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In-Depth: Life Sciences Law (formerly The Life Sciences Law Review) is an overview of the legal and regulatory frameworks governing pharmaceutical, biotechnology and medical device companies in key jurisdictions worldwide. It covers the major rules and restrictions throughout the life cycle of regulated products, from discovery to clinical trials, the marketing authorisation process and post-approval controls. It also examines the most consequential recent trends and developments in the sector.

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Practical perspectives from the World Health Organization

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Summary

Introduction

The World Health Organisation (WHO), established in 1948, is the specialised agency of the United Nations (UN) dedicated to global health. This chapter provides insights into both the technical and policy aspects of WHO's work, highlighting the role of and impact on innovative pharmaceutical companies.

WHO's core objectives include preventing the spread of diseases and improving the well-being of all people. Since its inception, WHO has repeatedly evolved, expanded and refined its mandate to better address emerging health threats.[1] A critical part of this evolution has been its growing collaboration with non-state partners, including private pharmaceutical companies.[2]

These private-sector partnerships are vital for delivering new, safe and effective medicines quickly to where they are needed most. To support this goal, WHO provides well-established and tested technical services, such as pre-qualification (PQ) and emergency use listing (EUL) of health products and the international non-proprietary names (INNs) programme for pharmaceutical substances:

1. PQ: established in 2001, WHO's PQ programme helps ensure the quality, safety and efficacy of health products for priority diseases, especially those intended for UN agencies or procurement in developing countries. To date, WHO has pre-qualified approximately 1,500 products. This process involves specialised technical assistance to guide recipients towards meeting international regulatory norms and standards, ultimately helping them achieve PQ status for essential goods and services.
2. INNs: since 1953, WHO has been responsible for assigning INNs to pharmaceutical substances or active ingredients, ensuring they have unique, globally recognisable names. The INN system facilitates clarity among drug authorities, manufacturers, healthcare professionals and researchers worldwide. A key principle of the system is that these names are in the public domain, so any party can use them without restriction.

In the field of outbreak response, WHO had made significant headway through its work on, for example, the Ebola virus; however, the covid-19 pandemic exposed areas where WHO still needs more robust tools and mechanisms for prevention, preparedness and response such events. Among others, WHO is taking steps to address long-standing issues, such as inequitable resource distribution, by (1) developing new access-to-medicines arrangements through a proposed Pandemic Treaty, and (2) leveraging an expanded mandate for equitable product distribution under the International Health Regulations (IHR):

1. Pandemic Treaty: under negotiation at the time of writing, the Pandemic Treaty aims to strengthen global preparedness, prevention and response for future pandemics. By setting clearer obligations for surveillance, data sharing, vaccine and countermeasure access, and coordinated public health measures, it seeks to establish a more equitable and effective global response – underpinned by

solidarity, transparency and timely resource allocation. It is expected that the Treaty will be agreed at the World Health Assembly in May 2025. Further negotiations are likely to take place on specific arrangements that will impact companies specifically, such as the pathogen access and benefit-sharing system.

2. IHR: the IHR forms a legally binding framework for protecting global health security, obliging countries to strengthen core public health capacities for surveillance, detection, assessment and reporting of potential public health emergencies of international concern (PHEIC). Originally adopted in 1969 and significantly revised in 2005, the IHR covers 196 countries (all WHO Member States plus additional signatories). They aim to ensure rapid, coordinated action against emergent health threats while minimising disruptions to travel and trade. The latest amendments in 2024 underscore the importance of equitable access to medical products in responding to crises, including pandemic emergencies.[3]

Both the Pandemic Treaty and the IHR will have significant repercussions on companies.

Through these evolving legal and policy instruments, WHO is adapting to the changing nature of global health challenges – and intensifying its impact on the private sector. The remainder of this chapter explores in greater detail how these technical and policy frameworks influence the pharmaceutical industry, shape the regulatory environment and create both opportunities and obligations for companies worldwide.

Year in review

In the wake of the covid-19 pandemic, WHO initiated several reforms to enhance global public health preparedness and response. A significant development is the amendment of the IHR in May 2024, which now include a defined 'pandemic emergency' category. This addition aims to facilitate prompt international action during health crises by clearly delineating the criteria for such emergencies. The updated IHR also emphasises equitable access to medical resources, particularly for developing nations, thereby strengthening global health security.

Concurrently, WHO Member States are negotiating a comprehensive Pandemic Treaty to bolster international collaboration in preventing, preparing for and responding to future pandemics. This accord seeks to address gaps identified during the covid-19 response, focusing on areas such as research and development, regulatory system strengthening and equitable access to vaccines and treatments.

WHO continues to support the INN system, which assigns unique names to pharmaceutical substances, ensuring clear communication and avoiding prescription errors. The organisation is also working to improve the PQ programme. These initiatives are crucial in maintaining global health standards and ensuring that essential medicines and health technologies are safe, effective and accessible, particularly in low-resource settings.

