



Research and Innovation Working Group

Priority Topic 3

Deliverable 3.1 - RIWG support, from the perspective of research and technological development, for the “Alliance for Local and Regional Production and Innovation”, under discussion in the G20 Health Working Group (HWG).



Reminder as of ‘updated deliverables’ shared after the 2nd RIWG meeting:

The support of RIWG to this initiative under the HWG will be developed by a set of comments and contributions made by the RIWG members and invited countries to the text of the “Alliance for Local and Regional Production and Innovation” issue note, prepared by the HWG coordination.

The RIWG coordination circulated the above-mentioned issue note, asking for contributions related to basic and applied science, technological development and innovation. All the comments and suggestions were compiled in a single document and will be sent to the chair of the HWG.

RIWG coordination will not merge, summarize, delete, interpret, or complement the text sent by the members and invited countries. The work will be focused only on the compilation and systematization of the comments and suggestions.

Final outcome: a collection of comments and contributions to the “Alliance for Local and Regional Production and Innovation” issue note.

Note: the final decision on acceptance and utilization of the comments and contributions from the RIWG to the “Alliance for Local and Regional Production and Innovation” issue note will be made exclusively by the G20 Health Working Group.



Considering the proposal of the “Global Alliance for Local and Regional Production, Innovation, and Equity in Access, focusing on Vaccines, Treatments, Diagnosis and other health technologies (VTDs) for Neglected Populations and Diseases and Vaccines”, hereby referred to as the “Alliance for Local and Regional Production and Innovation”, under discussion in the G20 Health Working Group (HWG), whose issue note is attached to this form, please provide by 13 May your comments and contributions:

1) G20 Member/Invited country/International Organization name:

Canada, Spain, Saudi Arabia, Japan, Angola, Germany, Norway, European Union, Indonesia, Republic of Korea, Russia, African Union, Italy, Singapore, Switzerland and India.

2) General comments and contributions to the issue note

Canada

Canada greatly appreciates Brazil’s holistic thinking on the proposed Alliance for Regional Production and Innovation, and we are keen to continue to work with G20 partners to facilitate the long-term sustainability of regional vaccine manufacturing initiatives, from market shaping through to local production capacity building. Canada is committed to addressing barriers to equitable access to vaccines, diagnostics and treatments in low- and middle-income countries and welcomes sustainable public-private and multisectoral efforts to strengthen local and regional production and innovation.

We reaffirm the importance of leveraging existing initiatives to avoid duplicating efforts within the global health architecture, as noted on page 10 of the proposal document. The G20 must ensure the proposed Alliance aligns with and does not preclude the outcome of the



intergovernmental negotiating body (INB) negotiations on the pandemic prevention, preparedness and response accord. It will also be important to understand how the Alliance would complement existing initiatives, such as the mRNA Hub in South Africa, PAHO's mRNA Platform, the WHO's Health Technology Access Pool (HTAP), the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi's African Vaccine Manufacturing Accelerator (AVMA). We welcome information on how these existing initiatives and stakeholders have been consulted on the Alliance concept.

Canada supports the voluntary transfer of technology and licensing from patent holders to advance regional production and innovation. Efficient technology transfer needs the voluntary participation of all actors, and we encourage initiatives and agreements that promote technology and expertise transfer on mutually agreed terms, as these will play an important role in facilitating and accelerating manufacturing capacity in LMICs. We also believe that the importance of data collection and sharing is a major lesson from the pandemic, and Canada is committed to continuing to develop its data capturing capabilities in order to contribute to international data sharing as a means of surveillance and identifying possible pathogens of concern to drive investments of highest impact.

Spain

Spain does not have any additional comments, but we would like to highlight several points regarding the proposal:

Launching a Joint Call Research is in line with our commitment with the cooperation and collaboration with lower income countries, and specially with the CELAC area, and we strongly support the idea of building on existing initiatives to avoid duplications.

Spain has already funding agencies that will be able to participate in joint projects: ISCIII <https://www.isciii.es/Paginas/Inicio.aspx> and CDTI <https://www.cdti.es/>

Additionally, ISCIII work as the reference center in public health in scientific terms for the entire list of diseases where technical collaboration is needed.

Saudi Arabia



Although the KSA has made significant progress in infectious disease control outputs and outcomes, progressive need remains towards developing a resilient and globally competitive infectious disease research effort. Notable reminders of how vulnerable the increasingly interconnected world is to the global impact of new emerging diseases including HIV/AIDS, severe acute respiratory syndrome, the H5N1 strain of avian influenza, the 2009 pandemic H1N1 influenza virus and more recently the pandemic of COVID-19.

Establish an alliance for “One Health Approach.”

The One Health concept aims to improve plant, animal & human health through multi-sectoral, & transdisciplinary approaches for better disease control and pandemic preparedness

Issues related to human, animal, and environmental health must be addressed collectively through the One Health approach. We emphasize the need to create virtual spaces for collaborations and capacity development for technologies related to disease modelling, environmental surveillance, and other critical tools. We need to facilitate the development of data standards for One Health for better information sharing. We recommend creation of a network of ‘One Health Institutes’ for facilitating collaboration in this space and engagements with the existing multilateral structures such as Quadripartite to advance the One Health agenda. (hence controlling or eradicating the list of infectious diseases you provided).

We are currently establishing the Pandemic Preparedness and Prevention Research Consortium (P3RC) in the region, aiming to mitigate the impact of future pandemics through research and preparedness efforts.

Our commitment to combat the Dengue virus extends to cutting-edge genomic surveillance initiatives that we are currently developing. This involves the genomic surveillance of Dengue virus in clinical samples collected from diverse regions and diverse samples including clinical, mosquito, and wastewater samples. Leveraging state-of-the-art technologies, we conduct complete genome analyses. This dual approach ensures a high-resolution view of the viral genomes, contributing to the identification of genetic variations and serotyping.

In tandem with genomic surveillance, we spearhead vector surveillance initiatives, integrating Artificial Intelligence (AI) for hotspot detection and real-time quantification. Our approach includes employing sequence-dependent identification of vector-borne viruses and monitor other pathogens in near real time. This multifaceted strategy extends to the molecular monitoring of vectors harboring Wolbachia bacteria, a key aspect in understanding and managing vector populations. By synergizing advanced genomic technologies and intelligent surveillance methodologies, we aim to fortify our defenses against Dengue virus and its vectors, fostering a proactive approach to disease prevention and control.

KSA is uniquely positioned to host such a “Consortium” due to major religious mass gatherings hosted by KSA such as Umra and Hajj. Furthermore, just in the month of Ramdan 2024 the Kingdom successfully hosted 30 million pilgrims within a month. Accordingly, our mission is to prevent, detect, and control future pandemics through conducting impactful research in infectious diseases at a global level.



(text below is also from Saudi Arabia (version from June 30, 2024))

We appreciate Brazil's initiative and commitment to addressing the critical issues of global health equity and innovation. Saudi Arabia is dedicated to contributing effectively to these efforts. We kindly request consideration of the following points:

Avoiding Duplication of Efforts: To prevent the redundancy of efforts and resources, it is essential to map the current landscape of initiatives such as the Global Alliance for TB Drug Development (TB Alliance), Global Fund to Fight AIDS, Tuberculosis and Malaria, GAVI, the Vaccine Alliance among others. By leveraging and integrating with these established networks, the proposed Alliance can build upon existing successes and address gaps without duplicating activities.

Leveraging Unique National Strengths and Challenges: Saudi Arabia is establishing the Pandemic Preparedness and Prevention Research Consortium (P3RC) in the region, aimed at mitigating the impact of future pandemics through research and preparedness efforts. With a particular focus on Middle East Respiratory Syndrome (MERS-CoV), Dengue Fever, and Tuberculosis (TB), the Research, Development, and Innovation Authority (www.rdia.gov.sa) is launching and funding a national mission to reduce the incidence of infectious diseases and will coordinate the necessary efforts in Saudi Arabia.

Coordination Between G20 Tracks: Effective communication and coordination between the G20 Health Working Group (HWG) and other relevant G20 research and development tracks are crucial. This will ensure a unified approach and prevent fragmentation of efforts.

