

### PANDEMIC ACCORD:

# AN OPPORTUNITY TO ADVANCE POLITICAL COMMITMENT TO ANTIMICROBIAL RESISTANCE

By Aliénor Devalière

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### Pandemic Accord: An Opportunity to Advance Political Commitment to Antimicrobial Resistance

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### **EXECUTIVE SUMMARY**

As world leaders reflect on lessons learned from the COVID-19 pandemic and other global outbreaks to address gaps and improve future responses, current discussions on an international treaty on pandemic prevention and preparedness offer a unique opportunity at a critical time to address the growing public health threat of antimicrobial resistance (AMR).

AMR has emerged as one of the greatest public health challenges of the twenty-first century, threatening the effective prevention and treatment of an ever-increasing number of infections caused by bacteria, parasites, viruses, and fungi that are resistant to the medicines commonly used to treat them. AMR is a borderless and cross-cutting threat that affects everyone.

Tackling this challenge requires an international framework advancing effective and enhanced collaboration, synergies, policies, and interventions within and among countries. Meaningful engagement of policymakers and civil society is crucial in order to develop an appropriate governance structure, to increase global solidarity, accountability and transparency mechanisms, and to define the shape and content of the future instrument.

This policy brief compiles strategic information for policy makers and civil society to continue prioritizing the AMR response and use the on-going political efforts for international pandemic preparedness to jointly address the threat emerging from AMR.

It aims to describe the main components of a potential future pandemic preparedness and response instrument, outline why AMR should be included, explain why and how policymakers and civil society can impact the drafting process, define objectives related to AMR, and lastly, to offer some key recommendations.

Engagement of policymakers and civil society is crucial to create appropriate governance structures, and to establish global solidarity, accountability, and transparency mechanisms to address AMR.

#### INTRODUCTION

Often referred to as a 'silent pandemic',<sup>1</sup> antimicrobial resistance (AMR) is one of the biggest threats to global health, food security, and development today.<sup>2</sup> Certain antimicrobials are now becoming ineffective, and infections more difficult to treat. Misuse and overuse of antimicrobials are the main drivers of the development of drug-resistant

pathogens. The rapid spread of multidrugresistant bacteria - the so-called 'superbugs' - is especially alarming as it causes infections that no longer respond to any existing antibiotic treatments, and increases the risk of disease spread, severe illness and death.

Latest figures reveal that AMR has now become a leading cause of death globally, higher than HIV/AIDS or malaria.

Currently, AMR affects millions of people around the globe every year. The World Health Organization (WHO) has ranked AMR among of the top 10 global public health threats.<sup>3</sup> A 2022 systematic analysis reporting the global burden of AMR estimated that in 2019 alone, about 4.95 million deaths were associated with AMR, out of which about 1.27 million were directly attributable to resistance.<sup>4</sup> These latest figures reveal that AMR has now become a leading cause of death globally, higher than HIV/AIDS or malaria.<sup>5</sup>

In response to the lessons learnt from the COVID-19 pandemic, and in anticipation of future pandemics, governments have launched negotiations on a pandemic instrument called the *WHO Convention, Agreement or other International Instrument on Pandemic Prevention, Preparedness and Response* – in this brief, it is referred to as the 'Pandemic Treaty'. Chile was the first country to put forward the idea of a pandemic treaty, in April 2020. The suggestion was taken up by the President of the European Council, Charles Michel, at the Paris Peace Forum in November 2020. "When a pandemic strikes, everyone is vulnerable. Next time, the world must be prepared. [...] Working together to build new solutions to protect what is most precious: our health and our lives." The COVID-19 crisis has shown policymakers that governments, despite years of high-level political commitments, are not well-equipped to face the many challenges of addressing global public health pandemics and the increasing threat of AMR. The covided the pandemics and the increasing threat of AMR.

According to WHO's Director-General Dr Tedros Adhanom Ghebreyesus, alongside more than 20 world leaders, the main goal of this treaty is to "foster an all-of-government and all-of-society approach, strengthening national, regional and global capacities and resilience to future pandemics".<sup>8</sup> It would also embrace a One Health approach, connecting the health of humans, animals, and our planet. Through its rules and norms, the Treaty could strengthen mutual accountability and shared responsibility, transparency, and cooperation within the international system. The current process of drafting and negotiating a Pandemic Treaty is being led by WHO, and more specifically, by an Intergovernmental Negotiating Body ('INB'). The process is expected to conclude in 2024 at the 77<sup>th</sup> World Health Assembly.

Public health experts and advocates are calling for the inclusion of AMR in the Pandemic Treaty. A new binding international framework could bring together the global

coordination and enforcement measures necessary to ensure a coherent and unified response.

Although discussed in the public health sphere, the issue of AMR is still not yet widely known. Policymakers and civil society have a key role to play in deepening and sharing knowledge, raising public awareness and strengthening political will.

The future Pandemic Treaty offers a key opportunity to holistically and globally address transnational issues and challenges associated with AMR, which no country can solve individually. Preparing for subsequent pandemics will require extensive global coordination across human, animal, and environmental health sectors, as well as within and among countries. While interconnections between countries and sectors may facilitate the spread of disease, they can also facilitate the sharing of knowledge,

Preparing for subsequent pandemics will require global coordination across human, animal, and environmental health sectors, as well as within and among countries. technology, and know-how. If shared globally and equitably, such cooperation can benefit all countries.

This policy brief aims to (I) outline the key potential features of a future Pandemic Treaty, (II) explain why AMR should be included in the Treaty, (III) describe why and how policymakers and civil society can impact the process, (IV) suggest what policies related to AMR should be sought, and (V) offer some recommendations.

### I. WHAT IS THE PURPOSE OF A PANDEMIC TREATY?

In the spirit of collective solidarity, led by WHO, all countries should work together towards the development of a new international treaty for pandemic preparedness and response. This kind of joint commitment would represent a milestone in advancing pandemic preparedness at the highest political level, and in assuring that countries are working jointly towards addressing a challenge that cannot be tackled by each government separately. It will be rooted in the WHO Constitution, underpinning the principle of health for all, by involving other relevant organisations key to this endeavour. WHO's Director-General, Dr Tedros, highlighted that "with 194 Member States and 152 country offices, WHO has unique expertise, a unique global mandate, unique global reach and unique global legitimacy".9

### a) Background

The current legal framework for pandemic preparedness and response is drawn from the International Health Regulations (IHR). Introduced 53 years ago and last revised in 2005, the IHR require countries to improve their core capacities, including legislation, coordination, and surveillance, to detect and respond to national health emergencies.<sup>10</sup> However, the effectiveness of the IHR has been called into question in the context of the

COVID-19 pandemic. The current system has little power to ensure governments comply with their responsibilities or accurately report on their capacities to prepare for and respond to health emergencies. Another limitation is that the IHR primarily addresses capacities at the national level, which does not improve global oversight and coordination.<sup>11</sup>

Some of these limitations have been acknowledged in the Report of the Review Committee on the Functioning of the IHR (2005) during the COVID-19 Response, presented at the WHA in 2021. This report noted that "too many countries still did not have the public health capacities in place to protect their own populations and to give timely warnings to other countries and WHO." <sup>12</sup> In its report, the Committee proposed a set of 40 recommendations requiring urgent action, including more meaningful cooperation during and between health emergencies, greater transparency, more frequent exchanges of detailed real-time data and experiences at all levels, and faster sharing of genome sequences and pathogen samples.

