green public procurement using environmental criteria as a mitigation option during the stage of pharmaceutical production.<sup>54</sup> The EU recognises the need for sustainable or green public procurement.<sup>55</sup> There is growing focus on the green public procurement of pharmaceuticals specifically. For instance, the European Commission has committed to '[d]iscuss[ing], with the relevant Member State authorities, the possibility of using procurement policy to encourage greener pharmaceutical design and manufacturing'.<sup>56</sup> The Commission's Pharmaceutical Strategy includes

<sup>49</sup>ibid 7. See also Pruden et al (n 35) 882.

<sup>50</sup>See, e.g., I Frost et al, 'Global Geographic Trends in Antimicrobial Resistance: The Role of International Travel' (2019) 26 *Journal of Travel Medicine* 1.

<sup>51</sup>WHO (n 12) 2. See also OECD, 'Pharmaceutical Residues in Freshwater: Hazards and Policy Responses' (OECD Publishing 2019).

<sup>52</sup>Swedwatch (n 8) 10–11; Changing Markets Foundation and Ecostorm (n 6) 5; WHO (n 1).

<sup>53</sup>See, e.g., United Nations Development Programme (UNDP), 'Sustainable Health Procurement Guidance Note' (UNDP 2020).

<sup>54</sup>OECD (n 51) 14–16.

<sup>55</sup>See Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC [2014] OJ L 94/65 recital 91; Commission (EU) 'Making Public Procurement Work in and for Europe' (Communication) COM(2017) 572 final, 3 October 2017, 8; Commission (EU) 'Europe 2020: A Strategy for Smart, Sustainable and Inclusive Growth' (Communication) COM(2010) 2020 final, 3 May 2020. See generally P Kunzlik, 'Green Public Procurement – European Law, Environmental Standards and 'What to Buy' Decisions' (2013) 25 *Journal of Environmental Law* 173.

<sup>56</sup>Commission (EU), 'European Union Strategic Approach to Pharmaceuticals in the Environment' (Communication) COM(2019) 128 final, 11 March 2019 (EU Strategic Approach) 9.

public procurement as one important area to achieve 'green production' conditions.<sup>57</sup> The Commission has also committed to encouraging international cooperation to address the environmental risks in other countries where pharmaceutical emissions from manufacturing and other sources (such as human and animal use and disposal) may contribute, among other things, to the spread of AMR.<sup>58</sup> The 2023 proposals for a Regulation and a Directive laying down procedures for the authorisation and supervision of medicinal products for human use *inter alia* seek to make medicines more environmentally sustainable.<sup>59</sup> For instance, they require the environmental risk assessment for antimicrobials to include 'an evaluation of the risk for antimicrobial resistance selection in the environment due to the entire manufacturing supply chain inside and outside the Union, use and disposal of the antimicrobial'.<sup>60</sup>

Public procurement of pharmaceuticals is the source of government-led regulation for incorporation of production-related environmental criteria, which form the object of compatibility analysis in the next section. Such criteria could impose different requirements in relation to the pharmaceutical manufacturing process. These requirements could include compliance with environmental laws in countries of production, including discharge limits; disclosure of producers' discharge levels; and disclosure of identity or location of sub-contracted parties.<sup>61</sup> As discussed in Section 2.1, an enabling regulatory environment is currently missing. However, the growing recognition of the AMR challenge could result in a regulatory awakening in the short to medium term.

Some countries already encourage the use of public procurement to promote environmentally friendly pharmaceutical manufacturing and supply chain practices. The former prevent or control the discharge of antibiotic effluent into the environment, and the latter facilitate the identification of potential sources of discharge—both regulating the emergence of AMR in the environment. Since 2015, Sweden's National Agency for Public Procurement has proposed award criteria and special contract terms into tenders for hospital procurements by 21 regions to help procurers identify sustainable products that *inter alia* provide information on the location of the manufacture and formulation of APIs.<sup>62</sup> In 2019, the Norwegian government introduced a pilot sustainable procurement programme to reward antibiotic manufacturers for good environmental and supply chain practices. The supplier's environmental and supply chain policies comprise 30% of the Norwegian Hospital Procurement Trust's (*Sykehusinnkjøp HF*) overall pharmaceutical procurement score criteria.<sup>63</sup> New Zealand's drug regulator MEDSAFE requires all approved

drugs to specify the name and address of the actual site of manufacture (API for prescription medicines).<sup>64</sup> The English NHS is one of the buyers of pharmaceuticals from China and India, and the United Kingdom is committed to '[w]ork with other countries to ensure responsible antimicrobial procurement from manufacturers with transparent world class environmental stewardship in their supply chains'.<sup>65</sup>

