WHO Roadmap for Access: 2019-2023

Policy brief

Executive Summary

At the direction of the 71st World Health Assembly (WHA) held in May 2018, the World Health Organization (WHO) has been working at breakneck speed to develop a comprehensive "roadmap" detailing all of WHO's proposed activities related to increasing access to medicines and vaccines. Released in December 2018, the draft roadmap, which has already been subject to significant text litigation by member states, proposes eight main areas for WHO's access work between 2019–2023, and is broken down into two strategic areas:

1. Strategic area: Ensuring the quality, safety, and efficacy of health products
    a. Activity: Regulatory system strengthening.
    b. Activity: Assessment of the quality, safety, and efficacy/performance of health products through prequalification.
    c. Activity: Market surveillance of quality, safety, and efficacy/performance.
2. Strategic area: Improving equitable access to health products
    a. Activity: Research and development (R&D) for medicines and vaccines that meet public health needs.
    b. Activity: Application and management of intellectual property (IP) to contribute to innovation and promote public health.
    c. Activity: Evidence-based selection and fair pricing and financing policies.
    d. Activity: Procurement and supply chain management for quality-assured health products.
    e. Activity: Appropriate prescribing, dispensing, and rational use of medicines.

Each of these broad areas is accompanied by a results framework that sets expected deliverables. The current intent is to present the draft roadmap to the WHO Executive Board (EB) in January where the text will be negotiated to get as close to consensus as possible, followed by a final round of edits and endorsement by the WHA in May 2019.

This timeline is extremely aggressive, especially given the controversy surrounding some of the proposed areas of work. Historically, there has not been agreement among member states that WHO should expand its work on pricing and IP policies, and some of the most heated debates of the past decade have centered on these specific areas. While there will likely be significant additional negotiations on the specific text of the roadmap, it is almost certain that some form of the roadmap and/or an associated resolution will be approved.

Background

WHO's work on access to medicines—in its most recent iteration—dates to the formation of the Commission on Intellectual Property Rights, Innovation and Public Health in 2003. The commission was created to propose novel policy approaches to balancing incentives for innovation with the need to achieve affordable pricing. The group has evolved multiple times in the 15 years

since its formation, and most recently took the form of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), though the mandate has remained much the same. At every stage, these advisory bodies found themselves at the center of a political firestorm, caught between member states, civil society advocates, and industry representatives, all ascribing to deeply entrenched positions as to what the root cause of lack of access to medicines and vaccines is; high prices due to IP creating exclusivity or a broader set of systemic issues. Unfortunately, none of the proposals put forward by the various commissions have had the desired impact for a variety of reasons, including ongoing disagreements leading to a lack of resources to implement them fully.

As a result of these fundamental disagreements and lack of progress by the various commissions, WHO's global strategies—which govern the WHO Secretariat's work in technical areas—on access to medicines have routinely been among the most contentious on the governing bodies' agendas and countries have generally not been able to reach meaningful consensus.

This roadmap is itself the result of highly complex parliamentary and legal maneuvering at the 2018 WHA, at which member states attempted to forge their own compromise proposal, only to ultimately request that WHO produce the roadmap outlining proposed activities as a precondition for approving any new areas of work, such as those outlined in the various commission reports published over the years. GHTC fully expects this roadmap to feature prominently on the 2019 agendas for the EB and WHA, both in terms of time allocated as well as in attention paid by member states.

Strategic area: Ensuring the quality, safety, and efficacy of health products

Regulatory system strengthening

Actions

1. Develop and implement WHO technical guidelines, norms, and standards for quality assurance and safety of health products.
2. Support improvement of regulatory systems, promoting reliance and collaboration.
3. Strengthen preparedness for entry of medicines, vaccines, and other health products into countries experiencing a public health emergency or crisis.

Key considerations

Over recent years, significant progress in addressing regulatory barriers to access has been made, and WHO intends to build on that through this area of work. Sound regulatory support for access to medicines ensures both timely access to medicines, as well as appropriate safety guidelines and pharmacovigilance activities. Technical standards and assistance supporting systems in achieving these targets have historically been viewed as falling within WHO's core technical mandate and are not expected to be controversial.

Assessment of the quality, safety, and efficacy/performance of health products through qualification

Action

1. Maintain and expand the prequalification service.

Key considerations

The WHO prequalification (PQ) program has proven to be an invaluable asset in helping promote access to quality-assured health technologies. The roadmap commits WHO to strengthening the PQ program and to expanding it to better reflect the full scope of the essential medicines and diagnostics lists. This initiative will likely receive broad support.