Based on these recommendations, the IHR framework is currently being revised. Regarding the timeline and potential overlap of the revision of the IHR and the negotiations of the Pandemic Treaty, diplomats hope that by the time the negotiations over IHR reform get underway in early 2023, the INB will have made some progress on the Pandemic Treaty – and specific pandemic reform issues can be allocated to one of the processes to avoid duplications and allow smaller diplomatic delegations to engage in both processes. Where governments have reached a consensus on surveillance through a revision of the IHR, this could be integrated or acknowledged in the Pandemic Treaty. The aim is to make the two processes complementary.<sup>13</sup>

The Treaty will also draw on the lessons learnt from the COVID-19 pandemic. It was clear that many national governments lacked solid preparedness plans, core public health capacities and organised multisectoral coordination with clear commitment from the highest national leadership. The Independent Panel for Pandemic Preparedness and Response stated that 'preparedness planning is a core function of governments and of

Many national governments lacked solid preparedness plans, core public health capacities and organised multisectoral coordination with clear commitment from the highest national leadership.

the international system and must be overseen at the highest level'.<sup>14</sup> The Panel called on political decision-makers at every level to champion major change, and to make the necessary resources available to render it effective.

"There will be other pandemics and other major health emergencies. No single government or multilateral agency can address this threat alone"; "The question is not if, but when. Together, we must be better prepared to predict, prevent, detect, assess and effectively respond to pandemics in a highly coordinated fashion. The COVID-19 pandemic has been a stark and painful reminder that nobody is safe until everyone is safe." <sup>15</sup>

### b) Process and timeline

A key milestone was reached on 1 December 2021, when WHO Member States reached consensus to start the process of drafting and negotiating a 'WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, with a view to adoption under Article 19, or under other provisions of the WHO Constitution as may be deemed appropriate by the INB'. <sup>16</sup>

Article 19 of the WHO Constitution grants the World Health Assembly (WHA) the authority to adopt conventions or agreements on any matter within WHO's competence.<sup>17</sup> However, only one legally binding instrument has been established under Article 19 to date: the WHO Framework Convention on Tobacco Control.<sup>18</sup> This international treaty has significantly contributed to protecting people from tobacco by tackling complex factors with cross-border effects such as trade liberalisation, advertising, promotion, and illicit trade.

It should be noted that while Article 19 is the provision under which the instrument should be adopted, there is still the possibility of considering the suitability of Article 21, as work progresses.

The December decision established an Intergovernmental Negotiating Body ('INB') in charge of drafting and negotiating the Pandemic Treaty. The INB Bureau is comprised of six delegates, one from each of the six WHO regions, headed by the co-chairs Mr Roland Driece of the Netherlands and Ms Precious Matsoso of South Africa. After several meetings in 2022, the INB presented a so-called 'Conceptual Zero Draft' at its third meeting (5 to 7 December 2022), and negotiations will begin at the fourth INB meeting, scheduled to start on 27 February 2023. The INB will then deliver a progress report to the 76<sup>th</sup> World Health Assembly (WHA) in May 2023, with the aim of finalising it by May 2024 for consideration by the 77<sup>th</sup> WHA. Some experts consider this to be an ambitious timeframe, as it usually takes years to build the consensus needed for this sort of international agreement. Proponents of the Treaty remain optimistic given the urgent need to have such an agreement in place.

### Timeline of the process

April 2020	Chile first put forward the idea of a pandemic treaty
Nov. 2020	Announcement of the proposal for an international treaty on pandemics by Charles Michel, President of the European Council
Feb. & March 2021	G7 support & Joint call from 25 head of government and international agencies for a treaty
1 Dec. 2021	Decision at the World Health Assembly to launch the process to develop a global accord on pandemic prevention, preparedness and response
24 Feb. 2022	First meeting of the Intergovernmental Negotiating Body (INB) to agree on ways of working and timeline
April 2022	First round of public hearings addressed the guiding question: "What substantive elements do you think should be included in a new [Pandemic Treaty]?"
July 2022	Second meeting of the INB to discuss progress on a working draft
Sept. & Oct. 2022	INB four Informal Focused Consultations with experts
Sept. 2022	Second round of public hearings addressed the guiding question: "Based on your experience with the COVID-19 pandemic, what do you believe should be addressed at the international level to better protect against future pandemics?"
Dec. 2022	Presentation of the 'Conceptual Zero Draft'
May 2023	76 <sup>th</sup> World Health Assembly: Delivery of a progress report
May 2024	77 <sup>th</sup> World Health Assembly: Expected adoption of the instrument

### c) Main Benefits of a Pandemic Treaty

### Improve framework for surveillance, alert, response, implementation, equitable access and research and development (R&D)

A Pandemic Treaty could improve the global cooperation framework for surveillance, alert, response, and implementation for pandemic prevention, preparedness, and response measures, as well as strengthening R&D, and assuring global equitable access within this pharmaceutical system.

#### Better surveillance of pandemic risks

Surveillance means gathering and analysing health-related information for the purpose of undertaking and guiding public health action.<sup>19</sup> Tailored surveillance can provide the virological and epidemiological information needed to inform and determine crucial actions that may save lives. The earliest possible recognition of a novel pathogen is critical to containing it. Recording and providing this data should therefore be the priority.

#### **Better alerts**

The COVID-19 crisis revealed that the current alert system does not operate quickly enough when faced with a fast-moving respiratory pathogen, and that the legally binding IHR are, in their current form, a conservative instrument that serves to impede rather than facilitate rapid action.<sup>20</sup> Communication about public health threats could be made more accurate by introducing additional levels of alert, corresponding to the degree of threat. This would, in turn, improve transparency and support the potential legitimacy of restrictive or health-related measures.

#### **Better response**

The COVID-19 pandemic has demonstrated that global supply chains and logistics systems need to be more resilient to cope with global health threats. All countries should have uninterrupted access to essential supplies, medicines, and equipment from anywhere in the world. Global coordination for effective stockpiling may also improve pandemic response.

It is also critical that the scientific community is able to mobilise quickly, and that manufacturers of health products are able to rapidly scale up their manufacturing capacity. A globally coordinated approach to discovering, developing, and delivering effective and safe medical solutions, such as vaccines, medicines, diagnostics and protective equipment, would benefit collective health security.

### Better implementation

The resilience of national public health systems is crucial. Countries need to be able to rely on their public health systems in order to effectively respond to pandemic outbreaks and rapidly implement the appropriate measures.

#### Ensure equitable and sustainable access

The uneven access to vaccination, as well as to treatments and testing, is one of today's preeminent global challenges regarding the COVID-19 pandemic. The significant inequity in access to vaccines (and other health technologies) must be addressed, as it is not only a manifestation of global inequality, but also threatens the effectiveness of international efforts to control the pandemic. Scaling up the development and supply of treatments, therapeutics and diagnostic tests is crucial to saving lives.<sup>21</sup> A global strategy with clear goals, milestones and priority actions is needed.

Equitable access requires equitable resource allocation. Many of the countries most impacted by global health threats are also among the poorest, making it difficult, if not impossible, for them to shoulder the financial and resource burden of a pandemic. As the COVID-19 pandemic has shown, high-income and upper-middle-income countries have retained the majority of vaccines and technologies, raising significant concerns around equity, fostering nationalism, deterring cooperation, and – despite steps taken within the

ACT-A framework and COVAX - weakening the international solidarity required for a global response. Equitable resource allocation needs to be based on global resource pooling, so that all countries can meet their respective needs.

