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Drawing from AMR Experience for Better Prevention, Preparedness, and Response to Complex Health Threats under a One Health Approach

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11.1 INTRODUCTION

Antimicrobial resistance (AMR) is the ability of microorganisms to resist the action of antimicrobials – including antibiotics, antivirals, antifungals, and antiparasitics – to which they were initially sensitive. While this phenomenon occurs naturally through genetic changes in pathogens, the overuse and misuse of antimicrobials, combined with their uncontrolled release into the environment, have accelerated the evolutionary process of microbes, making them more adept at developing drug resistance. The World Health Organization (WHO) considers this unnatural development of AMR as one of the top ten global public health and development threats.[1] The estimated impact of AMR suggests a global toll of 10 million human deaths annually by 2050 and a cumulative cost of US$100 trillion if urgent measures are not taken.[2] Consequently, AMR is often referred to as 'the silent pandemic'.

As a global public good, safeguarding antimicrobials and mitigating the threat of AMR are the responsibilities of all countries and people.[3] Due to its complexity, AMR also requires coordinated efforts across various sectors, including human health, animal and plant health and production, and environmental protection, in line with the One Health approach. Overuses and misuses have been reported – both in the human healthcare sector and in animal and plant production – that require attention.[4] These include the excessive use of antimicrobials for non-therapeutic purposes, such as for growth promotion, as well as the availability of substandard and counterfeited antimicrobials that facilitate sub-therapeutic doses that are not effective and exacerbate further resistance development.[5] Unregulated discharges from hospitals, farms, and

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[1] 'Ten Threats to Global Health in 2019'. Available at: www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019.

[2] Jim O'Neill, 'Tackling Drug-Resistant Infections Globally. Final Report and Recommendations' (2016). Available at: https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf; See also, Interagency Coordination Group on Antimicrobial Resistance (IACG). 'No Time to Wait: Securing the Future from Drug-resistant Infections. Report to the Secretary-General of the United Nations' (2019) Available at: www.who.int/docs/default-source/documents/no-time-to-wait-securing-the-future-from-drug-resistant-infections-en.pdf.

[3] Ponnu Padiyara, Hajime Inoue, and Marc Sprenger, 'Global Governance Mechanisms to Address Antimicrobial Resistance' (2018) 11 *Infectious Diseases: Research and Treatment* 1178633718767887.

[4] O'Neill, 'Tackling Drug-resistant Infections Globally'; Interagency Coordination Group on Antimicrobial Resistance (IACG), 'No time to wait'.

[5] Interagency Coordination Group on Antimicrobial Resistance (IACG), 'No time to wait', 4.

pharmaceutical companies that include antimicrobial-contaminated waste and other residues have transformed the environment into a reservoir for resistant bacteria and other pathogens.[6] The need for coordinated and collective multisectoral action has prompted the recognition of AMR as the 'quintessential' One Health challenge.[7]

From a governance standpoint, a One Health approach to AMR underscores the need for multisectoral policy and regulatory responses that promote joint interventions. Policies and legal frameworks must create an environment where institutions and stakeholders work collaboratively and are accountable for contributing to common goals. International collaboration is essential for addressing AMR, as it knows no borders. Countries must ensure multisectoral coordination at the national, regional, and global levels, along with consistency between domestic policies and international trade. In this context, identifying regulatory areas and strategies to curb AMR serves as the first step in driving this action. Innovative governance mechanisms should be established to facilitate the transition from coordination to collaboration and, ultimately, to integrated actions.

This chapter's objective is to derive lessons from the global, regional, and national governance of AMR under a One Health approach that may be successfully applied to other complex health challenges, with a focus on policies, institutional frameworks, and relevant legal aspects. The global governance of AMR will be described, along with governance challenges and regulatory solutions at the national level. The chapter proposes the regulatory framework of the European Union on AMR as a case study to conclude with concrete insights on AMR governance and regulation that can be applicable to other areas demanding a One Health response.

11.2 THE IMPORTANCE OF GOVERNANCE IN ADDRESSING AMR

There is broad consensus that appropriate governance structures are instrumental to addressing AMR. By Resolution WHA68.7 the World Health Assembly adopted the Global Action Plan (GAP) for AMR and urged WHO member states to develop National Action Plans (NAPs) in line with the GAP and international standards, while addressing national and local governance arrangements.[8] The GAP called upon member states to set up effective and enforceable regulation and governance for antimicrobial use.

Institutional fragmentation, scattered responsibilities and poor coordination are broadly recognised as drawbacks for the comprehensive, sustainable, and effective implementation of AMR objectives.[9] Dame Sally Davis, former Chief Medical Officer of the UK, has been quoted to affirm 'the biggest problem of AMR is not the science, it is the governance'.[10] As a multifaceted problem, AMR requires inter/intra-institutional coordination to be addressed. Studies have shown that a fragmented institutional structure makes coherent action in deal-

[6] United Nations Environment Programme, *Bracing for Superbugs: Strengthening Environmental Action in the One Health Response to Antimicrobial Resistance* (Geneva, 2023) 10, 14.

[7] T. P. Robinson, D. P. Bu, J. Carrique-Mas, E. M. Fèvre, M. Gilbert, and D. Grace, 'Antibiotic Resistance Is the Quintessential One Health Issue' (2016) 110(7) *Transactions of the Royal Society of Tropical Medicine and Hygiene* 377–380.

[8] Resolution WHA68.7, 'Global Action Plan on Antimicrobial Resistance', 26 May 2015, paras 1–2 and Annex 3, para. 49.

[9] Jon Pierre, Daniel Carelli, and Guy Peters, 'The Four Worlds of Politics and Administration in the EU: How Institutional Arrangements Shape the Struggle against Antimicrobial Resistance' (2023) 31(12) *Journal of European Public Policy* 4088–4115.

[10] Ibid.

ing with issues such as AMR more difficult. Socioeconomic analysis has revealed correlations between strong governance and lower levels of AMR.[11] The sectors involved in AMR governance pursue different objectives and often lack understanding and communication of each others' objectives and regulation, hindering collaboration and challenging the implementation of joint solutions.[12] Even in the absence of explicit conflict, the traditional separation between human, animal health, and the environment creates specific challenges for institutional coordination,[13] as does the fact that each of these areas is governed by different legal frameworks based on different international legal instruments and principles of international law. Finally, the fact that stakeholders are typically aligned with specific ministries and that resources differ greatly among sectors indicates serious barriers to coordinated or integrated governance. At the global level, Rogers Van Katwyk has highlighted that past attempts to tackle AMR have failed because stewardship regimes have been too narrow in national or sectoral scope, and policy responses too fragmented, pointing out the need for more structured and comprehensive AMR governance responses.[14]

Under a One Health approach, AMR governance must encompass all relevant sectors under a framework of equity and transdisciplinarity. A framework of equity would require specific administrative structures and financial mechanisms that do not prioritise one sector over another, ensuring equal roles and responsibilities under a framework of shared accountability.

A systems approach to AMR governance would emphasise network-centric approaches that encourage relationship building among organisations, systems organisation to improve organisational structures and functions, and the flow of knowledge and data across institutions. Systems have been defined as a set of different elements so connected and interrelated as to perform a unique function not performable by the elements alone.[15] Systems thinking facilitates understanding of complex and wicked problems and is particularly useful in relation to areas such as health and food systems where contexts are often changing,[16] and interventions may yield unexpected results.[17] By promoting systems-based transdisciplinarity, members representing different fields work together to develop shared conceptual and methodological frameworks that not only integrate but transcend their respective perspectives.[18]

[11] Peter Collingnon, Prema-chandra Athukorala, Sanjaya Senanayake, and Fahad Khan, 'Antimicrobial Resistance: The Major Contribution of Poor Governance and Corruption to This Growing Problem' (2015) 3(e0116746) *PLoSONE* 10. Available at: https://doi.org/10.1371/journal.pone.0116746. See also Andrea Maugeri, Martina Barchitta, Federico Puglisi, and Antonella Agodi, 'Socio-Economic, Governance and Health Indicators Shaping Antimicrobial Resistance: An Ecological Analysis of 30 European Countries' (2023) 19(1) *Global Health* 12.

[12] Arne Ruckert, Patrick Fafard, Suzanne Hindmarch, et al., 'Governing Antimicrobial Resistance: A Narrative Review of Global Governance Mechanisms' (2020) 41(4) *Journal of Public Health Policy* 515–528.

[13] D. Wallinga, G. Rayner, and T. Lang, 'Antimicrobial Resistance and Biological Governance: Explanations for Policy Failure' (2015) 129(10) *Public Health* 1314–25. See also Pita Spruijt and Arthur C. Petersen, 'Multilevel Governance of Antimicrobial Resistance Risks: A Literature Review' (2015) 25(8) *Journal of Risk Research* 945–958.

[14] Susan Rogers Van Katwyk, Alberto Giubilini, Class Kirchhelle, et al., 'Exploring Models for an International Legal Agreement on the Global Antimicrobial Commons: Lessons from Climate Agreements' (2023) 31 *Health Care Anal* 25–46. Available at: https://doi-org.fao.idm.oclc.org/10.1007/s10728-019-00389-3.

