

## **G7 Finance Ministers' Statement on Actions to Support Antibiotic Development**

1. COVID-19 has demonstrated the importance of strengthening preparedness for global health threats, including the “silent pandemic” of antimicrobial resistance (AMR). AMR is already having significant impacts on our economies and health systems, leading to an estimated 700,000 deaths globally from drug-resistant infections annually<sup>i</sup>.
2. Despite this AMR threat, different factors including market failure contribute to the lack of development of new antibiotics, with no new class of antibiotic coming to market for more than three decades. There is also a need to tackle the spread of AMR across the One Health spectrum of human, animal, and environmental health, including through ensuring the appropriate use and stewardship of antibiotics and considering AMR impacts when making public and private investments across the One Health spectrum.
3. In recognition that AMR has long-term health and economic consequences, all G7 members commit to expedite their implementation of existing strategies, outlined in our respective AMR Action Plans and related strategies, and to take additional specific and appropriate steps to address the antibiotic market failure and create the right economic conditions to preserve essential existing antibiotics and ensure their access, strengthen AMR antibiotic research and development, and bring new drugs to market where they meet identified public health needs (see annex A for examples of G7 action). Recognising country-specific circumstances and member state competences, possible steps could include exploring a range of market incentive options, with a particular emphasis on supporting relevant pull incentives, implementing new pilot projects, contributing to new national governance structures to develop economic strategies to strengthen antibiotic development, and exploring legislative and regulatory measures. To promote greater G7 coherence and recognising the value of antimicrobials to our health systems, economies and societies, these efforts will be underpinned by the G7 Shared Principles for the Valuation of Antimicrobial Therapeutics adopted by G7 Health Ministers on 17 November (see separate document).
4. In addition, we welcome the establishment of the \$1bn AMR Action Fund<sup>ii</sup> by industry to help bring up to four new antibiotics to market by 2030; activities by different global institutions and partnerships to promote antibiotic development, access, and stewardship including in low- and middle-income countries such as GARDP, BARDA, CARB-X, IMI, and SECURE<sup>iii</sup>; and efforts by a number of public and private investors, including the Investor Action on AMR initiative<sup>iv</sup>, development banks, and finance institutions to better assess and mitigate AMR risks and impacts in their investments and financing strategies.
5. We are committed to strengthen and intensify our action across the G7. Recognising that this is a multi-year and multi-stakeholder effort, we ask our finance and health officials to work with relevant technical agencies, international organisations, industry, and investors to continue this dialogue and share best practice. We call on the Global AMR R&D Hub and the World Health Organization to support this work and prepare a progress update for G7 Finance and Health Ministers in 2022. We will also support efforts to revitalise AMR-related action at the G20, including through actions to strengthen pandemic preparedness.

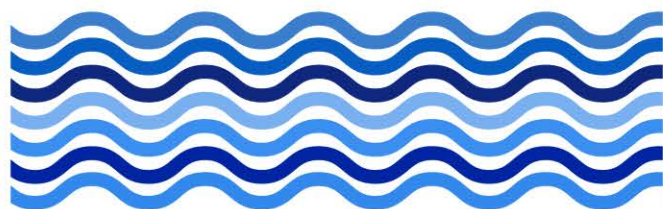
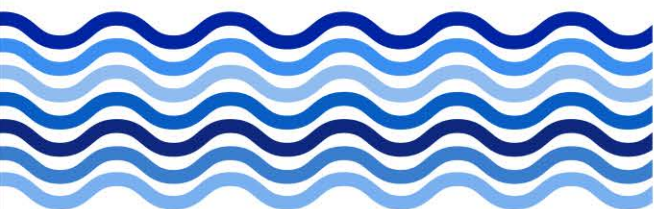
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<sup>i</sup> [Review on Antimicrobial Resistance](#)

<sup>ii</sup> [AMR Action Fund](#)

<sup>iii</sup> [\(GARDP\) Global Antibiotic Research and Development Partnership](#); [\(BARDA\) Biomedical Advanced Research and Development Authority](#); [\(CARB-X\) Combating Antibiotic-Resistant Bacteria Accelerator](#); [\(IMI\) Innovative Medicines Initiative](#); and [\(SECURE\) initiative](#). See also [G7 Health Ministers' communique](#), 4 June, paragraph 25, for further detail