Market surveillance of quality, safety, and efficacy/performance

Action

1. Support strengthening national capacity to ensure the quality, safety, and efficacy of health products.

Key considerations

Once products have been approved for market entry by the relevant regulatory authority, their quality and safety must be monitored once the products have entered either the commercial or public sector supply chains. This activity commits WHO to assist countries to develop the capacity to conduct appropriate surveillance and quality assurance of products on the market. This type of technical assistance is well within WHO's established mandate and should not attract controversy.

Strategic area: Improving equitable access to health products

Research and development for medicines and vaccines that meet public health needs

Actions

1. Continue to set priorities for health R&D in areas of compelling health need.
2. Coordinated actions on health R&D.
3. Support improved capacity for R&D and clinical trials in countries.

Key considerations

This set of activities falls squarely into WHO's convening, normative, capacity building, and priority-setting mandate and reflects, for the most part, a continuation of work WHO is already doing, including support for the Global Observatory on Health Research and Development, through which WHO specifically identifies technologies or diseases for which there is no commercial market as being priorities for this area of work.

Application and management of intellectual property to contribute to innovation and promote public health

Actions

1. Foster innovation and access to health products by appropriate IP rules and management.
2. Provide technical support and capacity building.

Key considerations

Issues regarding IP policies implicitly underpin the debate around pricing and are equally as fraught. Like the debate on pricing, one side of the IP argument is that market exclusivity (through patent protections) allow companies to charge unreasonable prices, while the opposing side counters that exclusivity is necessary to provide incentives for novel research by allowing companies to accrue the benefits of new products for a period prior to generic competition. Many product development partnerships (PDPs), which are unique nonprofit organizations that bring together actors across sectors, argue that IP is neither inherently good or bad, it is what organizations choose to do with it that determines impact.

Historically, WHO has shied away from engaging directly on health-related IP issues due to significant pressure from some member states who believe that IP issues do not fall within WHO's mandate and are best addressed through the World Trade Organization and the World Intellectual Property Organization. As a result, this proposed area of work represents an expansion beyond WHO's current activities and will likely prove controversial as a result.

Evidence-based selection and fair and affordable pricing

Specific actions

1. Support processes for evidence-based selection, including health technology assessment and their implementation.
2. Encourage more transparent and better policies and actions to ensure fairer pricing and reduction of out of pocket payments.

Key considerations

Pricing has been and continues to be the third rail of the access to medicines debate. On one hand, some argue that due to the high cost of R&D, which involves investments in failed technologies, companies need to charge high prices in order to recoup investments and make a profit to provide incentive for future innovation. On the other hand, there is a significant constituency arguing that human life should never take second place to commercial interests and that there are better ways to support health innovation than a profit-based model. This proposed group of activities will likely be a focus of significant contentious debate given that it does represent a meaningful expansion of WHO's mandate into a policy space that has historically been the purview of the World Trade Organization.

Procurement and supply chain management for quality-assured health products

Specific actions

1. Support collaborative approaches for strategic procurement of health products.
2. Support countries for efficient procurement and supply chain management of health products.
3. Improve capacity for detecting, preventing, and responding to shortages of medicines and vaccines.
4. Support for adequate supply management and appropriate use of health products in emergencies and crisis situations.

Key considerations

Improving procurement and supply chain management to help ensure reliable supply chains and avert stockouts is generally accepted as both a necessary part of any comprehensive solution to the access problem, as well as an area in which WHO is playing a significant role in convening stakeholders to ensure countries receive the technical support they need. A key outstanding question in this area, however, is whether WHO has the internal capacity to help countries operationalize supply chain recommendations, and whether that is WHO's role to engage at that level.

Appropriate prescribing, dispensing, and rational use of medicines

Specific actions

1. Consolidate interventions that improve use.
2. Take disease/condition specific actions.
3. Support capacity for monitoring.

Key considerations

One item in the chain of access that often goes overlooked is that roughly half of all medicines prescribed, dispensed, or sold globally are inappropriate, according to WHO. While antibiotics are widely overused—contributing to the growth of antimicrobial resistance—controlled substances are dramatically under-utilized, and only 10 percent of people requiring treatment receive it. Addressing these and other concerns is a consensus position across the global health community, and this item should not provoke significant debate given that these activities fall squarely within WHO's existing mandate to provide technical assistance and capacity building to member countries.