



Global Antibiotic Research and Development Partnership (GARDP): World Health Assembly Briefing Note (2021)

The Global Antibiotic Research and Development Partnership (GARDP) is a not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. GARDP was created by the World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi) in 2016 to ensure that everyone who needs antibiotics receives effective and affordable treatment, no matter where they live. We aim to develop five new treatments by 2025 to fight drug-resistant infections, focusing on sexually transmitted infections, sepsis in newborns and infections in hospitalized adults and children. GARDP is funded by the governments of Germany, Japan, Luxembourg, Monaco, Netherlands, South Africa, Switzerland, United Kingdom, as well as private foundations. www.gardp.org

In 2020, GARDP's key accomplishments included completion of a landmark observational study on neonatal sepsis, signing the first agreement under our Serious Bacterial Infections programme to bring a potentially new treatment to market, and continued patient enrolment, including a new site in The Netherlands, as part of our phase 3 trial of a new treatment for gonorrhoea. As part of our scientific affairs activities, we organized 17 REVIVE webinars and launched a new online Antimicrobial Encyclopaedia. On the discovery and exploratory research front, we screened over 24,000 compounds from five different partners, and Daiichi Sankyo joined the GARDP-led Antimicrobial Resistance (AMR) Screening Consortium alongside Eisai and Takeda.

In advance of the 74th annual World Health Assembly, GARDP would like to offer its perspectives on the following topics.

- Findings of the Independent Panel on Pandemic Preparedness and Response (IPPR)
- Agenda Item 13.5: Antimicrobial Resistance
- Agenda Item 13.4: Global strategy and plan of action on public health, innovation and intellectual property
- Agenda Item 16: Committing to implementation of the Global Strategy for Women's, Children's and Adolescents' Health (2016–2030)
- Agenda Item 26.4: The global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections, for the period 2016–2021.

Pandemic preparedness and response

GARDP welcomes the report of the Independent Panel for Pandemic Preparedness and Response (IPPR). We agree with the recommendations of the Independent Panel to improve the international response to the COVID-19 pandemic, including the importance of all Member States applying non-pharmaceutical measures systematically and rigorously, measures to improve both supply and equitable access to COVID-19 medical countermeasures between and within countries, and the importance of WHO developing a roadmap with a strategy to end the COVID-19 pandemic.

GARDP also supports measures to improve the collective ability of governments, international agencies, civil society, and the private sector to improve pandemic preparedness and response over the long term. We agree with the need for comprehensive reforms to governance, systematic financing (including new international financing) to prepare for future pandemic threats, improved surveillance to detect and accelerate response to pandemic threats, and measures to improve the development of and equitable access to medical countermeasures and other essential supplies.

We believe such recommendations not only apply to future viral pandemics but should be applied to antimicrobial resistance (AMR), a silent pandemic of drug-resistant infections related to currently known pathogens. Considering the health, economic, and social consequences of AMR today and the projected impact over the ensuing decades, governments should respond with the urgency that AMR deserves, including appropriate policies, systems, and countermeasures to alleviate human suffering today and to forestall far more serious consequences in the future. Furthermore, while there is limited data on bacterial co-infections and secondary infections in people with COVID-19, future viral pandemics could carry a more

significant risk of hospitalisation and secondary bacterial infections, and therefore health systems will require timely access to both antibiotics to treat these infections and other therapeutics and diagnostics.

We urge Member States to make the necessary investments to address AMR now to blunt any negative consequences over the ensuing decades. While it may not have been possible to predict the emergence of a novel coronavirus in late 2019, the causes and consequences of AMR are well-known, as are the investments and strategies that can ensure governments can proactively respond.

Agenda Item 13.5: Antimicrobial Resistance

GARDP welcomes the Secretariat report for on-going activities to implement the WHO Global Action Plan (GAP) on AMR, including the publication of target product profiles (TPPs) to guide the development of antibacterial agents to treat enteric fever, gonorrhoea, neonatal sepsis, and urinary tract infections. New investments are needed to both address the on-going burden and anticipated impacts of AMR over the ensuing decades, much as governments must broadly prepare for future pandemic risks. The latest review of antibacterial agents in clinical and preclinical development is an urgent reminder that Member States should prioritize and invest in the development of desperately needed antibacterial treatments. As WHO noted in its latest report, the 43 antibiotics currently in clinical development are insufficient to address the problem of drug resistance.

GARDP recommends that governments invest in the discovery and development of novel antibacterials across all stages of discovery and development.

