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New Amendments to the International Health Regulations: Strengthening Access to Health Products in Emergencies and Pandemics

By Viviana Munoz Tellez

The International Health Regulations amendments entered into force on September 19, 2025 across most World Health Organization (WHO) Member States. These updates don't give WHO any new powers but help countries work better together to advance fair and timely access to health products such as vaccines, treatments and diagnostics needed to respond to health emergencies. The real challenge now is implementation and building the necessary capabilities to make these improvements function.

Les modifications apportées au Règlement sanitaire international sont entrées en vigueur le 19 septembre 2025 dans la plupart des États membres de l'Organisation mondiale de la santé (OMS). Ces mises à jour ne confèrent aucun nouveau pouvoir à l'OMS, mais aident les pays à mieux collaborer afin de promouvoir un accès équitable et rapide aux produits de santé tels que les vaccins, les traitements et les diagnostics nécessaires pour faire face aux urgences sanitaires. Le véritable défi consiste désormais à mettre en œuvre ces améliorations et à développer les capacités nécessaires pour les faire fonctionner.

Las enmiendas al Reglamento Sanitario Internacional entraron en vigor el 19 de septiembre de 2025 en la mayoría de los Estados miembros de la Organización Mundial de la Salud (OMS). Estas actualizaciones no otorgan nuevos poderes a la OMS, pero ayudan a los países a colaborar mejor para promover un acceso justo y oportuno a los productos sanitarios, como vacunas, tratamientos y diagnósticos, necesarios para responder a las emergencias sanitarias. El verdadero reto ahora es la aplicación y el desarrollo de las capacidades necesarias para que estas mejoras funcionen.

19 September 2025 marks the entry into force of the [amendments to the International Health Regulations \(IHR\)](#), the oldest instrument of multilateral collaboration in global health security.

The Member States of the World Health Organization (WHO) approved revisions to the IHR (2005) at the 77th World Health Assembly (WHA) in 2025. Against a backdrop of weakening commitment to multilateral solutions, mounting nationalist pressures, and deliberate misinformation about WHO overreach, the adoption of IHR amendments represented a significant diplomatic accomplishment.

As regulations adopted under article 21 of the WHO Constitution, the IHR are legally binding on all Member States. That said, they can make reservations to the IHR. For the new amendments of 2025, a Member State could notify the WHO Director-General (DG) on whether it wished to reject or reserve on any or all of the amendments, before 19 July 2025. The amendments otherwise become binding on Member States as of 19 September 2025.

The process of IHR amendments entry into force contrasts with other agreements such as the Pandemic Agreement, adopted under article 19 of the WHO constitution, which requires the ratification by States Parties before it can enter into force.

The United States will not be bound to the amendments to the IHR, as it has issued a formal rejection of the IHR amendments. A few other countries also opted to [reject the IHR amendments](#), mainly for reasons of asserting national sovereignty over health security matters.

In our view, the rejection of the 2025 amendments is misguided. The IHR amendments do not restrict country sovereignty over health issues. It does not give WHO any enforcement power over Member State obligations under the revised IHR, nor does it change the non-binding nature of the recommendations that the WHO DG can issue under the IHR. The IHR serve to strengthen all States Parties' capabilities to prevent and control public health risks and events before these become global health emergencies. Importantly, the IHR amendments now require building and maintaining capacities for providing access to health services and

health products needed to respond to public health emergencies and strengthen the commitment for collaboration, assistance and financing for the implementation of the regulations.

The Regulations now include in the scope events that may constitute a "pandemic emergency", to complement events that constitute a "public health emergency of international concern". This aligns to the scope of the Pandemic Agreement as adopted by the World Health Assembly in May 2025.

The WHO has a facilitator's role to remove barriers to timely and equitable access by States Parties to relevant health products, after the determination of and during a public health emergency of international concern, including a pandemic emergency, based on public health risks and needs. To this effect, the DG can take several actions, including to conduct a review and update on the availability and accessibility, including affordability, of relevant health products for the public health response; make use of WHO-coordinated mechanisms, or facilitate their establishment and coordinate allocation and distribution mechanisms and networks that facilitate timely and equitable access to relevant health products based on public health needs; support States Parties in scaling up and geographically diversifying the production of relevant health products; share the product dossier related to a specific relevant health product for the purpose of facilitating regulatory evaluation and authorization by the State Party; and support States Parties to promote research and development and strengthen local production of quality, safe and effective relevant health products.

Moreover, States Parties should encourage relevant stakeholders operating in their respective jurisdictions to facilitate equitable access to relevant health products and make available relevant terms of their research and development agreements for relevant health products.

The new amendments have also made the availability of and accessibility to relevant health products central in the criteria for the issuance, modification or extension of temporary or standing recommendations by the WHO DG (Articles 15, 16, and 17).

Article 44 of the Regulations concerning collaboration with other States Parties and assistance has been amended to extend to preparedness for an event of pandemic emergency or public health emergencies of international concern, to strengthen sustainable financing to support the implementation of the Regulations, notably to facilitate access to health products.

The core capacities that States Parties are required to develop, strengthen and maintain, as elaborated in Annex 1 of the Regulations, as amended, are expanded from prevention and surveillance to include preparedness and response. New prevention core capacities include to prepare, provide for and facilitate access to health services necessary for responding to public health risks and events and to engage relevant stakeholders, including communities, in preparing for and responding to public health risks and events.

Other new elements on core capacities include those in relation to access to health services and health products needed for the response and logistical assistance (e.g. equipment, medical and other relevant supplies and transport).

Next steps

With the IHR amendments now in force in most WHO Member States, the focus should shift to implementation at the country level. The amendments need to be implemented, particularly those addressing access to health services and products. This implementation effort also requires the global health community to work together to address persistent gaps

in IHR compliance, such as supporting developing countries to overcome the systemic challenges that prevent them from building core capacities. The WHO must also update the assessment processes to reflect the amendments.

The WHO reorganization process must also ensure that the organization can effectively guide country implementation of the IHR, with priority assistance directed toward least developed and developing countries.

Finally, the ongoing negotiations on the annex on the [Pathogen Access and Benefit-Sharing System](#) (PABS) under [the newly adopted Pandemic Agreement](#) and its future implementation, should be informed by the IHR to ensure complementarity. The expectation is that the Pandemic Agreement can help to fill the many remaining gaps for effective global and equitable pandemic prevention, preparedness, response and recovery, and take lessons from the COVID-19 pandemic so that the stark inequity in timely access to health products and the concentration in the production of health products, are not repeated when the next global health emergency hits. Despite current geopolitical challenges and the challenges faced by multilateral institutions like the WHO, real action to rebuild collective capacity and solidarity for addressing global threats remain both achievable and urgent for global health security and to serve the national self-interests of States Parties.

Author: Viviana Munoz Tellez is Coordinator of the Health, Intellectual Property and Biodiversity Programme (HIPB) at the South Centre.

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**For more information, please contact Anna Bernardo of the South Centre:
Email abernardo@southcentre.int, or telephone +41 22 791 8050.**