Government-led regulation—whether in the pharmaceutical producing or purchasing countries—is not the only (or primary) source of production-related environmental criteria for green public procurement measures.<sup>66</sup> The Pharmaceutical Supply Chain Initiative (PSCI), a group of 54 pharmaceutical and healthcare companies, and the AMR Industry Alliance, formed of 100 life sciences companies and associations, have developed and adopted voluntary measures to improve the sustainability of manufacturing and supply chains, as well as antibiotic discharge limits.<sup>67</sup> For example, PSCI's principles for responsible supply chain management include management of releases of active pharmaceuticals into the environment.<sup>68</sup> The AMR Industry Alliance's Common Antibiotic Manufacturing Framework went further and gave companies a methodology for conducting risk assessments and establishing minimum site requirements to control antibiotic manufacturing waste streams and meet environmental standards.<sup>69</sup> The AMR Industry Alliance has also published risk-based targets for discharge concentrations of antibiotics.<sup>70</sup> As a result, pharmaceutical companies are setting and enforcing antibiotic discharge limits on their manufacturing units albeit to a greater extent on their own units than those of their suppliers.<sup>71</sup> In 2022, the AMR Industry Alliance's Antibiotic Manufacturing Standard formalised the abovementioned framework, requiring antibiotic manufacturers to meet the antibiotic's recommended predicted no effect concentration (PNEC) or the level at which a substance will not have an adverse effect on its environment.<sup>72</sup> This standard was co-developed by the Alliance and the British Standards Institution, which is the national standards body of the United Kingdom. Certification systems are also being used to identify and incentivise pharmaceutical manufacturing units that adopt

<sup>64</sup>See New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), 'Guidelines on the Regulation of Therapeutic Products in New Zealand – Manufacture of Medicines' (December 2023).

<sup>65</sup>HM Government, 'Tackling Antimicrobial Resistance 2019–2024 – The UK's Five-Year National Action Plan' (UK Department of Health and Social Care 2019) 48.

<sup>66</sup>See, e.g., K Mitkidis, 'Sustainable Procurement of Pharmaceuticals: A Tool to Combat Global Antimicrobial Resistance' in Rubin et al (n 35) 253, 259–260.

<sup>67</sup>See N Schaaf et al, 'Reducing Emissions from Antibiotic Production, White Paper on Policies, Technologies, and Enabling Conditions for Sustainable Antibiotics Manufacturing' (Stockholm International Water Institute 2020).

<sup>68</sup>Pharmaceutical Supply Chain Initiative, 'PSCI Principles for Responsible Supply Chain Management' (third version, PSCI 2023); Pharmaceutical Supply Chain Initiative, 'Pharmaceutical Industry Principles for Responsible Supply Chain Management – Implementation Guidance' (PSCI 2011).

<sup>69</sup>AMR Industry Alliance, 'Common Antibiotic Manufacturing Framework' (AMR Industry Alliance Secretariat 2018). See also AMR Industry Alliance, 'Industry Roadmap for Progress on Combating Antimicrobial Resistance' (AMR Industry Alliance Secretariat 2016).

<sup>70</sup>AMR Industry Alliance, 'AMR Alliance Science-Based PNEC Targets for Risk Assessment' (AMR Industry Alliance Secretariat 2023).

<sup>71</sup>Access to Medicine Foundation, 'Antimicrobial Resistance Benchmark 2021' (Access to Medicine Foundation 2021) 20.

<sup>72</sup>AMR Industry Alliance, 'Antibiotic Manufacturing Standard: Minimizing Risk of Developing Antibiotic Resistance and Aquatic Ecotoxicity in the Environment Resulting from the Manufacturing of Human Antibiotics' (AMR Industry Alliance Secretariat 2022).

<sup>57</sup>Commission (EU), 'Pharmaceutical Strategy for Europe' (Communication) COM(2020) 761 final, 25 November 2020, 12.

<sup>58</sup>Commission (EU), 'Pathway to a Healthy Planet for All, EU Action Plan: "Towards Zero Pollution for Air, Water and Soil"' (Communication) COM(2021) 400, 12 May 2021.

<sup>59</sup>Commission (EU), Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, 2023/0132 (COD) (26 April 2023).

<sup>60</sup>*ibid* art 22(4).

<sup>61</sup>Malmqvist and Munthe (n 16) 276. See also M Ågerstrand et al, 'Improving Environmental Risk Assessment of Human Pharmaceuticals' (2015) 49 *Environmental Science and Technology* 5336, 5341–5342; Bengtsson-Palme et al (n 39).

<sup>62</sup>National Public Procurement Agency (n 17).

<sup>63</sup>Norwegian Hospital Procurement Trust (n 17).

production-related environmental criteria. The United Kingdom's national AMR action plan includes a commitment to '[c]ollaborate with industry to promote the development of a global environmental stewardship certification system that can distinguish responsible manufacturers of antimicrobials'.<sup>73</sup> In 2023, the AMR Industry Alliance and the British Standards Institution developed a certification program (BSI Kitemark™) that will enable manufacturers of APIs and finished drug products to demonstrate that they adhere to the abovementioned Antibiotic Manufacturing Standard.<sup>74</sup>

Formal public procurement regulation is beginning to incorporate elements of the pharmaceutical industry's voluntary regulation. For example, informed by the Access to Medicine Foundation's AMR Benchmark<sup>75</sup> and the AMR Industry Alliance, the NHS's evaluation criteria that manufacturers must meet to qualify for a procurement contract requires that they confirm and demonstrate their organisations' commitment to good antimicrobial manufacturing and environmental practice.<sup>76</sup> The manufacturers should be signatories to the AMR Industry Alliance's Declaration. They should also demonstrate compliance with the Alliance's manufacturing standards, good antimicrobial manufacturing practices and environmental standards throughout the supply chain. This includes compliance with discharge limits at their own and/or their suppliers' manufacturing sites and external wastewater treatment plants. The European Commission's 2023 proposals for a Directive on a Union code on medicinal products for human use include a requirement to evaluate the risk for AMR selection in the environment due to the entire manufacturing supply chain inside and outside the European Union. Such selection for AMR could be a response to the discharge of antibiotic effluent above a specific concentration. The proposed Directive emphasises the need to take 'into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics'.<sup>77</sup>