A well-designed treaty should incentivise innovation sharing through global health governance in order to reduce shared vulnerabilities and strengthen preparedness across countries.<sup>22</sup>

### A collective R&D system

Although the COVID-19 crisis exposed the fragmentation of the research and development (R&D) system, it was still a time of unprecedented innovation and scientific collaboration, during which novel technologies and safe and effective vaccines were produced in record time.<sup>23</sup> This has sparked a debate about global fairness and solidarity, exploring the notion of a collective R&D system that connects talent and resources, creating products that are treated as global public goods, available and affordable for all in an equitable manner.<sup>24</sup>

The 2020 assessment of the R&D preparedness ecosystem for the GPMB (Global Preparedness Monitoring Board) identified the importance of unaddressed gaps in outbreak response: "it may be time to consider a new treaty on pandemic threats that not only strengthens surveillance and, equally as important, reporting, but also virus sequence and isolate sharing, and puts in place agreements and funding structures for key R&D activities that need to occur both regionally and globally".<sup>25</sup> The report also highlights that expecting engagement from WHO in every aspect of R&D preparedness and outbreak response might be counter-productive and unrealistic, and that several global organisations have a key role to play. As a start, a framework to define roles, responsibilities, and rules for R&D should be established – and the Pandemic Treaty would seem to be the right place for this.

An international expert group has recommended that a Pandemic Treaty should establish global norms to ensure and enhance both pre-pandemic and crisis-related funding for relevant R&D and set standards for managing R&D funding. It will be critically important to put measures in place to ensure there is sufficient funding from all sources (public and private), and for all stages of R&D.<sup>26</sup>

### Ensure better global cooperation, robust coordination, and accountability mechanisms

Existing international legal mechanisms lack the coordination and enforcement measures necessary to ensure a consistent and unified pandemic response, or are not written with pandemic preparedness, prevention, and response in mind.

Managing public health threats as well as the AMR crisis will require global cooperation that can best be achieved through the robust coordination and accountability mechanisms offered under global health law.<sup>27</sup>

To implement effective global cooperation, accountability mechanisms are key safeguards to ensure that all parties answer for their respective obligations. A major gap in existing international health agreements is a lack of accountability mechanisms to assess and monitor compliance, as well as to incentivise or sanction non-compliance with regulation, independently and objectively. For a global agreement to succeed in preventing and mitigating pandemics, standards must be set, and countries and international bodies held accountable for their commitments and obligations under those standards.<sup>28</sup>

Binding and transparent accountability mechanisms should therefore be put in place through the Pandemic Treaty, to ensure robust, reliable, responsive, and harmonised monitoring and accountability mechanisms. For a borderless threat like AMR, global governance mechanisms are particularly important in order to mitigate their emergence and spread. These accountability mechanisms must not only ensure that all countries conduct appropriate surveillance and report new bacterial or viral threats, but also establish binding obligations for all countries to coordinate and cooperate on R&D, and to uphold equitable access to medical countermeasures, including affordability, supply, and distribution.

### d) One Health as an overarching principle

Public health experts and advocates highlight the need to integrate One Health as an overarching principle in the Treaty. The One Health approach currently features in Article 17 of the draft pandemic instrument, under Chapter IV on strengthening and sustaining capacities for pandemic prevention, preparedness, response, and recovery of health systems. It should, however, span across the entire instrument.

One Health supports a collaborative, multisectoral, and transdisciplinary approach - working at local, regional, national, and global levels - with the goal of achieving optimal health outcomes that recognise the interconnection between people, animals, plants, and their shared environment.<sup>29</sup> The One Health approach aims *inter alia* to prevent outbreaks

AMR is a key One Health priority, alongside food safety and food security, vector-borne diseases, environmental contamination, and other health threats shared by people, animals, and the environment.

of zoonotic spill over and mutations, and to reduce antibiotic-resistant infections. The approach is based on four main pillars: communication, collaboration, coordination and capacity building.

### e) Remaining uncertainties

The ongoing discussions on the contents of the Treaty have raised several important questions:

### Various degrees of ambition between Member States

Since the beginning of the process, there have been differences in the approaches and expectations among WHO Member States, covering both the legal implications of the instrument and its scope.

When discussions on the legal form of a pandemic instrument started, more than 70 countries, including the European Union and the United Kingdom, were advocating for a strong, legally binding international treaty. In contrast, other countries, including the United States, India, and Brazil, were reluctant to commit to a legally binding agreement.<sup>30</sup> According to Lawrence Gostin, a professor at Georgetown University and founding O'Neill Chair in global health law: "more (states) are quite concerned that strong binding standards would violate their national sovereignty, and they are reluctant to sign on to anything that is too prescriptive".<sup>31</sup>

At the second INB meeting, in July 2022, members agreed, through consensus, that a new international instrument on pandemic prevention should be legally binding.<sup>32</sup> According to the background information provided by WHO, a treaty can have a mix of both binding and non-binding elements: 'the Health Assembly could adopt a legally binding instrument (under either Article 19 or 21 of the Constitution), and that instrument could contain both legally binding and non-legally binding provisions, with the non-binding provisions being, for example, recitals, principles, recommendations or aspirations.' <sup>33</sup> This will be reflected with the varying use of "shall" (legally binding) and "should" (non-legally binding).

In addition, there are still disagreements over the scope of the future instrument. Certain countries, including the USA, the European Union, and some African countries such as Zambia, are pushing to include AMR in the Treaty, while some are advocating for it to be only partially included, and others still are willing to exclude AMR from the Treaty entirely. These divisions risk negatively impacting the outcomes of the negotiations, potentially watering down proposals on AMR.

#### The central principle of equity

Many public health experts and civil society organizations have raised the opportunity to put equity at the core of the Pandemic Treaty, broadly integrated as an overarching principle. They have warned of the risk of a 'North-North treaty' that does not address the priorities of the 'Global South' – and have highlighted the need to develop appropriate mechanisms rooted in global equity. Several countries, particularly those that have suffered from being unable to purchase COVID-19 vaccines, have demanded that equitable access and distribution are included in the Pandemic Treaty. To ensure equity,

countries must have access to the technical, financial, and technological resources they require to achieve compliance under the agreement.

Academics have pointed out that future pandemic governance must also place greater emphasis on equity for social determinants of health, particularly in the areas of gender, age, race, geography, and socioeconomic status. Previous infectious disease instruments have largely ignored these intersectional areas of policymaking, which has been detrimental to marginalised populations, who may be among those most affected by the policies and their long-term effects. These instruments frequently fail to take into account how the intent and implementation of a policy can have a significantly different impact on marginalised populations (who do not have adequate resources) and those populations that do.<sup>34</sup>

Without appropriate enforcement measures to ensure equity, solidarity, and access, the Pandemic Treaty could remain an empty shell.

### Sustainable funding

One of the biggest challenges is financing pandemic preparedness and response. Existing global health funds are financed on a voluntary basis by countries and corporations. Voluntary contributions lead to disproportionate funding that fails to meet the needs of high-risk countries. Political interference in funding and distribution of existing global health funds is also a huge issue.