[15] Eberhardt Rechtin and Mark W. Maier, 'The Art of Systems Architecting' in Annette J. Krygiely (ed.), *Behind the Wizard's Curtain. An Integration Environment for a System of Systems*. (Cooperative Research Program (CCRP), US Library of Congress 1999). Available at: www.dodccrp.org/files/Krygiel_Wizards.pdf.

[16] Ross Arnold and Jon Wade, 'A Definition of Systems Thinking: A Systems Approach' (2015) 44 *Procedia Computer Science* 669–678.

[17] Kevin Queenan, Julie Garnier, Liza Rosenbaum Nielsen, et al., 'Roadmap to a One Health Agenda' (2017) *CABI Reviews* 1–17. Available at: https://doi.org/10.1079/PAVSNNR201712014.

[18] Scott J. Leischow, Allan Best, William M. Trochim, et al., 'Systems Thinking to Improve the Public's Health' (2008) 35(2 Suppl) *American Journal of Preventive Medicine* S196–203.

11.3 GLOBAL GOVERNANCE OF AMR

11.3.1 *Evolution of AMR Global Governance*

To date, global action to address AMR has mostly relied on soft law instruments and political declarations led by different intergovernmental organisations. In 2011, the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the World Animal Health Organization (WOAH) recognised the significance of AMR as one of the three topics that require multisectoral collaboration to advance the One Health approach, alongside rabies and zoonotic influenza.[19]

Following Resolution WHA68.7,[20] 2015 was a crucial year for AMR, with the adoption of the GAP, the launching of the Global Antimicrobial Resistance and Use Surveillance System (GLASS),[21] and the establishment of the UK Fleming Fund to fight AMR. In May 2016 the landmark AMR report 'Tackling Drug-resistant Infections Globally' by Jim O'Neill was published. Commissioned by the UK government and the Wellcome Trust, this report illustrated the economic and social risks resulting from AMR and offered concrete actions to address the global AMR challenge.[22]

At the 71st Session of the United Nations General Assembly (hereinafter General Assembly) in September 2016, the High-level meeting on AMR adopted a Political Declaration on antimicrobial resistance included in Resolution 73/1. This Resolution emphasised the relevance of the One Health approach, recognising the interconnection between the animal, human, and environmental dimensions in combating AMR. It also called for the engagement of relevant government sectors in developing and implementing multisectoral national action plans, policies, and regulations, tailored to each country's context and legal system. With this declaration, countries committed to developing multisectoral One Health national action plans for AMR and ensuring their implementation through appropriate regulatory frameworks. The Declaration also called for the establishment of an 'Ad hoc inter-agency coordination group' to provide practical guidance for sustained global AMR action. As a follow-up to this Political Declaration, the different intergovernmental organisations working on matters relevant to AMR joined forces within the Interagency Coordination Group on Antimicrobial Resistance (hereinafter Interagency Coordination Group) to identify shared solutions.

In its 2019 report, the Interagency Coordination Group on AMR resulting from this UN General Assembly Resolution proposed the creation of a One Health Global Leadership Group on Antimicrobial Resistance, supported by a Joint Secretariat managed by FAO, WHO, and WOAH (at the time, OIE).[23] Additionally, the Interagency Coordination Group recommended the establishment of an Independent Panel on Evidence for Action against Antimicrobial Resistance for action against AMR in a One Health context.[24]

[19] Food and Agriculture Organization of the United Nations (FAO), The World Organisation for Animal Health, and the World Health Organization (WHO), 'High Level Technical Meeting to Address Health Risks at the Human-Animal-Ecosystems interface' (Mexico City, 2011). Available at: www.fao.org/4/i3119e/i3119e.pdf.

[20] Resolution WHA68.7, 'Global Action Plan on Antimicrobial Resistance', 26 May 2015. Available at: https://iris.who.int/bitstream/handle/10665/193736/9789241509763_eng.pdf?sequence=1

[21] See at www.who.int/initiatives/glass.

[22] O'Neill J, Tackling drug-resistant infections globally: Final report and recommendations (Review on Antimicrobial Resistance, Wellcome Trust & HM Government, May 2016) https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf

[23] IACG, 'No Time to Wait: Securing the Future from Drug-resistant Infections'. Report to the Secretary-General of the United Nations, p. 21, recommendation E2. Available at: www.who.int/publications/i/item/no-time-to-wait-securing-the-future-from-drug-resistant-infections.

[24] Ibid., recommendation E3.

In response to the mandates from UN General Assembly and the Interagency Coordination Group, FAO, WHO and WOAH signed a Memorandum of Understanding (MoU) in 2018,[25] which was later expanded to include UNEP in 2022, creating a quadripartite framework (the Quadripartite).[26] The MoU provides a legal and formal framework for the four organisations to enhance integrated and coordinated efforts at the human, animal, plant, and ecosystem interface to reinforce national and regional health systems and services. AMR is precisely one of the major areas of cooperation.

Over time, these partner organisations have created governance structures for AMR, including a Joint Secretariat with rotating chairmanship, an Executive Committee composed of the Directors-General, and a Senior Management Group. They have also developed mechanisms to enhance consultation and coordination, including cooperation among technical experts, the organisation of annual executive coordination meetings, and the appointment of liaison officers at the global level. Under the quadripartite framework, the Quadripartite Joint Secretariat on AMR supports global, regional, and national AMR initiatives. This includes the development of a Joint Strategy on AMR, facilitating effective policy and legislative responses to AMR in countries.[27]

Established in November 2020, the Global Leaders Group on AMR (hereinafter Global Leaders Group) is composed of heads of state, regulators, and high-level public and private experts, including the principals of the Quadripartite. It collaborates with public and private stakeholders globally to prioritise AMR on international and national agendas. The Global Leaders Group has published several statements and guidance on topics such as AMR in food systems.[28] It has also advocated for AMR's inclusion in the Pandemics Treaty and the organisation of a UN General Assembly High-level meeting in 2024.

The AMR Multi-Stakeholder Partnership Platform (the Platform) serves as a neutral forum for discussion among the various sectors relevant to AMR, fostering coordinated actions and facilitating engagement among governments, academia, civil society, the private sector, and intergovernmental organisations. It also serves as space for developing specific coordinated joint actions through members-driven action groups. The Platform was launched on 15 November 2023.

Furthermore, AMR has been a recurrent topic in G7 and G20 ministers' declarations. G20 ministers have addressed AMR in their declarations since 2016 (Hangzou Summit) and including the 2017 Hamburg Summit, the G20 Action Plan on AMR approved in Buenos Aires in 2018, and the Bali Summit in 2022, in which ministers committed to embracing a multi-sectoral One Health approach to AMR. In August 2023, G20 Health Ministers recalled their commitment to 'tackle AMR comprehensively following the One Health approach' and indicated multi-sectoral governance and coordination as a necessary step. Also, G7 Ministers have consistently addressed AMR in their declarations since 2014 (Brussels summit declaration), and

[25] 'Memorandum of Understanding between the United Nations Food and Agriculture Organization and the World Organization for Animal Health and the World Health Organization Regarding Cooperation to Combat Health Risks at the Animal-Human-Ecosystem Interface in the Context of the One Health Approach and Including Antimicrobial Resistance' (30 May 2018). Available at: www.who.int/zoonoses/MoU-Tripartite-May-2018.pdf.

[26] 'Memorandum of Understanding between the Food and Agriculture Organization of the United Nations and the World Organization for Animal Health and the World Health Organization and the United Nations Environment Programme Regarding Cooperation to Combat Health at the Animal-Human-Ecosystem Interface in the Context of the "One Health" Approach and Including Antimicrobial Resistance' (17 March 2022). Available at: www.fao.org/3/cb9403en/cb9403en.pdf.

[27] Jorge Pinto Ferreira, Daniela Battaglia, Alejandro Dorado García, et al., 'Achieving Antimicrobial Stewardship on the Global Scale: Challenges and Opportunities' (2022) 10(8) *Microorganisms* 1599.

[28] Global Leaders Group, 'A Pocket Guide for Ministers across Sectors' (2022). Available at: www.amrleaders.org/docs/librariesprovider20/default-document-library/a6-pocket-guide_final.pdf?sfvrsn=797cf4cb_5&download=true.

more substantially in the Leader's declarations of 2015, 2016, 2018 (recalling the One Health approach), 2021, and 2022.

At the time of writing this chapter, countries were preparing for a forthcoming UN General Assembly High-Level meeting on AMR scheduled for September 2024.

In summary, the global governance of AMR has been spearheaded by intergovernmental organisations such as the UN and the Quadripartite. The UN General Assembly played a pivotal role by issuing landmark Resolutions that laid the groundwork for subsequent intergovernmental efforts. The resulting governance framework incorporated various components, including policy-makers represented by the Global Leaders Group, scientific expertise to be facilitated by the forthcoming Independent Panel of Experts, and stakeholders' participation through the AMR Multistakeholders platform. This structure fosters multidisciplinary and multilevel knowledge exchange, political involvement, and widespread public participation; three fundamental elements consistent with the principles of One Health.