Japan



In light of the experience of COVID-19, ensuring equitable access to MCM remains a crucial issue. As stated in the "G7 Hiroshima Vision for Equitable Access to Medical Countermeasures", which was announced at the G7 Hiroshima Summit last year under the Japanese Presidency, it is important to promote efforts based on the principles of equity, inclusivity, efficiency, affordability, quality, accountability, agility, and speed in order to build and strengthen the end-to-end ecosystem of global MCM, including production.

We understand that the "Alliance for Local and Regional Production and Innovation" is currently under discussion in the G20 Health WG, and Japan has expressed concern about the potential for duplication of efforts among various initiatives and institutions. On the other hand, neglected diseases require a multisectoral approach due to the lack of resources for research, prevention and treatment as well as their close relationship to social factors. Therefore, we would like to introduce the following summary of Japan's policies for infectious disease control and the international joint research program with developing countries to solve global issues including infectious diseases.

In Japan, "National Action Plan", which is currently being revised based on the experience of COVID-19, highlights the strengthening of international cooperation as a cross-cutting issue. We recognize the importance of international cooperation with foreign research institutes for the research and development of vaccines, diagnostics, and therapeutics. It also highlights that the contribution to international cooperation such as to support to developing countries is one of the important efforts to confront infectious diseases across borders. In addition, domestically, we promote research and development of vaccines, therapeutics, and therapies that are not in demand in the market in peacetime. We believe this will lead to the measures for neglected diseases for which research and development are difficult to be conducted due to the market not working well.

In addition, Japan has been implementing "Science and Technology Research Partnerships for Sustainable Development (SATREPS)" since 2008, which is an international joint research initiative utilizing ODA. It aims to resolve global issues such as infectious diseases, global-scale environmental issues and carbon neutrality, bio resources, and disaster prevention and mitigation, and to develop human resources, based on the needs from developing countries. Through SATREPS, 35 programs related to infectious diseases have been implemented to date, and we will continue to support research and development not only for conventional infectious diseases but also for tackling new infectious diseases.

Edit of the concept note is not requested from us, but we would like to make one suggestion. While experts for the advisory committee are listed in the governance section of the document, we recommend inviting researchers not only from medicine and natural sciences but also from humanities and social sciences academia. In order to cope with the issues such as institutional and ethical aspects and social acceptance



that arise when new technologies are utilized in society, Japan is promoting the utilization of variety of knowledge including the humanities and social sciences. We believe that this approach will function effectively in the Alliance, too.

Angola

- Technology transfer for local production;
- capacity building for innovation.
- equity in access of vaccines, treatments, diagnosis and other health technologies;
- building more resilient, robust and transparent supply chains.
- creating a fair, transparent, and equitable global mechanism of cooperation and mutual benefits.
- robust and sustainable investment.
- health technologies and products are so highly protected by IPR
- strengthening resources for better research, infrastructure, and treatment of neglected diseases
- New comment: We support the creation of the Alliance and maintain our initial contributions.

Germany

- Duplication of activities should be avoided. There are already several initiatives and funding programs that cover goals and tasks assigned to the proposed alliance, particularly with regard to (1) R&D of therapies and diagnostics against neglected and poverty-related infectious diseases, and (2) the establishment and expansion of research capacities in regions affected by these diseases.
- Examples of existing initiatives include product development partnerships such as “Drugs for Neglected Diseases initiative“ (DNDi); the European and Developing Countries Clinical Trials Partnership (EDCTP); and the partnership Unite4TB. There already exists a high degree



of networking between existing R&D initiatives and stakeholders. In our view, sufficient financing to leverage the potential of these existing initiatives is needed instead of a new initiative duplicating activities.

- The proposed Alliance has a wide range of envisaged tasks – including launch of joint research projects, production, technology transfer and control of market equilibrium parameters. However, the amount of financing is unclear as it will be on a voluntary basis. First, the funding needs to be discussed in order to clarify whether the funding level covers the intended range of tasks.
- Technology transfer and knowledge sharing needs to be on voluntary and mutually agreed terms.
- As to the tentative list of diseases, it is not obvious to us on which scientific criteria the diseases have been chosen.
- In our view, the list is too long. For many of the proposed diseases (e.g. HIV, Malaria) there already are long-existing and successful initiatives. ~~Therefore, the initiative should choose only very few diseases, for which there is hardly anything in development or on the market, yet, such as Dengue. That way, the initiative could set an example and could show its added value.~~

Norway

We are aware that the latest draft of the Alliance has not been circulated to the G20 Health Group. We are coordinating our response with our colleagues represented in HWG. Therefore, we will not offer any written comments at this time. We appreciate the opportunity to provide a statement during our discussion of the topic in Recife.

European Union

We wish to thank the Brazilian presidency for sharing the concept note for an Alliance for Local and Regional Production and Innovation with a focus on neglected diseases and populations under the G20 research track.

In terms of process, we note that a parallel consultation on the proposed concept for the Alliance is being carried out under the G20 health track. We are concerned that this may generate duplication and confusion, and would invite the presidency to consider bringing all discussions and decisions on the Alliance under the G20 health track.

In line with the European Commission's previous intervention under the G20 health track in Brasilia, we would like to submit the following comments for your consideration when developing the next iteration of the concept paper:



1. Context:

The Covid pandemic exposed an equity gap in access to medical countermeasures that can be closed by inter alia building worldwide strategic autonomy and local and regional capacities for innovation, manufacturing and distribution. It also showed that a holistic, ecosystem approach is crucial, addressing the whole value chain not only innovation and local production but also absorption capacity and last-mile delivery, as well addressing broader challenges like vaccine hesitancy and enhancing vaccine uptake.

Over the past years, a **plethora of global health actors** and international collaborations have addressed these challenges, covering also neglected diseases and vaccine development. The **global landscape is fragmented** with many ongoing initiatives, such as WHO's mRNA vaccine technology transfer programme and World Local Production Forum and I-MCM-Net, CEPI's Regionalized Vaccine Manufacturing Collaborative Framework hosted, GAVI's Africa Vaccine Manufacturing Accelerator, and last-but-not-least the Global Research Collaboration for Infectious Disease Preparedness GloPID-R, in which international and national health research funders coordinate and align funding for global research preparedness and emergency response to priority needs, gaps and opportunities.

With its recent **Global Health Strategy**, the EU is already contributing substantially to global efforts, working to address global health disparities and enhance equitable access to healthcare and essential medical products. For example, together with its Member States, the EU has already invested massively in end-to-end R&D, manufacturing and access to vaccines, medicines and health technologies in Africa, mobilising 1,3 billion EUR through the **MAV+ flagship** initiative.

Furthermore, we are actively extending our efforts to include **Latin America and the Caribbean** through an ongoing initiative designed to bolster the regional production capacities and supply chains towards health resilience and security.

The EU also supports **regional and global research** partnerships. The most prominent is the **European and Developing Countries Clinical Trials Partnership** (EDCTP) with Sub-Saharan Africa which has a budget of 1,6 billion EUR (2021-2027) and spends about 80% of funding on clinical studies on poverty-related neglected infectious diseases in Sub-Saharan Africa, with great success. For example, the two malaria vaccines recently recommended by the WHO have been developed with EDCTP support.

Shortages of medicines have been a serious concern in the EU as well. With the establishment of the **EU Critical Medicines Alliance**, we aim to enhance global supply chain resilience, promote international cooperation, and seek diversification opportunities for critical medicines.



We are ready to contribute our experience with these EU initiatives and collaborations as we further explore and develop the concept for the Alliance.

2. Scope and objectives of the Alliance

We generally believe that it is crucial to **build coherence** in the system and create a measure of **convergence** among the global, continental and regional initiatives who work to address existing gaps in neglected diseases innovation, manufacturing, capacity and financing.

In this sense, a **mapping/landscape analysis** should be conducted as an initial step. This would help the proposed Alliance:

- better identify gaps and needs, and formulate specific objectives;
- build on and link with established global and regional collaborations in research and development, and manufacturing;
- avoid duplication and bring added value in an already fragmented landscape.

On the scope (i.e. list of diseases), we reiterate the need for clear **criteria and evidence base for selecting the list of priority diseases**. We believe a narrower focus at the beginning would be more appropriate, in a “**pilot-like**” exercise targeting one or two priority diseases.

We stress the need to ensure **enabling environments** for innovation and access, based on **voluntary technology transfer on mutually agreed terms** and to work on **regulatory strengthening**. We would also like to see a holistic approach where adequate attention is given to tackling important **barriers to equitable access such as limited absorption capacity** for last-mile delivery.