According to the UN Development Programme, more than 50 of the poorest developing countries are in danger of defaulting on their debt.<sup>35</sup> The severe lack of funding for low-income countries, tied to their own fiscal challenges, will be a critical problem for funding allocation and the sustainability of a future pandemic instrument.

In June 2022, G20 finance and health ministers agreed to establish a Financial Intermediary Fund (FIF) to address the financing gap for Pandemic Prevention, Preparedness and Response (P3R). Next steps should specify the actions to be funded, the amount of funds needed, the nature and level of contributions, the criteria for use, and distribution.<sup>36</sup> It remains to be seen how this Fund will be aligned with the Pandemic Treaty. Other countries have recently suggested the idea of a funding instrument situated at the WHO.

Overall, the value of the Pandemic Treaty will depend on its ability to actually respond to the challenges it addresses. What matters most, therefore, is the content of the commitments, and how well these are supported by mechanisms that encourage their implementation.

### II. WHY SHOULD AMR BE ADDRESSED IN A PANDEMIC TREATY?

### a) AMR is one of the greatest global health threats of our time

AMR is one of the greatest global threats to public health today - and the phenomenon stretches well beyond the health domain. AMR is closely associated with issues caused by globalisation, the environmental crisis and climate change. Given the ease with which pathogens can cross borders, countries should be incentivised to ensure that they can address outbreaks before they spread.<sup>37</sup>

Over the past decade, global institutions have come together to discuss and address the AMR threat. AMR has been included within the global health security agenda and has featured in G20 discussions since 2016. In 2019, WHO named AMR one of the 10 most urgent global health threats.<sup>38</sup> Despite this, political action and financial investments to tackle this growing crisis have fallen short. The private sector's disinvestment in AMR, particularly for the development of new countermeasures, has not been compensated by public investment, leaving a critical gap.

If the opportunity to address AMR in a pandemic instrument is not seized now, the next pandemic could be caused not by zoonotic diseases, pathogens that can be passed from animals to humans, but instead by existing pathogens that have become resistant to antimicrobial medicines. A substantial global health threat in its own right, the diminishing

The next pandemic could be caused by existing pathogens that have become resistant to antimicrobial medicines.

effectiveness of antimicrobials also poses an additional threat during zoonotic pandemics, as the treatment for many zoonoses relies on antimicrobials to reduce the severity and mortality rate of secondary bacterial infections.<sup>39</sup>

The pathogen that caused the COVID-19 pandemic, SARS-CoV-2, has drawn attention to the importance of zoonotic diseases - diseases that can be transferred from animals to humans. Many infectious diseases that are widespread among humans have their origin in the animal realm. Experts estimate that there are still around 1.7 million unknown viruses among wild mammals and birds. Of these, approximately 700,000 have the potential to cross over to humans.<sup>40</sup>

Although the magnitude of the AMR problem remains hard to estimate in lower-middle-income countries (LMICs), due largely to a lack of proper surveillance programs and therefore of data, these countries are disproportionately affected. A combination of factors relating to poor hygiene and sanitation, limited access to adequate healthcare infrastructure, and lack of regulation make the spread of AMR easier and faster in LMICs. The ongoing COVID-19 pandemic is amplifying additional challenges in an already complex scenario, favouring the overuse of antibiotics in LMICs, and reducing public awareness of the serious threat of AMR.<sup>41</sup>

### b) The potential of a legal instrument, international framework, or mechanism

The shortcomings in IHR design and implementation are also reflected in the failure of global governance efforts related to AMR. Widespread overuse and misuse of antibiotics have led to rising rates of AMR, critically hindering much-needed global cooperation.

Surveillance of drug-resistance in bacteria is key to identifying where resistance is evolving and where new treatments are needed. Such surveillance will only be effective if data and information are shared openly and without retaliation measures against countries that do so. Effective surveillance extends to hospital-level identification of emerging drug resistance. Appropriately collected and analysed data from routine drug susceptibility testing in health facilities not only inform local responses by local healthcare professionals, but also contribute to national and international surveillance and are vital in setting R&D priorities. Inclusion of AMR in a Pandemic Treaty could help coordinate and develop synergies between AMR and pandemic preparedness response surveillance efforts.<sup>42</sup>

Based on the Global Action Plan on AMR, WHO launched the Global Antimicrobial Resistance and Use Surveillance System (GLASS) in 2015, which was intended as a collaborative effort to standardise AMR surveillance. Over 109 countries have now enrolled in GLASS, and data collection methods have expanded over the last seven years.<sup>43</sup> Any new or expanded surveillance systems should be harmonised with GLASS and other existing surveillance systems.

A pandemic instrument can do more than just strengthen preparedness. Governments must take additional steps to ensure antibiotics and diagnostics to combat AMR can be quickly manufactured, registered, distributed, and allocated between and within countries. While a pandemic may be an adequate incentive for private companies to invest in clinical development, registration, production, and commercialisation, companies might not necessarily invest enough, either independently or through partners, to ensure adequate supply, affordability, and availability for all countries and people in need. Only governments backed by political will and legal rules can ensure technologies are made available as a global public good – meaning that they are available and accessible to all who need them.

One practical solution to this issue would be the creation of an instrument to establish legally binding obligations that ensure equitable allocation of supply, through a pooled procurement system for pandemic-related health technologies and antibiotics. Systems that support pooled demand or procurement can improve balance between supply and demand and facilitate equitable allocation between countries. Pooled procurement has been shown to reduce prices, especially when used for higher volume products.<sup>44</sup>

Legally binding obligations that ensure equitable allocation of pandemic-related health technologies and antibiotics would be a practical solution to more equitable access. However, pooled procurement does not necessarily lead to equitable access. Equitable allocation was not achieved with respect

to COVAX, a pooled procurement entity established to purchase and allocate COVID-19 vaccines. COVAX relied on countries' solidarity and voluntary contributions, both of which were insufficient to reach the intended targets on time as governments simultaneously had to deal with their own public health emergencies.

### c) A One Health approach to AMR

A One Health approach to the surveillance and monitoring of infectious diseases is fundamental to effective global pandemic responses. Like zoonoses, some new antimicrobial-resistant strains of bacteria arise at the human-animal-environment interface, especially in food and agricultural systems where antimicrobials are used in intensified agricultural practices. Surveillance is therefore needed for: the early detection and flagging of potential zoonoses and antimicrobial-resistant pathogens in animals; tracking emerging variants of zoonoses and the spread of resistant pathogens among humans, to identify population transmission patterns; and the sharing of information with researchers and policy-makers at local and global levels, to coordinate global pandemic responses.<sup>45</sup> During the 4<sup>th</sup> INB Informal Focused Consultation on AMR, experts highlighted the need to strengthen measures related to prevention, and to look at the causes and drivers of disease emergence. The Treaty must incentivise a multisectoral and multidimensional approach to working systemically together.

However, a broader One Health approach does not cover all the specifics of AMR and should not dilute AMR-related challenges. The two should complement one another without overlapping. At this stage, the Conceptual Zero Draft mentions, under the One Health principle, the 'attention to the prevention of epidemics due to pathogens resistant to antimicrobial agents' (Article 4, point 14).