11.3.2 *International Law Instruments Applicable to AMR*

Besides the legal instruments and policy structures mentioned earlier, the multifaceted nature of issues pertinent to AMR spans across various international instruments. These instruments play a crucial role in shaping the global governance of AMR.[29]

For instance, the International Health Regulations (IHR) provide a framework for cooperation among countries to prevent, protect against, control, and respond to the international spread of diseases, including those related to AMR. Some scholars have suggested that the emergence and spread of AMR bacteria,[30] especially those for which there is no suitable treatment, may constitute a public health emergency of international concern under the terms of the International Health Regulations. Under these circumstances, countries would be required to notify the WHO under Article 6 of the IHR.[31] Under this view, applying the IHR to AMR could serve to strengthen global AMR surveillance and response, and to contain AMR. This opinion, however, is debatable to the extent that AMR does not meet the definitional requirements of a Public Health Emergency of International Concern.[32] Moreover, relying on a possible declaration of a Public Health Emergency of International Concern to address AMR globally would not put sufficient emphasis on the need for 'deep prevention' to effectively address the AMR 'silent pandemic'.[33]

[29] Van Katwyk, 'Exploring Models for an International Legal Agreement on the Global Antimicrobial Commons', 25–46.

[30] Didier Wernli, Thomas Haustein, John Conly, et al., 'A Call for Action: The Application of The International Health Regulations to the Global Threat of Antimicrobial Resistance' (2011) 8(4) *PLoS Medicine* e1001022.

[31] It is noteworthy that the proposals for amendment of the IHR submitted by WHO member states and some regional integration organisations, currently under consideration of the Working Group on Amendments to the International Health Regulations (2005), do not include any new provision incorporating the One Health approach. A stronger collaboration between the WHO and the other partners from the Quadripartite is only foreseen in a proposal advanced by India for revision of Article 6, where it is added that if the notification received by WHO involves the competency of FAO, WOAH, or UNEP, these entities should be immediately notified. All relevant information on the revision process are available at www.who.int/teams/ihr/working-group-on-amendments-to-the-international-health-regulations-(2005).

[32] According to Article 1 IHR, a PHEIC is a 'an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response'.

[33] On the concept of 'deep prevention' see J. Vinuales, S. Moon, G. Le Moli, and G. L. Burci, 'A Global Pandemic Treaty Should Aim for Deep Prevention' (2021) 397(10287) *The Lancet* 1791–1792; G. Le Moli, J. E. Viñuales, G. L. Burci, A. Strobeyko, and S. Moon, 'The Deep Prevention of Future Pandemics through a One Health Approach:

Beyond the IHR, several agreements under the World Trade Organization apply to AMR. The Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) would be applicable for countries approving import restrictions to detect and stop the entrance of animals or animal products potentially contaminated with antimicrobial residues or resistant pathogens. In this respect, several international reference standards have approved detailed and granular guidance on antimicrobial use and AMR.[34] Quality standards for antimicrobials could also be influenced by the Agreement on Technical Barriers to Trade (TBT Agreement).

Similarly, access and availability of safe and effective antimicrobials are influenced by the intellectual property rights provisions in the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement), which may have an impact on the equitable access to antimicrobials in all countries if the flexibilities granted under TRIPS are not taken into consideration.[35] Other potentially relevant international agreements include the International Convention on the Harmonized Commodity Description and Coding System concerning customs procedures.[36]

The international trade of antimicrobials could be protected by the UN Convention of Contracts for the International Sale of Goods and, although soft law, the 2016 Principles of International Commercial Contracts of the International Institute for the Unification of Private Law (UNIDROIT). The UN Convention against Transnational Organized Crime could be also applicable to networks that trade in substandard, illegal, or counterfeit medicines, as long as they meet the definition of transnational crime. Finally, the illegal trade of animals, including wildlife, which could constitute an important avenue for the transmission of resistant pathogens across countries, is also influenced by the Convention on International Trade of Endangered Species of Wild Flora and Fauna (CITES).

The global governance of AMR is further shaped by international reference standards and guidance documents. The Quadripartite publication 'International Instruments on the Use of Antimicrobials across the Human, Animal and Plant Sectors' identifies key international guidance documents that may support the development of AMR policies and regulation across sectors.[37] In addition to different guidance documents published by the WHO, these standards include the updated Codex Alimentarius Code of Practice to Minimize and Contain Foodborne AMR,[38] the Guidelines for Risk Analysis of Foodborne AMR,[39] and the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR.[40] They also include the AMR-specific standards and articles introduced by the WOAH into the Terrestrial and the Aquatic Animal Health Codes,[41] which are periodically updated. These standards guide countries to apply a One Health approach to AMR governance and regulation and, while they are not

What Role for a Pandemic Instrument?' (2022) *Global Health Centre Policy Brief*. Retrieved from https://hdl.handle.net/1887/3561531.

[34] See, among others, the standards approved by the Codex Alimentarius Commission in www.fao.org/fao-who-codexalimentarius/thematic-areas/antimicrobial-resistance/en/.

[35] Joanna Hanefeld, Mishal Khan, Goran Tomson, and Richard Smith, 'Trade Is Central to Achieving the Sustainable Development Goals: A Case Study of Antimicrobial Resistance' (2017) 358 *BMJ* j3505.

[36] Van Katwyk, 'Exploring Models for an International Legal Agreement on the Global Antimicrobial Commons' 25–46.

[37] FAO, OIE, and WHO, 'International Instruments on the Use of Antimicrobials across the Human, Animal and Plant Sectors' (2019). Available at: www.who.int/publications/i/item/9789240013964 (last accessed on 22 October 2023).

[38] Codex Alimentarius, 'Code of Practice to Contain Foodborne Antimicrobial Resistance' (CXC 61-2005).

[39] 'Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance' (CXG 77-2011).

[40] 'Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR' (CXG 94-2021).

[41] See www.woah.org/en/what-we-do/standards/codes-and-manuals/.

legally binding in nature, the fact that both Codex and WOAH are nominated as reference international setting bodies in the SPS Agreement gives them a relevant regulatory role.

These international agreements and standards shape the regulatory framework for AMR at both the international and national levels. Conducting a mapping exercise of international obligations and the division of roles and functions at the national level helps identify the key actors and areas requiring coordination. Similarly, in the context of One Health, multisectoral governance mechanisms must consider existing international obligations across various sectors. This includes sectors such as health, agriculture, environment, trade, and intellectual property. Strengthening collaboration across these sectors is essential for addressing the complex challenges posed by One Health comprehensively.

11.3.3 *From Soft Law to a Binding Global Framework for AMR*

Global opinion has long debated the best international law instrument to address AMR. Some scholars advocate for flexible soft law instruments or a mix of binding and non-binding models.[42] These models propose progressively introducing new norms that create political momentum, fostering voluntary compliance and adaptive governance models,[43] and granting AMR the flexibility that is needed for every area based on science and uncertainty. Other academics signal the limitations of soft law and propose a legally binding instrument that anchors concrete binding obligations and provides for accountability mechanisms.[44] The Paris Agreement has been proposed as a model to develop a binding AMR instrument given the similarities between climate change and AMR and the challenges to be overcome.[45] Any successful legal intervention must strive for a balance between access, conservation, and innovation.[46] Measures must span across the human health, animal, agriculture, and environmental sectors and aim to preserve the efficacy of antimicrobials to achieve intergenerational justice, ensuring wins for present and future generations.[47] In summary, the adoption of a One Health approach to regulating AMR at a global level is imperative. This approach ensures that AMR regulation aligns with principles of multisectoriality, equity across sectors and disciplines, and stakeholder participation.

The COVID-19 pandemic strongly influenced the discussions on a potential global level response to AMR, connecting this to the more specific topic of pandemic prevention, preparedness, and response (PPPR). The devastating impact of the pandemic placed pandemic prevention high on the international agenda and the possibility of crystalizing AMR as a silent pandemic within an international treaty gained scholarly support.[48] At the time of writing this

[42] Padiyara, 'Global Governance Mechanisms to Address Antimicrobial Resistance'; Arne Ruckert, Patrick Fafard, Suzanne Hindmarch, et al., 'Governing Antimicrobial Resistance: A Narrative Review of Global Governance Mechanisms' (2020) 41(4) *Journal of Public Health Policy* 515–528; Ruckert, 'Governing antimicrobial resistance: a narrative review of global governance mechanisms'.

[43] Rubin, Olivier. 'The Glocalization of Antimicrobial Stewardship' (2019) 15 *Global Health* 54. Available at: https://doi.org/10.1186/s12992-019-0498-2.

[44] Padiyara, 'Global Governance Mechanisms to Address Antimicrobial Resistance'; Connor Rochford, Devi Sridhar, Ngaire Woods, et al., 'Global Governance of Antimicrobial Resistance' (2018) 391(10134) *The Lancet* 1976–1978. Available at: https://doi.org/10.1016/S0140-6736(18)31117-6.

[45] Van Katwyk, 'Exploring Models for an International Legal Agreement on the Global Antimicrobial Commons' 25–46.

[46] Ibid.

[47] Ibid.

