

G7 Shared Principles for the Valuation of Antimicrobial Therapeutics

“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.”

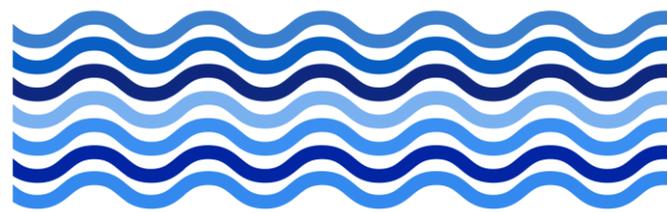
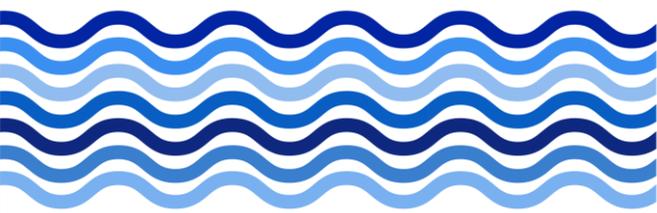
– G7 Health Ministers’ Meeting Communique, Oxford, 4 June 2021

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.

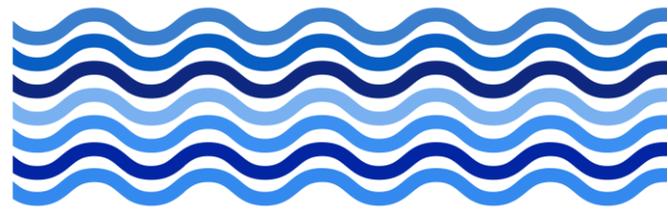
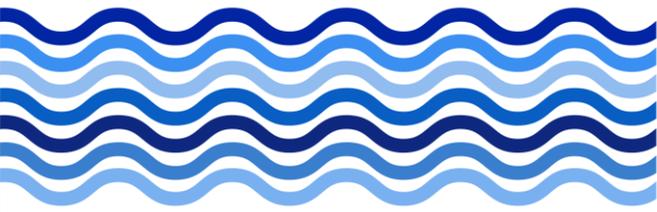


G7 Shared Valuation Principles

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 systems¹:
 - 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**² that maximise the benefits of the product to human health and minimise the risk of resistance emerging.

¹ 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 [Accessed 20 August 2021].

² 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 [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 usage³;
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 standards⁴, including measures to reduce the risk of sub-standard and falsified medicines entering into circulation;
 - d. adherence to high environmental standards⁵, 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.

³ 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.

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

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