On 20 January 2025, US President Trump signed an executive order on withdrawing the United States from the WHO (EO),[4] citing WHO's 'mishandling' of the covid-19 pandemic and other health crises, its 'failure to adopt urgently needed reforms', its 'inappropriate political influence' and its 'demand' for disproportionate payments. According to the EO, the United States will take short-term actions to initiate the withdrawal from WHO,

which will include halting funding, ordering an exodus of US expertise, engagement and representation, and ceasing US participation in multilateral negotiations (i.e., the Pandemic Treaty and amendments to the IHR). At the time of writing, it is unclear whether the United States will indeed proceed with the withdrawal or whether an agreement on the Pandemic Treaty can be reached if the United States leaves the negotiation table.

If the United State's withdrawal does occur, WHO stands to lose over 20 per cent of its funding. For the 2024–2025 period, the US contribution was projected at US$706 million, comprising US$264 million in assessed contributions and US$442 million in voluntary contributions. Losing this amount would significantly affect WHO's operational capacity and raise questions about how it might fill such a substantial financial gap.

Amid these uncertainties, WHO's ability to implement its newly expanded mandate – both under the amended IHR and any final version of the Pandemic Treaty – could be tested. Nonetheless, stakeholders, including pharmaceutical companies, should remain vigilant and engaged, as the evolving global health landscape is rapidly changing and may reshape international collaboration and public health priorities for years to come.

Technical services offered by WHO

WHO PQ and emergency use listing

WHO PQ of health products

WHO established PQ in 2001, which is a service provided to manufacturers to assess the quality, safety and efficacy of health products for priority diseases that are intended for supply to UN agencies and national procurement bodies in developing countries.[5] To date, WHO has prequalified around 1,500 products. Its key WHO PQ partners include the Bill and Melinda Gates Foundation; UNICEF; Unitaid; the Global Fund to Fight AIDS, Tuberculosis and Malaria; and Gavi.

PQ is particularly relevant for international procurement in the global health context. For example, Gavi will generally only procure vaccines that are prequalified or subject to an EUL.

WHO currently offers PQ services under six product streams:

1. Medicines: separate assessment routes are available for finished pharmaceutical products and active pharmaceutical ingredients (APIs).
2. Vaccines: vaccines eligible for PQ are set out in the Vaccines Prequalification Priority List,[6] which is divided into four categories of priority – high, medium, low and no priority.
3. In vitro diagnostic medical devices (IVDs): PQ is available for IVDs for priority diseases that are suitable for use in resource-limited settings. This product stream also assesses male circumcision devices.
4.

Immunisation devices: PQ is available for equipment needed for the safe storage, transport, monitoring and administration of PQ vaccines (e.g., freezers and transport units).

5. Vector control products: PQ is available for products used for the prevention of vector-borne disease, including bed nets, sprays and larvicides.

6. Inspection services: this division supports the work of the other PQ product streams by conducting inspections and assessments to evaluate the compliance of manufacturers with PQ standards.

Each product stream has separate assessment procedures and criteria, which manufacturers must navigate before WHO will approve a candidate product as a prequalified product. This chapter focuses on PQ for medicines.

PQ procedure for medicines

Before a manufacturer can apply for PQ for its medicine, WHO must issue an 'Invitation to Manufacturers to Submit an Expression of Interest for Product Evaluation' (EOI). WHO issues EOIs by therapeutic area following consultation with WHO disease programmes and clinical specialists. Typically, products or product types will only be included in an EOI if they are listed on the WHO Model List of Essential Medicines (or the equivalent list for children) or if recommended for use by a current WHO treatment guideline (although exceptions may apply, such as during public health emergencies). Current EOIs include medicines for treating HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, diarrhoea, influenza and covid-19 and for reproductive health. WHO also initiated a pilot PQ programme for human insulin products in 2019.[7]

For eligible products within the scope of an EOI, the manufacturer must prepare the PQ application based on the structure of the International Council on Harmonisation's common technical document, which can be submitted electronically as an eCTD via the WHO's ePQS Portal.[8] Three separate assessment routes are available:

1. Full assessment: this route is available for generic medicines only. WHO is responsible for the full assessment of the application, including conducting inspections of manufacturing sites and clinical testing units.
2. Abbreviated assessment: this route is available for generic or innovator medicines assessed by stringent regulatory authorities (SRAs). Applicants share relevant information with WHO, such as the SRA assessment report and inspection reports. WHO bases its PQ decision on that information.
3. Alternative listing procedure: applications are submitted under specific national procedures to the European Medicines Agency,[9] the US Food and Drug Administration (e.g., under the US President's Emergency Plan for AIDS Relief programme) or Health Canada for assessment in collaboration with WHO.

Most PQ medicines follow the full assessment route.[10] Assessment times vary depending on the quality of the submitted dossiers, although WHO's target assessment time frame is

within 270 days (plus clock stops) for applications under the full assessment route is and within 90 days (plus clock stops) for applications under the abbreviated assessment route.

During assessment, WHO assesses the medicine's dossier and verifies compliance of the medicine's manufacturing sites and clinical testing sites with WHO good practices (e.g., WHO Good Manufacturing Practices and Good Clinical Practices). Following a positive assessment, WHO adds the medicine to the PQ list and publishes a WHO public assessment report.

Similar procedures apply for PQ applications for APIs and products within the other PQ product streams.