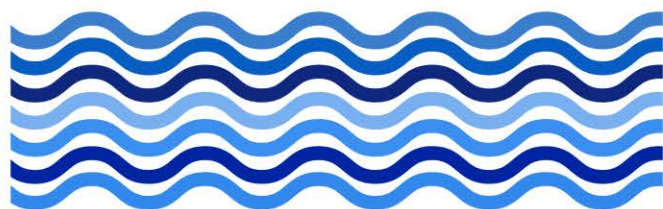
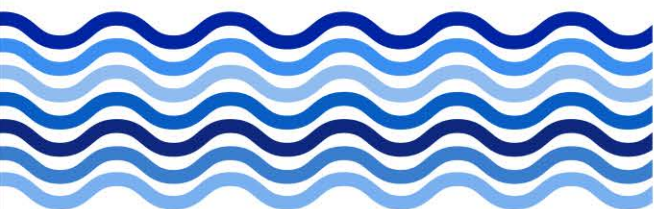
<sup>iv</sup> [AMR Investor Action](#)



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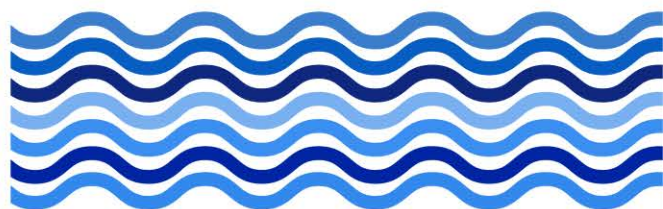
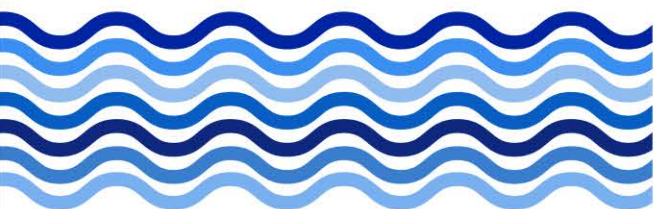
**Annex A**

G7 Member (links to AMR Action Plans and related strategies)	Examples of G7 actions to create the right economic conditions to preserve existing antibiotics and their access, strengthen antibiotic research and development, and bring new drugs to market
<p><b>Canada</b></p> <p><a href="#">Link</a></p>	<p>The Pan-Canadian Framework for Action on Antimicrobial Resistance (AMR) and Antimicrobial Use (AMU) was issued in 2017. The Framework identifies opportunities for action and desired outcomes under four pillars: surveillance, stewardship, infection prevention and control, and research and innovation.</p> <p>The Framework includes these opportunities for action with respect to research and innovation:</p> <ul style="list-style-type: none"> <li>• Support a cross-sectoral, multidisciplinary research network to facilitate antimicrobial discovery, best practices, behavioural research, and economic and production impacts across sectors and jurisdictions.</li> <li>• Explore mechanisms to develop the capacity and appropriate infrastructure required to further support the development of human and veterinary medicines and alternative tools.</li> <li>• Establish a fast-tracked cost-effective process for licensing antimicrobial drugs, alternatives to antimicrobials and new diagnostic tools in Canada to incentivise pharmaceutical investment without compromising safety, efficacy, and quality.</li> </ul> <p>The new Pan-Canadian Action Plan on AMR and AMU is being developed in cooperation with provincial and territorial governments, Indigenous partners, and stakeholders to define specific priorities for collaborative action and move forward with implementation.</p>
<p><b>EU</b></p> <p><a href="#">Link</a></p> <p><a href="#">Link</a></p>	<p>Following the implementation of the 2017 AMR EU Action plan, the EU Commission in November 2020 adopted the Pharmaceutical Strategy for Europe that will address several AMR challenges including issues around investment and raising AMR awareness. Flagship initiatives proposed in relation to AMR include measures to reduce excessive and inappropriate use of antibiotics and new incentive models to develop antimicrobials.</p> <p>Proposed initiatives related to AMR include to:</p> <ul style="list-style-type: none"> <li>• Pilot innovative approaches to EU R&amp;D and public procurement for antimicrobials and their alternatives aiming to provide pull incentives for novel antimicrobials. The pilot is on-going with proposals submitted in response to the Horizon Europe research calls currently being evaluated.</li> <li>• Promote investment and coordinate research, development, manufacturing, deployment, and use for novel antibiotics as part of the new EU Health Emergency Response Authority, prior to the start of the Authority’s operations on preparatory action on AMR.</li> <li>• Consider in the review of the pharmaceutical legislation to introduce measures to restrict and optimise the use of antimicrobial medicines. Explore new types of incentives for innovative antimicrobials. Work is on-going with ambitious timelines for the adoption of a legal proposal, including consideration of provisions relevant</li> </ul>