### d) Major impact on the global economy

According to ReAct, a global network dedicated to the problem of antibiotic resistance, "antibiotic resistance is costly, both for the individual and for society, and can accelerate economic segregation and increase inequalities. Second- and third-line antibiotics are generally more expensive than first-line alternatives, which means that patients who pay out-of-pocket for healthcare services must pay more to treat a resistant infection than a susceptible one. In addition, resistant infections generally take longer to treat, and require hospitalisation to a higher degree. These factors contribute to increased cost levels, which threaten to push economically disadvantaged individuals and households into poverty". 46

The COVID-19 pandemic has a major impact on the global economy, and on efforts to address the antibiotic pipeline. The lack of available treatments and vaccines at the

beginning of the pandemic has highlighted the need for more global coordination and solidarity in funding. A research study found out that governments - with public funds - have spent at least €93 billion on the development of COVID-19 vaccines and therapeutics globally since the outset of the pandemic.<sup>47</sup>

The fight against AMR has suffered from continued disinvestment in antibiotics by the private sector. The need for innovation to deliver new antibiotics is central to the wider response to AMR. According to the Global Research on Antimicrobial Resistance (GRAM) Project at the University of Oxford, 63 new antibiotics were developed for clinical use between 1980 and 2000, but only 15 more were approved between 2000 and 2018. The pipeline for new antibiotics is currently too weak to meet the threat of rising rates of drug resistance. This is primarily the result of the unattractive economic returns on antibiotic development. Much more concerted funding efforts are required, and several initiatives or programs have already been proposed by governments, civil society organisations, think tanks, academic institutions, and others who fund and carry out R&D to address drug-resistant infections. Many such incentive models are currently being considered, being piloted or have been officially launched in one or more countries.

The Pandemic Treaty could be an appropriate forum to coordinate funding needs at a global scale. According to a Lancet article, "spending needs to be directed to preventing infections in the first place, making sure existing antibiotics are used appropriately and judiciously, and to bringing new antibiotics to market".<sup>50</sup>

The long-term costs of inadequate preparedness will accumulate and multiply over time. The World Bank has warned that AMR could be as damaging to the global economy as the 2008 financial crisis, with a global increase in healthcare costs between US \$300 billion and US \$1 trillion per year. The research showed that a high-case scenario of AMR where antibiotics and other antimicrobial drugs no longer treat infections the way they are supposed to - could cause low-income countries to lose more than 5% of their GDP and push up to 28 million people, mostly in developing countries, into poverty by 2050. Beside antibiotics, this estimation also takes into account resistance to antifungals,

antivirals and anti-parasitic agents and gives a hint of the enormous potential economic consequences of inadequate global, regional, and national responses to the problem of AMR.

AMR could be as damaging to the global economy as the 2008 financial crisis, with a global increase in healthcare costs between US \$300 billion and US \$1 trillion per year.

All in all, potential impacts on GDP, global poverty, world trade, healthcare costs and livestock output are tremendous. Tackling AMR needs to be addressed as a critical issue for development, with potentially disastrous consequences for human and animal health, food production and global economies. Therefore, public, private, and not-for-profit sector capacity to respond to new or changing epidemics – including production capacity for drugs and diagnostics - must be financed, both before and during crises.

### e) No universal health coverage or robust pandemic response without effective antibiotics

Universal health coverage (UHC) is an equally important, though often overlooked, element in preventing health emergencies. Although UHC is technically focused on mitigating the financial burden of healthcare, it has often been used to describe the wider set of interventions necessary to ensure that all people have access to comprehensive health services. A crucial part of epidemic and pandemic preparedness and response is the strengthening of health systems, which supports essential public health functions like a robust health infrastructure, trained and protected healthcare workers, adequate funding, reliable supply chains, and evidence-based planning and coordination.<sup>52</sup>

To successfully reach Target 3.8 of the Sustainable Development Goals (SDGs) and achieve universal health coverage for all, antibiotic resistance must be addressed, managed and financed. If bacterial infections cannot be treated, then good quality healthcare cannot be delivered, and it will be very difficult to achieve sustainable financing of UHC unless antibiotic resistance is appropriately addressed.<sup>53</sup>

Antibiotics are still required during viral pandemics, due to the risk of secondary bacterial infections. Hospitalised patients with viral infections, especially influenza, are particularly susceptible to secondary infections caused by highly drug-resistant bacteria, such as pneumonia due to *Pseudomonas spp.* or MRSA.<sup>54,55</sup> At the outset of the SARS-CoV-2 pandemic, it was anticipated that secondary bacterial infections would also be common, resulting in the use of a considerable amount of antibiotics in patients with COVID<sup>56</sup>. The same precautionary approach will be taken by healthcare professionals in future viral pandemics. Stewardship is key in this regard as there is a risk of overuse and misuse of antibiotics, leading to increased prevalence of resistant infections, as shown in the recent CDC 2022 Special Report, 'COVID-19: US Impact on Antimicrobial Resistance'.<sup>57</sup>

# III. WHY SHOULD DECISION-MAKERS AND CIVIL SOCIETY CARE, AND HOW CAN THEY IMPACT THE PROCESS?

A global Treaty requires a concerted effort. No single country can address global health threats alone. In his opening remarks at the Special Session of the WHA in November 2021, WHO's Director-General, Dr Tedros, recalled the basis of the consensus and framework of the future instrument: "Nations coming together to find common ground is the only way to make sustainable progress against common threats". <sup>58</sup> The discussions around the Pandemic Treaty offer a unique opportunity, at a critical moment, to re-examine,

coordinate and strengthen global governance arrangements in order to better mitigate the human, economic and social consequences of disease outbreaks.

"Nations coming together to find common ground is the only way to make sustainable progress against common threats."

### - Dr Tedros Adhanom Ghebreyesus

One of the major challenges that threaten the success of a pandemic preparedness and response initiative is the inadequate engagement of key stakeholders, resulting in a lack of trust in public health institutions and decision-

makers.<sup>59</sup> Therefore, it is crucial that decision-makers, civil society and local communities are well informed, committed, and able to contribute effectively to the process in an inclusive and transparent manner. During the preliminary discussions, health experts have emphasised the need for civil society participation in all stages of decision-making and co-creation. The role of civil society is essential in bringing to light the needs and issues of communities and populations that are not always sufficiently taken into account, as well as in highlighting key values that are otherwise not prioritised.

### a) Time is of the essence

The drafting and negotiating process is currently underway. The INB publicly released the 'Conceptual Zero Draft' in early December 2022, and this draft will form the basis of negotiations starting in February 2023. This marks the beginning of what is likely to be a fastidious process, and multiple amendments are to be expected. Nevertheless, it is easier to amend a draft and fine-tune a proposal than to restart discussions and negotiations from scratch.

2023 will be a crucial year for moving discussions forward, as WHO aims to present the instrument for consideration by May 2024. Therefore, this is the moment for policymakers and civil society to invest in understanding the content and dynamics of the instrument, in order to seize the opportunity and effectively contribute to shaping the Pandemic Treaty. Ultimately, the content of the instrument will be determined by Member States, so involvement from all relevant stakeholders will be essential.

It is important to add that this Pandemic Treaty is the only opportunity on the horizon for establishing standards and guidelines to address the global AMR problem.

### b) Need for a multidisciplinary and inclusive approach

To ensure comprehensiveness, appropriateness and fairness, all countries should be able to contribute equally and meaningfully to the development of an international pandemic preparedness and response initiative. New legal governance instruments should be based on a strong sense of ownership by both high-income and lower-income countries. International cooperation and collaboration at the highest political levels is required to address specific issues during the evolution of a pandemic. At the Member State level, decisions are made both in the capital and within Geneva-based delegations. The sharing

of information with policymakers is key to ensure they are well informed and able to react rapidly.

