



EU Pharmaceutical Law Reform: A Chance to Meet Human Rights Standards

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Abstract: The European Commission has announced the largest reform of EU pharmaceutical legislation in over 20 years. It is worth exploring key elements of the proposals in light of the international human right to health and the duty to international assistance and cooperation.

The European Commission plans for the biggest reform of [EU pharmaceutical legislation](#) in a generation include proposals for a [new Directive](#) and [new Regulation](#). The aim is to create a single market for medicines ensuring that all patients across the EU have timely and equitable access to safe, effective, affordable medicines, while making medicines more environmentally sustainable and reducing the administrative burden of distribution. To achieve these objectives, the reform addresses the entire lifecycle of medicines. The proposals have not been well received by all sectors. The European Federation of Pharmaceutical Industries and Associations (EFPIA) [believes](#) they 'manage to undermine research and development in Europe while failing to address access to medicines for patients' and that 'the proposals, in their current form, put European

competitiveness at risk'. For the European Commission, several issues justify this reform: medicines authorised in the EU are still not reaching patients quickly enough nor are they equally accessible in all member states. There are significant gaps in addressing unmet medical needs, rare diseases and antimicrobial resistance. Moreover, high prices for innovative treatments and shortages of medicines remain an important concern for patients and healthcare systems. Revision of the EU pharmaceutical legislation offers a chance to solve these problems and to align the EU legal pharmaceutical landscape to human rights principles.

In this blogpost, I explore key elements of the proposals in light of the international human right to health, specifically in terms of availability, accessibility and affordability of medicines. I also introduce the human rights duty to international assistance and cooperation: some critical voices have stated the need for this proposal to consider the inequalities of low and medium income countries (LMIC) in accessing medicines.

Availability, accessibility and affordability of medicines and the international human right to health

A major aim of the revision is to make medicines more available, accessible, and affordable. This is in line with the international right to the highest attainable standard of health (right to health) as stated in Article 12 of the International Covenant of Economic, Social and Cultural Rights ([ICESCR](#)). This imposes a duty on states to provide health facilities, goods and services accessible to all, especially the most vulnerable or marginalised groups. A key document interpreting this right, the [General Comment No. 14](#) by the UN Committee on Economic, Social and Cultural Rights (CESCR), states that the right to health in all its forms and at all levels contains four essential elements that every state must ensure: availability, accessibility, acceptability and quality of health facilities, goods and services, the AAAQ framework. The following sections examine how the European Commission reform proposals relate to two AAAQ components, availability and accessibility.

Availability

A study on [access to medicinal products](#) conducted at the request of the European Parliament found that patients in the EU are increasingly unable to obtain their prescribed medications and that member states and pharmacy organisations have signalled a rise in shortages of medicinal products. COVID-19 exposed the fragilities of the system: at the outbreak of the pandemic European countries reported critical shortages of medicines used in intensive care units to treat the disease and its complications, stressing the need to increase availability.

The proposed legislation aims at addressing medicine shortages by introducing new monitoring requirements for national authorities and [European Medicines Agency \(EMA\)](#) and a stronger coordination role for the EMA. Manufacturers' obligations will be strengthened, including earlier reporting of shortages and withdrawals of medicines and development and maintenance of shortage prevention plans. In addition, the European Commission can adopt legally binding measures to bolster security of supply of specific critical medicines.

This is in line with what is stated in the availability component of the AAAQ framework which requires functioning public health and healthcare facilities, goods, services and programmes to be available in sufficient quantities within states.

Accessibility and affordability

The European Commission acknowledges the need for better access to innovative and affordable medicines for patients and national health systems. Thus, it has announced new incentives encouraging companies to make their medicines accessible to patients in all EU countries and develop products that address unmet medical needs.

According to the [General Comment No. 14](#), health facilities, goods and services have to be accessible to everyone without discrimination within the jurisdiction of the member state. Moreover, one dimension of accessibility is *economic accessibility or affordability* - health facilities, goods and services, whether privately or publicly provided, must be affordable for all, including socially disadvantaged groups.

This economic accessibility is an important point for the European Commission. A 2020 [report on health inequalities](#) in the European Union stated prohibitive expense as the most common reason for unmet need for medical examinations or treatment. According to a 2017 Eurostat breakdown of the financial burden of healthcare on household budgets, 34 percent stated that costs for medical care were somewhat of a financial burden while 11 percent perceived such costs as a heavy burden. The General Comment No. 14 states that equity demands poorer households should not be disproportionately disadvantaged over health expenses compared to richer households.

Extraterritorial human rights obligations

Responding to the EU's proposed reform of pharmaceutical regulations, Oxfam and the People's Vaccine Alliance [highlighted](#) the need to protect low and middle income countries (LMIC) as they experience the worst inequalities in accessing medicines and urged EU countries to place human rights before pharma profits in all negotiations.

The UN Special Rapporteur on the right to health [emphasised](#) that developing countries face obstacles blocking access to good quality medicines in an affordable and timely manner and stressed the intrinsic link between poverty and realisation of the right to health; developing nations have greatest need and least access to medicines.

A 2021 [article](#) synthesised evidence of the impacts of European Union law, regulation, and policy on access to medicines in non-EU LMICs and mechanisms and nature of those impacts. The study concluded that EU policymakers adopt measures with potential to influence medicines in LMICs despite limited evidence of their positive and/or negative impact. Moreover, it emphasised the need for principles for global equitable access to medicines to guide EU policy.

The planned legislation is an opportunity to engage with this question, therefore it is useful to remind ourselves of the existence of extraterritorial human rights obligations.

Articles 55 and 56 of the [UN Charter](#) oblige states to cooperate in solving health problems and promote universal respect for human rights. Also, in its [General Comment No. 3](#), the CESCR has emphasised that all member states should take steps, individually and through international assistance and cooperation, especially economic and technical, towards the full realisation of the rights recognised in the Covenant, such as the right to health.

Indeed, the [General Comment No. 14](#) states that the Covenant signatories should ensure that the right to health is given due attention in international agreements and should consider the development of further legal instruments. Similarly, signatory states have an obligation to ensure their actions as members of international organisations take proper account of the right to health.

Next steps

The proposals are now in the hands of the European Parliament and the European Council, which have equal weighting in determining the eventual shape of future reform. It is easy to foresee potential obstacles, including industry reticence. The Parliament has traditionally promoted establishment of a coherent pharmaceuticals policy which considers both public health and industrial aspects. The Council has called upon the Commission to cooperate with member states to develop and implement concrete action. The EU now has a golden opportunity to make a difference with this major and complex reform, by taking into account human rights standards and making medicines more accessible, available and affordable to all sections of society throughout all member states.