Regulatory status of PQ medicines in WHO Member States

The inclusion of a medicine on the WHO PQ list does not automatically permit the medicine to be marketed in WHO Member States; recipient countries still need to complete additional national registration procedures before the medicine can be imported and marketed in their jurisdiction. The regulatory and administrative processes for national registration of medicines on the PQ list varies between jurisdictions. These processes may cause additional delays, sometimes of up to two or three years in certain jurisdictions, before the medicine can be marketed nationally.

To address these delays, WHO initiated a voluntary Collaborative Registration Procedure for accelerated national registration, which has been adopted by 66 participating countries.[1-11] Under this procedure, the applicant submits the same dossier to the national regulator as the one it provided to WHO for PQ assessment (subject to minor local administrative differences, such as with respect to local labelling). WHO, with the applicant's permission, shares its full assessment report with the national regulator. The national regulator uses that data to support its decision regarding the national registration of the medicine, thereby reducing the duplication of assessment steps.

National regulators endeavour to issue an 'accelerated' decision on the application within 90 days of its acceptance of the submission and will notify WHO and the applicant within a further 30 days. This has enabled a consistent rise in national registrations of PQ products over recent years, with WHO reporting that nearly 1,000 product approvals have been granted under this procedure to date.[12]

Wider adoption and utilisation could help streamline the national registration of PQ medicines further. The latest version of WHO's IHR, as adopted through a resolution of the World Health Assembly in June 2024, seems to formalise aspects of the Collaborative Registration Procedure. It introduces the power for the WHO Director General to share with a WHO Member State, upon its request:

> the product dossier related to a specific relevant health product, as provided to WHO by the manufacturer for approval and where the manufacturer has consented, within 30 days of receiving such request, for the purpose of facilitating regulatory evaluation and authorization by the State Party.[13]

EUL procedure

The WHO EUL procedure runs in parallel to the PQ procedure and is a risk-based procedure for assessing unlicensed products, which aims to expedite the availability of these products to people affected by public health emergencies.[14] WHO developed the EUL procedure between 2014 to 2016 in response to the Ebola virus outbreak, and it is now available for vaccines, medicines and IVDs during PHEICs, such as vaccines and diagnostic tests for the covid-19 virus and mpox. The criteria for WHO to issue a PHEIC is set out in the IHR and, under the latest revisions, now include the concept of a 'pandemic emergency' as a higher level of health emergency above a PHEIC.[15]

To qualify for EUL assessment, applicants must satisfy the following criteria, unless otherwise agreed with WHO:

1. The disease for which the product is intended is serious or immediately life threatening and has the potential of causing an outbreak, epidemic or pandemic, and it is reasonable to consider the product for an EUL assessment.
2. With regard to vaccines and medicines, existing products have not been successful in eradicating the disease or preventing outbreaks.
3. The product is manufactured in compliance with current GMP (for medicines and vaccines) and under a functional quality management system (for IVDs).
4. The applicant will complete the development of the product and apply for WHO PQ once the product is licensed.[16]

Initial EUL applications must include details of the product's country and sites of manufacture, the presentations proposed for the product and information on any national emergency use authorisations already granted for the product by national regulators. If the product is accepted for EUL review, the manufacturer must submit its full product dossier for assessment. Abridged assessment procedures may be available for products with national emergency use authorisations in force. The results of all EUL assessments are published by WHO on its website, including negative assessment outcomes.

An EUL decision is intended to provide a time-limited emergency listing and is reassessed by WHO at 12-month intervals, or sooner if further data becomes available that may affect the original EUL decision. Recent examples of products that have received EULs include the covid-19 vaccines (14 covid-19 vaccines received EULs),[17] and, in November 2024, the first mpox was granted an EUL.[18]

Similar to the PQ procedure, an EUL for a product does not automatically permit the product to be marketed in all WHO Member States. It remains the prerogative of each recipient country to use the EUL as a basis to assess any emergency use authorisation of the product at a national level.

WHO programme on selection of INNs

Since 1953, WHO has been responsible for assigning INNs to pharmaceutical substances or active pharmaceutical ingredients.[19] The INN system was established to provide unique, globally recognisable names that can be used by drug and patent authorities, manufacturers, healthcare professionals and researchers worldwide. A fundamental

principle of the INN system is that INN names are public property and, therefore, can be used without any restrictions to identify pharmaceutical substances.

INN selection procedure

The INN names are selected by WHO based on the advice of experts from the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (the INN Expert Group). The INN Expert Group comprises specialists from around the globe, with pharmaceutical, chemical, biochemical and pharmacological expertise. The Group may invite co-opted experts in pharmaceutical trademarks and linguistics.

The INN selection follows a formal procedure.[20] Drug manufacturers submit their requests for new INNs to the WHO secretariat or through national nomenclature commissions (e.g., the United States Adopted Names programme in the United States). The WHO secretariat evaluates whether the suggested names comply with the general rules for selecting INNs and verifies the absence of any similarities or conflicts with existing names, such as chemical names, published INNs or trademarks. Once these assessments are complete, the WHO secretariat forwards all the information to the INN Expert Group.