3. Governance

Naturally, the governance structure should be established as a function of the **objectives and actions** foreseen, as well as the **scope** of the initiative in terms of the **diseases to be addressed**. Consequently, we should first focus on better defining those.

The proposed Alliance should be **lean** and inclusive, based on **partnerships**, and **facilitating coordination** between existing actors. We do not favour a heavy governance structure.

We also consider that **financing** should be on a **voluntary** basis, without establishing new funds but rather looking at how to tap into and better articulate or coordinate existing funding streams.



In conclusion, further reflections on governance along the broad lines outlined above would best follow once we have matured the concept of the initiative.

Indonesia

The proposal on the “Global Alliance for Local and Regional Production, Innovation, and Equity in Access, with a focus on Vaccines, Treatments, Diagnosis (VTDs), and other health technologies for Neglected Populations and Diseases, including Vaccines” referred as to as the “Alliance for Local and Regional Production and Innovation” is a crucial initiative for addressing health disparities and ensuring equitable access to healthcare worldwide and is essential drivers of progress towards achieving universal health coverage and ensuring that no one is left behind in the pursuit of better health outcomes for all. With the objective to facilitate, enhance, and fortify research and development efforts, foster international collaboration, and facilitate technology sharing, thereby broadening access for vulnerable communities and advancing health equity worldwide, the initiative will strengthen and support the effort for diseases control and prevention in alliances country member. However, there are several aspects that require clarification regarding the role, function, mechanism, contribution, and impact of the alliance. This entails clarifying how it will engage with diverse stakeholders, such as government agencies, businesses, research institutions, and community organizations, to stimulate economic development and innovation at the grassroots level. It's important to clearly outline the operational functions of the alliance, including its facilitation of research and development activities, provision of support for local businesses and entrepreneurs, promotion of collaboration and knowledge exchange, and advocacy for policies favoring local production and innovation. Additionally, detailing the mechanisms employed by the alliance to achieve its objectives, such as forming partnerships and networks, offering technical assistance and capacity building support, facilitating access to financing and resources, and implementing projects and initiatives to advance local and regional production and innovation, is necessary. The contribution that the alliance aims to make, encompassing economic growth, job creation, support for local businesses, innovation promotion, and sustainable development, must be described, specifying the key areas or sectors of focus and the anticipated outcomes of its interventions. Moreover, outlining how the alliance will monitor progress, evaluate outcomes, and assess the effectiveness of its interventions in meeting its objectives and fostering local and regional development is essential.



By elucidating these aspects, stakeholders can gain a clearer understanding of the alliance's mandate, operations, objectives, and expected outcomes, which can guide decision-making, resource allocation, and stakeholder engagement efforts.

Republic of Korea

The importance of global cooperation to resolve unmet medical needs and social priorities, which has been clearly seen due to COVID-19, is well expressed in the document, and it is very timely to form an inclusive and anticipatory alliance led by the G20.

G20 has sought to establish an "Alliance for Local Production and Innovation" to address public health crises and build a sustainable global health system. This Alliance aims to ensure equitable access to various health technologies, including vaccines, therapeutics, and diagnostics, while specifically focusing on neglected diseases and socially determined diseases to help bridge global health disparities. In this regard, there are several policy recommendations to consider for ensuring the sustainable operation of the Alliance as below.

1. Establish Guidelines for Patent and Intellectual Property Management

It is essential to establish consensus and guidelines on managing key technology patents and intellectual property rights, as observed during the COVID-19 pandemic.

2. Develop a Strategic Roadmap

To ensure greater feasibility, there is a need to present measures to establish a technical or mission roadmap with detailed objectives.

3. Share Past Experiences and Build a Repository of Best Practices

This issue is not unique to the Alliance alone, and by starting with discussions held in various places, we can save time and costs. Therefore, it is necessary to review the development of a mechanism that allows for knowledge and experience sharing.



In addition, while agreeing with the important issue of fair access to medical response measures, redundancy with existing activities of international organizations such as WHO & CEPI and financial issues about the establishment of new organizations need to be discussed more carefully.

African Union

Neglected tropical diseases (NTDs) affect over 1.7 billion people globally, with 40% residing in Africa's poorest and most vulnerable regions. This disproportionate burden on Africa is akin to half of malaria's impact and more than double that of tuberculosis, leading to profound social and economic consequences, including increased marginalization and stigmatization. The COVID-19 pandemic exacerbated this situation by disrupting community-based interventions and access to healthcare facilities, resulting in a 34% decrease in NTD treatment globally between 2019 and 2020.

Addressing NTDs requires comprehensive efforts, including strengthening local production and fostering innovation for equitable access to essential health products. Recognizing the evolving pandemics and their economic impacts on the continent, the African Union established the Africa CDC, which is leading the African Vaccine Manufacturing Accelerator (AVMA) under the Platform for Harmonized African Health Products Manufacturing (PHAHM) initiative. PHAHM's goal is to enable African vaccine manufacturers to supply over 60% of the continent's vaccine doses by 2040, with progressive targets of 10% by 2025 and 30% by 2030. This collaboration has initiated various vaccine manufacturing projects to enhance Africa's self-reliance in health emergencies.

Open innovation and intentional technology transfer are pivotal in bolstering local antigen production and facilitating backward integration for manufacturers. Limited technology transfers for drug substance production (antigens) and drug product production (form/fill/finish) are hindering Africa's potential. Robust investments in R&D are imperative for sustaining Africa's vaccine manufacturing ecosystem and enhancing health security. These efforts align with G20 priorities, emphasizing R&D promotion and manufacturing network diversification to



enhance local and regional resilience and capacities. Additionally, multi-sectoral response mechanisms are needed to ensure transparency, adaptability, interoperability of health systems, and a One Health approach.

The African Union therefore welcomes the establishment of a trusted Alliance for Local and Regional Production and Innovation, with focus on improving access to vaccines, treatments, diagnostics, and other health technologies, particularly for neglected diseases, underserved populations, and socially determined diseases, coupled with R&D. Regarding the functions of the alliance, it is essential to include promotion of shared infrastructure and R&D facilities, in the spirit of open science and innovation.

Italy

In line with the strategic vision of this proposal, we propose the following four specific topics, which should be considered high-level\top priority of G20 investments, to enable innovative solutions for Global Health in the short\medium term.

- 1) **RE-PURPOSE FOR GLOBAL HEALTH:** Re-purpose of existing drugs and medical devices as new solutions for early diagnosis and predictive and personalized therapies for neglected diseases. Re-purpose typically requires limited investments but it is not a sufficient real source of innovation worldwide.
- 2) **CIRCULAR GLOBAL HEALTH:** the use of recycled materials and/or innovative bio-materials for the production of drugs or medical devices could generate cost-effective therapeutic solutions which can become more and more affordable in developing countries for Neglected Populations and Diseases. The circular economy must be properly exploited as an opportunity for development of the Health Sector Production and Innovation in low-income countries.
- 3) **ADVANCED AND SUSTAINABLE AUTOMATED HEALTH PROCESS PRODUCTION:** Emerging technologies (Artificial Intelligence, Robotics & Automation, Health Data Platforms, etc.) can be now used for local and mobile production of innovative vaccines,



drugs and medical devices in developing countries. These solutions must have a top priority to be globally prepared and resilient for future pandemic scenarios. Possible synergies can also be explored with relevant National or Regional ongoing initiatives (e.g. the European Health Data Space (EHDS), the European public-private partnership for pandemic preparedness (BE READY), etc.).

- 4) **PROFESSIONALS FOR GLOBAL HEALTH:** especially in developing countries, education and professional training of professional profiles for emerging global health scenarios are fundamental needs to support innovation. This Alliance should promote and share a variety of specific training initiatives, provided in hybrid mode (in person and on-line), so to promote and support the global applications of innovative solutions for production processes, and also for caregivers, healthcare managers, etc.

Singapore

Singapore broadly expresses its support for the proposed establishment of the Alliance for Local and Regional Production and Innovation.

Considering the existence of numerous initiatives in this area, there is merit in the Alliance aligning, coordinating, and collaborating with such endeavours, including the Regionalised Vaccine Manufacturing Collaborative. This approach aims to minimise duplication, leverage synergies, and ensure comprehensive coverage.

