GHSA Proposal: Revamp Workforce Development & Medical Countermeasures Action Package

- Maximum 2–3 pages.
- Please follow the template outlined below.
- If you have any questions/concerns, please contact the GHSA thai.ghsacounit@gmail.com

Members

Global Health Security Agenda (GHSA) countries that have prioritized bolstering their own research and development (R&D) capacity to develop products to respond to health emergencies, particularly low- and middle-income countries (LMICs) or countries most severely impacted by disease outbreaks. Multiple countries have articulated interest in leveraging GHSA to support capacity-building for R&D of medical countermeasures. Goal is for specific countries to commit to contributing to revamped action package at the January 2021 GHSA Steering Committee meeting.

GHSAC member Global Health Technologies Coalition could provide operational support to Action Package leaders for meetings, building on other successful models such as the Biosafety and Biosecurity Action Package. The Chair would rotate on an annual basis among Action Package members.

Other stakeholders that could be included are WHO, GHSAC members, World Bank, and Private Sector Roundtable partners.

Issue

GHSA should revamp the scope of the Workforce Development & Medical Countermeasures Action Package and expand its mandate to explicitly embed support for R&D of medical countermeasures including diagnostics as part of its core priorities.

With global deaths from COVID-19 surpassing 2 million and counting, the pandemic has made clear that there are severe gaps in global health security preparedness. Scientists around the globe are racing to develop, manufacture, and deploy new diagnostics, therapeutics, vaccines, and other tools in record time to flatten the curve and shore up overburdened and fragile health systems. While it has never been more apparent that R&D of medical countermeasures is vital to enhance our capacity to prevent and combat threats as they emerge, capacity-building of R&D for medical countermeasures including diagnostics is noticeably absent from the GHSA framework as well as the International Health Regulations (IHR). Despite significant progress in the prioritization of R&D for global health security technologies, there is an outstanding need for improved investments in and accelerated development approaches to these technologies. The typical product development process spans basic research, applied research, national and global regulatory review, all the way to manufacturing, including for products where there may not be a defined market or technical and financial support. In order to address current and future pandemics, R&D should be integrated formally into both GHSA and IHR. While not every country needs a full suite of capabilities for end-to-end development of vaccines, diagnostics, therapeutics, and other technologies like personal protective equipment and oxygen therapies through manufacturing, every country should have a plan and pathway to gain access to these tools at an affordable price when needed.

A revamped Action Package focused on R&D would allow countries to coordinate global and regional research capacity strengthening activities to enhance preparedness capabilities and develop pathways to get access to the technologies they need. The current and past pandemics have shown that without clear

mechanisms and procedures to facilitate the equitable sharing of limited medical countermeasures, LMICs may be particularly disadvantaged in gaining access to the critical medical products they need. Creating a supportive ecosystem at the national, regional, and global levels for health security–related R&D is vital to ensuring that the necessary partnerships and tools are developed and that these tools are readily available when needed.[1] Many of the activities that support R&D capabilities also deliver co-benefits with respect to other global health security priorities, e.g. improving laboratory capacity, strengthening health systems, enhancing biosafety and biosecurity, etc.

Mandate

This refocused Action Package will serve as a platform that convenes countries, international organizations, industry, academia, and civil society to address the full scope of end-to-end product development and advance shared objectives in six main areas: country-global collaboration on clinical research, country capacity to support late-phase clinical trials, national and regional regulatory strengthening, cross-initiative coordination, manufacturing and procurement, and R&D capacity assessment. Countries will be supported as appropriate to develop and implement operational road maps—based on international standards, guidelines, and successful existing models—that specify the actions necessary to strengthen their national health security R&D ecosystems. The Action Package will also actively coordinate with other relevant Action Packages such as those on antimicrobial resistance, zoonotic disease, biosafety & biosecurity, and laboratory systems.

Strategic Objectives

1. Enhance coordination of global R&D processes through an existing global framework that can serve as a hub for end-to-end biomedical research expertise and galvanize greater R&D collaboration to advance health products to respond to emerging health threats at both the national and regional level.
2. Deepen international collaboration on health security R&D by convening relevant actors to identify barriers to communication and collaboration and develop road maps for improvement, including in relation to financing, data-sharing, and the coordination of targeted research calls.
3. Strengthen the ability of every country, especially LMICs, to participate in global and regional clinical trials for health security–related products, including by developing good practice principles and guidance and convening sources of external support to fill identified gaps.
4. Support the strengthening of national medicines regulatory frameworks and agencies with respect to health security–related products, with the aim of expediting rigorous assessments of product efficacy and safety, encouraging harmonization of processes at the regional level, and facilitating the appropriate use of emergency authorization systems, and prioritizing action in support of post-registration product procurement and storage.
5. Support the development of national and regional manufacturing and procurement plans for vaccines, diagnostics, therapeutics, and other technologies like personal protective equipment and oxygen therapies to combat outbreaks.

