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B7 POLICY RECOMMENDATIONS 2022

Reaffirming global commitment to health
across public and private sectors

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B7 Health Policy Working Group

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Introduction

The war in the Ukraine has brought a humanitarian crisis to Ukraine and to the heart of Europe. The G7 has thus far showed that it stands strong and aligned, also with economic sanctions. Industry fully supports these measures and welcomes all aligned actions among G7 member states and beyond. The B7 stands for peace and our priority will be to ensure that patients in Ukraine and Russia, as well as refugees arriving in EU member states and patients in other territories impacted by this war, have access to basic needs such as food, shelter and healthcare.

Effective pandemic and crisis prevention, preparedness, and responses must be planned and coordinated internationally. This requires sustained political leadership and will, global coordination, regulatory alignment, public-private partnerships, solidarity, and commensurate up-front and on-going financing. Implementation of the International Health Regulations, cooperation among WHO member states, and coordination across all sectors are therefore crucial.

Alongside the G20 and OECD, the G7 can be an additional forum for agenda-setting, provide political support and funding for pandemic response coordination, and address health, trade and financial issues. The B7 stands ready to support reaffirming the global commitment to health.

Key Recommendations

1. Strengthen health systems and ensure investments in health

In order to make health systems more resilient when facing and responding to future health threats, the G7 should ensure strategic investments into health. These investments should allow for predictable and long-term health financing as the foundation for strong health systems, which includes prevention and early detection, infrastructure, human resources, a reliable supply of medicines and technologies, and evidence-based policies.

2. Ensure equitable access to critical vaccines, therapeutics, and diagnostics globally

As part of future pandemic responses, the key drivers of access to medical products such as supply chains, open markets, healthcare delivery capabilities, and efficient regulatory approval processes should be strengthened. Strong multilateral cooperation and collaboration, which includes public-private partnerships, will support successful outcomes.

3. Promote innovation and improve the digitalization of health

We must continue to invest into the digitalization of healthcare by creating an interoperable environment where high-quality data can be shared and used to improve healthcare for patients and to drive innovation and develop new health products. Simultaneously, we must protect intellectual property to enable innovators to finance on-going investments in R&D. The G7 should ensure that IP-related incentives for innovation and knowledge sharing are maintained or strengthened.

In addition, the growing threat of an antimicrobial resistance (AMR) "silent pandemic" for public health worldwide is not only exacerbating the COVID-19 pandemic but will become even more alarming after the current global health crisis. Climate change is already affecting health in many ways.

1. Build Resilient and Sustainable Health Systems

1.1 Pandemic and Crisis Prevention, Preparedness, and Responses

Strengthen Health Systems

- The pandemic has highlighted the importance of resilient health systems. The state of a country's health infrastructure can have a major impact on health security worldwide.
- The G7 must ensure that health systems are sufficiently financed and well equipped to manage the backlog of postponed elective procedures as well as prepared for new variants of the current virus and future health crises, including antimicrobial resistance. Crucially, the G7 must ensure that these services are accessible to everyone, while working towards universal healthcare coverage (UHC) within the context of the United Nations Sustainable Development Goals (SDGs).
- The financing of health systems includes investment in health and health industries as first and foremost an investment in our societies' health, but also a relevant economic tool that secures jobs and growth specifically through innovative treatments and solutions.
- Prevention activities will be key to enable our healthcare systems to face long-term challenges – epidemic risks, ageing population, chronic diseases, antibiotic resistance – that threaten the sustainability of our healthcare systems.
- The G7 should advance outcome-based procurement processes, which can help to establish sustainability within healthcare facilities by considering life-cycle and long-term maintenance costs.

Advance Development Cooperation and Partnerships in Health

- A key element of every resilient health system is UHC, which ensures that all individuals and communities have access to high-quality essential health services, medicines, and health technologies without financial hardship. Achieving UHC requires a collective effort, especially in low- and middle-income countries. The G7 should promote international and cross-sectoral cooperation on global health topics, including development cooperation.
- The G7 should maintain existing incentives and consider additional options to enable the private sector to engage in strengthening health systems, notably by fostering projects carried out in collaboration between the public and

private sectors and promote international and cross-sectoral cooperation in global health topics, including development cooperation.

Financing for Pandemic Preparedness and R&D

- Pandemic preparedness requires risk anticipation and assessment, and strategic foresight skills.
- There has been a repeated failure to prioritize investments in pandemic preparedness at national, regional, and global levels. Because pandemics have often been viewed as distant or unlikely threats, funding for prevention and preparedness has not matched actual needs and risks. Investments in preparedness are a fraction of the costs of responses to pandemics.
- Increased national and international funding for pandemic preparedness and responses are needed. The G7 should ensure that its members build and maintain core capacities, infrastructure, and systems for pandemic preparedness and rapid responses.
- Funding to support countries in bolstering core capabilities, such as disease surveillance and laboratory capacity, is vital to ensure preparedness. G7 governments should guarantee sustained, predictable, and long-term funding to support proactive R&D to fuel science and platform technologies that can be rapidly mobilized in an emergency.