Clearly, there is a growing interest in, and adoption of, measures for green public procurement of pharmaceuticals that incorporate production-related environmental criteria to address the emergence of AMR in the environment and its adverse impacts on the environment. This is because AMR in the environment continues to pose a challenge, and the ongoing COVID-19 pandemic has led to an increase in the use of antimicrobials, which is likely to exacerbate the global challenge AMR poses for humanity.<sup>78</sup> However, to what extent are such measures compatible with international trade law? The next section addresses this question with reference to a specific WTO agreement, namely the GPA.

### 3 | COMPATIBILITY WITH THE WTO AGREEMENT ON GOVERNMENT PROCUREMENT

Green public procurement of pharmaceuticals can form part of the regulatory response to the emergence of AMR in the environment within and beyond the borders of the pharmaceutical producing countries. At the same time, such measures must be compatible with international trade law. That is, they must not create a barrier to free trade. This section examines the compatibility between measures for green public procurement of pharmaceuticals and international trade law with reference to the GPA, one of the plurilateral agreements annexed to the Agreement Establishing the WTO (WTO Agreement).<sup>79</sup> It draws on certain provisions of the General Agreement on Tariffs and Trade (GATT), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the WTO Agreement on Technical Barriers to Trade (TBT Agreement) for comparison or for guidance where the GPA is silent or ambiguous or where there is no GPA-specific jurisprudence.

The objective of the GPA is to ensure that public procurement measures adopted by countries to achieve different objectives (including environmental objectives) do not create a barrier to free trade. Notably, a WTO Panel has considered whether pharmaceutical products fall within the definition of 'government procurement'.<sup>80</sup> However, the GPA does not apply to all WTO members.<sup>81</sup> This means that not all countries engaged in the production, supply and/or procurement of pharmaceuticals may be parties to the GPA. Non-parties remain free to adopt their own rules concerning procurement, including the incorporation of environmental and other criterion. Currently, there are 22 parties to the GPA (covering 49 WTO members, including the United Kingdom, the United States and the EU and its 27 member states as one party). The parties to the GPA include some of the major pharmaceutical producing and purchasing countries as well as host countries of the largest pharmaceutical companies in the world. A further 35 WTO members, including China and India, as well as four international organisations, participate in the Committee on Government Procurement as observers.<sup>82</sup> Of these, 11 observers including China are in the process of acceding to the GPA.

The preamble to the WTO Agreement recognises the need to act in accordance with the principle of sustainable development and to protect and preserve the environment.<sup>83</sup> This preamble informs the interpretation of all the multilateral and plurilateral agreements annexed to the WTO Agreement,<sup>84</sup> including the GPA. Measures for

<sup>73</sup>HM Government (n 65) 47.

<sup>74</sup>British Standards Institution, 'BSI Kitemark™ for Minimized Risk of Antimicrobial Resistance' (June 2023) <<https://www.bsigroup.com/en-gb/kitemark/product-testing/bsi-kitemark-for-minimized-risk-of-amr/>>.

<sup>75</sup>Access to Medicine Foundation (n 71).

<sup>76</sup>National Institute for Health and Care Excellence (NICE), 'AMR4 – Antimicrobial Stewardship' - Annex 3: Award Questions and Criteria' (NICE 2021). See also NICE, '1.16 Part 3– Additional Questions – Minimum Criteria for New Antimicrobials' in ANNEX-1: SELECTION Questionnaire (SQ) Evaluation Criteria (new antimicrobials)' <[www.nice.org.uk/Media/Default/About/what-we-do/Life-sciences/evaluation-criteria-new.pdf](http://www.nice.org.uk/Media/Default/About/what-we-do/Life-sciences/evaluation-criteria-new.pdf)>.

<sup>77</sup>Commission (EU) (n 59) art 22(4).

<sup>78</sup>'Antimicrobial Resistance in the Age of COVID-19' (2020) 5 *Nature Microbiology* 779; T Johnson, 'A Trade-off: Antimicrobial Resistance and COVID-19' (2021) 3 *Bioethics* 1.

<sup>79</sup>Revised Agreement on Government Procurement (adopted 30 March 2012, entered into force 7 April 2014) 1915 UNTS 193 (GPA).

<sup>80</sup>Turkey-Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products, WT/DS583/ARB25 (25 July 2022).

<sup>81</sup>World Trade Organization, 'Agreement on Government Procurement – Parties, Observers and Accessions' <[www.wto.org/english/tratop\\_e/gproc\\_e/memobs\\_e.htm](http://www.wto.org/english/tratop_e/gproc_e/memobs_e.htm)>.

<sup>82</sup>WTO, Committee on Government Procurement, 'Participation of Observers in the Committee on Government Procurement (1994)' GPA/1 (5 March 1996) Annex 1, 2.

<sup>83</sup>Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, preamble, sixth recital.