[48] See, among others, Andrea M. Caceres, Kshitji K. Singh, T. Minssen, S. R. Van Katwyk, and S. J. Hoffman, 'Using the International Pandemic Instrument to Revitalize the Innovation Ecosystem for Antimicrobial R&D' (2022) 50(S2) *Journal of Law, Medicine & Ethics* 47–54.

chapter, the negotiations for the drafting of a Pandemic Agreement by the Intergovernmental Negotiation Body have been further prolonged after the missed opportunity of reaching consensus at the 77th session of the World Health Assembly. That said, different countries, international and non-governmental organisations have strongly advocated for AMR to be considered as a silent pandemic. A strong recognition of AMR as part of the Agreement would offer an excellent opportunity to consolidate soft law rules that have been broadly accepted by countries. It would recognise the mandate of the Conference of Parties to develop intergovernmental and consensus-based implementation guidance and to negotiate complementary binding (including an additional protocol) or non-binding more granular instruments on AMR.[49]

11.4 AMR GOVERNANCE AND REGULATION AT THE NATIONAL AND REGIONAL LEVELS

11.4.1 *Trends in the Development and Implementation of the GAP and NAPs*

Both the Global Action Plan for AMR and the Interagency Coordination Group report recommended that countries establish multisectoral coordination mechanisms for AMR governance and approve multisectoral National Action Plans (NAPs) to consolidate their policy objectives. Over the past years, many countries have advanced in establishing both. In 2023,[50] among the 175 countries responding to the Quadripartite Global Database for Tracking Antimicrobial Resistance Country Self-Assessment Survey (TraCSS), only eighteen declared not to have a multisectoral governance or coordination mechanism. A total of ninety-two countries reported having a formalised and functional multisectoral coordination mechanism, with thirty-five out of those countries utilizing these structures to implement integrated approaches to NAP implementation. This represents significant progress from the 2017 data, where forty-one countries declared lacking a multisectoral coordination mechanism, and only thirty-one reported having formal and functioning structures.

Regarding NAPs, a comparison between the TrACCS results of 2017 and 2023 under the topic 'Country Progress with Development of a NAP' reveals an observable increase in the number of countries incorporating a costed and budgeted operational plan and/or financial provisions for implementation.[51] Despite TrACSS being a voluntary self-assessment mechanism, the data indicates a positive shift towards more formalised governance structures such as joint work and integrated approaches. This positive movement is gradually followed by effective implementation, as reflected in financial allocations. This positive trend alleviates the pessimism regarding the implementation (or the lack thereof) of NAPs.[52] In 2018, FAO, WHO, and WOAH affirmed that despite countries declaring firm commitment, many countries had not implemented NAPs or aligned their domestic policies with global recommendations.[53] Empirical analysis also revealed that, following an initial momentum for NAP development

[49] Arne Ruckert, S. Lake, and Susan Rogers Van Katwyk, 'Developing a Protocol on Antimicrobial Resistance through WHO's Pandemic Treaty Will Protect Lives in Future Pandemics' (2024) 20(1) *Global Health* 10.

[50] See TrACCS. Available at: https://amrcountryprogress.org/#/visualization-view.

[51] Ibid.

[52] Mohan P. Joshi, Chifumbe Chintu, Mirfin Mpundu, et al., 'Multidisciplinary and Multisectoral Coalitions as Catalysts for Action against Antimicrobial Resistance: Implementation Experiences at National and Regional Levels' (2018) 13(12) *Global Public Health* 1781–1795.

[53] FAO, OIE, WHO. Monitoring Global Progress on Addressing Antimicrobial Resistance. 2018. Available at: https://iris.who.int/bitstream/handle/10665/273128/9789241514422-eng.pdf?sequence=1.

and the establishment of multisectoral structures, collaborations were challenging to sustain due to reliance on voluntary partnerships.[54]

The term 'isomorfic mimicry' was introduced to the AMR landscape to explain the differences between the content of the NAPs and their actual implementation.[55] This phenomenon elucidates why low and middle-income countries tended to develop NAPs following the recommendations of the GAP but were unable to implement them due to financial constraints, as well as institutional and political challenges. In 2022, the WHO published an 'Implementation Handbook for National Action Plans on Antimicrobial Resistance in the Human Health Sector' targeting national and subnational stakeholders working on AMR to help them 'guide and accelerate sustainable implementation' of NAPs-AMR.[56] This document includes concrete steps to set up a multisectoral governance mechanism promoting broad multisectoral engagement under the coordination of a higher-level authority.

TrACCS data allows for the conclusion that multisectoral AMR governance mechanisms have broadly been established with dissimilar success and standing challenges. However, informal mechanisms have shown signs of tiredness and weak accountability, compromising their long-term sustainability. Countries are facing challenges to setting up integrated mechanisms, such as integrated surveillance programs in the absence of a concrete framework for accountability and data sharing.

11.4.2 *Elements and Principles of AMR National Governance and the Role of Legislation*

Numerous authors have debated the best regulatory approach to establish a multisectoral governance mechanism for AMR at the national level. Some argue for flexible governance mechanisms to avoid the pitfalls of over-regulation. Rubin proposed a nuanced approach combining binding and non-binding instruments at multiple levels, emphasizing 'glocalisation', where global guidance adapts thoughtfully to local capacities and needs.[57] This chapter argues that national AMR governance should be based on horizontal and decentralised collaboration reflecting the principle of subsidiarity, by ensuring that global recommendations are adjusted to national regulatory and enforcement capacities and needs.[58] Birgand et al. suggested an AMR national governance model combining top-down power with 'network governance'.[59] In this decentralised approach, the central level shapes policies, and the local level, including beneficiaries and the private sector, defines bottom-up implementation mechanisms,

[54] Alvin Q. Chua, Monica Verma, Li Yang Hsu, and Helena Legido-Quigley, 'An Analysis of National Action Plans on Antimicrobial Resistance in Southeast Asia Using a Governance Framework Approach' (2021) 7 *Lancet Regional Health Western Pacific* 100084.

[55] Louise Munkholm and Olivier Rubin, 'The Global Governance of Antimicrobial Resistance: A Cross-Country Study of Alignment between the Global Action Plan and National Action Plans' (2020) 16 *Global Health* 109. Available at: https://doi.org/10.1186/s12992-020-00639-3. Olivier Rubin and Louise Munkholm, 'Isomorphic Dynamics in National Action Plans on Antimicrobial Resistance' (2022) 42(2) *Public Administration & Development* 142–153.

[56] World Health Organization, 'WHO Implementation Handbook for National Action Plans on Antimicrobial Resistance: Guidance for the Human Health Sector' (2022). Available at: www.who.int/publications/i/item/9789240041981.

[57] Rubin, 'The Glocalization of Antimicrobial Stewardship'.

[58] Ibid.

[59] Gabriel Birgand, Enrique Castro-Sánchez, Sonja Hansen, et al., 'Comparison of Governance Approaches for the Control of Antimicrobial Resistance: Analysis of Three European Countries' (2018) 7 *Antimicrobial Resistance Infection Control* 28.

enhancing democratisation and collaboration. Spruijt and Petersen advocated for flexible governance arrangements for scientific areas marked by constant evolution, uncertainty, and adaptiveness.[60]

However, flexible legal solutions must be coupled with clear roles and mandates and a functional accountability framework. In some legal systems, establishing a new interministerial group may require novel legislation that clarifies roles and responsibilities, introduces financial or reporting obligations, and sets up sustainable mechanisms for stakeholders' participation. Such legislation can facilitate the transition from coordination to collaboration and integration, enabling joint interventions. The challenge is to ensure that legislation fosters an enabling environment, preserving its flexibility while building trust among all members, including the private sector.

Anderson, Schulze, and Cassini proposed a governance framework for AMR based on three core governance pillars:[61] policy, implementation, and monitoring and evaluation (M&E). Suggested indicators for policy include: multisectoral coordination, accountability, equity, transparency, and sustainability, among others. These indicators represent important foundational principles for the functioning of a multisectoral governance mechanism. Crucial for the implementation of AMR NAPs, *accountability* demands binding obligations for coordinating authorities and ensuring enforcement. This ties closely to sustainability, as accountability mechanisms influence long-term institutional engagement beyond the political momentum. *Equity* among countries and populations introduces a human rights dimension, ensuring equitable access to antimicrobials and sanitary care, particularly for vulnerable groups. This aligns with the One Health principle of equity,[62] emphasizing accessibility and affordability of healthcare for all, and considering gender and socio-economic factors affecting AMR exposure.

In addition to the proposed principles of accountability and equity, an effective AMR governance structure should embody the principles of good governance, solidarity, and subsidiarity.[63] A well-established principle in public international law, *solidarity* safeguards human dignity amidst the reality of our shared vulnerabilities to the challenge of antimicrobial effectiveness reduction, an issue demanding integrated management. *Subsidiarity* directs the management to commence at the local level, acknowledging local communities' better understanding of their specific AMR challenges.

For effective *multisectoriality* under the equity principle, all relevant ministries should be involved in AMR management. The Global Leaders Group 'Pocket Guide for Ministers across Sectors' identifies as potentially relevant for AMR governance not only the ministries of health, agriculture, and the environment, but also the ministries in charge of finance, industry, education, research, and innovation.[64] Depending on a country's constitutional structure, decentralised and local authorities might be directly responsible for certain elements of AMR

[60] Pita Spruijt and Arthur Petersen, 'Multilevel Governance of Antimicrobial Resistance Risks: A Literature Review' (2020) 25 *Journal of Risk Research* 1–14.