Enhance Education and Training

- Health workers have been on the front line of the COVID-19 outbreak. Occupational hazards include exposure to COVID-19 and other pathogens, as well as a heavy workload. Medical technologies can reduce or even prevent such hazards. Hence, the G7 should promote investments in state-of-the-art equipment to better protect occupational health and safety of health workers and support development and training, which will also address staff shortages prevailing in many G7 countries. In addition, well paid, well trained, well equipped, and digitally connected community health workers (CHWs) are essential as the first line of defense to detect and report early signs of an outbreak and help contain it at its source.
- In addition to traditional educational pathways, digital approaches can significantly reduce the global shortage of qualified doctors, nurses, and healthcare workers. Digital solutions such as eLearning and innovative online platforms can also improve access to healthcare. The G7 should fund and support innovative digital approaches to ensure access to high-quality medical, nursing, and healthcare education. A reduction of barriers to the recognition of online learning platforms as part of medical and wider healthcare workforce education and training efforts is needed to ensure scalability, cost-effectiveness, modernization and sustainability of health systems.
- To strengthen sustainable health systems, it will be crucial that governments provide support through medium and long-term investments into capacity-building in order to ensure a critical mass of health workforce at all levels, and more importantly into creating conducive environments for health workers that avoids brain drain and specifically encourages service delivery for the most vulnerable populations.

Climate Change and Health

- Climate change is impacting the conditions in which people are born, grow, work, live, and age. It therefore also impacts the social determinants of health. Furthermore, climate change threatens the achievement of equitable population-wide health and wellness, as it disproportionately affects disadvantaged populations. In this regard, healthcare organizations have the possibility to lead by designing climate resilience programs that address both immediate needs as well as systemic challenges.
- To prevent environmental health threats to humans and animals and to combat many other challenges, a more collaborative and multidisciplinary approach is needed. One Health is an approach that connects the health of people, animals and our planet.

- The G7 should foster this proactive approach by supporting the healthcare industry through better targeted funding and ensuring an environment conducive to innovation. The G7 should define and promote partnerships for change, bringing together academia with the private and public sectors to act and follow the One Health approach when setting national policy.

Non-Communicable Diseases (NCDs)

- NCDs should return to the focus of global healthcare. Diseases such as cancers, mental health conditions, cardiovascular, dementias, and orphan diseases continue to pose the highest global disease burden, accounting for more than 70% of global deaths. In addition, patients living with NCDs have had a higher risk of severe COVID-19 effects. The disease burden of NCDs is strongly linked to economic prosperity for a post-pandemic world, as the main NCDs are estimated to account for a global GDP loss of US\$47 trillion between 2011 - 2025.
- At the same time, investing in healthcare can return more than 14 times the original investment by mitigating the impact of NCDs. The G7 should drive the fight against NCDs by investing in prevention, early diagnoses, and treatment solutions for all populations.
- During the COVID-19 pandemic, concerns about mental health have increased, with significant economic impacts. The G7 should therefore acknowledge mental health as a priority and invest into public health media campaigns, expand mental health screening, support early and targeted interventions, increase the capacity of mental health care systems, and prioritize mental health surveillance and research while fighting related stigma.

1.2 Ensure Equitable Access to Critical Vaccines, Therapeutics, and Diagnostics Globally

Facilitate the Production, Distribution and Administration of Vaccines, Therapeutics, and Medical Devices

- Despite scientific advances that have delivered medical countermeasures at historic speed and scale, more equitable distribution of pandemic products must be a shared goal. For example, given that large swaths of the global population remain unvaccinated, significant efforts are needed to address this vaccine gap. According to the global dashboard for vaccine equity, over 75% of people are vaccinated, while in low-income countries only 13% are fully vaccinated. However, it is increasingly clear that the global supply of vaccines now exceeds demand. The key challenge now is distribution and administration of vaccines, especially in parts of Africa. Unless these challenges are addressed there is a real risk that the pandemic will be prolonged and the global community impacted.
- The B7 calls on the G7 to strengthen the capacity of developing countries to work with industry and other governments to encourage distribution and administration of vaccines, related medical devices, and therapeutics, by ensuring financial and technical support for strengthening health infrastructure, demand generation, and voluntary licensing to develop additional localized manufacturing.
- The G7 should recognize the biggest drivers of sustainable and equitable access to medical products: strong health systems that reach marginalized populations, open and efficient supply chains and free markets that drive production, and regulatory approval processes that ensure speedy access to high-quality products.

