



Open letter from the biopharmaceutical industry to G20 Ministers in support of the advancement of the G20 Health Agenda

9 APRIL 2024

Dear G20 Health Ministers,

With ongoing negotiations in Geneva and less than six years left to achieve the Sustainable Development Goals (SDGs), the G20 forum serves as a key platform to promote constructive, coordinated, and collaborative solutions. Toward the Presidency's goal of "building resilient health systems," all global health stakeholders – including governments, civil society, academia, and the private sector – must work together on the collective imperative to "leave no one behind."

The biopharmaceutical industry is committed to work in collaboration with the Brazilian Presidency and the G20 to advance the priorities of the G20 Health Working Group (HWG). In support of the HWG's efforts to drive global health progress and as a key solutions partner, we would like to share our industry's experience and expertise to advance the G20 Health Agenda.

Biopharmaceutical industry support for G20 health priorities

The biopharmaceutical industry significantly contributes in many ways towards G20 HWG priorities, including in the areas of Immunization, Pandemic Preparedness and Response (PPR) (including equitable access), Anti-Microbial Resistance (AMR), Neglected Tropical Diseases (NTDs), Climate Change, and Women's Health. In the below sections, we set out our current engagement and 11 key proposals that would complement the G20 health agenda.

 Across all mentioned areas, we call on the G20 to preserve health innovation enablers¹ (e.g. intellectual property framework) in policies and programs in G20 countries and worldwide. These enablers fundamentally underpin legal security to enhance the potential for increased trade, investments, and voluntary collaborations², including technology transfer³ in G20 countries. Innovation is a critical driver for healthy and vibrant economies and societies, and it is key to ensure sustainable government funding and financing for innovation moving forward.

Strengthening immunization policies

In 2024, we celebrate the 50th anniversary of the Essential Programme of Immunization, highlighting its success in reducing child mortality by 80% and saving over a billion lives. This achievement reflects significant milestones, including the eradication of smallpox and the development of vaccines for diseases like measles, mumps, rubella, and hepatitis, among others. The renewed ambition on polio and introduction of vaccines against HPV and malaria in recent years continues this legacy of innovation and public health improvement.

¹ <u>https://www.ifpma.org/areas-of-work/fostering-innovation/</u>

² <u>https://www.ifpma.org/events/how-different-partnership-models-supported-the-response-against-covid-19/</u>

³ https://www.ifpma.org/publications/technology-transfer-a-collaborative-approach-to-improve-global-health/

The COVID-19 pandemic has underscored the critical impact of infectious diseases on healthcare systems and the global economy, highlighting the importance of vaccines in preventing diseases across all ages. Current challenges, such as the resurgence of measles and the "tripledemic" of COVID-19, influenza, and RSV, emphasize the ongoing battle against vaccine-preventable diseases amidst demographic shifts, noncommunicable diseases, AMR, climate change, and growing rates of vaccine hesitancy, disinformation and increasing mistrust in science.

To address these challenges, a life-course approach to vaccination programs, with expansion into adulthood, is a cost-effective public health intervention, crucial for promoting health and well-being, reducing disease burden, and enhancing economic resilience.^{4,5} The biopharmaceutical industry's innovation in developing 260 vaccine candidates across all diseases^{6,7} demonstrates its long-standing commitment to global health. Governments are urged to prioritize vaccination throughout life, recognizing its socioeconomic benefits and investing in comprehensive immunization programs to serve as primary health care (PHC) and universal health coverage (UHC) foundation and prepare for future health challenges, aligning with the WHO's Immunization Agenda 2030 and the UN SDGs.

• We call on G20 to adopt a prevention-first strategy, recognize the broader socioeconomic value of adult immunization programs and enable adequate and sustainable budget allocations for life-course immunization inclusion and implementation. These implementation efforts should include building acceptance and demand, garnering trust and public confidence in the safety and efficacy of vaccination, enhancing infrastructures to increase access while improving health system resilience and community protection, recovery from the pandemic, and to help prepare for future health emergencies.