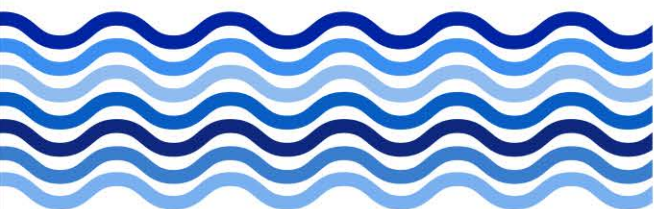


	<p>to AMR. The Commission is gathering views via an open public consultation on the pharmaceutical strategy (deadline 21 December 2021).</p> <ul style="list-style-type: none"> <li>Propose non-legislative measures and optimise the use of existing regulatory tools to combat AMR, including harmonisation of product information, draft evidence-based guidance on existing and new diagnostics, promote the prudent use of antibiotics, and communication to healthcare professionals and patients.</li> </ul>
<p><b>France</b></p> <p><a href="#">Link</a></p> <p><a href="#">Link</a></p>	<p>The first French interministerial national action plan, using a One Health approach for AMR, was adopted in 2016. This action plan is organised along five objectives: raising awareness among the public and healthcare professionals; education; research and innovation; monitoring and surveillance; and interministerial and international actions governance.</p> <p>On the strategic objective to improve innovation and maintain access to existing antibiotics, a structured dialogue between public and private sector stakeholders is underway to encourage innovation with the aim to come up with concrete measures, within the framework of the Strategic Industry Contract, launched in February 2019 and extended until 2022.</p> <p>France is also committed to ensure the availability of existing off-patent antibiotics (in humans and animals, while taking into account the environment) and identifying effective countermeasures.</p> <p>Using the EU Technical Support Instrument, the World Health Organization (WHO) in close collaboration with all French stakeholders in the human, veterinary, and environmental sectors (One Health approach), as well as the Directorate-General for Structural Reform Support (DG REFORM) of the European Commission, provide technical support to the French government. This 3-year project, co-funded by the European Commission and the WHO, started in November 2020.</p>
<p><b>Germany</b></p> <p><a href="#">Link</a></p>	<p>The current German Antimicrobial Resistance Strategy “DART 2020” takes up the development of new antibiotics. The follow-up strategy “DART 2030” is currently under development. It will as well take the topic into account.</p> <p>In 2020, Germany introduced a new reimbursement incentive for innovative antibiotics within the Act on Fair Competition among the Statutory Health Insurance Funds (GKV-FKG). The Joint Federal Committee – responsible for the benefit assessment of new pharmaceuticals prior to price negotiations between the pharmaceutical company and the national representation of statutory health insurance funds – can grant new antibiotics a special status called “reserve antibiotic”. The pharmaceutical company needs to apply for this status. The Joint Federal Committee only grants the status if the new antibiotics fulfils a pre-set of criteria such as proves to be effective in treatment of antibiotic-resistant "priority pathogens" as defined by WHO. The Robert Koch-Institute and the Federal Institute for Drugs and Medical Devices define the list of criteria.</p> <p>As a result, the pharmaceutical company does not need to prove an additional benefit of the reserve antibiotic to a comparator, yet the reserve antibiotic as such has an additional benefit. This leads to an advantage in German pricing processes and eventually to an appropriate value-based pricing for new innovative antibiotics. Cefiderocol (Fetcroja) manufactured by Shionogi was the first active substance which entered the new assessment procedure in November 2021.</p>

