

THE WAY FORWARD FOR **ACCESS** TO MEDICINES



BACKGROUND

At the 71st World Health Assembly (WHA), Member States will deliberate on issues critical for global health, such as access to, and shortages of, medicines, imbalances in the current research and development (R&D) model and the role of the World Health Organization (WHO) in addressing new threats and responding to structural challenges. Civil society will play an important and constructive part throughout these discussions.

The 13th General Programme of Work (GPW13), the draft of which was recommended for approval by the 142nd Session of the WHO Executive Board (EB142), notes that access to quality-assured medicines plays a crucial role in improving and expanding Universal Health Coverage (UHC). It adds that the high cost of medicines remains prohibitive for far too many people and sets out the plan for WHO to align its work more closely with the Sustainable Development Goals (SDG), especially SDG 3.8.

The WHA will consider the work of the expert panel appointed to evaluate the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA-PHI), as presented and discussed at the EB14

The WHA is also asked to adopt a draft decision requesting the Director-General begin work on a roadmap report on WHO activities and programmes to improve access to medicines and vaccines. The roadmap is to be drafted in the coming months, and submitted for approval by the WHO governing bodies.

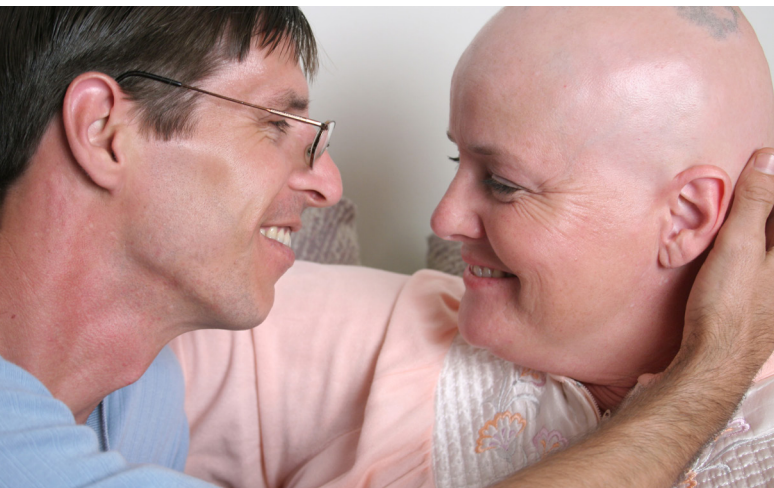
HEALTH ACTION INTERNATIONAL

Health Action International (HAI) comes to WHA71 on the back of a series of interventions made at various WHO governing bodies and other ad hoc meetings.

We believe that the implementation of GPW13, GSPOA-PHI and the design of the roadmap are

necessarily intertwined. It is therefore right that coherence be sought between these initiatives.

HAI welcomes all three of these initiatives, and urges the WHA to adopt the recommendations, taking into account certain important factors.



POLICY RECOMMENDATIONS

The three pillars of transparency, affordability and innovation should guide WHO actions on promoting and improving access to medicines.

For instance, mechanisms should be in place that replicate best practices in ensuring transparency in the promotion and defence of public health. Meanwhile, affordability and sustainability constitute critical components of public efforts to promote and improve access to medicines. The social function of innovation should not be forgotten—innovation has no sense without access.

GPW13

GPW13 is an ambitious blueprint for WHO reform, which also addresses global health challenges. Its alignment with other global initiatives and entities is particularly welcome.

We note positively WHO willingness to improve transparency and promote accountability at all levels of public health policies, programmes and actions. Transparency on issues such as pricing, R&D costs and clinical trial data should be given special consideration.

The WHO undoubtedly has a more active role to play in the promotion of sustainable innovation that responds to public health needs, rather than the current market-driven approach. High prices of medicines are linked to a patent-centred model of R&D. We therefore call on WHO to promote and support the design and development of feasibility studies for alternative innovation models based on delinkage between the cost of R&D and price of the product.

The WHO contribution to ongoing discussions regarding access to innovation should go beyond coordination and monitoring. It is time for the organisation to explore the possibility of an international treaty on biomedical research and present the options to Member States.

GSPOA-PHI

We encourage Member States to fund the implementation of the remaining activities in GSPOA and renew their commitment to fix a broken R&D system that still does not respond to the public health needs of large population groups.

We support collaboration with other organisations to move towards the more effective implementation of Article 66.2 (Technology Transfer) of the Trade-related Aspects of Intellectual Property (TRIPS) Agreement. The WHO should support the drafting of national legislation to make full use of the flexibilities contained within the TRIPS Agreement. Additionally, we call on WHO to continue collaborating with the Medicines Patent Pool, especially promoting the MedsPal database among member states and other stakeholders.

Member States and other international bodies, such as the European Commission, must heed the call to take into account the impact on public health of provisions that go beyond the requirements of the TRIPS Agreement when negotiating trade agreements. These include Supplementary Protection Certificates (SPC) and other intellectual property (IP) incentive mechanisms.

ROADMAP ON ACCESS TO MEDICINES AND VACCINES

We encourage WHO to engage with the widest possible range of stakeholders and concerned parties, including civil society, academia, and patient and consumers groups, to gather ideas, proposals and insights on how to better promote access. In doing so, stringent conflict of interest rules should also be applied.

We join our voice to those of Member States and non-state actors in asking WHO to keep working towards greater transparency in key areas such as the cost of R&D, pricing decisions and patents, and support existing initiatives, for example the R&D Observatory.

Recommendations by other entities, including the Consultative Expert Working Group on Research and Development (CEWG) and the High Level Panel on Access to Medicines, should be considered for inclusion in the roadmap.

It is important that IP-management tools, TRIPS flexibilities and other mechanisms be a core part of the roadmap and technical cooperation offered by WHO to Member States. To ensure the sustainability and final implementation of the roadmap, we ask the WHO Secretariat and Member States to ensure that the programmes and activities contained within the roadmap are fully funded, with less than 30 percent in voluntary contributions.

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