Preparing and responding to future pandemics

In March 2024, the global biopharmaceutical industry developed a set of <u>commitments for</u> <u>equitable access</u> to medical countermeasures in future pandemics. The statement has been signed by a broad range of trade associations representing the industry on a global level (<u>IFPMA</u> and the Developing Countries Vaccine Manufacturers Network, <u>DCVMN</u>), Europe (<u>EFPIA</u>), the United States (<u>PhRMA</u>), and Japan (<u>JPMA</u>), as well as the Biotechnology Innovation Organization (<u>BIO</u>). The statement supports the creation of a broad multistakeholder Partnership for Equitable Access and outlines a menu of commitments companies can make between pandemics – as well as when a pandemic hits – to help deliver equitable access to medical countermeasures on the basis of public health risks, needs, and demands, while preserving critical enablers for health innovation.

These commitments build on the July 2022 <u>Berlin Declaration</u>, proposing a framework to enhance the delivery of vaccines and treatments to priority populations during future pandemics. This initiative aims to reserve production allocations for these populations to improve equitable access, contingent on the strengthening of national health systems, funding mechanisms, and their capacity to utilize these resources effectively. The declaration underscores the need for immediate financing for pandemic response, the removal of export restrictions, and global cooperation to prevent trade restrictions on pandemic-related health products.

⁴ <u>https://www.ohe.org/wp-content/uploads/2023/12/Socio-Economic-Value-of-Adult-Vaccination-WS1-White-Paper Final Proofed 30.11.2023 clean-1.pdf</u>

⁵ 2023-FIN Business at OECD (BIAC) Health Forum Synthesis Report.pdf (hubspotusercontent-eu1.net)

⁶ https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/medicines-in-development-for-vaccines-2020.pdf

⁷ <u>https://www.vaccineseurope.eu/wp-content/uploads/2023/11/VaccinesEurope-PipelineReview2023.pdf</u>

For effective pandemic response, countries must have the necessary technical and health infrastructure, human resources, financial capacity, and political will to test, vaccinate, and care for their populations. It is crucial to build resilient health systems capable of quickly distributing and absorbing vaccines and medicines, while also maintaining ongoing healthcare services. Preparedness involves establishing robust regulatory systems with effective approval pathways and surveillance mechanisms to ensure continuity in clinical research, manufacturing, and medical supply.

Engaging G20 leaders and leveraging platforms like ANVISA's role in ICH and ICMRA is essential for building regulatory systems that adhere to international standards and support regulatory reliance and agility. Countries should continue to develop regulatory frameworks for emergency use authorizations to ensure rapid deployment of pandemic products, highlighting the importance of global collaboration in health crisis management.

- We encourage G20 governments, via their respective national regulatory authorities, to intensify efforts in promoting convergence and harmonization of regulatory requirements as national regulatory authorities continue to independently develop and mature globally. Leveraging G20 engagement, including ANVISA's leadership roles in ICH and ICMRA, is key to ensuring the implementation of internationally recognized regulatory standards, and the use of regulatory reliance and agilities.
- We call on G20 governments to preserve the innovation ecosystem that enabled the development of several countermeasures, refrain from trade restrictions, and allow the free movement of pandemic medical countermeasures, manufacturing inputs, raw materials, and personnel.
- We call on the G20 leadership to help gather a variety of stakeholders to work together with industry to help operationalize the <u>Partnership for Equitable Access</u> and the <u>Berlin Declaration</u> and shape a future where everyone is better protected from the threat of pandemics.

Fighting AMR

While AMR has been on the G20 agenda for many years, it remains a critical challenge. Five million deaths annually are associated with AMR and the WHO has labelled it as one of the top <u>10 global health threats</u>. Ahead of the 2024 UN High-Level Meeting on AMR, there is a pressing need for a concerted global effort to establish an ambitious agenda to address this rising threat. The <u>AMR Industry Alliance</u> plays a pivotal role in this fight, driving and measuring life-sciences industry progress in the fight against AMR across different areas, promoting collaboration, and pioneering initiatives like the <u>Antibiotic Manufacturing Standard</u> that mitigates the environmental dimension of AMR.