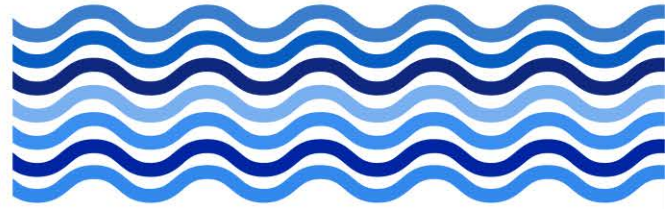
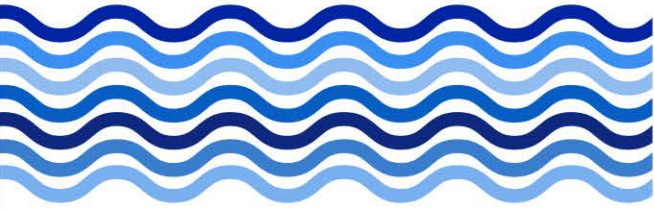




<p><b>Italy</b></p> <p><a href="#">Link</a></p> <p><a href="#">Link</a></p>	<p>In 2017, Italy adopted its first National Action Plan on Antimicrobial Resistance 2017-2020. The plan set out six areas of interest: antibiotic resistance surveillance and prevention; appropriate use and surveillance of antimicrobial consumption; surveillance, prevention and control of healthcare associated infections; training of healthcare staff; information and education of the population; and research and innovation.</p> <p>A new “AMR committee AIFA-OPERA” (2021-2024) within the Italian Medicines Agency (AIFA) has been created which would provide advice on antibiotics including proposals for new models to incentivise antibiotic research and development. Its short-term goals include development of recommendations based on the best scientific evidence of antibiotic therapy of infections for both hospitals and general practitioners, and strengthening antibiotic monitoring systems. The long-term goals comprise development of coherent actions, including awareness campaigns, creation of a network of centres of excellence to support AIFA-OPERA’s training and research activities.</p>
<p><b>Japan</b></p> <p><a href="#">Link</a></p>	<p>Japan’s AMR National Action Plan 2016-2020 is structured around six areas: public awareness and education; surveillance and monitoring; infection prevention and control; appropriate use of antimicrobials; research and development; and international cooperation. Within this, the government made a commitment to push incentives for the research and development of antibiotics.</p> <p>At the Tokyo Meeting of Health Ministers on Antimicrobial Resistance in April 2016, “Asia-Pacific One Health Initiative on AMR (ASPIRE)” was declared to jointly identify and address the challenges posed by AMR in the Asia Pacific region. At the Tokyo AMR One Health conference in February 2021, working groups were established that represent the four pillars of ASPIRE: 1) surveillance system and laboratory network; 2) health-care management; 3) antimicrobial access and regulation; and 4) research and development.</p> <p>Japan has a special pricing scheme of drugs to promote innovation. Started in 2010 and applied to special premium to drugs that demonstrate a high degree of benefit relative to other drugs, in 2020 its scope was extended to cover antimicrobials to stimulate innovation.</p>
<p><b>UK</b></p> <p><a href="#">Link</a></p>	<p>The UK’s 20-year vision for AMR aims to drive innovation that will support the development of new antimicrobials and support sustainable supply and access to products in the future. This is supported by the UK’s AMR National Action Plan for 2019-24, issued in January 2019, which includes a key commitment ‘develop and test new models for national purchasing arrangements that de-link the price paid for antimicrobials from the volumes sold, using a NICE led healthcare technology assessment to support robust stewardship’.</p> <p>The idea of the payment approach is to move away from paying for individual packs of antimicrobials and, instead, make an annual payment based on the health benefits to patients and the wider value to the NHS.</p> <p>In December 2020, NHS England and Improvement, in collaboration with the National Institute for Health and Care Excellence (NICE) and the Department of Health and Social Care (DHSC), selected the first antimicrobial drugs to be purchased via the UK’s innovative ‘subscription-type’ payment model.</p> <p>Following a rigorous process with expert clinical input, two treatments, Cefiderocol (Fetcroja) manufactured by Shionogi, and ceftazidime with avibactam (Zavicefta)</p>