<sup>84</sup>United States – Import Prohibition of Certain Shrimp and Shrimp Products (Appellate Body Report) WT/DS58/AB/R (6 November 1998) para 129.



green public procurement of pharmaceuticals can be compatible with the GPA if they fulfil certain requirements.<sup>85</sup> These requirements are reflected in the principle of non-discrimination (Section 3.1) and the general exceptions (Section 3.2). Although the preamble to the GPA does not refer to environmental protection, it recognises that procedural commitments in the GPA should be sufficiently flexible to accommodate the specific circumstances of parties, creating room for the adoption of measures to achieve non-trade objectives.<sup>86</sup> Further, several substantive provisions of the GPA are relevant explicitly or by implication. These include the technical specifications and tender documentation (Section 3.3) and the conditions for participation and award criteria (Section 3.4). The rest of this section examines the extent to which measures for green public procurement of pharmaceuticals are compatible with the GPA.

### 3.1 | The principle of non-discrimination

As with all trade measures, measures for green public procurement of pharmaceuticals that incorporate production-related environmental criteria are expected to follow the principle of non-discrimination. The preamble to the GPA states that government procurement measures should not 'afford protection to domestic suppliers, goods or services' or 'discriminate among foreign suppliers, goods or services'.<sup>87</sup> Further, according to Article IV:1 of the GPA, each party must provide 'treatment no less favourable than the treatment the Party, including its procuring entities, accords to domestic goods, services and suppliers; and goods, services and suppliers of any other Party'.<sup>88</sup> Green public procurement measures that incorporate production-related environmental criteria relating to the discharge of antibiotic effluent in the environment would discriminate among pharmaceutical manufacturer or supplier countries based on whether they adopt this criterion. Examples of this include the requirement to meet the antibiotic's recommended PNEC under the AMR Industry Alliance's Antibiotic Manufacturing Standard in the NHS evaluation criteria or to take into account existing international standards in the European Commission's proposals. Further, the COVID-19 pandemic has highlighted the over-dependence on certain countries for APIs and finished drug products and the need to develop domestic manufacturing capacity for essential medicines and vaccines.<sup>89</sup> In these circumstances, measures for green public procurement of pharmaceuticals may violate the principle of non-discrimination if countries that have historically relied on other countries for APIs apply such measures to afford

protection or to provide more favourable treatment to domestic pharmaceutical manufacturers or suppliers.

Processes and production methods (PPMs) relate to how a product is produced, manufactured or obtained in its country of origin.<sup>90</sup> In the SPS Agreement, PPMs form part of SPS measures and are to be taken into account in risk assessments by members.<sup>91</sup> In the TBT Agreement, the definitions of a technical regulation and of a standard encompass PPMs of products.<sup>92</sup> However, these two agreements focus on product-related PPMs or PPMs that relate directly to the characteristics of the product itself rather than the production process.<sup>93</sup> In other words, whether a polluting or non-polluting process produces pharmaceuticals is irrelevant, although it may be important for environmental protection. The environmentally safe discharge of antibiotic effluent into the environment as a part of the pharmaceutical manufacturing process is not discernible in the final product, and it would be regarded as a non-product-related PPM.<sup>94</sup> Notably, non-discrimination provisions in the GATT, the SPS Agreement and the TBT Agreement include the words 'like products'.<sup>95</sup> These words are missing from Article IV of the GPA because of the unique nature of government procurement where the government is also the consumer.<sup>96</sup> This is significant because otherwise it is difficult to establish the likeness of products where the measures relate to the production process.

As discussed in Section 2.2, measures for green public procurement of pharmaceuticals that incorporate environmental criteria seek to address a situation where the adverse impacts resulting from the discharge of antibiotic effluent into the environment, from pharmaceutical manufacturing units, are first experienced locally in the country of production but the long-term effects include the emergence of AMR in human beings and the environment in other jurisdictions also. The SPS Agreement only covers measures to protect humans, animals and plants within the territory of the importing member.<sup>97</sup> Similarly, under the TBT Agreement, trade-restrictive technical regulations must be 'necessary to fulfil a legitimate objective', including 'protection of human health or safety, animal or plant life or health, or the environment'.<sup>98</sup> This would exclude measures designed to protect the environment of the producing or exporting country. However, as noted by McCrudden in the context of GATT:

[i]t is quite commonly accepted that process-based measures motivated by environmental concerns are

<sup>90</sup>M Matsushita et al, *The World Trade Organization: Law, Practice and Policy* (2nd edn, Oxford University Press 2006) 808.

<sup>91</sup>Agreement on the Application of Sanitary and Phytosanitary Measures (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 493 (SPS Agreement) art 5(2) and Annex A.

<sup>92</sup>Agreement on Technical Barriers to Trade (adopted 15 April 1994, entered into force 1 January 1995) 1868 UNTS 120 (TBT Agreement) Annex I.

<sup>93</sup>Matsushita et al (n 90) Section 9.2.

<sup>94</sup>See generally R Howse and D Regan, 'The Product/Process Distinction – An Illusory Basis for Disciplining 'Unilateralism' in Trade Policy' (2000) 11 *European Journal of International Law* 249.

<sup>95</sup>General Agreement on Tariffs and Trade (adopted 30 November 1947, entered into force 1 January 1948) 55 UNTS 194; SPS Agreement (n 91); TBT Agreement (n 92).

<sup>96</sup>Davies (n 85) 437.

<sup>97</sup>SPS Agreement (n 91) Annex A.

<sup>98</sup>TBT Agreement (n 92) art 2.2.