As AMR is a cross-cutting strategic issue, several ministries will need to engage with one another and coordinate their approach, including the Ministries of Health, Economy, Finance, Cooperation and

Sustained political leadership and effective governance were key factors in the COVID-19 response and will continue to influence future pandemic preparedness and response.

Development, Agriculture and Food, and Climate Change. Within the One Health framework, a multidisciplinary approach is essential. International collaboration between governments, policymakers, academics, microbiologists, front-line clinicians, veterinarians, the food and agriculture industry and the public are equally critical in order to understand and tackle AMR.<sup>60</sup>

Sustained political leadership and effective governance were key factors in the COVID-19 response and will continue to influence future pandemic preparedness and response. Good governance requires that health decision-making processes and institutions at national and international levels are accountable, transparent, equitable, inclusive, participatory, and consistent with the rule of law.<sup>61</sup> These principles should be at the core of the ongoing process.

According to a WHO Member States briefing developed in March 2021<sup>62</sup>, the Treaty can offer:

- an all-of-government approach, because in almost all cases its ratification goes through a national legislative (parliamentary) process;
- a whole-of-society approach, bringing in stakeholders from all sectors of society, especially in its implementation; and
- a long-term and sustained focus among governments and stakeholders, especially when treaties are concluded in the form of framework conventions.

Regarding the process steps, the INB has been seeking the following inputs so far:

- written inputs to the working draft from Member States and relevant stakeholders;
- regional consultations during the WHO Regional Committees of 2022;
- four informal focused consultations (IFCs) on selected key issues, involving experts
   with one specifically covering "One Health and antimicrobial resistance, climate change, and zoonoses"<sup>63</sup>; and
- public hearings (two rounds, in April and September 2022), to allow interested parties and stakeholders to express their views.

Within this framework, numerous health experts and non-governmental organizations have been able to share their input and feedback. According to a non-state actor in official relationship with WHO, thousands of written inputs and short videos have already been submitted.

The WHO website is currently the only source of publicly available information on the topic. The INB's Bureau has developed the Conceptual Zero Draft of the Pandemic Treaty in order to start negotiations at the fourth INB meeting, scheduled to start on 27 February 2023. <sup>64</sup> Between the publication of the Conceptual Zero Draft in December 2022 and the release of a report in May 2023, the INB will organise drafting groups to support the drafting of the report in early 2023. According to one source, these groups will probably be composed of several Member States and experts. Concrete wording proposals will therefore become key to move forward in the process.

### c) Unique opportunity to shape the Pandemic Treaty draft

As the Conceptual Zero Draft is built upon in the upcoming negotiations, a key next step will be to provide concrete wording proposals. A few organisations are already gathering and brainstorming in order to support Member States' recommendations.

A Policy Brief from the Global Strategy Lab<sup>65</sup>, a Canadian interdisciplinary research laboratory, defines specific wording for concretely addressing AMR in the Pandemic Treaty text. It outlines several options – rated as good, better, or best – that could serve as entry points for incorporating AMR into the draft text. The analysis took the strategic objectives from WHO's Global Action Plan on AMR<sup>66</sup> and used them as benchmarks for key global actions needed for AMR.

Among other recommendations, the Policy Brief suggests:

- a) including AMR in the definition of "pandemic" (the pandemic instrument could establish a baseline definition of the term "pandemic" that includes bacterial pathogens of concern);
- b) outlining the connection between the pandemic instrument and WHO's Global Action Plan on AMR as the normative guide for the implementation of Member States' AMR related obligations under the pandemic instrument; and
- c) establishing One Health mechanisms that allow Member States to efficiently address One Health issues related to pandemic prevention, preparedness, and response through subsequent actions and agreements.

### d) Key role of national parliaments

The national parliament is a powerful institution that can play a key role in conveying clear messages and helping to restore dialogue and trust with citizens.

When it comes to the participation of Member States, the national parliament is a powerful institution that can play a key role in conveying clear messages and helping to restore dialogue and trust with citizens.

Once adopted, international treaties require ratification at a national level, depending on the national legal system in place as well as on the eventual legal basis. National law determines whether a treaty is to be ratified by the executive or by parliament, and which procedure must be followed. Most national legal systems require formal approval of an international treaty by a high-level political authority. In most cases, the national parliament is consulted and informed. This reaffirms the pivotal role of national parliaments.

Parliamentarians can join forces to make themselves and their support heard. As an example, several members of parliament from around the world have come together in a global collaborative network called UNITE, committed to making real political impact towards ending infectious diseases as a global health threat<sup>67</sup>. Dr Ricardo Baptista, the Portuguese member of parliament who is founder and President of UNITE, declared:

"We finally have the scientific evidence and technological means to end HIV/AIDS, viral hepatitis and other infectious diseases as global health threats. However, political awareness, advocacy, leadership and accountability are still lacking. As representatives of Citizens, we parliamentarians must do more for the societies we live in. Therefore, it is our mission to UNITE current and former legislators from around the world to give a coordinated, effective and strong political response to end infectious diseases as a global health threat".

Alongside the listed infectious diseases, AMR is also one of the network's key priorities.

As highlighted by a member of parliament from Tanzania, Neema Lugangira, during a panel discussion on the role of parliamentarians in the Pandemic Treaty at the World Health Summit 2022, capacity building for parliamentarians is essential. Members of parliament need to be well informed and educated to create an efficient bridge with citizens and become real allies of the Ministry of Health. Parliamentarians have a major

role to play in raising awareness and building a solid network with national focal points. This is all the more important during a public health crisis.

The topic of AMR should be opened up beyond the remit of experts and academics, so that all citizens have a sense of understanding and ownership of the issue.

Members of parliament need to be well informed and educated to create an efficient bridge with citizens and become allies of the Ministry of Health.

### e) Other institutions working in parallel

In addition to the discussions at the G20 and G7 level, a few bodies have recently been created to support pandemic preparedness and response, and these have key interactions with WHO's current review process:

### The Global Preparedness Monitoring Board (GPMB)

The GPMB is an independent monitoring and accountability body to ensure preparedness for global health crises. Co-convened by the Director-General of the WHO and the President of the World Bank, the GPMB is comprised of global leaders and experts from

a wide range of sectors, including medicine, global health, veterinary epidemiology, environment, human rights, economics, law, gender, and development.<sup>68</sup>

A GPMB 2020 report, entitled 'A World in Disorder'<sup>69</sup>, called for negotiations on an international framework agreement for health emergency preparedness and response. GPMB continues to actively advocate for such a framework and welcomes the proposals for a Pandemic Treaty.

## The Independent Panel for Pandemic Preparedness and Response (IPPR); and Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response

The Independent Panel began its work in September 2020, and submitted its main report, 'COVID-19: Make it the Last Pandemic'<sup>70</sup>, to the WHA in May 2021. The report contains the Panel's findings and recommendations for action to curb the COVID-19 pandemic and to ensure that any future infectious disease outbreak does not become another catastrophic pandemic.

The Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response gathered many global experts to review the functioning of the IHR during the COVID-19 response, and proposed recommendations to the WHA in May 2021<sup>71</sup>. It constitutes a useful basis for moving forward and making the processes of the IHR and the Pandemic Treaty complementary.