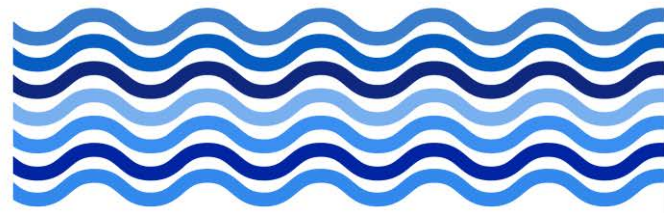
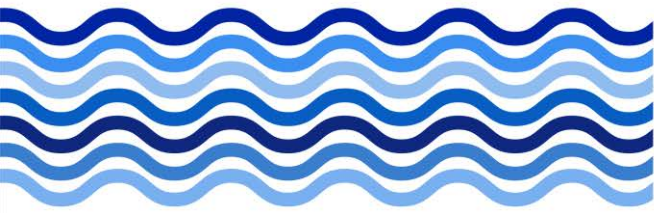


	<p>manufactured by Pfizer, were selected to move to an innovative health technology evaluation process.</p> <p>The evaluation process for the two products is in progress by NICE, applying a framework for the evaluation of antimicrobials developed for this project. A special NICE Advisory Committee has been established for this project and the Committee meetings, where the patient and public health benefits will be considered and captured, are scheduled in January and February 2022. The guidance from these meetings will be used by NHS England in final commercial discussions with the companies. It is anticipated that these products will be made available to patients via a subscription-based payment model from Spring 2022.</p>
<p><b>US</b></p> <p><a href="#">Link</a></p> <p><a href="#">Link</a></p>	<p>Prioritising incentives and other action, including market entry, to address the antibiotic and antifungal R&amp;D pipeline is a longstanding priority of the U.S. Department of Health and Human Services (HHS). Efforts are covered in the US Government’s first (2015-2020) and second AMR National Action Plan (NAP) 2020-2025. Both NAPs direct federal agencies to accelerate the US response to antibiotic resistance by presenting coordinated, strategic actions to improve the health and well-being of all Americans across the One Health spectrum. The 2015-2020 NAP directed federal agencies to establish an accelerator for the pipeline of antibiotics, and other therapeutics, diagnostics, and vaccines, resulting in CARB-X.</p> <p>Two of the 2020-5 NAP’s five strategic goals are directly related to supporting antibiotic development: Goal 4 – accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines; and Goal 5 – improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control and antibiotic research and development.</p> <p>In addition to early R&amp;D support by CARB-X, HHS’s Office of the Assistant Secretary for Preparedness and Response’s Biomedical Advanced Research and Development Authority has dedicated late-stage clinical development support to promote antibiotic research and development.</p> <p>In addition to actions under the NAP, the United States has implemented additional steps including:</p> <ul style="list-style-type: none"> <li>• Generating Antibiotic Incentives Now Act (GAIN Act) of 2012, which provides benefits to manufacturers of Qualified Infectious Disease Products (QIDPs) including 5 years of additional nonpatent exclusivity.</li> <li>• The 21st Century Cures Act which took steps to streamline clinical trials for antimicrobials that treat serious or life-threatening infections for which there are unmet medical needs.</li> <li>• Centers for Medicare &amp; Medicaid Services (CMS) issued a final rule expanding the pathway for certain new antibiotics, with a QIDP designation, to receive an add-on payment for the use of the appropriate antibiotic. CMS also issued a rule requiring all acute-care hospitals that participate in Medicare or Medicaid to develop and implement an antibiotic stewardship program as part of their infection control efforts showing the benefit of linking stewardship requirements to efforts to address the R&amp;D pipeline.</li> </ul>



Additionally, AMR-related legislation known as the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act was introduced in the U.S. Congress. This Act aims to address shortcomings in the antibiotic development market and increase public health preparedness by keeping novel antibiotics on the market and improving appropriate use across the health care system. While current contracts between the government and drug makers base payment on volume, the PASTEUR Act would establish a subscription-style model which would offer antibiotic developers an upfront payment in exchange for access to their antibiotics, encouraging innovation and ensuring the U.S. health care system is prepared to treat antibiotic resistant infections.