Organization

To be confirmed during work planning with input from interested countries and stakeholders.

[1] Guidance on R&D ecosystems and priorities has been articulated in numerous sources, including but not limited to the National Academies of Sciences, Engineering, and Medicine's *Global Health Risk Framework: Research and Development of Medical Products: Workshop Summary*; the UN High-Level Panel's report on the *Global Response to Health Crises*; the World Health Organization's *A research and development Blueprint for action to prevent epidemics*; and the World Bank's *Money and microbes: strengthening clinical research capacity to prevent epidemics*.

Value Added

This Action Package will foster innovations in science and technology leading to the development of better tools for preventing, detecting, and responding to disease outbreaks. Participating countries will aim to promote the strengthening of national research and product development and delivery infrastructure, catalyze public-private collaboration and partnerships, accelerate safe and effective product development, and reduce barriers limiting access to technologies, such as costly and unclear regulatory processes and limited lab and manufacturing capacity. Programmatic activity arising from the Action Package would, where appropriate, be incorporated into and costed/evaluated in the context of National Action Plans for Health Security. As noted in the recent Global Preparedness Monitoring Board (GPMB) report,[2] the World Bank and other International Financial Institutions (IFIs) could provide the funding for R&D capacity in LMICs through IFI financing and develop mechanisms to provide resources for global R&D for health emergencies.

This Action Package will serve as a platform to help strengthen connections between health security actors at the national level and stakeholders in globally focused institutions such as the product development partnerships, the Coalition for Epidemic Preparedness Innovations (CEPI),[3] the Global Observatory on Health R&D,[4] the World Health Organization's (WHO) R&D Blueprint,[5] and IFIs like the World Bank thereby fostering a more effective local-to-global feedback loop. Work under the Action Package will seek to avoid duplication with that underway in other fora and will add value by helping to break down silos and contributing to cross-initiative coordination.

Activities & Initiatives

Short-term (2021)

1. Convene participating countries and other stakeholders to develop and agree on the overall work plan and operational structure for the Action Package.
2. For each of the country-related strategic priorities (ideally working in sub-groups by priority):
    a. Develop an agreed-upon tool, including indicators and metrics, for gaining an overall understanding of country R&D capacities and regional gaps in the relevant strategic priority areas, informed by the Global Health Security Index[6] and landscaping done by WHO's ESSENCE of health research initiative.[7]
    b. Define scope of R&D for GHSA (e.g., pre-clinical research through manufacturing)
    c. Encourage the identification and implementation of new actions from public- and private-sector GHSA partners to strengthen R&D for health security.

Longer-term (2021–2024)

1. Track execution of actions from public- and private-sector GHSA partners to improve R&D for health security.
2. Assist countries in developing road maps to address gaps in national R&D capacity, as appropriate for individual country contexts and within the framework of National Action Plans for Health Security.

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[2] GPMB 2nd annual report: *A World in Disorder*
[3] CEPI COVID-19 Manufacturing Survey Results Analysis
[4] Global Observatory on Health R&D
[5] WHO R&D Blueprint
[6] 2019 Global Health Security Index
[7] WHO ESSENCE on Health Research

3. Hold dialogue on regional regulatory harmonization and other bottlenecks that hamper the uptake of new technologies.
4. Facilitate countries' (particularly LMICs') ability to participate in clinical trials for emerging and reemerging infectious diseases.
5. In collaboration with the Joint External Evaluation Alliance, convene countries and other stakeholders identifying sources of and priorities for external support for the implementation of R&D road maps within National Action Plans for Health Security.
6. Collaborate with the World Bank and other IFIs on strategic research capacity and product development investments, as outlined in the 2020 GPMB report.
7. Develop national and regional plans to manufacture or procure vaccines, diagnostics, therapeutics, and other technologies like personal protective equipment and oxygen therapies to combat outbreaks.
8. In 2023–2024: re-assess, on request and normally in association with a Joint External Evaluation process, countries that have initially undertaken a baseline assessment and pursued a road map, to measure progress achieved.