The capabilities and capacities developed to address endemic diseases can be repurposed during crises to combat emerging pathogens or future pandemics. Hence, it is advisable for the Alliance to coordinate its efforts with the World Health Organisation (WHO)'s medical countermeasures mechanisms. Additionally, other complementary capabilities such as regulatory expertise, and clinical trial networks, can be leveraged effectively.

Partnership with academia and the private sector are vital, necessitating adequate incentives and support for research, development, and innovation to foster a robust pipeline of products, and sustainable market deployment.



Singapore looks forward to contributing further to discussions aimed at enhancing accessibility to vaccines, treatments, and diagnostics for neglected diseases, drawing from our expertise and experience in these domains. For instance, following the WHO's declaration of Zika as a public health emergency in 2016, a Zika research project was initiated by researchers from the Agency for Science, Technology and Research (A*STAR). This initiative yielded several breakthroughs, including the development of a three-way diagnostic kit to detect strains of the Zika, Dengue and Chikungunya viruses, as well as elucidating the interaction between the Zika virus and the gene associated with microcephaly.

Switzerland

- Switzerland would like to commend the Brazilian Presidency for the choice of RIWG's priorities and reiterate our commitment to support this work at the nexus of innovation and health. As this topic is being discussed in detail in the HWG, we refer to our inputs in that context and limit our comments on some specific issues on Research and innovation.
- Switzerland recognizes the importance of international research collaboration for robust pandemic preparedness and actively supports global health research and innovation through several key initiatives:
 - We directly fund Swiss participation in Horizon Europe, where researchers collaborate with European partners on developing, manufacturing, and ensuring access to vaccines for low- and middle-income countries.
 - Switzerland champions the One Health approach in numerous Horizon Europe projects. This approach fosters collaboration between human health, animal health, and environmental science researchers, acknowledging the interconnectedness of these fields in vaccine development and deployment.
 - We fund the participation of researchers in projects of the European Partnership for Global Health. These research collaborations bring together African and European researchers to tackle neglected tropical and emerging infectious diseases.
- More specifically and with regards to challenges related to the diseases which the Alliance aims focusing on, Swiss authorities have a long-standing financial engagement with research centres such as the Swiss Tropical and Public Health Institute, the Swiss TPH. This institution is a world-leading institute in global health and combines expertise on novel diagnostics, drugs and vaccines for several of these diseases, namely HIV/AIDS, Tuberculosis, Malaria, Helminthiasis, Chagas, Dengue, and Zika, with active research collaborations in low- and middle-income countries.
 - • Further, The Swiss government has been an early supporter and funder of several product development partnerships, called PDPs. These include the Foundation for Innovative New Diagnostics (FIND), the Medicines for Malaria Ventures (MMV), and the Drugs for Neglected Diseases initiative (DNDi). The PDP model has been effective beyond product



development: their processes and partnerships ensure that products are brought to markets and thus to the end beneficiaries. Additionally, they contribute to building local capacities and strengthen local health systems. This model is in the spirit of the Alliance for Regional Production and Innovation. We would therefore caution not to duplicate existing initiatives and efforts.

- We stand ready to support further work in this area and share our long-standing experience.

India

India highly appreciates the Global Alliance document and acknowledges that the current fragmented state of the research and innovation ecosystem is characterized by siloed approaches to global challenges, and so it is imperative to focus on leveraging collaborative strengths and aligning R&D capabilities for developing affordable and accessible medical counter measures (MCMs). This necessitates a concerted effort towards practical applications aimed at curbing possible forthcoming emergencies. The necessity for substantial investment in high-quality research and innovation, particularly in VTDs, extends beyond financial resources; it requires the establishment of a well-thought-out collaborative framework.

We believe that the Alliance for Local and Regional Production and Innovation as proposed under the Brazilian G20 presidency must be revolving around Research & Innovation, Production, Delivery and Distribution. Pertinently, the first step should be fostering creation, identification and collaboration among national champions, Regional Centres of Excellence (CoEs), and Regional Research Networks (RRNs). Such a network must prioritize its need and extent of support of these entities while facilitating the translation of discoveries from research institutions into clinical applications.

We feel that focus must move towards creating VTD Global and regional R&D and Manufacturing Networks, alongside a Global MCMs coordination platform. These networks should streamline efforts, promote knowledge sharing, overcome barriers such as insufficient funding and lack of technical support and accelerate the development and production of essential medical countermeasures. A structured MCM lifecycle, guided by frameworks like ARPI and aligned with existing initiatives such as the WHO Blueprint for Epidemics, should ensure efficiency and effectiveness. This must include the creation of a shared knowledge platform, data banks and vaccine library, prioritizing research and development efforts towards addressing pathogens with epidemic or pandemic potential.



Furthermore, a globally accessible database covering priority pathogens and ongoing research, coupled with a focus on disease-agnostic technologies, can promote inclusivity and address challenges related to information asymmetry and inequitable access to solutions. Fostering collaboration and innovation within a structured framework holds the potential to promote a global R&D network with a focus on regional research and development needs that will aim to drive impactful solutions for future global health challenges, ensuring the timely development and deployment of medical countermeasures to safeguard public health worldwide.

As far as innovation is concerned, we feel that RIWG should work towards establishing a shared knowledge platform, similar to Global Vaccine Research Collaborative (GVRC) proposed by PATH and CEPI under India's G20 presidency. The platform may consist of a dedicated open-access digital database focusing on pathogens with epidemic or pandemic potential. Additionally, creation of a vaccine library within this knowledge base, housing research-grade vaccine constructs, reagents, and potential clinical candidate vaccines resulting from ongoing vaccine R&D may be vital elements.

We also need to take cognisance of existing partnerships and principles such as the WHO Blueprint for Epidemics to be an efficient and effective path towards impact-driven Collaboration. Such a collaboration could factor in a globally accessible database covering priority pathogens, ongoing research on VTDs, development of disease agnostic technologies as well a balance of flexibility and inclusivity, which would certainly help to address challenges such as the asymmetry of information, lack of availability of critical materials, low attention to certain products needed by small patient populations as well as the inequitable access to potential solutions.

We believe that for the disease-focused priorities, a significant aim could be to support early discovery and translational science consortia and networks, including those based in low-and middle-income countries (LMICs). Best practices can be adopted from successful initiatives like the TB Drug Accelerator, which has increased productivity in TB drug discovery by integrating the work of ~25 different groups. Moreover, collaborations across global centres of excellence with established technology platforms and expertise such as Gene therapy, stem cell therapy, mRNA/DNA-based platforms, nanoparticle technologies, CRISPR, AI/ML, etc. could be supported for development and validation of the disease-agnostic platforms.

In conclusion we would like to emphasize on the fact that a global alliance for local and regional production, innovation, and equity in access to health technologies offers significant potential to improve healthcare for neglected populations. However, it requires careful consideration of investment, regulatory standards, IP norms, necessary infrastructure for manufacturing, distributing, and storing vaccines and treatments,



as well as market dynamics to overcome the associated challenges. Balancing these factors is crucial to ensure that the benefits are realized and sustained in the long term.

Moreover, as the current version of the Global Alliance document is yet to be made available to the G20 Health Working Group (HWG), we reserve our final comment on the document, as necessary, between now and the conclusion of the G20 HWG Meeting.

3) Proposal of new text, suppression, or alternative language (please copy and paste table below as many times you need to conclude your comments)

Canada

Page (4) Paragraph (2)		
Current text ¹ (copy and paste the entire paragraph)	Proposed new text ²³ (highlight in red the changes, including deletion)	Comments or justification (optional)
Ensuring access to safe, effective, quality, and affordable medicines, vaccines, diagnostics, and other health products is a component of the full realization of the right to health and is instrumental for achieving Universal Health Coverage. It is also essential for reducing health inequalities and improving health outcomes, especially in developing countries, which face high prices, limited negotiating	Ensuring access to safe, effective, quality, and affordable medicines, vaccines, diagnostics, and other health products is a component of the full realization of the right to the enjoyment of the highest attainable standard of physical and mental health and is instrumental for achieving Universal Health Coverage. It is also essential for reducing health inequalities and improving health outcomes, especially in developing	Edited to align with language on page 3 in paragraph 4 and in alignment with the international Covenant on Economic, Social and Cultural Rights (ICESCR) Article 12.