In the event that the proposed Act is not enacted into law, HHS has begun the process required to establish a novel payment mechanism with the HHS FY23 proposed legislative program.



# G7 Shared Principles for the Valuation of Antimicrobial Therapeutics

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*“We recognise the need to value antimicrobials in a way which takes account of the positive impacts they bring to healthcare systems and wider society, in addition to benefiting individual patients... We will develop a set of shared valuation principles, based on public health needs and taking into account the WHO priority pathogen list, that could subsequently be applied to new and existing antimicrobial products by G7 countries on a voluntary basis.”*

– G7 Health Ministers’ Meeting Communique, Oxford, 4 June 2021

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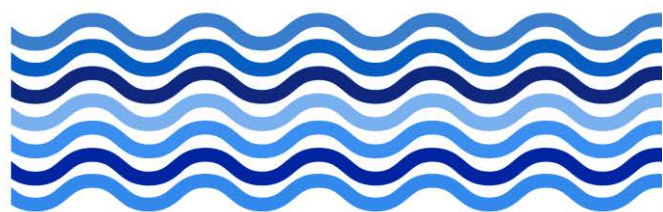
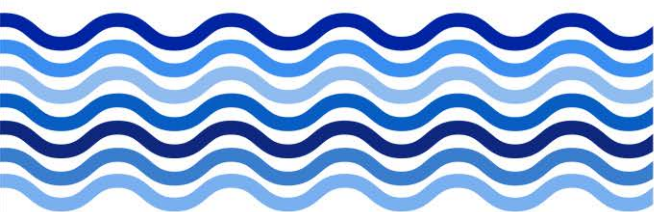
## Preamble

- i. Antimicrobial therapeutics (‘antimicrobials’) are key infrastructure for functioning health systems and societies within the G7 and around the world, conferring benefits far beyond those received by any individual patient. In our Oxford Declaration of June 2021, we, the Health Ministers of the G7, agreed that acknowledging this wider importance of antimicrobials could help to incentivise innovation, stewardship, and access.
- ii. To help secure a sustainable supply of high-quality, effective, and clinically necessary new and existing antimicrobials for human medicine, we agree that national and/or regional plans for the valuation, procurement, payment and/or reimbursement of antimicrobials may reflect these wider benefits when deemed relevant and appropriate by national authorities, and according to the rules of each country in matter of pricing.

## Principles in Practice

- iii. The shared valuation principles might be applied to any existing or future antimicrobial market incentive so as to promote a level of global coherence - and therefore overall global impact - across different national and/or regional plans.
- iv. We recognise that our healthcare systems, contexts and needs are different, with the principles having different relevance, applicability or feasibility for each of us, and, as such, are non-binding. We therefore will use the shared valuation principles to guide our efforts, where possible and relevant, and will continue to share best practice.





