Medicine Pricing and Access in Europe

Medicine pricing has a major impact on patients' ability to access them, as well as other health technologies. Excessive and unaffordable medicine prices are a significant global challenge, with governments, international organisations and technical agencies scrambling to respond with varying degrees of success. High prices can affect the economic sustainability of public health systems and, in the case of non-reimbursed products, can place patients faced with out-of-the-pocket expenses under catastrophic financial stress.

For the most part, in the European Union (EU), medicine pricing is a national competence, and part of a wider framework of integrated legislative, regulatory, and administrative decisions and processes. However, poor transparency, such as difficulties in accessing public procurement contracts and price setting decisions, as well as poor collaboration between stakeholders, are common obstacles to any evaluation of the affordability of treatment and access to medicines.

In this report, we examine these issues and some of the actions already taken to address them by EU Member States, using Italy and the Netherlands as primary examples.

The recommendations laid out in the report are:

Global

- WHO should provide leadership and play a more prominent role in assessment and analysis of medicine pricing. In the short-term, this should include issues of pricing and affordability of vaccines and medicines in deliberations related to COVID-19 responses, such as discussions on a Pandemic Preparedness Treaty.
- Additionally, WHO Member States should collaborate with existing initiatives, such as the R&D Observatory, and share all data related to public support for research and development, especially for those pharmaceutical products finally marketed. This collaboration should extend to the COVID-19 Technologies Access Pool (C-TAP),
- Conclusions of the Fair Pricing Forum should be coded in a single working document to be used as roadmap for WHO technical assistance activities as well as elaboration and updates of the EML.

European Union

- Disclosure, albeit partial, of vaccine contracts between the European Commission and pharmaceutical manufacturers should be extended to other public procurement schemes, both at regional (voluntary inter-country cooperation) and national levels.
- Within the framework of initiatives, such as the European Pharmaceutical Strategy and the European Health Emergency Preparedness and Response Authority (HERA), the issue of public return on public investment should be translated into enforceable clauses regarding the price of products developed with public funding/support.
- Orphan medicine legislation and other incentives should be thoroughly examined,

particularly measures like data exclusivity and intellectual property instruments, such as Supplementary Protection Certificates (SPC), to avoid misuse and unintended consequences like price gauging and extended monopolies.
- The Oslo Medicines Initiative conclusions should include specific steps on how WHO-EURO is going to implement resolution WHA72.8, including workplan and budget, as well as other initiatives, including C-TAP.

National

- Italy and the Netherlands should take their proposals and experiences of curbing medicines prices to the Council of the European Union and promote the topic of access to medicines in upcoming Presidencies, with special emphasis on putting an end to confidentiality clauses in public procurement of medicines contracts
- EU Member States should adapt WHA72.8 in their national legal and regulatory framework, involving all relevant stakeholders: regulatory authorities, industry, academy, and civil society.
- Governments should adapt their legal and regulatory framework to make full use of TRIPS flexibilities and allow for import of generic drugs when there are no therapeutic alternatives to excessively high-priced patented medicines.

Download the full report here.