<sup>85</sup>See A Davies, 'The National Treatment and Exceptions Provisions of the Agreement on Government Procurement and the Pursuit of Horizontal Policies' in S Arrowsmith and RD Anderson (eds), *The WTO Regime on Government Procurement: Challenge and Reform* (Cambridge University Press 2011) 429.

<sup>86</sup>See L Casier, 'Canada's International Trade Obligations: Barrier or Opportunity for Sustainable Public Procurement?' (International Institute for Sustainable Development 2019) 15.

<sup>87</sup>GPA (n 79) preamble.

<sup>88</sup>ibid art IV:1.

<sup>89</sup>United Nations Industrial Development Organization (UNIDO), 'Pharmaceutical Capacity and Infrastructure' (UNIDO 2022).

not protectionist, at least if the environmental effects at issue do not entirely and exclusively take place in the country of production.<sup>99</sup>

The green public procurement measures discussed in Section 2.3 fall into this category.

### 3.2 | Exceptions

Where measures for green public procurement of pharmaceuticals violate the principle of non-discrimination, it may be possible to justify them under the general exceptions in Article III:2 of the GPA. Article III:2(b) of the GPA allows a party to impose or enforce measures ‘necessary to protect human, animal or plant life or health’ provided their application does not ‘constitute a means of arbitrary or unjustifiable discrimination between Parties where the same conditions prevail or a disguised restriction on international trade’. This provision has not yet been the subject of interpretation in WTO dispute settlement proceedings. However, guidance can be drawn from the GATT/WTO jurisprudence on Article XX of GATT, which is close in its structure and its *chapeau* language to the GPA exception.<sup>100</sup> Article XX of GATT envisages a two-tier analysis of the measure: (1) it falls under one of the exceptions, and (2) it satisfies the *chapeau*'s requirements. Application of this two-tier analysis to the measures for green public procurement of pharmaceuticals demonstrates that they would fall into the general exception.

First, such green public procurement measures can be argued to be ‘necessary for the protection of human, animal or plant life or health’ under the GPA.<sup>101</sup> The discharge of antibiotic effluent into water bodies affects human, animal and plant life and health. In *Brazil – Tyres*, the Appellate Body noted that ‘a panel might conclude that an import ban is necessary on the basis of a demonstration that the import ban at issue is apt to produce a material contribution to the achievement of its objective’.<sup>102</sup> According to Davies, in that case, the Appellate Body interpreted ‘the necessity test in a flexible manner which could be relevant where the challenged procurement measure is one of several strategies to achieve a public policy goal’.<sup>103</sup> The Appellate Body further stated: ‘Substituting one element of this comprehensive policy for another would weaken the policy by reducing the synergies between its components, as well as its total effect’.<sup>104</sup> In the case of measures for green public procurement of pharmaceuticals, no less trade restrictive measures are available because it is imperative to arrest the negative impact of the uncontrolled discharge of antibiotic effluent from the pharmaceutical production process, which leads to the emergence of AMR in the environment.

Second, the application of such measures does not ‘constitute a means of arbitrary or unjustifiable discrimination between Parties where the same conditions prevail or a disguised restriction on international trade’ under the GPA.<sup>105</sup> Country-based measures can be adopted based on relevant and acceptable differences but there should be no discrimination between countries where ‘the same conditions prevail’ according to the GPA.<sup>106</sup> In other words, the pharmaceutical purchasing country can apply the green public procurement measures that distinguish between pharmaceutical manufacturer or supplier countries on the basis of relevant and acceptable differences.<sup>107</sup> However, they must not discriminate between foreign and domestic pharmaceutical manufacturers or suppliers. The term ‘disguise’ implies an intention to ‘conceal the pursuit of trade-restrictive objectives’,<sup>108</sup> which ‘can most often be discerned from the design, architecture, and the revealing structure of a measure’.<sup>109</sup> A measure for green public procurement of pharmaceuticals is less likely to be intended to restrict trade and more likely to achieve a non-trade objective that protects human and environmental health as well as the economy. This is because of the global interest in access to medicines, the limited number of countries with the required manufacturing capacity and the global challenge posed by AMR. However, as mentioned in Section 3.1, the recognition of the need to ensure ‘drug security’ and future efforts to realise this objective could raise questions about the trade-restrictive or non-trade-objective-promoting nature of such green public procurement measures. In addition to the non-discrimination provision and the exceptions, several substantive provisions of the GPA are relevant for a compatibility analysis. The next two sub-sections focus on these provisions.

### 3.3 | Technical specifications and tender documentation

Article X of the GPA deals with ‘technical specifications and tender documentation’. This provision reveals opportunities for the inclusion of environmental criteria in measures for public procurement of pharmaceuticals.<sup>110</sup> The definition of ‘technical specifications’ in Article I of the GPA explicitly includes tendering requirements for procurement of goods that lay down ‘the processes and methods for their production’.<sup>111</sup> According to Kunzlik, this provision accommodates product-related PPMs as well as non-product related PPMs.<sup>112</sup> Therefore, this definition of technical specifications would cover non-product-related tendering requirements for public procurement of

<sup>105</sup>GPA (n 79) art III:2(b).

<sup>106</sup>McCrudden (n 99) 505 (referring to Article III:2(b) of the GPA).

<sup>107</sup>*ibid.*

<sup>108</sup>*European Communities – Measures Affecting Asbestos and Asbestos-Containing Products* (Panel Report) WT/DS135/R (5 April 2001) para 8.236.