The INN Expert Group reviews the request and selects a name by consensus.[21] The Group may also decide not to propose an INN at all. The newly selected INNs are initially designated as 'proposed INNs' and published in the 'INN Proposed List' of the 'WHO Drug Information'.[22] The INN Proposed List is open for a four-month objection period during which interested parties can submit comments or objections regarding the proposed INNs.[23] If WHO receives a formal objection, it may either reconsider the proposed name or engage with the objecting party to resolve the issue and encourage the withdrawal of the objection. As long as the objection exists, the name cannot be published as an official INN (referred to as the 'recommended INN').

The final step in the INN selection process is the publication of the 'proposed INN' as a recommended INN in the 'INN Recommended List' of the WHO Drug Information. The names are published in Latin, English, French, Spanish, Arabic, Chinese and Russian.

General principles for devising INNs

In principle, INNs are assigned to single, well-defined substances and not to mixtures of substances or uncharacterised substances. INNs are not assigned to herbal preparations, homoeopathic products or substances that have been used for a long time for medical purposes under well-established names.

Historically, INNs were assigned primarily to chemical active substances; however, with the development of recombinant technology, INNs are currently being assigned to biological substances such as recombinant proteins (e.g., monoclonal antibodies and fusion proteins) and gene-, cell- and cell-based gene therapies. The INN programme has published a series of policy documents on INNs for biological and biotechnological substances that provide detailed guidance.[24] Companies should carefully consider timing when submitting an INN application because the information about the pharmaceutical substance, such as genetic sequence, will become public.

Two main principles guide the construction of INNs:

1. INNs should be distinctive in sound and spelling. They should not be inconveniently long and not be liable to confusion with other names in common use.
2. The INN for a substance belonging to a group of pharmacologically related substances should, where appropriate, show this relationship by using a common 'stem'.

Regarding point (b), stems indicate the pharmacologically related group to which the INN belongs. For example, *-fungin* is a stem used for antifungal antibiotics, *-parin* is used for heparin derivatives, *-iran* is used for small interfering RNA, and *-cel* is used for cell-based substances.

Modified INNs

To avoid the multiplication of entries for different salts and esters, among other things, INNs are usually designated for the active part of the molecule. If an INN user (e.g., a pharmacopoeia commission, regulatory body or a manufacturer) requires an INN for a salt of ester of the recommended INN, they must create a modified INN themselves by adding the inactive moiety of the molecule to the existing INN. WHO leaves the creation of modified INNs to the users and does not publish modified INNs in any of its lists.

Protection of INNs

To safeguard the public nature of INNs, while circulating the INN Proposed List and INN Recommended List to WHO Member States, national pharmacopoeia commissions and other relevant bodies designated by the Member States, the Director General attaches a-*note verbale*. The *note verbale* requests Member States to take necessary steps to prevent acquisition of proprietary rights on the names. In addition, the INN secretariat may issue a protection letter, requesting the regulatory authorities in the relevant WHO Member State to act on the registration of trademarks that are too similar to INN.

WHO policy and coordination in disease response

Key provisions of Pandemic Treaty

In 2021, in the aftermath of the covid-19 pandemic, WHO Member States proposed the creation of a new Pandemic Treaty, aimed at addressing critical gaps in global health governance. While there is much to unpack for pharmaceutical companies (e.g., on supply chains), this contribution focuses on two draft articles: Draft Article 12 on equitable access to pandemic-related health products, and Draft Article 11 on technology transfer.[25]

The negotiations surrounding these two provisions have proven to be some of the most controversial, sparking intense debate among Member States and stakeholders over issues such as obligations to donate medical countermeasures to WHO, payment requirements of pharmaceutical companies to WHO's budget, impacts on intellectual property (IP) rights, product pricing, disease prevention measures, structuring of global supply chains and geographic distribution of local production capacity. Developing

countries have criticised what they saw as insufficient commitments from high-income nations to ensure equitable access to vaccines and treatments, while many developed countries resisted proposals for mandatory technology transfer or expanded IP flexibilities and have fiercely advocated for a distinct chapter on prevention measures.

Although the 2024 US elections and the start of US President Trump's presidency have injected considerable uncertainty into the Pandemic Treaty process – some countries have declared that US non-participation would be a deal-breaker – negotiations continue. One scenario under discussion in Geneva involves concluding a high-level agreement with minimal commitments, especially concerning the pathogen access and benefit-sharing system (PABS) envisaged under Draft Article 12, while an intergovernmental working group works out the details later.

On 15 January 2025, the WHO Intergovernmental Negotiating Body held its first preparatory meeting, where delegates suggested that PABS remain open for industry from non-members of the Pandemic Agreement but cautioned that 'competitiveness arguments' could thwart progress if the United States remains on the sidelines. Despite these challenges, at the time of writing, it is still anticipated that the Pandemic Treaty will be adopted by the 78th World Health Assembly in May 2025,[26] even if not all the initially proposed provisions make it into the final text.