[61] Michael Anderson, Kai Schulze, Alessandro Cassini, Diamantis Plachouras, and Elias Mossialos, 'A Governance Framework for Development and Assessment of National Action Plans on Antimicrobial Resistance' (2019) 19(11) *Lancet Infectious Diseases* e371–e384.

[62] See the principles of One Health enunciated by OHHLEP in One Health High-Level Expert Panel (OHHLEP). 'One Health: A New Definition for a Sustainable and Healthy Future' (2022) 18(6) *PLoS Pathogens* e1010537. Available at: https://doi.org/10.1371/journal.ppat.1010537.

[63] Thana Campos-Rudinsky, 'A Principled Account of AMR Global Governance Solidarity, Subsidiarity, and Stewardship' (2023) 31 *Health Care Analysis* 1–6.

[64] Global Leaders Group, 'Pocket Guide for Ministers across Sectors' (2022). Available at: www.amrleaders.org/resources/m/item/pocket-guide.

management and deserve recognition of their roles and mandate. Collaborating with the diversity of actors that are part of the private sector (from the pharmaceutical industry to farmers) is also vital, as they can contribute significantly to NAP development and implementation and to AMR effective regulation, through co-regulation and self-regulation strategies.

A rapid check of national legislation using AMRLex,[65] a FAO-based repository of AMR relevant policies and legislation in the food and agriculture sectors, reveals that, while most countries have adopted policies, strategies, or national action plans for AMR (155 are included in the WHO NAP Library), only a few have translated these commitments into specific legislation. Most of these instruments establish multisectoral governance mechanisms and define their composition and functions. Typically led by the Ministries of Health, these bodies vary widely in composition, with Ministries of Health, Agriculture, and Environment often included, alongside a diverse array of other entities, as exemplified by the national committees established in Guinea and Algeria.[66] There are exceptions to this trend where members have a shared responsibility to lead coordination. For instance, in Ecuador's Comité Nacional de Prevención y Control de la Resistencia Antimicrobiana,[67] the Presidency alternates among members. The Executive Order issued by the President of the United States of America of 2014 provides another interesting example, by establishing a multisectoral task force and a Presidential Advisory Council.[68] This global, albeit partial, overview emphasises the diverse strategies nations employ in translating AMR objectives into legislative action and highlights the importance of learning from innovative approaches across different jurisdictions.

11.4.3 *The Role of Sector-Specific Legislation*

In addition to a multisectoral governance mechanism backed by appropriate legislation, a conducive legal framework for AMR should encompass sector-specific laws that not only incorporate international guidance and best practices but also promote collaboration and coordination across various sectors and foster effective compliance and enforcement.

Sector-specific legislation is instrumental in shaping the availability and access to antimicrobials. It can introduce antimicrobial use requirements for products entering the food supply chain and regulate the disposal and release of antimicrobials into the environment. Jeleff's empirical research underscores the need for a shift from non-binding to legally binding obligations, particularly in antimicrobial stewardship programs and consumption surveillance in hospitals.[69] Legally binding individual responsibilities, as suggested by Munkholm and Rubin,[70] can enhance implementation and enforcement. Hoffman, Bakshi and Van Katwyk argue that

[65] See https://amr-lex.fao.org/.

[66] Guinea – Arrêté A/2021/1238/MS/SGG portant Création, Organisation, Composition et Fonctionnement du Comité National de Pilotage de la Lutte Contre la Résistance aux Antimicrobiens. Available at: https://faolex.fao.org/docs/pdf/gui219519.pdf; Algeria – Décret exécutif n° 17–310 du 4 Safar 1439 correspondant au 24 octobre 2017 portant création, missions, organisation et fonctionnement du comité national multisectoriel de lutte contre la résistance aux antimicrobiens. Available at: https://faolex.fao.org/docs/pdf/Alg172305.pdf.

[67] Ecuador – Acuerdo Interinstitucional N° 1-2020 – Crea el Comité Nacional de Prevención y Control de la Resistencia Antimicrobiana. Available at: https://faolex.fao.org/docs/pdf/ecu196277.pdf.

[68] United States of America, 'Executive Order – Combating Antibiotic-Resistant Bacteria'. Available at: https://faolex.fao.org/docs/pdf/usa176919.pdf.

[69] Maren Jeleff, Christian Haddad, and Ruth Kutalek, 'Between Superimposition and Local Initiatives: Making Sense of 'implementation gaps' as a Governance Problem of Antimicrobial Resistance' (2023) 4 *SSM – Qualitative Research in Health* 100332. Available at: https://doi.org/10.1016/j.ssmqr.2023.100332.

[70] Munkholm and Rubin, 'The Global Governance of Antimicrobial Resistance'.

effective AMR strategies must extend beyond individual behaviour change and incorporate institutional-level action.[71]

Relevant legal sectors for AMR include, among others, public health, animal health, food safety laws, and laws regulating the environment, waste, and pollution control. These sectors have traditionally been regulated in silos, with one sector usually regulated under specific legislation implemented by one Minister. While it is probably neither possible nor desirable to fully eliminate these silos, sector-specific legislation should incorporate appropriate mechanisms to enable multisectoral coordination across them.

The Quadripartite One Health Legislative Assessment Tool for AMR, launched in November 2023, warns against the risks of horizontal cross-sectoral AMR legal instruments that regulate fragments of different sectors. The Tool proposes a combination of horizontal AMR legislation addressing multisectoral issues, such as multisectoral governance, coupled with legal responses to be addressed in sector-specific laws.[72]

As results from this section, implementation of AMR under a One Health approach demands national mechanisms for coordination, collaboration, or integration of policies and strategies of common interest. While these mechanisms can take various shapes, it is important that they are accompanied by a substantive accountability mechanism that facilitates their long-term sustainability. Legislation can serve to provide legal basis to these mechanisms. This legislation should co-exist with sector-specific legal instruments incorporating international guidance into national law. Sector-specific legislation should preserve its internal consistency avoiding fragmentation. The solution is not to merge laws for AMR but to ensure that all sector-specific laws include the appropriate cross-references to work harmoniously, contributing to common goals.

11.5 CASE STUDY: THE EU REGULATORY FRAMEWORK FOR AMR

In 2022 the European Commission and its member states identified AMR as one of their top three priority health threats.[73] This recognition underscores the EU's strong commitment to combating AMR. Since the early years of the twenty-first century, the EU has been at the forefront, championing an active regulatory agenda targeting AMR and acting as a catalyst for global efforts.

While the EU's regulatory experience in tackling AMR is specific to its constitutional structure and division of powers between the regional and national levels, it provides an interesting model that integrates overarching cross-sectoral instruments with sector-specific legal reforms. Furthermore, it demonstrates a gradual and holistic incorporation of a One Health approach to multisectoral coordination that began with the health and agriculture sectors, and progressively integrated environment. This final stage aligns with the adoption of ambitious EU environmental initiatives exemplified by the European Green Deal.[74]

The EU is supported by several scientific agencies whose competences are particularly relevant to AMR, and more in general, to the implementation of the One Health approach. The European Food Safety Authority (EFSA), the European Medicines Agency (EMA), and the

[71] Stephen J. Hoffman, Reema Bakshi, and Susan Rogers Van Katwyk, 'How Law Can Help Solve the Collective Action Problem of Antimicrobial Resistance' (2019) 33(7) *Bioethics* 798–804.

[72] See www.qjsamr.org/technical-work/one-health-legislative-assessment-tool-on-amr. See also Ambra Gobena, Carmen Bullon, and Teemu Viinikainen, 'Regulatory Frameworks to Address Antimicrobial Resistance in the Food and Agriculture Sectors' (2024) *FAO Legislative Study* 122.

[73] HERA Factsheet, 'HEALTH UNION: Identifying Top 3 Priority Health Threats' (8 July 2022). Available at: https://health.ec.europa.eu/publications/hera-factsheet-health-union-identifying-top-3-priority-health-threats_en.

[74] 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions The European Green Deal' COM/2019/640 final (2019).

European Centre for Disease Prevention and Control (ECDC) work together in the development of Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA). The European Environment Agency (EEA) also has a preeminent and increasing role.[75]

Against this background, this section presents a non-comprehensive overview of the various regulatory initiatives pursued by the EU to tackle AMR. While this model may not be directly applicable at the national level, its clear sectoral approach to AMR interventions, coupled with targeted cross-sectoral actions and robust financial support, positions the EU as an instructive case study.

11.5.1 *Public Health Regulation in the European Union*

The EU's approach to public health has been shaped by its distinctive constitutional framework, regulatory nature, and its historical emphasis on internal market development.[76] The delineation of competencies between the EU and its member states is meticulously outlined in its foundational treaties. These treaties have evolved over the years from an initial focus on the establishment of an internal market, to increased integration in areas of common interest. The Treaty of Lisbon of 2007 recognised public health as a shared competency between the EU institutions and the member states, unlike policies such as the agricultural policy, where sovereignty is largely transferred to the EU institutions. This acknowledgment underscores the EU's commitment to a collaborative approach in addressing health challenges, achieving a nuanced balance between central coordination and member state autonomy.