<sup>109</sup>*Japan – Taxes on Alcoholic Beverages* (Appellate Body Report) WT/DS/11/AB/R (1 November 1996) 29.

<sup>110</sup>GPA (n 79) art X.

<sup>111</sup>*ibid* art I.

<sup>112</sup>P Kunzlik, ‘International Procurement Regimes and the Scope for the Inclusion of Environmental Factors in Public Procurement’ in OECD (ed), *The Environmental Performance of Public Procurement: Issues of Policy Coherence* (OECD 2003) 157, 159. See also McCrudden (n 99) 482.

<sup>99</sup>C McCrudden, *Buying Social Justice: Equality, Government Procurement, & Legal Change* (Oxford University Press 2007) 480.

<sup>100</sup>*ibid* 491. See also Kunzlik (n 22) 201–202.

<sup>101</sup>GPA (n 79) art III:2(b).

<sup>102</sup>*Brazil – Measures Affecting Imports of Retreaded Tyres* (Appellate Body Report) WT/DS332/AB/R (17 December 2007) (*Brazil – Tyres*) para 151.

<sup>103</sup>Davies (n 85) 440.

<sup>104</sup>*Brazil – Tyres* (n 102) para 172.

pharmaceuticals that incorporate environmental criteria relating to the discharge of antibiotic effluent in the environment during the production process.

Article X:1 of the GPA requires that the technical specification should not create 'unnecessary obstacles to international trade'.<sup>113</sup> The GPA does not define this term, but Article 2.2 of the TBT Agreement, after referring to this term, states: 'technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create'.<sup>114</sup> The indicative list of legitimate objectives in the TBT Agreement includes protection of human health or safety, animal or plant life or health or the environment. In the present case, the risks resulting from non-fulfilment of the legitimate objective is an increase in the risk posed by AMR, which is a global human, animal and environmental health challenge. In any case, as discussed in Section 3.2, Article III:2 of the GPA provides for certain exceptional circumstances in which parties could adopt green public procurement measures.

Article X:2(b) of the GPA states that the technical specification shall, where appropriate, 'be based on international standards, where such exist; otherwise, on national technical regulations, recognized national standards or buildings codes'.<sup>115</sup> Article I of the GPA defines a standard as a 'document approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for goods or services, or related processes and production methods, with which compliance is not mandatory'.<sup>116</sup> Measures for green public procurement of pharmaceuticals may incorporate voluntary 'international' standards, such as those developed and adopted by the AMR Industry Alliance, within the tender process, as in the case of the NHS evaluation criteria (see Section 2.3). This may result in the AMR Industry Alliance gaining the status of a 'recognised body' under the GPA.<sup>117</sup> The technical specification may also incorporate certification systems that reward responsible pharmaceutical producers such as the one developed by the AMR Industry Alliance and the British Standards Institution (see Section 2.3).

The GPA acknowledges the importance of environmental considerations, and the technical specifications and evaluation criteria now include explicit references to the environment. For instance, Article X:6 of the GPA provides: 'For greater certainty, a Party, including its procuring entities, may, in accordance with this Article, prepare, adopt or apply technical specifications to promote the conservation of natural resources or protect the environment'.<sup>118</sup> A combined reading of this provision with the definition of technical specifications discussed above, which includes PPMs,<sup>119</sup> creates an opportunity for the incorporation of non-product-related environmental criteria in measures for public procurement of pharmaceuticals. Further, according to Article X:7(c) of the GPA, the tender documentation shall include the

relative importance of evaluation criteria.<sup>120</sup> The illustrative list of evaluation criteria, in Article X:9 of the GPA, includes environmental characteristics.<sup>121</sup> These provisions may encourage the WTO dispute settlement body to 'adopt a broad interpretation of the possibilities for including environmental criteria' in the GPA.<sup>122</sup> The technical specifications or environmental characteristics in the evaluation criteria for green public procurement of pharmaceuticals may include non-product related PPMs concerning the concentration limits of antibiotic effluent discharged from pharmaceutical manufacturing units into water bodies, such as the recommended PNEC in the AMR Industry Alliance's Antibiotic Manufacturing Standard. Although these provisions leave it at the discretion of the parties to include environmental considerations in technical specifications and evaluation criteria, it is hoped that pharmaceutical purchasing countries such as EU member states will respond positively to address AMR given the commitment expressed in policy documents (see Section 2.3).

### 3.4 | Conditions for participation and award criteria

The conditions for participation in public procurement include legal, economic, financial, technical and professional requirements. The conditions as set out in the GPA do not explicitly incorporate any environmental considerations. Article VIII:1 of the GPA states that the conditions for participation must be 'essential to ensure that a supplier has the legal and financial capacities and the commercial and technical abilities to undertake the relevant procurement'.<sup>123</sup> These conditions focus on capacities and abilities in respect of the procurement that do not include environmental criteria rather than the contract that might include such criteria.<sup>124</sup> However, certain other provisions of the GPA could be interpreted to include environmental considerations. Article VIII:4 of the GPA permits parties to exclude suppliers with 'final judgments in respect of serious crimes or other serious offences'.<sup>125</sup> The non-exhaustive list of grounds for exclusion of suppliers does not include environmental laws but Arrowsmith envisages exclusion of suppliers for breaches of environmental legislation.<sup>126</sup> Of course, domestic legislation must consider such breaches to be 'serious crimes or other serious offences'. At present, however, domestic environmental legislation in China and India (and for that matter most jurisdictions) is largely silent in respect of the discharge of antibiotic effluent into the environment, as discussed in Section 2.1.