### IV. POLICY RECOMMENDATIONS: HOLISTIC AND SYSTEMATIC RESPONSE TO THE THREAT OF AMR

### a) Inclusion of AMR as a key global health threat in the Pandemic Treaty

As laid out in this brief, AMR should be included as one of the major global health threats in the Pandemic Treaty. Ongoing discussions suggest it could feature either in the text of the Treaty itself, or in a protocol. A protocol could be more specific, establishing additional rights and obligations, going beyond the general terms of the Treaty. This will be an important point of development in the coming months.

When comparing the Conceptual Zero Draft to the INB July working draft<sup>72</sup>, it is clear that progress has been made when it comes to addressing AMR. There are more provisions on AMR in the Conceptual Zero Draft (seven, versus three in the INB July working draft) and it is also decoupled from climate change. However, it is still primarily addressed within the framework of a One Health approach. At this stage, there is just one specific point made on AMR in the preamble:

"Noting that antimicrobial resistance is often described as a silent pandemic and that it could be an aggravating factor during a pandemic" (point 24). In order to properly address AMR, further actions, proposals and calls for awareness are required.

The relationship between climate change and AMR remains relatively underreported, although the topic of health and climate change is drawing increasing attention. The Lancet has just published its first 2022 Countdown Europe report on health and climate change, which highlights the urgent need to take opportunities for accelerated action in line with climate targets to support a healthy, climate-resilient future for all people.<sup>73</sup> AMR is unfortunately not mentioned in the report.

Nevertheless, 'antimicrobial resistance and climate change exacerbate each other,' as Professor Sabiha Essack said<sup>74</sup>.

'If you look at the informal settlements in South Africa, the slums in India, or the Favelas in Brazil – the constellation is always very similar: high population density in a warm climate. This is a combination that promotes antibiotic resistance', she added.

Human impact on the environment is the main source of both climate change and AMR genes – and the two can be jointly addressed.

However, while both AMR and climate change cause and/or exacerbate pandemics, legal frameworks, policies and interventions are different. The Treaty should address all the drivers of pandemics, encompassing the specifics of each, and strengthening synergies with other existing relevant instruments.

Human impact on the environment is the main source of both climate change and AMR genes – and the two can be jointly addressed.

### b) Reinforce and build on AMR national action plans

The Pandemic Treaty could strengthen the support countries receive with the implementation of their AMR national action plans. AMR national action plans are now fully developed in most countries but must be resourced by governments at the national level. Governments are ultimately responsible and accountable for introducing and distributing new antibiotics in a manner that ensures responsible use, as well as equitable and affordable access, and minimises resistance development.

Within the first round of the INB public hearing in April 2022, some public health organisations such as the European Public Health Alliance (EPHA) have issued the recommendation that the 'Treaty should include specific AMR measures such as setting target and performance indicators and supporting countries to develop and implement national AMR action plans'. To this end, WHO developed an implementation handbook in February 2022, offering a practical approach to the implementation of AMR national action plans within the human health sector. The handbook also aims to outline a process and collate existing WHO tools to prioritise, cost, implement, monitor and evaluate national action plan activities. Some of these elements can be translated into the Pandemic Treaty, with

a view to accelerating the national implementation of AMR action plans and strengthening the global response to AMR.

### c) Increase funding and resources to AMR

To address pandemic preparedness and AMR, a stable, predictable, and sufficient global funding mechanism is required.

The Pandemic Treaty could be an efficient tool for pushing governments to allocate the necessary resources to AMR, especially since an international treaty will have a strong normative impact on where governments allocate resources. Each party shall plan and provide financial support, in line with its national fiscal capacities, for the effective implementation of the instrument. Funding for the implementation of AMR national action plans will also be crucial.

### d) Access and stewardship mechanisms

Inappropriate antibiotic use is a global problem, and lack of stewardship of these lifesaving drugs is a major driver of antibiotic resistance. However, the lack of access to antibiotics causes eight times more deaths every year than the estimates for antibiotic

Inappropriate antibiotic use is a global problem, and lack of stewardship of these life-saving drugs is a major driver of antibiotic resistance.

resistance (5.7 million deaths versus 700,000). Most new antibiotics are only available in fewer than 10 countries - and rarely for children and babies - for up to a decade after adult use is approved. Lack of good stewardship coupled with lack of access to old and new drugs can be especially problematic for some LMICs, where the burden of drugresistant infections can be high.<sup>77</sup>

AMR stewardship is a mechanism to promote appropriate use of existing antimicrobials for clinical efficacy, but also to sustain effectiveness of new antimicrobials during development. The goal of AMR stewardship is to improve the quality and cost-effectiveness of care, improve patient/animal outcomes and decrease the further emergence and spread of AMR. According to a blog post from Uzo Chukwuma, Chief of the Infectious Diseases Branch and Immunisation Program Manager at the Indian Health Service, 'at a minimum, effective stewardship programs include a well-developed reporting and surveillance system, sufficient diagnostic capabilities, a trained workforce, and active regulatory system'.<sup>78</sup>

With respect to the establishment of a Global Framework for Development and Stewardship to Combat Antimicrobial Resistance, the WHO Draft Roadmap states that access, stewardship and innovation have been shown to be effective methods for combatting AMR rise and spread.<sup>79</sup> Based on these three main pillars, the framework also recognises aspects of infection prevention and control as essential for fighting AMR. Stewardship policies need to be designed in a way that ensures that access to antimicrobials is not compromised and is expanded where needed.

It is worth noting the following point from the conclusion of the Global Strategy Lab's AMR Policy Brief:

"If one AMR-specific provision can be included in a pandemic instrument, it should focus on promoting antimicrobial stewardship, as such efforts are needed to sustain the effectiveness of existing antimicrobials and are unlikely to be implemented at socially optimal levels without coordinated global action such as through an international agreement like the pandemic instrument." <sup>80</sup>

### e) Prioritisation of unmet needs according to global urgency

Whilst all seven of the leading bacteria have been identified as 'priority pathogens' by the WHO, only two have been a focus of major global health intervention programmes – *S. pneumoniae* (primarily through pneumococcal vaccination) and *M. tuberculosis*.

The public sector should exert leadership to identify and set priorities for drug development and ensure timely access of antibiotics. This includes prioritising clinical development, while acknowledging country-by-country differences, according to public health priorities identified by WHO<sup>81</sup>. This is increasingly feasible thanks to the collection of surveillance data from the WHO GLASS surveillance program on the prevalence of drugresistant bacteria and attributable mortality<sup>82</sup>. This system should work in close collaboration with the surveillance system(s) of the future Pandemic Treaty.

### f) AMR requires a broader response

A Pandemic Treaty could certainly address some of the key challenges of AMR, but it cannot cover it all.

Some academics have cautioned against expecting too much from a Pandemic Treaty: "we do see a very real risk of so much being proposed for inclusion within a single accord that it seems unlikely that it will be able to achieve it all." <sup>83</sup> The process first requires consensus among Member States, followed by national ratification. Tensions are not only springing up between Member States, but also within national ministries.

Even if AMR is well integrated into an efficient pandemic instrument, governments and other stakeholders will need to take many other steps, at the national level and through cooperation, to successfully tackle drug-resistant infections in the long term.

Beyond the fact that antibiotic R&D remains underfunded and that the existing pipeline is unable to respond to current resistance development, there are serious issues with global supply chains, availability, access and affordability of antibiotics, as well as their

responsible management, including through stewardship.<sup>84</sup> The necessary global rules should not only be developed in emergency situations, when governments are primarily focused on addressing the needs of their own population, but ideally ahead of time.