EU member states have traditionally hesitated to transfer sovereignty powers in public health from the state to the EU level.[77] This reluctance is attributed, in part, to the significance of the health budget and the nature of health systems, which gain legitimacy through a direct political process.[78] For these reasons, despite the heightened attention to health policies prompted by the COVID-19 pandemic, with both global and EU health policies experiencing expansion, scholars caution that this focus might be ephemeral, drawing parallels with historical trends in the field.[79]

Before 1992, references to public health were primarily associated with the establishment of the internal market and were regulated as exceptions to free trade arrangements, echoing international trade law and the SPS agreement.[80] The Cassis de Dijon case at the European Court of Justice exemplifies this, confirming that countries can only impose restrictions on the free movement of goods under certain exceptions, including the protection of public health and the defence of consumers.[81]

[75] It is noteworthy that, in November 2023, the five European Agencies relevant to One Health published the document 'Cross-Agency Knowledge for One Health Action', which includes references to AMR. Available at: www.efsa.europa.eu/sites/default/files/2023-11/one-health-2023-joint-statement.pdf.

[76] Scott Greer and Holly Jarman, 'What Is EU Public Health and Why? Explaining the Scope and Organization of Public Health in the European Union' (2021) 46(1) *Journal of Health Politics, Policy Law* 23–47.

[77] Eleanor Brooks and Anniek de Ruijter, 'Towards More Comprehensive Health Law and Policy Research' (2021) 16 *Health Economics, Policy, and Law* 104–110.

[78] Brooks and de Ruijter, 'Towards more comprehensive health law and policy research'.

[79] Eleanor Brooks, Anniek de Ruijter, and Scott Greer, 'Covid19 and European Union Health Policy: From Crisis to Collective Action' in Vanhercke, Spasova, and Fronteddu (eds.) *Social Policy in the European Union: State of Play 2020* (ETUI aibsl, Brussels, 2020) 220. Available at: www.etui.org/sites/default/files/2020-12/Social%20policy%20in%20the%20European%20Union%20state%20of%20play%202020-web.pdf.

[80] Anniek de Ruijter, *EU Health Law and Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press, 2019). Cited in Scott Greer and Holly Jarman, 'What Is EU Public Health and Why? Explaining the Scope and Organization of Public Health in the European Union' (2021) 46(1) *Journal of Health Politics, Policy and Law*.

[81] Judgment of the Court of Justice of 20 February 1979, *Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein*. Case 120/78. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61978CJ0120.

Following the Maastricht Treaty in 1992, and more prominently with the revisions of the EU foundational treaties in Amsterdam (1997), Nice (2002), and finally in Lisbon (2007), the EU progressively gained the capacity to intervene in public health. Article 168 of the Lisbon Treaty recognises a high level of health protection as a core objective and principle for all EU policies and activities with EU action, complementing national policies and fostering cooperation between member states. The EU acquired the ability to initiate the establishment of common guidance and conduct periodic monitoring and evaluation (Article 168.2). Under this article, the regulatory capacity of the European Parliament and the Council over health matters is limited to the quality and safety of human tissues, veterinary, and phytosanitary fields, and the quality and safety of medicinal products and devices. Additionally, the EU Parliament and the Council may approve incentives to protect and improve human health (Article 168.4), with the Council empowered to adopt recommendations upon the Commission's proposal (Article 168.5).

This background is essential to understand the evolution of AMR regulation in the EU. To dig into this topic, this section identifies some of the key elements of the EU regulatory framework for antimicrobial resistance, emphasizing its character as a shared policy marked by diverse and dissimilar responses across the EU member states. The intention is not to provide an exhaustive account of the very prolific legislative production and accompanying initiatives of the EU, but to show growth and evolution in the development of a robust AMR regulatory framework under a One Health approach.

11.5.2 *EU Cross-Sectoral AMR Regulatory Instruments*

The EU institutions have led the way in developing policies and regulatory frameworks to address antimicrobial resistance. The first Community Strategy to combat AMR was approved in 2001,[82] alongside Council Recommendations regarding the prudent use of antimicrobial agents in human medicine.[83] Framed by the above-mentioned constitutional division of powers and responsibilities, the regulatory framework for AMR primarily comprises soft law instruments, including Council recommendations and Conclusions, the Commission Action Plan on AMR, and the monitoring reports approved by the Commission and its specialised agencies on AMR, AMR surveillance and other specific AMR aspects of cross-cutting nature. These soft law instruments have influenced the revision and update of various sector-specific AMR-relevant legislation across various domains such as food and veterinary controls, veterinary medicines, feed, waste, wastewater, and soon, the authorisation of pharmaceuticals for human use.

Early documents, such as the Community Action Plan 2001 and the Council Recommendations and Conclusions of 2001, 2002,[84] and 2008,[85] focused on both the human and animal sectors, addressing aspects related to the coordinated management of medicines, antimicrobial stewardship, and the development of new medicines.[86] The slightly later second Commission Action Plan of 2011 and the Council Conclusions of 22 June 2012 introduce references to the One Health approach emphasizing the intersection between the human and

[82] Communication from the Commission on a Community Strategy Against Antimicrobial Resistance, COM/2001/0333 final Volume I, 26 June 2001.

[83] Council Recommendation of 15 November 2001 on the Prudent Use of Antimicrobial Agents in Human Medicine, OJ L 34, 5 February 2002, 13.

[84] Council Recommendation (2002/77/EC) on the Prudent Use of Antimicrobial Agents in Human Medicine.

[85] Council Conclusions on Antimicrobial Resistance (10 June 2008). Available at: www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/101035.pdf.

[86] Council Conclusions of 23 November 2009 on Innovative Incentives for Effective Antibiotic, OJ C 302 (12 December 2009) 10.

the veterinary sectors.[87] One Health is also expressly mentioned in the European Parliament Resolutions on AMR adopted in May,[88] and October 2011,[89] 2012,[90] and 2015.[91]

However, it was in 2017, with the introduction of the last EU One Health Action Plan Against AMR (the 2017 AMR Action Plan) that the role of the environment was highlighted, and thus better encompassing the overarching One Health approach to the AMR issue and challenges.[92] EU actions under the plan aimed at focusing on the areas with the highest added value for member states such as promoting the prudent use of antimicrobials, enhancing cross-sectorial work, improving infection prevention, consolidating surveillance of AMR and antimicrobial consumption, and reporting.

In the same vein, the 2023 Council Recommendations on stepping EU actions to combat AMR under a One Health approach[93] encourages member states to implement One Health Action Plans for coordinated AMR response involving all sectors, including the environment, to ensure their full implementation. The recommendations further suggest concrete and measurable targets to reduce antimicrobial use, which consider national situations. Similarly, the European Parliament resolution of 1 June 2023 on EU action to combat AMR adopts a One Health approach and encourages members to foster multisectoral and sustainable AMR coordination and integrated surveillance addressing the environmental sector.[94]

The Commission's overview report of member states' One Health National Action Plans against AMR of November 2022 showed that while most member states have enacted NAPs under a One Health approach,[95] these Action Plans varied considerably in terms of implementation, with measures related to the environment often missing. Furthermore, weaknesses in the areas of financing, monitoring, control, and evaluation were identified that could compromise the long-term sustainability of the NAPs.

11.5.3 *Sector-Specific Legislation*

In addition to the aforementioned cross-cutting AMR legal soft law instruments, the EU has undergone a comprehensive revision of sector-specific legislation across key legal areas crucial for AMR. This revision encompasses the regulation of antimicrobials, measures to prevent the contamination of food and the environment with antimicrobials, and initiatives related to disease prevention and animal welfare that minimise the need for antimicrobials.

[87] Council Conclusions of 22 June 2012 on the Impact of Antimicrobial Resistance in the Human Health Sector and in the Veterinary Sector – a 'One Health' Perspective, OJ C, C/211, 18.07.2012, p. 2, CELEX. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012XG0718(01).

[88] European Parliament Resolution of 12 May 2011 on Antibiotic Resistance. Available at: www.europarl.europa.eu/doceo/document/TA-7-2011-0238_EN.html.

[89] European Parliament Resolution of 27 October 2011 on the Public Health Threat of Antimicrobial Resistance. Available at: www.europarl.europa.eu/doceo/document/TA-7-2011-0473_EN.html.

[90] European Parliament Resolution of 11 December 2012 on the Microbial Challenge – Rising Threats from Antimicrobial Resistance (2012/2041(INI)). Available at: www.europarl.europa.eu/doceo/document/TA-7-2012-0483_EN.html.

[91] European Parliament Resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance (AMR) (2017/2254(INI)). Available at: www.europarl.europa.eu/doceo/document/TA-8-2018-0354_EN.html.

[92] Commission's Communication of 29 June 2017 'A European One Health Action Plan against AMR' (the '2017 AMR Action Plan'). Available at: https://health.ec.europa.eu/system/files/2020-01/amr_2017_action-plan_0.pdf.

[93] See https://ec.europa.eu/commission/presscorner/detail/en/IP_23_1843.

[94] European Parliament Resolution on EU Action to Combat Antimicrobial Resistance. 2023/2703(RSP).