Award criteria are used to select the best bidder to whom the public procurement contract should be awarded. Article XV:5 of the

<sup>113</sup>GPA (n 79) art X:1.

<sup>114</sup>TBT Agreement (n 92) art 2.2.

<sup>115</sup>GPA (n 79) art X:2(b).

<sup>116</sup>ibid art I.

<sup>117</sup>See generally Corvaglia (n 22) 625 (discussing private standards and the GPA).

<sup>118</sup>GPA (n 79) art X:6.

<sup>119</sup>A Reich, 'The New Text of the Agreement on Government Procurement: An Analysis and Assessment' (2010) 12 *Journal of International Economic Law* 989, 1012.

<sup>120</sup>GPA (n 79) art X:7(c).

<sup>121</sup>ibid art X:9.

<sup>122</sup>S Arrowsmith, 'The Revised Agreement on Government Procurement: Changes to the Procedural Rules and Other Transparency Provisions' in Arrowsmith and Anderson (n 85) 323.

<sup>123</sup>GPA (n 79) art VIII:1.

<sup>124</sup>Reich (n 119) 1013.

<sup>125</sup>GPA (n 79) art VIII:4.

<sup>126</sup>Arrowsmith (n 122) 323.

GPA provides that the procuring entity shall award the contract to the supplier who has submitted the most advantageous tender or the lowest bidder (where price is the sole criterion) based solely on the evaluation criteria.<sup>127</sup> This provision refers to the advantage to the procuring entity rather than the society,<sup>128</sup> for example, through environmental protection. Of course, where environmental considerations form part of the evaluation criteria, the most advantageous tender for the procuring entity may be the one that meets the environmental criteria in respect of the discharge of antibiotic effluent into the environment. An example of this would be the NHS evaluation criteria discussed in Section 2.3. Further, Article XV:5 of the GPA permits the procuring entity to determine that it is not in the public interest to award the contract.<sup>129</sup> The definition of the term ‘public interest’—whether restricted to the interest of the public in the purchasing country or widened to encompass global public interest, for example, in addressing AMR—may influence the award criteria.

#### 4 | THE WAY FORWARD

An obstacle to the regulation of AMR in the environment is the gap in knowledge concerning monitoring, including uncertainty relating to the source and extent of the problem, and its adverse impacts.<sup>130</sup> This gap affects the development of regulation including standards relating to the discharge of antibiotic effluent from pharmaceutical manufacturing units into the environment. In such a situation, measures for green public procurement of pharmaceuticals ought to be based on the precautionary principle to prevent or mitigate the risk of the adverse impacts. Further, some of these measures may operationalise the polluter pays principle where the production-related environmental criteria encourage pharmaceutical manufacturing units to internalise the environmental costs.<sup>131</sup> For instance, the proposed reform of the Urban Wastewater Directive includes an extended producer responsibility scheme, which would make producers of medicinal products for human use responsible for the removal of micropollutants (which include antibiotics) at treatment plants.<sup>132</sup> In fact, the incorporation of the principle of prevention of pollution at source and the polluter pays principle into EU environmental law has influenced the adoption of regulatory approaches such as green public procurement of pharmaceuticals. The EU's Strategic Approach to Pharmaceuticals in the Environment ‘stresses that, in order to ensure the effectiveness of regulatory actions, it is crucial that they are taken in line with the precautionary principle and the principle that environmental damage should as a priority be rectified at source, highlights that the polluter pays principle should apply; primarily covering the

manufacturing process’.<sup>133</sup> These environmental principles ought to underpin production-related environmental criteria in regulatory instruments adopted by the host countries of pharmaceutical manufacturing units or the pharmaceutical purchasing countries. However, the GPA does not recognise the precautionary principle (or for that matter any other environmental principle except sustainable development) as the basis for the adoption of trade measures with non-trade objectives.<sup>134</sup>

The GPA engages with the environmental principle of sustainable development through the lens of ‘sustainable’ procurement. Walker and Phillips define sustainable procurement as ‘the pursuit of sustainable development objectives through the purchasing and supply process, and involves balancing environmental, social and economic objectives’.<sup>135</sup> The 2030 Sustainable Development Agenda includes Sustainable Development Goal (SDG) 12—‘Ensure sustainable production and consumption patterns’, and SDG target 12.7 specifically calls on all countries to promote and implement sustainable public procurement policies and action plans. Although there are no specific SDGs or indicators relating to AMR in the environment, several existing SDGs and indicators are AMR-sensitive and indirectly relate to AMR in the environment.<sup>136</sup> There are opportunities for consideration of green procurement of pharmaceuticals here but an overwhelming emphasis on SDGs, and the fact that the GPA's approach to non-trade objectives is informed by a narrow understanding of sustainable procurement may not lead to a holistic long-term approach. For instance, the GPA states that sustainable procurement is to be practiced in a manner consistent with the principle of ‘best value for money’ and parties' international trade obligations.<sup>137</sup> Instead, what is required is a life-cycle approach to sustainable procurement.<sup>138</sup>

Public procurement measures adopted by pharmaceutical purchasing countries, such as MEDSAFE's requirement for information about the manufacturers of APIs and finished drug products, could also ensure that global supply chains respect, protect and promote the human rights of individuals and communities in the pharmaceutical producing countries, including the right to environment. In fact, the United Nations Guiding Principles on Business and Human Rights explicitly affirm the duty of the State to protect against human rights abuses by business enterprises that ‘receive substantial support and services from State agencies’, including through the State's procurement activities.<sup>139</sup> Further, recent policy initiatives on responsible global value chains envisage the integration of responsible business

<sup>127</sup>EU Strategic Approach (n 56).