Governments will need to take many steps, at the national level and via international cooperation, to successfully tackle drug-resistant infections.

### g) Other pandemic preparedness response mechanisms already addressing AMR

An entire pandemic preparedness and response infrastructure is emerging, and the future Pandemic Treaty could play an important role in this framework. These instruments and investment facilities should be aligned to ensure proper coordination and consistency at all levels. Launching too many parallel initiatives risks diluting the effectiveness of a global instrument to face pandemics.

### The Financial Intermediary Fund for Pandemic Prevention, Preparedness and Response

Established mid-2022, the Financial Intermediary Fund (FIF) is a collaborative partnership among donor countries, co-investors, foundations, and civil society organisations. It is hosted by the World Bank, with WHO as technical lead. This fund aims at financing critical investments to strengthen pandemic prevention, preparedness, and response capacities at national, regional, and global levels, with a focus on LMICs. The Fund will provide additional dedicated resources for pandemic prevention, preparedness, and response, incentivise countries to increase their investments, enhance coordination among partners, and serve as a platform for advocacy.<sup>85</sup>

In particular, the FIF can finance countries' capacity for laboratory systems, disease surveillance, emergency communication and management, community engagement and health workforce. Beyond country support, the FIF will assist in strengthening efforts on a regional and global level to share epidemiological data, coordinate procurement for medical and non-medical countermeasures and harmonise regulatory measures. The FIF can support peer-to-peer learning, provide targeted technical assistance, and help with the systematic monitoring of PPR capacities. A Governing Board, composed of donor and recipient countries as well as non-state actors, will establish the overall work program and make funding decisions<sup>86</sup>.

The first calls for proposals have opened end of January 2023. The main challenges will be setting up an inclusive and transparent mechanism, achieving results, mobilising sufficient financial resources and coordinating with existing structures. An alignment with the Pandemic Treaty, and a specific reference to the FIF in the Treaty, is recommended.

### New national-/regional-level PPR mechanisms

Drawing on the lessons learnt from the COVID-19 pandemic, new national and regional mechanisms of prevention and preparedness are being developed.

At the European level, the European Commission is working on a new body, called the European Health Emergency Preparedness and Response Authority (HERA). HERA's task is to ensure that the EU and Member States are much more ready to act in the face of a cross-border crisis. It will complement the work of existing European health agencies, and

work in collaboration with international partners primarily to address international supply chain bottlenecks, expand global production capacity, reinforce global surveillance, facilitate international cooperation and provide support for medical countermeasures. It is expected that €30 billion will be invested in HERA.<sup>87</sup> Once again, these large financial investments call for alignment with global initiatives.

Several public health advocates have raised the issue of HERA's good governance structures and rules.<sup>88</sup> They have called for clear governance rules, including for transparency and accountability safeguards, and the inclusion of all relevant non-state actors - key issues that apply to all global publicly funded initiatives.

HERA, like the European Union as a whole, has made addressing AMR a key priority in its 2023 Workplan<sup>89</sup> and overall focus, including strengthening access and stewardship in LMICs through entities such as GARDP and SECURE, an initiative that seeks to strengthen sustainable access to critical antibiotics in health systems at the national level.

#### **G7 Pact for Pandemic Readiness**

Members of the G7 have gathered around a Pact for Pandemic Readiness, a strategic and conceptual exercise to decisively improve implementation, coordination and cooperation of their actions in the area of collaborative surveillance and rapid response. The Pact will reflect the intentions of the G7 countries, with the goal of sending a clear signal to leaders worldwide while providing further political, technical or financial support. As mentioned in the Pact, this initiative should be supportive of the Pandemic Treaty and does not preempt or replace proposed lines of actions.<sup>90</sup>

In order to reduce fragmentation, duplication and redundancy, all the relevant ongoing initiatives must be aligned to reinforce cohesion, consistency and coherence, and maximise synergies and outputs.

#### CONCLUSION

The current Pandemic Treaty negotiations represent a key opportunity to address some of the global challenges of the growing threat of AMR. Tackling the drivers and the impact of AMR presents significant challenges, for countries and the international community alike. It requires both multisectoral coordination and strong sector-specific responses. Overall, while existing regulations already cover some aspects of the prevention, monitoring, response, control and management of AMR, the global governance architecture would benefit from an overarching Pandemic Treaty that addresses the remaining gaps and ensures appropriate global coordination and communication across countries. The national and global implementation of One Health approaches is already paving the way for integrated strategies for reducing the use of antibiotics and combatting AMR.<sup>91</sup>

# The overarching goal is to reconstruct and maintain international solidarity.

According to GARDP, the development of a Pandemic Treaty, many of the measures that may be included in a pandemic instrument, including investments in surveillance, infection prevention measures,

manufacturing capacity, production and sharing of data, training of healthcare workers and pooled procurement, can positively impact pandemic preparedness and response as well as addressing AMR.

At the end of November 2022, the European Commission released its EU Global Health Strategy<sup>92</sup> in which it calls for strong action on AMR and identifies it as a critical aggravating factor during pandemics. Antimicrobials also pollute the environment and affect biodiversity. "Countries, institutions and global stakeholders must collectively and comprehensively address these challenges as a priority". The EU is calling for the inclusion of concrete provisions on antimicrobial resistance in the pandemic agreement as an important contribution.

Whether the challenge is to sustainably and cooperatively address global health issues or climate change, the overarching goal is to reconstruct and maintain international solidarity. There is also unanimous agreement that governments cannot wait for the next

crisis before they act. As WHO's Director-General, Dr Tedros, stated: "the importance of a legally binding instrument cannot be overstated: it will be our collective legacy for future generations". 93

"The importance of a legally binding instrument cannot be overstated: it will be our collective legacy for future generations."

- Dr Tedros Adhanom Ghebreyesus

### **KEY POLICY RECOMMENDATIONS**

- Recognise and urgently address the **global threat of drug-resistant** infections. The future pandemic instrument must be pathogen neutral and should include all microbes with pandemic potential, including bacteria.
- Make **affordable access** to existing and new antimicrobials, vaccines, and diagnostics a global priority, taking into account the needs of all countries.
- Ensure **equity and equitable access** as core principles guiding pandemic preparedness and response.
- Improve awareness and understanding of AMR issues. Antibiotic effectiveness
  must be seen as a **global public good**, especially with respect to future
  generations, and should be central for pandemic preparedness and response.
  Preserving antibiotic effectiveness while ensuring equitable access is a shared
  global responsibility.
- Enshrine the **One Health approach** at the core of the Pandemic Treaty.
- Ensure multistakeholder and multisectoral engagement at all stages of policy development.

- Establish a decision-making process that is accountable, transparent, equitable, inclusive, participatory, and consistent with the rule of law. It should also set out clear mechanisms for **monitoring accountability**, paired with adequate resources for implementation, especially for LMICs.
- Ensure **low- and middle-income countries are equal partners** in a comprehensive global response.
- Lay out a **R&D** preparedness and response agenda at a global level.
- Guarantee **sustainable and adequate funding** to invest in necessary R&D and countermeasures.
- Promote **antimicrobial stewardship** at a national level to sustain the effectiveness of existing antimicrobials while assuring equitable access.
- Align all the relevant ongoing initiatives to maximise synergies, outputs, consistency, and coherence.

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