[95] Overview report: Member States' One Health National Action Plans against Antimicrobial Resistance (17 November 2022). Available at: https://health.ec.europa.eu/publications/overview-report-member-states-one-health-national-action-plans-against-antimicrobial-resistance_en.

11.5.3.1 Regulation of Antimicrobials

A robust legal framework for medicines and medical devices is in place to protect the access, safety, and quality of these products.[96] It covers the whole life cycle, from authorisation to recall and surveillance, as well as monitoring, control, and disposal.

11.5.3.2 Human Medicines

In the realm of human medicines, the need for addressing AMR and the demand for new antimicrobials are at the basis of the Commission's proposed legislative package to revise the EU pharmaceutical legislation.[97] Comprising proposals for a Regulation,[98] and a Directive,[99] this package seeks to reform the current system governing the development, authorisation, and distribution of medicines. Its objectives include improving accessibility, affordability, and availability while addressing the environmental impact of medicine production and the presence of antimicrobials in the environment under a One Health approach. The proposed legislation aims to provide incentives for innovation and research to facilitate the development of new antimicrobials. Furthermore, in alignment with the 2017 AMR Action Plan, the Commission has adopted EU Guidelines for the prudent use of antimicrobials in human health.[100]

11.5.3.3 Veterinary Medicines

AMR considerations have played a pivotal role in the revision of the EU Regulation 2019/6 on veterinary medicinal products.[101] This regulation encompasses all stages of the veterinary medicine life cycle, including stewardship and use, access, pharmacovigilance, and control. It emphasises that veterinary medicines must be used for therapeutic purposes rather than for prophylaxis. The implementation of this regulation involves various delegated regulations, including those governing data collection on the volume of sales and use of antimicrobial medicinal products in animals.[102] Additionally, it serves as the foundation for Commission delegated Regulation (2021/1760) that establishes the criteria to reserve certain antimicrobials for the treatment of human infections only.[103] Finally, in the implementation of this Regulation,

[96] See https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu_en. See also the proposals for the revision of pharmaceutical legislation in https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en.

[97] See https://ec.europa.eu/commission/presscorner/detail/en/IP_23_1843.

[98] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No. 1394/2007 and Regulation (EU) No. 536/2014 and repealing Regulation (EC) No. 726/2004, Regulation (EC) No. 141/2000 and Regulation (EC) No. 1901/2006 COM/2023/193 final.

[99] 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. COM/2023/192 final.

[100] Commission notice – EU Guidelines for the prudent use of antimicrobials in human health. C/2017/4326 OJ C 212 (1 July 2017).

[101] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (1) and in particular Article 37(4) thereof. OJL4/43 (7 January 2019).

[102] Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals OJ L 123, 9.4.2021, 7–20. Also, Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council OJ L 35 (17 February 2022).

[103] Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans. C/2021/3552 OJ L 353 (6 October 2021).

the EU introduced a common logo that must appear on websites offering veterinary medicines for sale at a distance.[104]

Regulation 2019/6 consolidates an evolution that was initiated with the prohibition of antibiotic growth promoters in 2003,[105] the 2015 EU Guidelines on the prudent use of antimicrobials in animal health,[106] and the revised rules for the packaging and labelling of veterinary medicinal products in 2022.[107] Additionally, in 2019, and as part of the implementation of the 2017 AMR Action Plan, Regulation 2019/4 introduced revised rules on the manufacture, authorisation, and use of medicated feed, including rules on the prescription and safe disposal of unused or expired products.[108]

11.5.3.4 Food Safety

AMR has also influenced the regulation of food production and controls in Europe. The EU's 2020 Farm to Fork Strategy incorporates specific AMR objectives, including a reduction by 50 per cent in the sales of antimicrobials for farmed animals and in aquaculture.[109] Furthermore, Regulation 2017/625 on official controls on food and feed, animal health and welfare, plant health and plant protection products, includes several references to antimicrobial resistance. Finally, the establishment of maximum residue limits for pharmacologically active substances in food of animal origin is regulated through Regulation 470/2009.[110]

11.5.3.5 Integrated Surveillance

Compliance with food and veterinary legislation falls under the oversight of the Food and Veterinary Office (FVO), a division of the Directorate General for Health and Food Safety with a dedicated focus on Commission controls. The FVO conducts targeted audits on antimicrobial resistance and the findings are presented in various reports available in the FVO website.[111] These reports delve into One Health antimicrobial resistance policies and regulation and evaluate key aspects such as multisectoral coordination mechanisms, NAP, environmental monitoring, antimicrobial use, and laboratory capacity. The audits provide useful insight into the effectiveness of policies and serve as mechanism for the implementation and enforcement of the legislation.

[104] Commission Implementing Regulation (EU) 2021/1904 of 29 October 2021 adopting the design of a common logo for the retail of veterinary medicinal products at a distance OJ L 387 (3 November 2021).

[105] Regulation (EC) No. 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition prohibiting the use of antibiotic growth promoters OJ L 268 (18 October 2003) 29.

[106] Commission notice – EU Guidelines for the prudent use of antimicrobials in animal health. C/2015/4326 OJ C 299/7 (11 September 2015).

[107] Regulation (EU) 2022/839 of the European Parliament and of the Council of 30 May 2022 laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 OJ L 148 (31 May 2022) 6–7.

[108] Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No. 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC *OJ L 4* (7 January 2019) 1–23.

[109] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Farm to Fork Strategy for a fair, healthy, and environmentally friendly food system. COM/2020/381 final (20 May 2020).

[110] Regulation (EC) No. 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No. 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No. 726/2004 of the European Parliament and of the Council OJ L 152 (16 June 2009).

[111] See https://ec.europa.eu/food/audits-analysis/audit-report.

Additionally, in the early twenty-first century, the EU established an integrated framework to facilitate cross-border controls relevant to the identification and control of AMR bacteria. Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents incorporates antimicrobial resistance monitoring related to zoonoses within its scope.[112] This Directive mandates member states to ensure the comprehensive collection, analysis, and publication of data concerning the occurrence of antimicrobial resistance-related zoonoses. Similarly, Regulation (EU) 2022/2371 addressing serious cross-border threats to health encompasses the collection of comparable and compatible data and information on AMR within the context of national prevention, preparedness, and response plans.[113]

11.5.3.6 *Environmental Protection*

The 2017 EU AMR Action Plan recognises the environment as one of the important pillars to address AMR, emphasizing the need for an EU strategic approach to pharmaceuticals in the environment. The plan highlights the need to revise key directives, including the Urban Waste Water Treatment Directive and the Water Framework Directive to understand the occurrence and spread of antimicrobials in the environment.[114]

In 2019, the Commission published a Communication outlining a Strategic Approach to Pharmaceuticals in the Environment.[115] This document identified six action areas covering all stages of the pharmaceutical life cycle, from production to disposal and waste management. This Communication aligns with the later EU Action Plan 'Towards a Zero Pollution for Air, Water, and Soil' adopted by the Commission in 2021 and approved as part of the European Green Deal.[116] This includes a zero pollution vision for 2050 and key targets to reduce pollution by 2030, including the reduction by 50 per cent in the use of antimicrobials in farm animals and aquaculture.

In 2022 the Commission put forth two directives on water and wastewater.[117] Both Directives include several references to AMR and introduce new mechanisms to collect AMR data in water and wastewater. Lastly, it is worth noting the Commission proposal on nature restoration,[118] which expressly mentions One Health and pollution from pharmaceuticals.

[112] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC OJ L 325 (12 December 2003) 31–40. This Directive is complemented by the Commission implementing decisions on the monitoring and reporting of AMR, including the Commission Implementing Decision (EU) 2020/1729 of 17 November 2020 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU OJ L 387 (19 November 2020) 8–21.

[113] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU [2022] OJ L 314/26 (6 December 2022).

[114] 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 OJ L 327 (22 December 2000).

[115] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, European Union Strategic Approach to Pharmaceuticals in the Environment. COM (2019) 128 final.

[116] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, and the Committee of the Regions Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil'. COM/2021/400 final/.

[117] Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy; Directive 2006/118/EC on the protection of groundwater against pollution and deterioration; and Directive 2008/105/EC on environmental quality standards in the field of water policy. COM (2022) 540 final (26 October 2022). Also, Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast). COM/2022/541 final (26 October 2022).

[118] Proposal for a Regulation of the European Parliament and of the Council on nature restoration. COM/2022/304 final (22 June 2022).