To counteract the declining investment in antibiotic research and development (R&D) as a result of unique market challenges, the creation of an ecosystem that appropriately values the importance of antibiotic innovations to societies is essential. The <u>AMR Action Fund</u>, launched with a \$1 billion commitment from over 20 biopharmaceutical companies and non-industry investors, aims to deliver 2 to 4 new antibiotics by 2030. However, broader policy reforms are needed to support renewed R&D investment and sustainable access to these critical medicines.

• We call on G20 governments to foster a viable antibiotic R&D ecosystem, including supporting pull incentives that enable the R&D investment needed to deliver new antibiotics, ensuring sustainable access to antibiotics while encouraging appropriate use, and advancing reimbursement reforms that are decoupled from volume of sales

and capture the value that antibiotics bring to societies beyond treating individual infections.

- We call on G20 governments to leverage the role of vaccines in addressing AMR through inclusion of vaccination as an intervention in AMR National Action Plans and enhance data collection to inform effectiveness of vaccines in reducing antibiotic use and combating AMR.
- We call on G20 governments to support broad adoption of the <u>BSI Independent</u> <u>Certification Scheme</u> of the <u>Antibiotic Manufacturing Standard</u>, encouraging certification through third-party evaluation and promoting environmental stewardship in antibiotic production and procurement.

Addressing neglected tropical diseases and climate change

The biopharmaceutical industry is dedicated to supporting the WHO 2030 roadmap for NTDs through donations of medicines and diagnostics, supplemented by funding from donors and governments. This commitment extends to investing in R&D for new treatments and ensuring their effective distribution, crucial for the control, elimination, and eradication of NTDs. By collaborating with global and local partners, the industry aims to co-create sustainable health systems that support countries in transitioning toward self-sufficiency and achieving long-term health impacts. The intersection of climate change and global health, particularly its impact on NTDs and infectious diseases at large, demands urgent attention and requires a coordinated effort from all sectors.

The industry is aligned with the Brazilian government's efforts to prioritize climate change globally, acknowledging the crucial connection between health and climate change, notably at COP28 through the inaugural Declaration on Climate and Health and a dedicated Health Day. This alignment underlines the sector's commitment to environmental responsibility, with pharmaceutical companies setting ambitious net-zero goals to reduce carbon emissions in their operations and supply chains. The industry's investment in research for new health solutions reflects a broader commitment to addressing the health impacts of climate change.

- We call on G20 governments to integrate their experiences from NTD initiatives into broader health and climate strategies, ensuring that the dual challenges of NTDs and climate change are addressed comprehensively. This approach should include assessing and filling funding gaps for NTDs to maintain treatment production and delivery, emphasizing the need for streamlined funding across health threats like malaria and lymphatic filariasis, which share common vectors.
- We call on G20 governments to actively foster sustainable partnerships with research institutions and the biopharmaceutical industry, which can accelerate R&D and distribution of treatments for neglected diseases. By leveraging each other's strengths and resources, we can amplify our impact so that no one is left behind in the fight against NTDs.

Women's health

The biopharmaceutical industry has made significant strides in improving women's health and fosters their participation in the workforce. Through the development of innovative medications and treatments specifically tailored to address women's healthcare needs (e.g. contraceptives, hormone replacement therapies, and treatments for conditions like osteoporosis, migraine, and breast cancer), women have gained greater autonomy over their health, thereby facilitating their pursuit of career opportunities. Women's health treatments have a role in reducing absenteeism and enhancing productivity in the workplace. The biopharmaceutical industry not

only contributes to women's well-being but also fosters women's economic empowerment and a more inclusive workforce.

• We call on G20 governments to strengthen their support and initiatives aimed at women, by eliminating access barriers and promoting reimbursement policies for innovative treatments addressing women's health.

Conclusion

The <u>G20's health commitments</u> are multi-pronged, complex and intersecting challenges where collective action from the broader global health community is essential, including working in partnership with the private sector. Through our robust portfolio of collaborative initiatives, we take this opportunity to firmly highlight our industry's value to advance the G20 health agenda. We reiterate our commitments to constructively engage as a solutions partner with the G20 HWG.