¹ If just reallocation of the paragraph to a different part of the text, please copy and paste the paragraph in the first column, leave the second column blank and insert the new number of page and paragraph in the “comments or justification” third column.

² If deletion of the entire paragraph, just mention in the second column “delete paragraph”

³ If addition of an entire new paragraph, keep the first column blank and write the new proposal text in the second column. Please do not forget to indicate in the first line of the table in which page and paragraph your new proposal would fit.



<p>power, shortages, limited infrastructure, and patent protection.</p>	<p>countries, which face high prices, limited negotiating power, shortages, limited infrastructure, and patent protection.</p>	
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Page (10) Paragraph (3)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The Alliance shall unite leaders across different sectors. It will contribute to ensure equitable access to health technologies for neglected diseases that affect disproportionately vulnerable populations. It will seek to collect the world’s best public and private groups that invest in health technologies and develop a joint mission to shape the future of global health innovation and responsible investment through accelerating innovation, promoting collaboration, the engagement of all relevant actors, combining public and private.</p>	<p>The Alliance shall unite leaders across different sectors. It will contribute to ensure equitable access to health technologies for neglected diseases that affect disproportionately vulnerable populations. It will seek to collect the world’s best public and private groups that invest in health technologies and develop a joint mission to shape the future of global health innovation and responsible, sustainable investment through accelerating innovation, promoting collaboration, the engagement of all relevant actors, combining public and private.</p>	<p>Proposed change for clarity in support of the longer term functioning of the Alliance.</p>

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Page (10) Paragraph (5)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The Alliance would be a mechanism that facilitate the following types of collaboration:</p> <ul style="list-style-type: none"> • Develop a Mechanism to facilitate technology transfer and co-development; • Launch Joint Research Calls; • Promote technical cooperation; • Share past experiences and develop a repository for best practices and examples of successful technology transfer and co-development; • Mechanisms to guarantee stable demand and efficient scale. 	<p>The Alliance would be a mechanism that facilitate the following types of collaboration:</p> <ul style="list-style-type: none"> • Develop a Mechanism to facilitate voluntary technology transfer and co-development; • Launch Joint Research Calls; • Promote technical cooperation; • Share past experiences and develop a repository for best practices and examples of successful technology transfer and co-development; • Mechanisms to guarantee stable demand and efficient scale. 	<p>Proposed change for clarity, in alignment with the language used on page 7 in paragraph 6.</p>

Page (12-13) Paragraph (5)

Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The Alliance shall collaborate on the following initial list of diseases, the priorities among which will be jointly defined by the Alliance:</p> <ul style="list-style-type: none"> • Dengue • Chagas Disease • Onchocerciasis • Hanses Disease • Zika • HIV/AIDS • Chikungunya • Syphilis • Tuberculosis • Trachoma • Malaria • Filariasis • Schistosomiasis • Lupus • Geohelminthiasis • Pertussis • Brucellosis • Meningitis 	<p>The Alliance shall collaborate on the following initial list of diseases, the priorities among which will be jointly defined by the Alliance:</p> <ul style="list-style-type: none"> • Dengue • Chagas Disease • Onchocerciasis • Hanses Disease • Zika • HIV/AIDS • Chikungunya • Syphilis • Tuberculosis • Trachoma • Malaria • Filariasis • Schistosomiasis • Lupus • Geohelminthiasis • Pertussis • Brucellosis • Meningitis 	<p>Canada would like to propose the inclusion of polio on the list of diseases. As long as polio exists anywhere, it is a threat everywhere. Variant poliovirus has appeared in locations long considered to be polio free. Recent incidents are relevant as they were related to the spread of virus from places where the Global Polio Eradication Initiative continues to battle the poliovirus and underscore the need to stop virus transmission in those places.</p>



<ul style="list-style-type: none">• Cholera• Human Rabies• Leishmaniasis• Toxoplasmosis• Spotted Fever	<ul style="list-style-type: none">• Cholera• Human Rabies• Leishmaniasis• Toxoplasmosis• Spotted Fever• Polio	
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Spain

(no changes submitted)

Saudi Arabia

(no changes submitted)

Japan

(no changes submitted)

Angola

Page (6) Paragraph (1)		
Current text ⁴ (copy and paste the entire paragraph)	Proposed new text ⁵⁶ (highlight in red the changes, including deletion)	Comments or justification (optional)
While there is strong support to geographically diversify production, initiatives are needed to operationalize it.	While there is strong support to geographically diversify production, initiatives are needed to operationalize it. Those initiatives should be developed in local or regions of most impact neglected diseases, therefore the support should address the local or region of impact.	The initiatives, whose support is available, should be developed in regions with the greatest impact of neglected diseases, in order to quickly make vaccines, medicines, treatments and other technologies available to the vulnerable population.

Page (12-13) Paragraph (list of diseases)

⁴ If just reallocation of the paragraph to a different part of the text, please copy and paste the paragraph in the first column, leave the second column blank and insert the new number of page and paragraph in the “comments or justification” third column.

⁵ If deletion of the entire paragraph, just mention in the second column “delete paragraph”

⁶ If addition of an entire new paragraph, keep the first column blank and write the new proposal text in the second column. Please do not forget to indicate in the first line of the table in which page and paragraph your new proposal would fit.

Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
To add to the list of diseases	Scabies/Scabies, Human African Trypanosomiasis, Snake Bite Poisoning, Dracunculosis, Buruli Ulcer and Yaws.	To have more regional relevant diseases in the document.

Germany

Page (4) Paragraph (1)		
Current text ⁷ (copy and paste the entire paragraph)	Proposed new text ⁸⁹ (highlight in red the changes, including deletion)	Comments or justification (optional)
It is also essential for reducing health inequalities and improving health outcomes, especially in developing countries, which face high prices, limited negotiation power, shortages, limited infrastructure and patent protection.	It is also essential for reducing health inequalities and improving health outcomes, especially in developing countries, which face high prices, limited negotiation power, shortages and limited infrastructure. and patent protection.	This sentence lists patent protection in the same context as high prices, shortages and limited infrastructure, and thus suggests that patent protection may have a negative impact on health

⁷ If just reallocation of the paragraph to a different part of the text, please copy and paste the paragraph in the first column, leave the second column blank and insert the new number of page and paragraph in the “comments or justification” third column.

⁸ If deletion of the entire paragraph, just mention in the second column “delete paragraph”

⁹ If addition of an entire new paragraph, keep the first column blank and write the new proposal text in the second column. Please do not forget to indicate in the first line of the table in which page and paragraph your new proposal would fit.



		outcomes. On the contrary, patent protection positively affects health outcomes because it provides a necessary incentive for innovation – especially in insufficient markets.
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Norway

(no changes submitted)

European Union

We request the Chair to first clarify the proposed format for the G20’s endorsement of the proposed Alliance: would it be referred to in the Leaders’ declaration, and/or in the research ministerial communiqué, and/or in the health ministerial communiqué. Would this be complemented by Terms of References that are annexed to the declaration or the communiqué(s)?

Indonesia

Page (2) Paragraph (2)		
Current text ¹⁰ (copy and paste the entire paragraph)	Proposed new text ¹¹¹² (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The Brazilian proposal is to develop an alliance for local and regional production and innovation and equity in access, with a focus on neglected diseases and populations, as well as on vaccines: The “Global Alliance for Local and Regional Production, Innovation, and Equity in Access, focusing on Vaccines, Treatments, Diagnosis and other health technologies (VTDs) for Neglected Populations and Diseases and Vaccines”, is hereby referred to as the “Alliance for Local and Regional Production and Innovation”. This proposal stems from</p>	<p>The Brazilian proposal is to develop an alliance for local and regional production-innovation and innovation-production and equity in access, with a focus on neglected-vulnerable populations, and neglected diseases, and other determined diseasesas well as on vaccines: The “Global Alliance for Local and Regional Production, Innovation, Production, and Equity in Access, focusing on Vaccines, Treatments, Diagnosis and other health technologies (VTDs: Vaccines, Medicines, Therapeutics, and Diagnostics) for Neglected-Vulnerable Populations, Neglected and Diseases and Vaccines”, is hereby referred</p>	<ul style="list-style-type: none"> - Change the word sequence - Alliance needs to be clarified - Diseases : will only focus on neglected diseases or other priority diseases as well - VTDs explanation

¹⁰ If just reallocation of the paragraph to a different part of the text, please copy and paste the paragraph in the first column, leave the second column blank and insert the new number of page and paragraph in the “comments or justification” third column.