Draft Article 12: PABS

Draft Article 12 creates the PABS. This system is designed to facilitate, among other things, companies' access to 'materials and sequence information on pathogens with pandemic potential' (PABS materials and SI) and, on an equal footing, ensure the rapid, timely, fair and equitable 'sharing of benefits' from accessing or using[27] these materials. PABS materials and SI will be defined by an intergovernmental working group that will be set up to negotiate a separate 'PABS instrument' in the years following the adoption of the Pandemic Treaty.[28]

Older negotiation drafts provide an indication of which diseases are considered capable of triggering a pandemic emergency, and by extension, are likely to be in scope of the PABS, based on the list included in Annex 2 to the IHR. Among the diseases are smallpox, poliomyelitis from poliovirus, human influenza cause by a new subtype, severe acute respiratory syndrome (SARS), pneumonic plague, yellow fever, viral haemorrhagic fevers (Ebola, Lassa and Marburg), West Nile fever and other diseases that are of special national or regional concern (e.g., dengue fever, Rift Valley fever and meningococcal disease).

Although WHO Member States do not have an explicit obligation to share PABS materials and SI to the PABS, it is expected that they will do so on a voluntary basis through WHO-coordinated mechanisms, such as the WHO BioHub.[29] The WHO BioHub project was launched in response to the covid-19 pandemic and, at the time of writing, is in its pilot phase, providing access to SARS-CoV-2 for non-commercial purposes only. Sharing of SARS-CoV-2 is done through one or more of the laboratories designated as a WHO BioHub Facility after the recipient has signed a material transfer agreement. The same principles are expected to also apply to the PABS.

Once operational, if manufacturers wish to access PABS materials and SI through the PABS, they will likely need to enter into a contract with WHO and agree to share monetary (e.g., annual fees) and non-monetary (e.g., sharing research results and technology

transfer) benefits. In addition to these general obligations that will apply at any time, the Pandemic Treaty will require manufacturers of 'vaccines, therapeutics, and diagnostics for the pathogen causing the emergency' to allocate up to 20 per cent[30] of their real-time production of safe, effective and quality-assured vaccines, therapeutics and diagnostics to WHO. Of this, at least 10 per cent must be made available free of charge. In the latest draft of the 12th meeting of the Intergovernmental Negotiating Body in December 2024, these obligations would apply in the event of a pandemic emergency declared under the IHR, but negotiators are also considering to introduce further obligations at 'lower level' public health emergencies, namely after the declaration of a PHEIC or to prevent outbreaks from progressing into PHEICs and pandemics in cases where affected developing countries lack equitable access or for WHO stockpiles.

Draft Article 11: transfer of technology and know-how

Draft Article 11 focuses on the transfer of technology and know-how as a means to ensure the equitable sharing of pandemic-related health products, especially with jurisdictions that have limited resources. The primary goal of this provision is to diversify manufacturing capabilities across the globe, particularly in developing countries. By enabling local production of critical health products, the Pandemic Treaty aims to reduce global disparities and enhance preparedness for future pandemics. The goal is to reduce reliance on a few manufacturing hubs (located in 'the Global North') and thereby address disparities exposed during the covid-19 pandemic.

To achieve this goal, Article 11 encourages parties to take measures to facilitate technology transfer through, among other things, licensing, capacity building, relationship facilitating, incentives or conditions linked to research and development, procurement or other funding and regulatory policy measures. A highly contentious issue during the negotiations is whether technology and know-how transfer should be voluntary. This term 'voluntary' has been removed and reintroduced in various drafts of the treaty, with the December 2024 version placing the word in brackets, signalling ongoing disagreement among negotiators. This debate reflects broader tensions over how to balance IP rights and public health imperatives.

Governments are also expected to make available licences for pandemic-related technologies they own, particularly for the benefit of developing countries and to encourage private rights holders to follow suit. Transparency is emphasised, with parties urged to publish the terms of licensing agreements to promote equitable global access. In pandemic emergencies, additional obligations are placed on manufacturers: they are encouraged to reduce or waive royalties on pandemic-related health products to enhance affordability and accessibility, particularly in developing countries.

Article 11 envisions the establishment of regional or global technology transfer hubs, coordinated by WHO, to further streamline the sharing of critical knowledge and technical expertise. It places significant pressure on manufacturers, particularly those producing publicly funded health products, to enter into technology transfer agreements.

The scope of Article 11 extends beyond vaccines, encompassing a category of 'pandemic-related health products' that is defined in a broad and non-exhaustive way: the definition lists 10 categories of products, as well as 'other health technologies', so there is really no limit to which products may be covered. The only requirement to be in scope is

whether the product is 'needed' for prevention, preparedness and response to a pandemic emergency.

Technology transfers would not only cover human pharmaceuticals but also medical devices and IVDs (e.g., ventilators, syringes, monitoring devices and software), manufacturers of personal protective equipment (e.g., gloves, masks and gowns), chemicals companies (e.g., insecticides, bleach, chlorine, alcohol at 70 to 90 per cent concentration and soap). It could also cover veterinary pharmaceuticals.

During the covid-19 pandemic, owing to shortages in human- authorised sedatives necessary to intubate patients, veterinary sedatives with equivalent APIs were used as alternatives in hospitals. Nothing in the definition requires that the necessary products be used on-label or that they be authorised. Also during the pandemic, an Ebola treatment and an antimalarial agent with anti-inflammatory and immunomodulatory activities were considered as early treatment options. Hypothetically, even off-label use of diabetic medicinal products could be considered 'needed for prevention, preparedness and response' if they address a comorbidity (e.g., obesity) to the communicable disease.