<sup>128</sup>Van Calster (n 22) 305.

<sup>129</sup>H Walker and W Phillips, ‘Sustainable Procurement: Emerging Issues’ (2009) 2 *International Journal of Procurement Management* 41.

<sup>130</sup>See WHO et al, ‘Antimicrobial Resistance and the United Nations Sustainable Development Cooperation Framework: Guidance for United Nations Country Teams’ (WHO et al 2021).

<sup>131</sup>World Trade Organization, ‘Committee on Government Procurement, Decision on Sustainable Procurement’ GPA/113 (30 March 2012).

<sup>132</sup>A Semple, ‘Reform the EU Procurement Directives and WTO GPA: Forward Steps for Sustainability?’ in GL Albano et al (eds), *Charting a Course in Procurement Innovation and Knowledge Sharing* (Academics Press 2012) 85.

<sup>133</sup>United Nations Human Rights Office of the High Commissioner, ‘Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework’ (United Nations 2011) 6 and 8.

<sup>127</sup>GPA (n 79) art XV:5.

<sup>128</sup>Reich (n 119) 1013.

<sup>129</sup>GPA (n 79) art XV:5.

<sup>130</sup>See J Bengtsson-Palme et al, ‘Towards Monitoring of Antimicrobial Resistance in the Environment: For What Reasons, How to Implement It, and What Are the Data Needs?’ (2023) 178 *Environment International* 108089.

<sup>131</sup>See generally OECD (n 51).

<sup>132</sup>Council and Parliament Provisional Agreement on Proposal for a Directive of the European Parliament and of the Council concerning Urban Wastewater Treatment (1 March 2024) <<https://data.consilium.europa.eu/doc/document/ST-7108-2024-INIT/en/pdf>>.

conduct in public procurement measures.<sup>140</sup> Although the GPA contains no explicit references to human rights, a broad interpretation of some of the provisions discussed in Section 3 could be used to address the adverse impacts on human rights, of the emergence of AMR in the environment.

## 5 | CONCLUSION

The emergence of AMR due to the discharge of antibiotic effluent from pharmaceutical manufacturing units into the environment represents a global public health and environmental challenge. This article examined the compatibility of green public procurement measures that incorporate pharmaceutical production-related environmental criteria and are adopted by pharmaceutical purchasing countries, with international trade rules contained in the WTO's GPA. Such criteria could require compliance with antibiotic discharge limits or disclosure of the antibiotic manufacturer's discharge levels or the identity or location of sub-contracted parties. Such green public procurement measures may violate the principle of non-discrimination in the GPA because they distinguish pharmaceuticals based on the environmental impact of the manufacturing process. However, the general exceptions in the GPA may permit the adoption of such measures on the ground that they are necessary to protect human, animal and/or plant life or health from the adverse effects of the discharge of antibiotic effluent into the environment, they apply to both foreign and domestic manufacturers/suppliers and they are intended to achieve non-trade (human and environmental health) objectives rather than to restrict trade. In addition, the GPA's provisions relating to technical specifications, tender documentation, conditions for participation and award criteria enable the adoption of such measures, explicitly or by implication. Technical specifications cover non-product-related tendering requirements that incorporate production-related environmental criteria based on existing international standards such as those developed by the AMR Industry Alliance. Although the conditions for participation in public procurement do not include environmental considerations, the future development and inclusion of standards in domestic regulation presents an opportunity. Finally, a holistic interpretation of 'public interest' in the award criteria to encompass long-term human and environmental health and the inclusion of production-related environmental criteria into the evaluation process can ensure compatibility between green public procurement measures and the GPA.

This article contributes a distinctive perspective to the debate on trade and environment, that is, the use of trade rules to regulate, for non-trade objectives, trade in a product that is essential for human

health. At the same time, it is important to note that this analysis is based on a status quo where pharmaceutical manufacturing capacity is concentrated in a few, developing countries. The need for domestic and regional drug security, highlighted by the COVID-19 pandemic, may trigger an increase in pharmaceutical production in other countries raising concerns of eco-imperialism. This is especially relevant to the application of the non-discrimination provision in the GPA and other international trade law instruments. Nevertheless, the grave implications of inaction or inadequate action to address the AMR challenge highlight the need for a fundamental shift in law's response to global environmental challenges—from a largely accommodationist approach towards non-trade objectives towards a flexible, responsive approach that incorporates environmental principles. After all, the international trade regime cannot opt out of the war on superbugs.

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### DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article, as no datasets were generated or analysed during the research.

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<sup>140</sup>OECD, 'Leveraging Responsible Business Conduct through Public Procurement' (OECD 2019); OECD, 'Integrating Responsible Business Conduct in Public Procurement' (OECD 2020).