¹¹ If deletion of the entire paragraph, just mention in the second column “delete paragraph”

¹² If addition of an entire new paragraph, keep the first column blank and write the new proposal text in the second column. Please do not forget to indicate in the first line of the table in which page and paragraph your new proposal would fit.

<p>the understanding that the G20 can play a decisive role in reducing health inequalities, including disparities in access to vaccines, medicines, diagnostics, and other health technologies, especially for vulnerable populations</p> <p>The pandemic revealed the necessity for robust and sustainable investment in developing countries on: (1) research and development (R&D); (2) capacity to produce locally</p> <p>and regionally vaccine, treatments and diagnostics as well as other health technologies</p> <p>(VTDs) through the diversification of local and regional production and mechanisms of technology transfer and co-production between developed and developing countries; (3)</p>	<p>to as the “Alliance for Local and Regional <u>Innovation and Production</u>—and Innovation”.</p> <p>This proposal stems from the understanding that the G20 can play a decisive role in reducing health inequalities, including disparities in access to vaccines, medicines<u>therapeutics</u>, diagnostics, and other health technologies, especially for vulnerable populations.</p> <p>The pandemic revealed the necessity for robust and sustainable investment in developing countries on: (1) research and development (R&D); (2) capacity to produce locally</p> <p>and regionally vaccine, treatments—<u>medicine, therapeutics</u> and diagnostics as well as other health technologies</p> <p>(VTDs) through the diversification of local and regional production and mechanisms of technology transfer and co-production between developed and developing countries; (3) building more resilient, robust and transparent supply chains; (4) creating a fair, transparent</p>	
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<p>building more resilient, robust and transparent supply chains; (4) creating a fair, transparent and equitable global mechanism of cooperation and mutual benefits; among others.</p>	<p>and equitable global mechanism of cooperation and mutual benefits; among others.</p>	
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Page (3) Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>Equity In The Access To Vaccines, Medicines, Diagnostics And Other Health Products</p>	<p>Equity In The Access To Vaccines, Medicines, Therapeutics, Diagnostics And Other Health Products<u>Technologies</u></p>	<p>- VTDs as previous paragraphs</p>

Page (4) Paragraph (2)		
Current text (copy and paste the entire paragraph)	Proposed new text	Comments or justification (optional)

	(highlight in red the changes, including deletion)	
Ensuring access to safe, effective, quality, and affordable medicines, vaccines, diagnostics, and other health products is a component of the full realization of the right to health and is instrumental for achieving Universal Health Coverage. It is also essential for reducing health inequalities and improving health outcomes, especially in developing countries, which face high prices, limited negotiating power, shortages, limited infrastructure, and patent protection.	Ensuring access to safe, effective, quality, and affordable vaccines, medicines, therapeutics diagnostics, and other health products is a component of the full realization of the right to health and is instrumental for achieving Universal Health Coverage. It is also essential for reducing health inequalities and improving health outcomes, especially in developing countries, which face high prices, limited negotiating power, shortages, limited infrastructure, and patent protection.	- <u>As above</u> - <u>Health products or technologies to make consistent</u>

Page (4) Paragraph (3)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
The field of neglected diseases should be viewed more broadly, where the most marginalized and vulnerable populations who are disproportionately affected by neglected diseases should have universal	The field of neglected diseases should be viewed more broadly, where the most marginalized and vulnerable populations who are disproportionately affected by neglected diseases should have universal access to VTDs	- as well as other health equipment, materials and services is the same as other health products in previous paragraph? As

<p>access to VTDs as well as other health equipment, materials and services. To guarantee this access, countries, especially the developing ones must strengthen their HEIC, as presented in the figure below.</p>	<p>as well as other health equipment, materials and services. To guarantee this access, countries, especially the developing ones must strengthen their Health Economic-Industrial Complex (HEIC), as presented in the figure below.</p>	<p>there are VTDS and others (product/equipment, materials, services)</p> <ul style="list-style-type: none"> - HEIC <p>explantation <u>explanation</u></p>
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Page (4) Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>Neglected diseases and vulnerable populations</p>	<p>Neglected diseases and vulnerable populations</p>	<ul style="list-style-type: none"> - Need to be clarified of the heading, as there is information on neglected diseases but less information on vulnerable populations

Page (4) Paragraph (4)		
Current text (copy and paste the entire paragraph)	Proposed new text	Comments or justification (optional)

	(highlight in red the changes, including deletion)	
Neglected diseases and socially determined diseases are closely related. Neglected diseases are a diverse group of diseases that disproportionately affect poor and marginalized populations, more prevalent in developing countries. Neglected diseases are often almost absent from the global health agenda and receive insufficient attention and resources for research, prevention, and treatment. They generate devastating health, social, and economic consequences.	Neglected diseases and socially determined diseases are closely related. Neglected diseases are a diverse group of diseases that disproportionately affect poor and marginalized populations, more prevalent in developing countries. Neglected diseases are often almost absent from the global health agenda and receive insufficient attention and resources for research, prevention, and treatment. They generate devastating health, social, and economic consequences.	- Need clarification on other diseases beside <u>besides</u> neglected diseases which are <u>socially determined diseases</u> . Will both are the focus of the alliance?

Page (5) Paragraph (2)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
Socially determined diseases, or diseases that disproportionately affect vulnerable populations, are illnesses and infections that impact populations facing greater poverty and social vulnerability more intensely. These	<u>Socially determined diseases, or diseases</u> that disproportionately affect vulnerable populations, are illnesses and infections that impact populations facing greater poverty and social vulnerability more intensely. These	- Need clarification on other diseases besides neglected diseases which are <u>socially determined diseases</u> . Will both are the focus of the

<p>diseases are not confined to the list of neglected diseases and include conditions such as tuberculosis, malaria. They are correlated with social, economic, and environmental determinants of health that contribute to disparities in health outcomes, requiring a multisectoral approach in the development of comprehensive and structural public policies. Such policies should encompass other aspects such as clean water, basic sanitation, education, social protection, among others.</p>	<p>diseases are not confined to the list of neglected diseases and include conditions such as tuberculosis (TB), malaria and other diseases. They are correlated with social, economic, and environmental determinants of health that contribute to disparities in health outcomes, requiring a multisectoral approach in the development of comprehensive and structural public policies. Such policies should encompass other aspects such as clean water, basic sanitation, education, social protection, among others.</p>	<p>alliance? If yes then need to be included in the subheading</p> <ul style="list-style-type: none"> - socially determined diseases are only focus on tbc and malaria? - Addition of TB and other diseases, after tbc and malaria
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Page (5) Paragraph (3)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>Neglected diseases are a significant public health concern, with 16 countries bearing 80% of the burden. Conservative estimates indicate that neglected diseases account for some 14.5 million disability-adjusted life years (DALYs), with significant variation among developing and developed countries³.</p>	<p>Neglected diseases are a significant public health concern, with 16 countries bearing 80% of the burden. Conservative estimates indicate that neglected diseases account for some 14.5 million disability-adjusted life years (DALYs), with significant variation among developing and developed countries. Tuberculosis caused</p>	<ul style="list-style-type: none"> - Deleted (TB) as previously stated - Deleted other and other neglected diseases, - Propose to add other diseases if not only focus

<p>Tuberculosis (TB) caused an estimated 1.30 million deaths globally in 2022, with about 50% of TB patients and their households facing total costs that are catastrophic. Malaria also remains a major health challenge, with an estimated 249 million malaria cases and 608,000 malaria deaths in 85 countries in 2025. Children under 5 accounted for about 80% of all malaria deaths in the African region, while the Americas saw an increase in dengue cases. Therefore, addressing the challenges of neglected diseases, TB, malaria, and other neglected diseases requires a comprehensive approach that includes strengthening local and regional production, innovation, and equitable access to essential health products.</p>	<p>an estimated 1.30 million deaths globally in 2022, with about 50% of TB patients and their households facing total costs that are catastrophic. Malaria also remains a major health challenge, with an estimated 249 million malaria cases and 608,000 malaria deaths in 85 countries in 2025. Children under 5 accounted for about 80% of all malaria deaths in the African region, while the Americas saw an increase in dengue cases. Therefore, addressing the challenges of neglected diseases, TB, malaria, and other diseases requires a comprehensive approach that includes strengthening local and regional production, innovation, and equitable access to essential health products.</p>	<p>on neglected, TB and malaria</p>
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Page (5) Paragraph (HEADING)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)