Relationship between the Pandemic Treaty and the IHR

Draft Article 26(2) of the Pandemic Treaty makes clear that the Treaty and the IHR are to be 'interpreted so as to be compatible and mutually reinforcing'. The intention is that the two legal instruments will create a single regime that should function jointly. In legal terms, they must be read together, and key terms used in the Pandemic Treaty, such as 'pandemic emergency' and 'relevant health products' were defined in Article 1 of the IHR. In turn, the declaration of a PHEIC or pandemic emergency could trigger obligations enshrined in the Pandemic Treaty.

Amendments to the IHR

The IHR serves as the cornerstone of global health security, providing a legally binding framework to its 196 states parties and granting WHO a mandate to coordinate a global response to emerging public health threats, including a PHEIC; however, the covid-19 pandemic underscored critical gaps in the existing framework, prompting the 77th World Health Assembly to adopt significant amendments in May 2024.[31] These amendments are particularly notable for introducing 'pandemic emergency' as a new public health event, including 'equitable access to relevant health products' as one of the goals of outbreak response and granting WHO with very broad new powers to achieve this new goal.

Although the latest IHR amendments were largely shaped under US leadership, US President Trump's EO directs that the United States must take steps to ensure the amendments do not become binding. The United States can do that by submitting a rejection to the WHO Director General by 19 September 2025.

Whether the United States ultimately remains a WHO Member State – and, therefore, remains bound by the IHR – is unclear. Under Articles 21 and 22 of the WHO Constitution, the IHR applies only to Member States. Consequently, if the United States withdraws from WHO altogether, it would effectively remove itself from the IHR framework. At the time of writing, no public announcement has confirmed whether Rubio, the US Secretary of State,

Rubiohas submitted a notice of rejection, leaving the status of US participation in the IHR unclear.

Definition of 'pandemic emergency'

The IHR defines 'pandemic emergency' as a:

> public health emergency of international concern that is caused by a communicable disease and:
>
> (i) has, or is at high risk of having, wide geographical spread to and within multiple States; and
>
> (ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and
>
> (iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and
>
> (iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.[32]

The current wording describes a pandemic emergency as a higher level of health emergency than a PHEIC; however, a pandemic emergency is limited only to communicable diseases, whereas a PHEIC encompasses a broader range of public health risks, including communicable diseases, contaminated food, chemical or radiological hazards and other toxic releases.[33] While the IHR does not provide a definition of 'communicable disease', from a scientific point of view, a communicable disease should be understood as an infectious disease where infectious agents or viruses spread the disease from one person to another person or from animals to humans.[34]

The declaration of a pandemic emergency will follow the same procedure as the declaration of a PHEIC,[35] and will not explicitly grant any extraordinary powers to WHO; however, because of the higher level of health emergency associated with a pandemic, it will require a whole-of-system approach to achieve an equitable and solidarity-based global response.

Strong, legally binding mandate for WHO on equity and solidarity

One of the most significant amendments to the IHR is the inclusion of 'equity and solidarity' as key principles,[36] which now give WHO an explicit legal mandate to champion these values when implementing the IHR, specifically in relation to 'access to relevant health products'.[37] As under the draft Pandemic Treaty, the new term 'relevant health products' is broad and non-exhaustive, covering:

> those health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products,

> assistive products, antidotes, cell- and gene-based therapies, and other health technologies.[38]

The IHR does not expressly state whether WHO can create a list of relevant health products in advance of any PHEIC or pandemic emergency; however, another amendment of the IHR suggests that the WHO Director General could create an indicative list as part of their assessment of 'availability and accessibility including affordability of relevant health products'.[39]

While WHO cannot forcefully impose measures on companies, it was granted a robust legal mandate to 'facilitate, and work to remove barriers to, timely and equitable access' to relevant health products whenever a PHEIC or pandemic emergency is declared.[40] The term 'barriers' is not expressly defined, leaving room for WHO to interpret it broadly. Based on negotiation history, 'barriers' can encompass, among other things:

1. research and development (R&D) capacity limitations (lack of research infrastructure, scientific expertise or materials);
2. IP constraints (restricting local manufacturing or scaling-up of products);
3. pricing challenges (high costs that prevent timely access for vulnerable populations);
4. trade obstacles (export and import restrictions, and supply-chain bottlenecks);
5. financial hurdles (insufficient funding mechanisms for addressing the above issues); and
6. legal obstacles (inadequate legal authority at national or international levels).

Likewise, the IHR does not define 'equitable access'; instead, it requires that access be guided by 'public health risks and needs'. While 'public health risk' is defined,[41] 'public health need' remains open-ended, giving WHO considerable leeway to identify target populations that require the most urgent attention and through which acquisition of health products can be achieved in the most equitable matter. In any case, should the World Health Assembly fail to reach consensus on the Pandemic Treaty, it is expected that the WHO secretariat will make expansive use of these new powers under the IHR in a way that will have a tangible impact on companies.