Ensure Strong Supply Chains and Manufacturing Capabilities

- The pandemic is one of several reasons for uncertainty in global supply chains. It is likely that the transformation to a carbon-neutral global economy will place additional demands on logistics. Especially for the healthcare industry, uninterrupted and reliable supply routes are critically important. The G7 should commit to ensuring that health infrastructure is prepared for a stable post-pandemic global economy.

- Disruption of production and delivery of drugs and medical products limits the effective diagnosis and treatment of patients. The G7 should ensure resilient global supply chains through diversification of input sources, the alignment of international standards, strong intellectual property (IP) standards to facilitate cooperation and partnership, convergence of technical standards, rules-based trade, and open borders. The G7 should work together with industry and employers to develop a multilateral policy framework to enhance security of supply, inputs, and end-products to strengthen the overall resilience of strategic supply chains.
- Tariffs, taxes, and non-tariff trade barriers hamper the urgently needed exchange of goods worldwide to combat the COVID-19 pandemic. This places a burden on exporters and importers of health products.
- During the crisis, trade in COVID-19-related goods increased, making international planning certainty more important for companies. Any countries which have implemented export restrictions or export licensing for medical supplies should lift such measures as soon as possible in order not to affect the use of medical equipment, medicines and other essential goods and services. Therefore, the G7 should promote a WTO agreement on trade and health in which all WTO countries commit to remove current restrictions and refrain from implementing future restrictions in order to facilitate global trade in health goods and learn lessons from COVID-19.
- The G7 should advocate for stronger mutual recognition of approval procedures e.g. recognition of conformity assessment procedures for medical devices (US/EU) in order to allow future approval processes for urgently needed medical goods while maintaining all quality assurances.
- To support manufacturing, it is important to ensure that components which go into manufacturing (e.g. consumables) or equipment like bioreactors are the focus of expansion of those markets in non-pandemic times to support preparedness. In this respect, the G7 should foster governments and industry to work together to establish globally distributed manufacturing capabilities that can respond to exponential increases in demand. Further, Good Manufacturing Practice (GMP) standardization and acceptance, including interchangeability of components, would allow companies to move faster.

Promote Global Vaccination and Support the COVAX Initiative

- The GAVI COVAX facility is currently the only mechanism that aims to secure access to successful vaccines at the multilateral level. G7 countries should continue their commitment towards the GAVI COVAX facility to reach the WHO vaccination targets, bearing in mind that global vaccine supply increasingly exceeds demand in all markets and does not in itself constitute a viable solution in countries where healthcare delivery capacities are highly inadequate. In addition to healthcare delivery capacity, medical education and infrastructure are needed to achieve vaccination targets. Testing/diagnostic capacity and vaccination infrastructures may be needed on a permanent basis and would need to be firmly embedded in our health systems.

1.3 Continually Revitalize and Strengthen the Role of the World Health Organization (WHO), Multilateralism and Intersectoral Collaboration

Strengthen the Role of the WHO and other key players to Coordinate the Response to COVID-19 and Future Pandemics

- Effective and functional international health organizations are necessary for ensuring global health security. A pandemic requires a coordinated multilateral response. The WHO has played a crucial role by coordinating member states and working with industry partners.
- The G7 should continue to strengthen the WHO in its role of promoting evidence-based best practices to guide decision-makers.

Reinforce Multilateralism and Cross-Sector Collaboration

- Multilateral forums such as World Health Organization (WHO), World Trade Organization (WTO), World Intellectual Property Organization (WIPO), Organization for Economic Co-operation and Development (OECD), the G20 and the G7 should promote collective action on health issues and regulatory convergence. The much needed increase in inter-sectoral dialogue may also be organized by using existing networks and exchange formats such as the World Health Summit (WHS) which brings together stakeholders from politics, science, the private sector and civil society.
- A lack of global regulatory convergence limits access to medical products and creates challenges for developers of medical products, a problem that has been exacerbated during the pandemic. The G7 should promote bilateral recognition between regulators and the WHO to overcome these boundaries especially during crises.
- The COVID-19 pandemic has shown that the private sector remains a key partner in pandemic prevention, preparedness, and response, in innovating, producing, and delivering health and public health products and services. The business community welcomes WHO's negotiations on an international instrument on pandemic prevention and preparedness. The G7 should ensure private-sector engagement in WHO negotiations and establish an official channel for the private sector to substantively engage in the process. Whilst the private sector acknowledges the importance of frameworks that guide engagement with WHO, such as the Framework for Engagement with Non-State Actors – FENSA, these should not impede open and constructive interactions between the stakeholders which lead to concrete collaboration.