LOCAL AND REGIONAL PRODUCTION AND INNOVATION	LOCAL AND REGIONAL PRODUCTION INNOVATION AND INNOVATION PRODUCTION	<ul style="list-style-type: none"> - <u>Word sequence</u> - Need Explanation On The Scope Of Local And Regional Production And <u>Innovation</u>
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Page (6) Paragraph (2)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
Local and regional R&D, innovation, and production of strategic health products, diversified geographically, have the potential to improve access and safeguard populations in developing countries, including during health emergencies and other crises, provided the ecosystem is viable and sustainable. The momentum of discussions on pandemic prevention, preparedness, and response can be leveraged to expand and support the capacities of low and middle-income countries, contributing to the resilience of global	Local and regional R&D , innovation, and production of strategic health products <u>and technologies</u> , diversified geographically, have the potential to improve access and safeguard populations in developing countries, including during health emergencies and other crises, provided the ecosystem is viable and sustainable. The momentum of discussions on pandemic prevention, preparedness, and response can be leveraged to expand and support the capacities of low and middle-income countries, contributing to the resilience	<ul style="list-style-type: none"> - <u>R &D is part of innovation or it is separate activtites.</u> - Need clarification on the highlighted words, as pandemic, preparedness and response, health crises and emergencies will also be focus on the alliance?

production and distribution chains necessary to address health crises and emergencies	of global production and distribution chains necessary to address health crises and emergencies	
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Page (6) Paragraph (Sub heading)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
Reasearch and Development (R&D) – structural disparities between developed and developing countries	Research and Development (R&D) – structural disparities between developed and developing countries	- Typo research

Page (6) Paragraph (5)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
Data from the Global Observatory on Health Research and Development (WHO) reveal that a smaller portion of grant funding for health research reaches developing countries, with only 0.2% allocated to them. This disparity extends to noncommunicable diseases (NCDs) and neglected diseases, where funding remains	Data from the Global Observatory on Health Research and Development (WHO) reveal that a smaller portion of grant funding for health research reaches developing countries, with only 0.2% allocated to them. This disparity extends to noncommunicable diseases (NCDs) and neglected diseases , where funding remains	- Need clarification NCDs will also be focus on the alliance?

minimal. High-income countries boast significantly more health researchers and higher education institutions per	minimal. High-income countries boast significantly more health researchers and higher education institutions per	
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Page (8) Paragraph (6)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
International cooperation and collaboration can promote local and regional production of medicines, vaccines, and other health products. This can be achieved through technical	International cooperation and collaboration can promote local and regional production of vaccines, medicines, therapeutics, diagnostics and other health products. This can be achieved through technical	- As previously mentioned

Page (9) Paragraph (2)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
In order to tackle neglected diseases, Brazil proposes a broader vision of vaccines, diagnostics and treatments and other health technologies to be addressed through	In order to tackle neglected diseases, Brazil proposes a broader vision of vaccines, medicines, therapeutics, diagnostics and other health technologies to be addressed through	- As previously mentioned - Other health technologies?

<p>international cooperation and collaboration. It is suggested that complementary elements be involved in this process, such as health equipment, digital health and other technologies and health services. In this sense, we will operationalize a more systemic approach in relation to the industry services, including the technologies of the fourth technological revolution, such as artificial intelligence, big data, information technologies and connectivity, among others.</p>	<p>international cooperation and collaboration. It is suggested that complementary elements be involved in this process, such as health equipment, digital health and other technologies and health services. In this sense, we will operationalize a more systemic approach in relation to the industry services, including the technologies of the fourth technological revolution, such as artificial intelligence, big data, information technologies and connectivity, among others.</p>	
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Page (9) Paragraph (Heading)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>Discussing The Establishment Of An Alliance For Local Production And Innovation</p>	<p>Discussing The Establishment of An Alliance For Local and Regional Production <u>Innovation</u> And Innovation <u>Production</u></p>	<p>- Add and Regional as initiative title</p>

Page (9) Paragraph (4)

Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The G20 can discuss and support the establishment of a trusted Alliance for Local and Regional Production and Innovation, centered on the access to vaccines, treatments, diagnostics and other health technologies, with a focus on neglected diseases and populations, and socially determined diseases, as well as focused on research and development, production and access to vaccines.</p>	<p>The G20 can discuss and support the establishment of a trusted Alliance for Local and Regional Production and Innovation, centered on the access to vaccines, medicines, therapeutics, diagnostics and other health technologies, with a focus on neglected diseases and populations, and socially determined diseases, as well as focused on research and development, production and access to vaccines.</p>	<ul style="list-style-type: none"> - VTDs as previous comments - Other health technologies= Other health products= Other health materials? As previous comments - Are the focus only neglected diseases and socially determined diseases? As previous comment - Only vaccines or VTDs?

Page (10) Paragraph (3)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The Alliance shall unite leaders across different sectors. It will contribute to ensure equitable access to health technologies for</p>	<p>The Alliance shall unite leaders across different sectors. It will contribute to ensure equitable access to vaccines, medicines, therapeutics,</p>	<ul style="list-style-type: none"> - Explanation of leaders - Add VMTDs as previously mentioned

<p>neglected diseases that affect disproportionately vulnerable populations. It will seek to collect the world’s best public and private groups that invest in health technologies and develop a joint mission to shape the future of global health innovation and responsible investment through accelerating innovation, promoting collaboration, the engagement of all relevant actors, combining public and private.</p>	<p>diagnostics and health technologies for neglected diseases that affect disproportionately vulnerable populations. It will seek to collect the world’s best public and private groups that invest in health technologies and develop a joint mission to shape the future of global health innovation and responsible investment through accelerating innovation, promoting collaboration, the engagement of all relevant actors, combining public and private.</p>	<p>- Only neglected diseases?</p>
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Page (10) Paragraph (4)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The proposal is to use the capacity of the purchasing power of countries and international and regional organizations to provide institutional stability that favors public and private investments for the production and innovation for neglected diseases and vulnerable populations.</p>	<p>The proposal is to use the capacity of the purchasing power of countries and international and regional organizations to provide institutional stability that favors public and private investments for the production and innovation for neglected diseases and vulnerable populations.</p>	<p>- Only neglected diseases? - Proposed to add neglected diseases, socially determined diseases and other diseases decided by the alliance</p>

Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The Alliance would be a mechanism that facilitate the following types of collaboration:</p> <ul style="list-style-type: none"> • Develop a Mechanism to facilitate technology transfer and co-development; • Launch Joint Research Calls; • Promote technical cooperation; • Share past experiences and develop a repository for best practices and examples of successful technology transfer and co-development; • Mechanisms to guarantee stable demand and efficient scale. 	<p>The Alliance would be a mechanism that facilitate the following types of collaboration:</p> <ul style="list-style-type: none"> • Develop a Mechanism to facilitate technology transfer and co-development; • Launch Joint Research Calls; • Promote technical cooperation; • Share past experiences and develop a repository for best practices and examples of successful technology transfer and co-development; • Develop mechanism for capacity building and skill development; • Develop Networking and Collaboration Platforms • Mechanisms to guarantee stable demand and efficient scale. 	<ul style="list-style-type: none"> - Add capacity building and skill development - Develop Networking and Collaboration Platforms

Page (11) Paragraph (1)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
The Alliance for Local and Regional Production and Innovation would be inclusive and open to participation beyond G20 countries. The Alliance will foster a collaborative and diverse approach to promoting local and regional production and innovation for neglected diseases and socially determined diseases between the participants, as well as for vaccines. It could encompass the following representatives:	The Alliance for Local and Regional Production and Innovation would be inclusive and open to participation beyond G20 countries. The Alliance will foster a collaborative and diverse approach to promoting local and regional production and innovation for neglected diseases and socially determined diseases between the participants, as well as for vaccines . It could encompass the following representatives:	- As previous comments