GARDP also notes that many countries still lack adequate access to existing antibacterial treatments due to challenges with production, demand forecasting, registration, supply chain, and appropriate diagnostic and laboratory capacity in health systems. Access to diagnostics, treatments and vaccines should be a cornerstone of national and global efforts to address AMR.

GARDP recommends that new and existing mechanisms should be developed and funded to accelerate and secure equitable and affordable access to existing and new treatments for drug-resistant infections.

Agenda Item 13.4: Global strategy and plan of action on public health, innovation and intellectual property

GARDP recognises the importance of the Global Strategy and plan of action on public health, innovation and intellectual property (GSPoA), especially in light of the challenges to innovation and access during the COVID-19 pandemic and to address antimicrobial resistance. **GARDP supports efforts of WHO and Member States (and partners) to promote and strengthen local production of quality medicines and other health technologies, including diagnostics, medicines, and vaccines to address antimicrobial resistance.**

Timely registration of antibiotics continues to be a major impediment to ensuring access to quality antibiotics for people in need. **GARDP supports investments in WHO (as well as appropriate regional and national bodies) to strengthen and improve the capacity of national and regional regulatory functions and systems. This includes support for phase IV post-marketing trials.**

Agenda Item 16: Committing to implementation of the Global Strategy for Women's, Children's and Adolescents' Health (2016–2030)

GARDP notes the importance of investing in measures to improve access to antibiotics that can reduce neonatal and under five mortality, including investments to address a chronic lack of research and development to meet their needs. At present, infectious diseases, including pneumonia and sepsis, are a leading cause of death and disability in children under the age of five. Children, and especially newborn babies, are among the most vulnerable to drug-resistant infections and bear the brunt of a heavy burden of illness and death.

In response, GARDP has established a Children's Antibiotics Programme as one of its main pillars of work, including working with the public and private sector to address the need for new antibiotics for children. This includes the development of new antibiotics as well as providing evidence to support the use of existing

antibiotics (used in adults) for babies and children. GARDP has completed one of the largest observational studies on neonatal sepsis, collecting clinical information from more than 3,000 newborns in 19 hospitals in 11 countries across Europe, Asia, Latin America and Africa. Outcomes such as antibiotic use, duration of treatment and mortality rates have been recorded and analysed and will help build the evidence base to evaluate future interventions that could be used to treat neonatal sepsis, as well as to update WHO guidelines for treatment of sepsis in neonates. GARDP has also joined the WHO-led Global Accelerator for Pediatric Formulations Network (GAP-f), which seeks to promote innovation and access to quality, safe, efficacious and affordable medicines for children.

GARDP recommends that Member States call for increased investment in the development of new treatments to reduce under-five mortality, improved generation of evidence to improve treatment guidelines, and the necessary investments to ensure health systems can treat drug-resistant infections in a timely fashion with skilled care and appropriate medical technologies.

Agenda Item 26.4: The global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections, for the period 2016–2021.

GARDP looks forward to the development of new global health sector strategies for HIV, viral hepatitis and sexually transmitted infections (STIs) for the period of 2022 – 2030. We take note of the Secretariat report to the 148th Session of the Executive Board on STIs, which stated the growing threat of drug resistant infections, including that ‘thirty-two of the 64 countries monitoring gonorrhoea antimicrobial resistance reported decreased susceptibility or resistance to extended-spectrum cephalosporins, last-line treatment in *Neisseria gonorrhoeae*.’

Recognizing the growing concern with drug-resistant infections, GARDP has established a Sexually Transmitted Infections Programme, with a first focus on gonorrhoeae. There are 87 million new infections from gonorrhoea every year. Untreated gonorrhoea can have serious and permanent consequences including infertility in men and women, pelvic inflammatory disease and life-threatening ectopic pregnancy. Gonorrhoea also increases the risk of HIV transmission.

GARDP is developing, in partnership with Entasis Therapeutics, zoliflodacin, a novel, first-in-class antibiotic active against resistant strains of gonorrhoea. Zoliflodacin has been designed as an oral treatment option, which has the potential for significant benefits compared to the current standard of care of intramuscular injections.

GARDP recommends that Member States ensure that a new health sector strategy for sexually transmitted infections includes increased investments in surveillance, development of new tests and treatments to address current and future needs, and the appropriate introduction and optimal use of novel and existing therapies for which robust strategies for appropriate use and stewardship will be needed.