2. Promote Innovation and Improve the Digitalization of Health

2.1 Promote Scientific Research and Create an Innovative Environment

Ensure Protection of Intellectual Property Rights (IPR)

- The protection of intellectual property is critical for enabling development of new and innovative health solutions through support for on-going investments in R&D, and related partnerships. The G7 should ensure that IP-related incentives for innovation and knowledge-sharing are maintained or strengthened.
- Intellectual property has not been a barrier for the development and distribution of vaccines during the pandemic, nor of any medical technologies. Many innovative companies have leveraged their decades-long R&D capacity to launch the unprecedented development and delivery of diagnostics, medical devices, medical equipment treatments, vaccines, digital tools, and information-sharing faster than ever before. The COVID-19 response also has benefited from unprecedented collaboration among companies through hundreds of international voluntary licensing agreements, which have accelerated knowledge and technology-sharing, and leveraged manufacturing capacity to broaden supply and distribution – all made possible by clear and predictable IP rights. In particular, the G7 should also continue to promote voluntary IP licensing and technology transfer mechanisms, including engagement with the Medicines Patent Pool (MPP), advanced market commitments, and non-assert covenants, which has led to unprecedented medical technology development and sharing during the COVID-19 pandemic. In this respect, the G7 must advocate for sufficient intellectual property rights protection for pandemic technologies in the context of the WTO-TRIPS waiver.
- In order to promote production and distribution of vaccines, it is necessary to strengthen the connectivity of the supply chain, from procurement of raw materials and production to smooth and safe transportation. Therefore, this issue cannot be addressed only by focusing on intellectual property.

Promote Innovation and Create Incentive Models / Reimbursement Reforms

- The growing threat of antimicrobial resistance (AMR), a so-called “silent pandemic”, for public health worldwide not only exacerbates the COVID-19 pandemic but will become even more alarming after the current global health crisis. OECD data estimates up to 700,000 deaths may be caused globally each year by AMR.
- G7 should establish regular national benchmarking of national AMR programs to assure a steady pace of progress in addressing this silent pandemic. The G7 should combat antimicrobial resistance by creating innovative incentives that ensure investments in research and development of new antimicrobials, therapeutics and treatment concepts lowering the need for antibiotic therapy are made with the prospect of an ecosystem that rewards innovation. The G7 should also ensure sustainable access to and appropriate use of existing antibiotics as well as non-pharmaceutical interventions and devices.
- The G7 should also continue to recognize medical technologies (e.g. medical devices and in-vitro diagnostics) and vaccines as a vital tool for preventing infection and limiting opportunities for resistance. There is a clear opportunity to establish market-based incentives that appropriately incentivize a full spectrum of interventions, including prevention and management of healthcare-associated infections (HAIs) through medical technologies and vaccines, as well as to enable access to these tools, for example by encouraging widespread implementation of prevention and vaccination programs. The G7 should work towards adequate reimbursement frameworks that recognize the value of prevention.
- To maintain a sustainable market, reserve antibiotics for both the outpatient setting and for hospitals must be reimbursed using new reimbursement models that reflect their societal value and respect antibiotic stewardship (AMS).

2.2 Develop A Regulatory Framework for Data Exchange and Promote the Digitalization of Health Systems

Promote the exchange of data, its safety and interoperability

- The speed at which it has proved possible to develop and approve vaccines in the pandemic through expedited regulatory processes was unprecedented. Getting medicines to patients quicker while maintaining safety is a priority for regulatory agencies as well as stakeholders. Research and regulatory processes themselves were digitalized and accelerated and should be further streamlined going forward.
- To allow digitalization of healthcare, the G7 needs to invest in building data infrastructures that allow for interoperability between national and supranational level. It must be ensured that high-quality healthcare data can be used and shared between all relevant stakeholders (including industry / private research institutes) and across borders. This will help to improve health outcomes through data-driven decision-making as part of research and during public health emergencies, and accelerate access to medical products.
- The G7 needs to standardize digitalization and define minimum data quality requirements so that data can be analyzed and used across borders.
- The G7 should promote regulatory harmonization where possible regarding digital health regulations related to cross-border data-sharing, interoperability and other regulatory requirements.
- The use of artificial intelligence can assist physicians in making decisions, for example in diagnosing diseases as the volume of relevant data increases. A regulatory framework for responsible and safe use of artificial intelligence in the health sector should also be agreed at the international level.

- Digital solutions such as telemedicine can also improve access to healthcare even in remote or rural areas, bringing healthcare directly to the patients. The pandemic has underlined the benefits of digitalizing healthcare systems and the long road ahead, so the G7 should invest significant resources in the digitalization of healthcare. In addition, market access for digital health applications should be open to innovation. This includes speedy and transparent procedures that take into account the special features of digital products.
- The G7 should fund and support the digitalization of health and regulatory systems to ensure that access to medical products can continue even with stay-at-home orders.
- The G7 should ensure cybersecurity and data protection to allow patients access to their data.

Imprint

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