Page (12) Paragraph (Subheading)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
Key cooperation areas in production and innovation	Key cooperation areas in production and innovation	- Sub heading need to be in line with the content as it only mentioned regarding the diseases <u>diseases.</u>

		<ul style="list-style-type: none"> - Proposed to add other eooperation<u>cooperation</u> areas instead of only diseases<u>diseases</u>
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Page (12) Paragraph (7)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
The Alliance shall collaborate on the following initial list of diseases, the priorities among which will be jointly defined by the Alliance:	The Alliance shall collaborate on the following initial list of diseases, the priorities among which will be jointly defined by the Alliance:	<ul style="list-style-type: none"> - Add other important diseases such as hepatitis, leptospirosis. - Delete human in human rabies

Republic of Korea

Page (11) Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
	Distributors and Logistics Companies	Participation of distributors and logistics companies can enhance the stability and efficiency of distribution, enabling the establishment of cold and refrigerated supply chains tailored to the characteristics of the technology

Page (11) Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)

	Regulatory Harmonization and Knowledge Sharing Based on Learning	Harmonizing health technology regulations and approval procedures among member countries can improve accessibility
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Page (7) Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
It is also crucial to foster technology transfer and knowledge sharing on voluntary and mutually agreed terms, as well as public-private partnerships	It is also crucial to foster technology transfer, knowledge (data and IP) sharing on voluntary and mutually agreed terms, as well as public-private partnerships	Specific management measures for data and intellectual property rights related to knowledge sharing are needed

Page (7) Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)

<p>Additionally, long-term incentives are necessary, including public financing, tax incentives, market-shaping strategies, and technical and financial assistance, guided by principles such as transparency, safety, affordability, effectiveness, efficiency, and equity, and considered as a shared responsibility</p>	<p>Additionally, long-term and multi forms of incentives are necessary, including public financing, tax incentives, market-shaping strategies, and technical and financial assistance, guided by principles such as transparency, safety, affordability, effectiveness, efficiency, and equity, and considered as a shared responsibility</p>	<p>Emphasis on various types of incentives</p>
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Page (10) Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>The Alliance would be a mechanism that facilitate the following types of collaboration:</p>	<ul style="list-style-type: none"> • Define the gap between unmet medical needs and R&D; • Education; 	<p>- Identify the gap between R&D and unmet medical needs (treatment, vaccine, diagnosis, etc.) at present</p>

<ul style="list-style-type: none"> • Develop a Mechanism to facilitate technology transfer and co-development; • Launch Joint Research Calls; • Promote technical cooperation; • Share past experiences and develop a repository for best practices and examples of successful technology transfer and co-development; <p>Mechanisms to guarantee stable demand and efficient scale.</p>	<ul style="list-style-type: none"> • Public stewardship; • Building relationships; • Financing mechanism 	<ul style="list-style-type: none"> - Add analysis of local context and expected approach through education - Public Responsibility for Access - Formation of relationships for cooperation with Global South and match-making with LMIC (medium to low income countries) - Development of financing methods such as pre-paid pooled finance and blended finance for affordable prices for LMIC countries
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Page (12) Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)

<ul style="list-style-type: none"> • Dengue • Onchocerciasis • Zika • Chikungunya • Tuberculosis • Malaria • Chagas Disease • Hanses Disease • HIV/AIDS • Syphilis • Trachoma • Filariasis • Schistosomiasis • Geohelminthiasis • Brucellosis • Cholera • Leishmaniasis • Spotted Fever • Lupus • Pertussis • Meningitis • Human Rabies • Toxoplasmosis 	<ul style="list-style-type: none"> • AMR (antimicrobial resistance) 	<ul style="list-style-type: none"> - Antibiotics contributed to the improvement of human life as an off-balance sheet for civilization, but no one is responsible for introspection - No new type of antibiotic has been developed in the past 40 years (Big Pharma has left antibiotic-related businesses), and WHO has reserved new antibiotics - Long-term plans (such as public infrastructure, incentive schemes such as the Pasteur Act) are required to sustain the use of antibiotics
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Russia

Page (8) Paragraph (3)		
Current text ¹³ (copy and paste the entire paragraph)	Proposed new text ¹⁴¹⁵ (highlight in red the changes, including deletion)	Comments or justification (optional)
	Efforts for international harmonization of regulatory norms and practices should play an important role to avoid unjustified complexity, as well as to reliably ensure a given level of quality of pharmaceutical and immunobiological products and to strive to simplify the procedures of mutual recognition of registration data for drugs.	Additional

Page (9) Paragraph (3)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)

¹³ If just reallocation of the paragraph to a different part of the text, please copy and paste the paragraph in the first column, leave the second column blank and insert the new number of page and paragraph in the “comments or justification” third column.

¹⁴ If deletion of the entire paragraph, just mention in the second column “delete paragraph”

¹⁵ If addition of an entire new paragraph, keep the first column blank and write the new proposal text in the second column. Please do not forget to indicate in the first line of the table in which page and paragraph your new proposal would fit.



	The development of the system for mutual recognition of drugs registration, which are most requested for medical use, should play important role in this process.	Additional
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Page (10) Paragraph (5)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
	Mechanisms for harmonization of regulatory legislation, norms and practices.	Additional, last in the list

Italy

Page (4) Paragraph (2)

Current text ¹⁶ (copy and paste the entire paragraph)	Proposed new text ¹⁷¹⁸ (highlight in red the changes, including deletion)	Comments or justification (optional)
EQUITY IN THE ACCESS TO VACCINES, MEDICINES, DIAGNOSTICS AND OTHER HEALTH PRODUCTS	EQUITY IN THE ACCESS TO VACCINES, MEDICINES, DIAGNOSTICS MEDICAL DEVICES AND OTHER HEALTH PRODUCTS	“Diagnostics” (i.e., in-vitro diagnostic medical devices) are a sub-category of medical devices. There are other essential medical devices (therapeutics, rehabilitation, surgical, monitoring), which are not referred to as “diagnostics” and “Health Products”.

Page (4) Paragraph (2)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)

¹⁶ If just reallocation of the paragraph to a different part of the text, please copy and paste the paragraph in the first column, leave the second column blank and insert the new number of page and paragraph in the “comments or justification” third column.

¹⁷ If deletion of the entire paragraph, just mention in the second column “delete paragraph”

¹⁸ If addition of an entire new paragraph, keep the first column blank and write the new proposal text in the second column. Please do not forget to indicate in the first line of the table in which page and paragraph your new proposal would fit.

<p>All human beings have the right to enjoy the highest attainable standard of physical and mental health without distinction of race, religion, political belief, economic, or social condition. Access to health, which encompasses strengthening national health systems and financing actions that reduce the impact of social, economic, and environmental determinants on health, includes access to vaccines, medicines, diagnostics, and other health products</p>	<p>All human beings have the right to enjoy the highest attainable standard of physical and mental health without distinction of race, religion, political belief, economic, or social condition. Access to health, which encompasses strengthening national health systems and financing actions that reduce the impact of social, economic, and environmental determinants on health, includes access to vaccines, medicines, diagnostics medical devices, and other health products</p>	<p>Same as above</p>
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Page (5) Paragraph (3)		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)

<p>The field of neglected diseases should be viewed more broadly, where the most marginalized and vulnerable populations who are disproportionately affected by neglected diseases should have universal access to VTDs as well as other health equipment, materials and services.</p>	<p>The field of neglected diseases should be viewed more broadly, where the most marginalized and vulnerable populations who are disproportionately affected by neglected diseases should have universal access to VTDs as well as other health—equipment medical devices, materials and services.</p>	<p>As above, health equipment is a subset of medical devices. There are other essential medical devices that are not included in this definition</p>
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Page () Paragraph ()		
Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
<p>They generate devastating health, social, and economic consequences.</p>	<p>They generate devastating health, social, and economic consequences and represent a growing threat for high-income countries too, due to climate change (e.g., vector diseases such as malaria or dengue)</p>	<p>It can be important to stress that supporting neglected diseases in low-income countries is important, also for high-income countries, for preventing future health emergencies of public concern.</p>

Page (all the document) Paragraph ()



Current text (copy and paste the entire paragraph)	Proposed new text (highlight in red the changes, including deletion)	Comments or justification (optional)
...developing country...	... developing country low and middle-income countries...	Unless referred to a specific development scale, it can be more appropriate to use the term “low and middle-income country”.