Specific examples of new WHO powers

Under Article 13(8), WHO is granted several new powers,[42] which it can exercise either on its 'own initiative' or 'on request' by a state party.

Article 13(8)(a): assessments of health products

WHO will need to publish and update two types of assessments: assessments of public health needs and assessments of availability and accessibility, including affordability of relevant health products. At the time of writing, it is unclear how WHO will make the necessary assessments for these issues, or how it will collect the necessary information

(e.g., whether the state parties will be requested to submit necessary information and whether information provided by non-state actors will be taken into account).

While this power may seem like a soft power that does not directly affect companies, it may permit WHO to put significant pressure on specific companies through reputation, and name and shame.

Article 13(8)(b): coordination of allocation and distribution networks

WHO is authorised to use or create networks to distribute relevant health products based on public health needs. According to the negotiating documents, the problems that this Article seeks to overcome to achieve equitable access encompass (1) access and pooling of relevant health products and (2) equitable allocation and supply of those products to the state parties that most need them. This aligns with parallel proposals in the draft Pandemic Treaty (e.g., PABS), which would harmonise procurement and inventory systems worldwide.

Articles 13(8)(c) and 13(8)(e): support of manufacturing capacity and R&D

WHO can back efforts to diversify manufacturing (so that production sites are not concentrated in a handful of countries) and promote R&D, including technology transfers and other measures that reduce dependency on global supply chains. Although any mandatory transfer of IP or know-how remains controversial, the final IHR text leaves open-ended possibilities, allowing WHO to consider such actions if asked by a willing state party.

Article 13(8)(d): sharing of product dossiers for faster national approvals

If a manufacturer consents, WHO can share its product evaluation or dossier with a national regulator, potentially expediting local authorisation. This formalises aspects of existing WHO accelerated assessment procedures for PQ medicines and vaccines, but now with a global legal underpinning in the IHR. Nonetheless, confidentiality concerns remain as the IHR amendments do not explicitly require that regulators keep a company's proprietary information secret.

Engaging states and stakeholders

States parties are now expressly encouraged to engage with 'relevant stakeholders' (which could include pharmaceutical companies, research institutions and philanthropic foundations) within their jurisdictions to help meet WHO-led equitable access goals.[43] This collaboration is subject to applicable law and available resources, giving states some discretion; however, it also grants WHO a powerful mechanism to request that a government encourage private-sector entities to support global health measures, such as sharing data, manufacturing capacity or final products.

States may also be asked to share relevant terms of R&D agreements they have in place for health products that are crucial to pandemic responses – potentially including pricing, volume guarantees and licensing arrangements. While the text no longer mandates the

broad publication of all terms, a WHO request for such details could increase transparency around how critical products are researched, funded and supplied during emergencies.

Outlook and conclusions

Over the coming year, negotiations for the Pandemic Treaty are expected to be concluded at the 78th World Health Assembly in May 2025. If adopted, this landmark instrument will further empower WHO, particularly through PABS, to shape global preparedness and response efforts.

From the pharmaceutical industry's perspective, these new mechanisms – coupled with provisions on technology transfer – could open various engagement expectations, from co-development initiatives to contractual obligations ensuring a fairer distribution of vaccines and treatments. The addition of a pandemic emergency category also means that any severe communicable disease outbreak will likely demand more direct collaboration among Member States, manufacturers and WHO.

However, the potential withdrawal of the United States from WHO casts a shadow of uncertainty over these plans. If the United States withdraws its funding and expertise – or opts out of the Pandemic Treaty itself – the balance of negotiations could shift, and the Treaty's scope and impact may be considerably reduced.

Even if the Pandemic Treaty negotiations stall, the revised IHR will enter into force in 2025, conferring broad authority on WHO to 'prevent, prepare for, protect against, control, and provide a public health response' to both PHEICs and pandemic emergencies.[1-44] This expanded mandate includes the power to address critical issues, such as IP barriers, manufacturing bottlenecks and equitable access challenges – even without full US participation.

For pharmaceutical companies, the legal and regulatory landscape may shift significantly, amplifying the need to closely monitor developments at WHO and in national legislation. By staying engaged and proactively adapting their strategies, companies can better navigate an evolving framework that prioritises global solidarity and equitable health outcomes.

Endnotes

1 For example, the revision of the International Health Regulations (IHR) in 2005, following the 2002–2003 severe acute respiratory syndrome (SARS) outbreak, which introduced the concept of the 'public health emergency'. Following the covid-19 pandemic, the IHR was revised again to introduce the concept of 'pandemic emergency'. See Proposal for a Council Decision authorising Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024 (Amended IHR). ^ Back to section

2 One example of such public–private collaboration is the close work between WHO, the Global Influenza Surveillance and Response System (GISRS) and pharma industry representatives. See press release, ' 70 years of GISRS, decades of collaboration', WHO (29 July 2022). ^ Back to section

3 Press release, ' World Health Assembly agreement reached on wide-ranging, decisive pack
age of amendments to improve the International Health Regulations', WHO (1 June 2024). ^ Back to section

4 Executive Order, ' Withdrawing the United States from the World Health Organization', White House (20 Jan 2025) ^ Back to section