## G7 Shared Valuation Principles

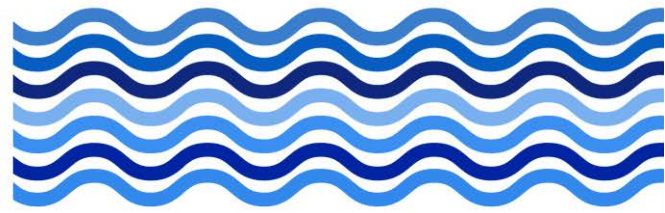
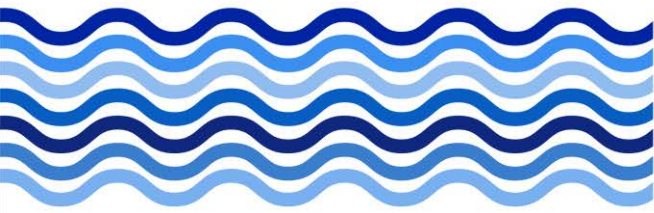
1. G7 members may - through valuation, procurement, payment and/or reimbursement assessments they deem appropriate according to national context - seek to **recognise the particular value of antimicrobials that respond demonstrably to an identified public health need**, as defined by our national health authorities, relevant domestic lists, and guided by the World Health Organization's priority pathogen list. Where antimicrobials do meet such an identified public health need, G7 members may, for example, consider using the principles contained in this document as part of their valuation processes.
2. Examples of **scientific attributes** attracting additional value may include, but are not limited to, one or more of the following examples of ways considered by some G7 members that antimicrobials benefit health systems<sup>1</sup>:
  - a. Antimicrobials are key **enablers** of medical and surgical therapies and procedures, which would otherwise be prohibitively risky (for example, chemotherapy, hip replacements, organ transplants, heart bypasses, vascular surgery and others).
  - b. Effective antimicrobials may **reduce the risk of transmission** of resistant pathogens and reduce the burden of infection on patients and healthcare settings delivering care.
  - c. Having access to a **diverse** range of antimicrobials to address the same pathogen reduces reliance on one antimicrobial and the risk of resistance emerging.
  - d. Unexpected outbreaks of resistant pathogens can be very damaging to health systems and countries, therefore having effective antimicrobials in reserve in case of a catastrophic increase in a particular resistant pathogen as an **insurance** policy against this potential issue is of benefit.
  - e. **Narrow-spectrum** antimicrobials that would spare the use of broad-spectrum antimicrobials OR broad-spectrum antimicrobials that are accompanied by science-based treatment guidelines and robust stewardship programmes.
3. Assessments by G7 members will seek to place value on such antimicrobials meeting an identified public health need when they are **accompanied by robust stewardship and access plans**<sup>2</sup> that maximise the benefits of the product to human health and minimise the risk of resistance emerging.

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<sup>1</sup> Rothery, C., Woods, B., Schmitt, L., Claxton, K., Palmer, S. and Sculpher, M., 2018. Framework for Value Assessment of New Antimicrobials. [online] pp.27-29. Available at: [www.eepru.org.uk/wp-content/uploads/2017/11/eepru-report-amr-oct-2018-059.pdf](http://www.eepru.org.uk/wp-content/uploads/2017/11/eepru-report-amr-oct-2018-059.pdf) [Accessed 20 August 2021].

<sup>2</sup> For example, guidance to support product developers ensure responsible stewardship and appropriate access in low- and middle-income countries (LMICs) can be found through the Stewardship & Access Plan (SAP) Development Guide. 2021 Available at: [www.carb-x.org/about/stewardship-and-access](http://www.carb-x.org/about/stewardship-and-access) [Accessed 20 August 2021]





4. G7 members might consider when deemed relevant the importance of **delinking reimbursement to pharmaceutical companies from volume of antimicrobial sales**, for antimicrobials meeting an identified public health need that are at high risk of market failure due to anticipated low levels of antimicrobial usage<sup>3</sup>;
5. G7 members may also acknowledge the importance of **incentivising or optimising access to certain antimicrobials that are no longer marketed but that are still clinically useful** (the so-called “forgotten antimicrobials”), where they meet an identified public health need and are appropriately stewarded.
6. When pursuing measures to encourage more sustainable antimicrobial drug development, G7 members may seek, where possible and relevant to the policy, to consider some or all of the following **guiding principles that could be required of incentive beneficiaries**:
  - a. publishing of global access and stewardship plans;
  - b. promotion of product affordability and improvement in access, particularly for low- and middle-income markets;
  - c. maintenance of high manufacturing standards<sup>4</sup>, including measures to reduce the risk of sub-standard and falsified medicines entering into circulation;
  - d. adherence to high environmental standards<sup>5</sup>, including the proper management of manufacturing waste and pollutants;
  - e. maintenance of robust end-to-end supply chains and mitigation plans for supply disruption;
  - f. reinforcement of appropriate promotional behaviours, including removing sales incentives;
  - g. consideration of the other commitments made by the AMR Industry Alliance in its 2016 Davos Declaration.

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<sup>3</sup> Rex, J. and Outterson, K., 2016. Antibiotic Reimbursement in a Model Delinked from Sales: A Benchmark-Based Worldwide Approach. SSRN Electronic Journal, 16, pp.500-05.

<sup>4</sup> As defined and considered acceptable by the national competent authority, in lieu of any agreed international standards.

<sup>5</sup> As defined and considered acceptable by the national competent authority, in lieu of any agreed international standards.