11.5.3.7 *Prevention*

As an integral aspect of AMR prevention and control, the EU has implemented new legislation aimed at enhancing animal health and resilience to disease threats, thereby reducing the reliance on antimicrobials. Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law') incorporates several references to antimicrobial resistance.[119] This regulation sets up the basis to regulate AMR surveillance in veterinary medicine,[120] facilitating the listing of diseases when the disease agent has developed resistance to treatment posing a danger to human or animal health.[121] It also includes resistance as part of the capacity development requirements for operators and animal health professionals,[122] and their awareness-raising responsibilities.[123]

11.5.3.8 *Financing*

Beyond common harmonisation rules, encompassing common objectives and obligations, the EU regulatory framework for AMR includes several financial mechanisms that contribute to the deployment of various incentives to tackle antimicrobial resistance. Among these instruments, the Common Agriculture Policy plays a significant role by providing financial incentives to enhance animal welfare,[124] improve biosecurity in farms, and promote organic farming and eco-schemes, thereby reducing the reliance on antimicrobials and implementing control mechanisms to prevent environmental pollution. The EU4Health programme (2021–2027)[125] includes AMR as one of its key areas of action. Similarly, the Horizon Europe programme for research and innovation provides funding for research and development in AMR.[126]

In conclusion, the EU has played a pioneering role in the regulation of AMR across its 27 members. The structure of the EU regulatory framework effectively combines cross-cutting and sector-specific legal instruments, establishing a holistic and comprehensive coordination framework. Instead of creating overarching AMR legislation leading to legal fragmentation, the EU regulatory spans various sectors, highlighting a One Health approach that recognises the interconnectedness of human, animal, and environmental health. The implementation of this framework is supported by specific monitoring and control mechanisms, involving data collection, sharing, and direct oversight through dedicated audits. Sustainability is further promoted through financial mechanisms encouraging the implementation of good practices, innovation, research, and development. The participatory approach to law-making, involving extensive

[119] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'). OJ L 153 (3 May 2021).

[120] Policy brief: European Antimicrobial Resistance Surveillance Network in Veterinary Medicine (EARS-VET). Available at: https://eu-jamrai.eu/wp-content/uploads/2021/02/201116_EUJAMRAI_policy-brief_WP7_EARS-Vet.pdf.

[121] Regulation (EU) 2016/429. Article 5.3(b)(ii).

[122] Ibid., Article 11.1.(e).

[123] Ibid., Article 12.1.(c)(iv).

[124] Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by member states under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the (EAFRD) and repealing Regulations (EU) No. 1305/2013 and (EU) No. 1307/2013. OJ L 435 (6 December 2021).

[125] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021–2027, and repealing Regulation (EU) No. 282/2014. OJ L 107 (26 March 2021).

[126] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing *Horizon Europe* – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No. 1290/2013 and (EU) No. 1291/2013 OJ L 170 (12 May 2021).

consultations with stakeholders and bottom-up development, facilitates consensus building and fosters effective behavioural change.

However, the challenge lies in ensuring sustainable implementation at the country level, where EU countries exhibit varying levels of compliance with EU *acquis*. This diversity in implementation and compliance underscores the need for concerted efforts to enhance uniformity and effectiveness across member states.

11.6 INSIGHTS FROM AMR GOVERNANCE THAT MIGHT BE FURTHER APPLICABLE TO OTHER COMPLEX HEALTH THREATS UNDER THE ONE HEALTH APPROACH

This chapter aims to derive insights from the global, regional, and national governance and regulation of AMR, as detailed in the preceding sections. These lessons are intended to provide a broader applicability beyond AMR, to other areas benefiting from a One Health approach.[127]

In this section, One Health is understood as an approach dedicated to providing a collaborative and integrated response to health-related topics that demands a multisectoral and multidisciplinary perspective encompassing human, animal, and environmental factors. As defined by OHHLEP, this approach should embody the principles of equity across sectors, maintaining sociological equilibrium, fostering inclusivity and parity, stewardship in resources management, and embracing transdisciplinarity.[128]

AMR governance provides an excellent example of the implementation of the One Health approach and One Health principles in practice. International governance and regulation of AMR have solidified over the years, gaining broad recognition at the UN General Assembly and through collaborative efforts by the Quadripartite and other Intergovernmental Organisations. The GAP for AMR served as a pivotal milestone, offering countries a structured governance model with concrete sector-specific objectives, necessitating a combination of cross-sectoral and sector-specific efforts. The Interagency Coordination Group contributed to a transparent, comprehensive, and inclusive process, paving the way to a solid international governance framework. This might further consolidate within the Pandemics Agreement.

At the national level, AMR regulation demands a combination of cross-sectoral coordination mechanisms and sector-specific legislation to enable multisectoral coordination and the incorporation of international guidance into sectoral laws. Multisectoral and multidisciplinary mechanisms should facilitate equitable involvement and leadership capacity for all sectors to avoid perpetuating existing power dynamics. All relevant stakeholders should have the opportunity to voice their concerns and see their rights represented with particular attention to Indigenous Peoples, local communities, and vulnerable populations. Equity across sectors and parity among stakeholders, combined with transparency and access to information, facilitate stewardship of natural resources and a renewed attention to all species and living organisms in socioecological equilibrium. An enabling regulatory framework, with a clear delineation

[127] See for example, the proposals advanced by Negri and Eccleston-Turner concerning the application of the AMR pilot experience to the prevention of and response to zoonoses with pandemic potential, in Stefania Negri and Mark Eccleston-Turner, 'One Health and Pathogen Sharing: Filling the Gap in the International Health Regulations to Strengthen Global Pandemic Preparedness and Response' (2022) 19(1) *International Organizations Law Review* 188–214 (Special Issue 'Reforming the International Health Regulations' with guest editors Gian Luca Burci, Lisa Forman, and Steven J. Hoffman).

[128] One Health High-Level Expert Panel (OHHLEP), 'One Health: A New Definition for a Sustainable and Healthy Future'.

of roles and responsibilities, would provide these multisectoral mechanisms with a structure, solidifying shared obligations for data sharing and reporting. Legislation may further facilitate the introduction of a common accountability framework and joint indicators, securing participation rights for all stakeholders and financial resources.

The experience of AMR further underscores the potential role of legislation in facilitating data sharing for integrated surveillance. Integrated data management encompasses obligations for data collection and reporting, interoperability, protection, exchange, and joint analysis among institutions, alongside rules governing the publication and access to data, and the right to information. Caution must be paid when engaging the private sector in data generation to avoid overriding data, reporting obligations, and imposing unnecessary burdens, particularly on smallholders.[129] In cases where data involve the collection of genetic or biological information, an appropriate mechanism for benefit sharing must be in place, ensuring that communities or countries producing such data have the right to enjoy the benefits generated.

Beyond the coordination mechanism, every specific sector should adhere to the principles of equity, sociopolitical parity, and socioecological equilibrium in their sector-specific interventions. In the context of One Health collaboration, every sector must ensure that sector-specific legislation pays attention to its potential impact on the environment, biodiversity, animal health and welfare, plant health, and human health and wellbeing. Sector-specific policies and legislation should facilitate the stewardship of common public goods. Similar to antimicrobials, stewardship should guarantee the sustainable management of other public goods and natural resources, particularly in situations of shared rights over such resources.

The main research argument of this chapter is that the elements discussed could apply to other complex global health challenges that require a One Health approach. These challenges include the management of complex zoonoses such as rabies and avian influenza, but also broader areas such as sustainable wildlife management, a multisectoral response to pollution control, climate change or agri-food systems transformation.

Introducing a One Health approach will indeed vary across the different topics, depending on their objectives, stakeholders involved, and areas of focus. Nevertheless, drawing from the analysis of AMR, several principles can be extrapolated and applied, with necessary adjustments, to regulate other topics within a One Health framework.

At the international level, effective implementation requires political commitment, scientific expertise, and inclusive stakeholder engagement to integrate a One Health approach comprehensively. This entails fostering collaboration across sectors, disciplines, and nations to address complex health challenges holistically. At the national and regional levels, establishing robust multistakeholder mechanisms is crucial for promoting multisectoral coordination and integration. Such mechanisms should be underpinned by comprehensive and multisectoral frameworks, ensuring clear delineation of roles and responsibilities for each stakeholder. Legislation can support these frameworks by introducing long-term accountability mechanisms.

Additionally, it is imperative for countries to enact separate sector-specific legislation for each relevant area, aligning with international standards and best practices, thereby facilitating the incorporation of global guidelines into national regulatory frameworks and preventing legal fragmentation. Strengthening the regulatory landscape does not entail the consolidation or

[129] Si Ruishi, Yumeng Yao, Xin Liu, Qian Lu, and Mingyue Liu, 'Role of Risk Perception and Government Regulation in Reducing Over-Utilization of Veterinary Antibiotics: Evidence from Hog Farmers of China' (2022) 15 *One Health* 100448. Maria Paula and David Demeritt, 'Paperwork and the Decoupling of Audit and Animal Welfare: The Challenges of Materiality for Better Regulation' (2017) 35 *Environment and Planning C: Politics and Space* 169–190.

merging of different legal instruments, but their harmonisation. Laws that have traditionally operated in isolation must incorporate provisions for cross-referencing and cross-fertilisation, thereby facilitating coordinated action across diverse sectors. By integrating complementary laws and regulations, nations can optimise their regulatory frameworks to effectively address complex health challenges under the One Health approach.

In conclusion, AMR is a complex intersectoral challenge requiring a One Health approach. Led by the Quadripartite, the development of an AMR governance framework has rapidly evolved, resulting in consolidated and new structures at the national, regional, and global levels. The lessons learnt in the governance and regulation of AMR serve as insightful references in structuring the path forward for other One Health issues and their governance and regulation in other areas of priority for global/planetary health. By embracing the One Health principles of equity, socioecological equilibrium, transdisciplinarity, sociopolitical parity, and stewardship within national institutional and regulatory frameworks, a balance can be achieved that fosters an equilibrium among the health of humans, animals, plant, and the environment.