5 Webpage, ' WHO Prequalification', WHO. ^ Back to section

6 Webpage, ' Vaccines Eligible for WHO Prequalification', WHO. ^ Back to section

7 Press release, ' WHO launches first-ever insulin prequalification programme to expand a
ccess to life-saving treatment for diabetes', WHO (13 Nov 2019). ^ Back to section

8 Webpage, ' ePQS Portal', WHO. ^ Back to section

9 Under the EU-M4all procedure for products intended exclusively for markets outside the EU. See Regulation (EC) No. 726/2004, Article 58; webpage, ' Medicines assessed under the 'EU-M4all' procedure', European Medicines Agency. ^ Back to section

10 It is estimated that about 80 per cent of medicines added to the PQ list for finished pharmaceutical products during the past five years were approved under the full assessment route based on WHO's medicines PQ database. ^ Back to section

11 Number correct as at 8 January 2025. See webpage, ' Collaborative Registration Procedure for prequalified medicines and va
ccines', WHO. ^ Back to section

12 Id. ^ Back to section

13 Amended IHR, Article 13(8)(d). ^ Back to section

14 Webpage, ' Emergency use listing', WHO. ^ Back to section

15 Webpage, ' International Health Regulations: amendments', WHO (1 Oct 2024). ^ Back to section

16 Publication, ' Emergency use listing procedur e' (version 9), WHO (Aug 2022). ^ Back to section

17 Report, ' WHO EUL/PQ status of COVID-19 Vaccines', WHO (21 May 2024). ^ Back to section

18 Webpage, ' LC16 KMB', WHO. ^ Back to section

19 The international non-proprietary name (INN) system was initiated in 1950 (World Health Assembly Resolution WHA3.11) and established in 1953 when the first list of INNs was published. ^ Back to section

20 International Nonproprietary Names: revised procedure, EB115/11, Annex 1. ^ Back to section

21 Id., Appendix. ^ Back to section

22 Webpage, ' L ists of Recommended and Proposed INNs', WHO. ^ Back to section

23 For example, an objection may be made that a proposed INN conflicts with an existing trademark. There have also been cases in which pharmaceutical companies have submitted formal objections when a proposed INN was too similar to the existing INN for their products. ^ Back to section

24 Webpage, ' INN for biological and biotechnological substances', WHO. ^ Back to section

25 The negotiations of the Pandemic Treaty are ongoing at the time of writing. The analysis in this chapter is based on the draft from 2 December 2024, which is not publicly available. The latest publicly available version is from 27 May 2024: Document A77/10, Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, WHO (27 May 2024). ^ Back to section

26 Document WHA77(20), Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, WHO (1 June 2024). ^ Back to section

27 At the time of writing, this is still to be negotiated. ^ Back to section

28 Pandemic Treaty, Article 12(2). ^ Back to section

29 Webpage, ' WHO BioHub System', WHO. ^ Back to section

30 At the time of writing, the final number is under negotiation. ^ Back to section

31 Document No. A77/A/CONF./14, Amendments to the International Health Regulations, WHO (2005). These amendments will come into force on 19 September 2025. ^ Back to section

32 Amended IHR, Article 1. As the negotiations of the Pandemic Treaty stalled in April 2024, and negotiators were concerned that the treaty will not be passed by the 77th World Health Assembly, the definition of 'pandemic emergency' was also introduced in the draft IHR amendments, ensuring it will be part of the global health legal framework. ^ Back to section

33 WHO guidance for the use of Annex 2 of the International Health Regulations (2005), p. 11. ^ Back to section

34 An inexhaustive list of communicable diseases could include the communicable diseases listed in Annex 2 of the IHR (e.g., smallpox, poliomyelitis from poliovirus, human influenza caused by a new subtype, SARS, pneumonic plague, yellow fever, viral haemorrhagic fevers (Ebola, Lassa and Marburg), West Nile fever and other diseases that are of special national or regional concern (e.g., dengue fever, Rift Valley fever and meningococcal disease), as well as other diseases monitored by WHO (e.g., HIV/AIDS, tuberculosis, malaria, viral hepatitis and sexually transmitted infections). See webpage, ' Communicable and noncommunicable diseases, and mental health', WHO. ^ Back to section

35 Amended IHR, Articles 12(4) and 49. ^ Back to section

36 Id., Article 3. ^ Back to section

37 Id., Article 13. ^ Back to section

38 Id., Article 1. This definition is almost identical to the definition of 'pandemic-related health products' under the Pandemic Treaty, so a similar analysis to the scope can be applied here. ^ Back to section

39 Id., Article 13(8)(a). ^ Back to section

40 Id., Article 13(8). ^ Back to section

41 Public health risk means 'a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger.' ^ Back to section

42 Traditionally, WHO guidance under the IHR (in Articles 15 and 16) took the form of 'temporary' or 'standing' recommendations, which lacked binding effect; however, Article 13(8) clarifies that WHO is now empowered to take other actions – above and beyond issuing non-binding guidance – to ensure equitable access to health products. This shift means WHO can actively facilitate solutions and coordinate international responses rather than simply recommending them. ^ Back to section

43 Amended IHR, Article 13(9). ^ Back to section

44 Id., Article 2. ^ Back to section

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