REPORT
MEDICINE PRICING AND ACCESS IN EUROPE AND BEYOND
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The price of medicines and other health technologies has a major impact on patients’ ability to access them. 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.

The Global Outlook
The World Health Organization has consistently identified prices as a critical factor in the promotion and guarantee of access to medicines. In this context, the joint WHO/Health Action International (HAI) methodology for the measurement of price, availability, and affordability of medicines on the WHO Essential Medicines List (EML) in low- and middle-income countries (LMICs) was a milestone that shaped—and continues to define to some extent—the technical assistance provided to Member States.

The methodology still guides policy efforts and other interventions in the field of prices and access to essential medicines in the Global South.

While the concern of the WHO/HAI pricing methodology was for essential medicines, which are generally generic, contemporary unease about unaffordable prices concerns so-called ‘innovative’ or repurposed medicines, which can demand prices of more than USD 1 million per treatment. Indeed, the launch of the WHO Fair Pricing Forum in 2017 (and subsequent editions in 2019 and 2021), and later the World Health Assembly Resolution (WHA72.8) on transparency of pharmaceutical markets demonstrate the political will of certain governments, including the Netherlands and Italy, to combat prices that threaten to cripple health systems. These countries have taken steps as part of the broader discussion at the highest level on the issue of medicine pricing. Separately, the European regional office of WHO, in collaboration with the Norwegian government, has launched the Oslo Medicines Initiative, which aims to “build a
new vision for collaboration between the public and private sectors to ensure better access to effective, novel, high-priced medicines.\textsuperscript{a}

\textbf{The European Context}

Actions within the EU are shaped by the institutional distribution of competencies dictated by treaties, with national governments being ultimately responsible for pricing and reimbursement decisions. In this case, of special relevance are Article 102(a) of the Treaty on the Functioning of the European Union (TFEU)\textsuperscript{iii} aimed at curtailing actions that may “directly or indirectly impose[ning] unfair purchase or selling prices or other unfair trading conditions”, and Directive 89/105 EEC—also known as the “Transparency directive”\textsuperscript{iv}—which established requirements of objectivity and verifiability for pricing and reimbursement procedures. However, it can be reasonably claimed that it has never been fully embraced by EU Member States.

The European Commission has looked at pricing of pharmaceuticals mainly as part of the single market portfolio, intervening against excessive market dominance, price gouging and other actions contrary to free competition.\textsuperscript{v} It has recently placed affordability of medicines at the centre of the new \textit{European Pharmaceutical Strategy}, a landmark document which, among other things, attempts to address unmet medical needs and medicines shortages with specific references to a more robust cooperation on prices:

Governments have also directed the Council of the European Union to follow up on the issue of medicine pricing; of special relevance are two Council conclusions:

1. Innovation for the benefit of patients (2014/C 438/06) approved under Italy’s Presidency in 2014.
2. Strengthening the balance in the pharmaceutical systems in the EU and its Member States (2016/C 269/06), under the 2016 Dutch Presidency, attempts to reconcile the reward for innovation and the assurance of affordability of medicines, pointing out the information asymmetry which remains problematic in access to medicines.\textsuperscript{vi}

In parallel, the European Parliament has approved several resolutions on the need to ensure affordable and justifiable prices for medicines, one of which was the landmark report in 2019 on EU options for improving access to medicines.\textsuperscript{vii}

“Decisions on the pricing and reimbursement of medicines are the purview of Member States. The Commission will step up co-operation with and among Member States on the affordability and cost-effectiveness of medicines and will launch a group to steer cooperation between national pricing and reimbursement authorities and healthcare payers. It will support mutual learning through information and best-practice exchange, including on public procurement and the coverage of pharmaceutical costs by social protection systems, price-increase criteria and rational prescribing”.\textsuperscript{vi}
**European Medicine Price Database (EURIPID)**

The EURIPID Collaboration is a voluntary and strictly non-profit cooperation between competent authorities between (mainly) European countries to build and maintain a database of information on national prices of medicines in a standardised format. The EURIPID database contains data on official prices of publicly reimbursed medicines, primarily in the out-patient setting, that are published by public authorities in line with the EC Transparency Directive. However, the database has several limitations that hamper transparency. One crucial challenge to the impact of EURIPID is that the database only contains publicly available data (listed prices) on reimbursement prices as published by national authorities. This means it brings little new content to the table and is at the mercy of national authorities’ reporting habits.


Additionally, several voluntary inter-country cooperation schemes have been pursued among Member States with various approaches, results, and degrees of success. 2015 saw the launch of the first formal cross-country cooperation scheme between EU Member States, the **Beneluxa Initiative**, which was welcomed by many as a defining moment in the quest for greater transparency and accountability in pharmaceutical markets. While ambitious in its scope and having booked some successes in joint negotiations for *Zolgensma* and *Spinraza*, it has failed to uphold the transparency standards on medicine prices it was supposed to achieve.

The Valletta Declaration Group followed in 2017 and, at the time of writing, there are several formal and informal collaborations active in the EU. The experience of Beneluxa shows that the coordination processes are complex and lengthy, that for greater collaboration reforms may be needed to make key national structures and agencies more cohesive, and that there is an acute need for greater transparency.

**National Examples**

The introduction of high-priced innovative medicines and treatments in Europe is a trend that has gained pace since 2014 with the European Medicines Agency’s marketing approval of sofosbuvir for the treatment of hepatitis C, marketed in the Netherlands at €52,000 for a 12-week treatment. This was followed by the approval of a range of high-priced cancer treatments and medicines for orphan diseases (diseases with small patient numbers), placing the issue of access to medicines and the economic sustainability of public health systems firmly on the agenda of EU Member States. Governments have come under increasing public pressure to act decisively to ensure affordability not only of newly marketed products, but also of medicines and treatments subject to speculation and price jacking, thereby ensuring the economic sustainability of public health systems. There is no doubt, the COVID-19 pandemic has added a sense of urgency to the task.

Experiences from the Netherlands and Italy show the possibilities and limitations of curbing excesses and safeguarding public interest regarding affordability. While in some cases, public announcements did not translate into specific actions, in others there was a delay in implementation or opposition by the pharmaceutical industry placed a hold on the measure.
Combination of Administrative and Legislative Actions to Curb Pharmaceutical Spending at the Domestic Level

There is a need to build on political will by enacting new legislation or amending existing laws. In some instances, administrative decrees will need to be drafted and approved in order for the new norm to come into force, which in most cases will involve collaboration between several ministries or departments.

In 2017, the Italian health ministry authorised the importation of generic versions of sofosbuvir for personal use, with an official price of €8,000, when there was no therapeutic alternative available. The New Pricing and Reimbursement Decree, approved in August 2019 by the Ministry of Health and the Ministry of Economy and Finance and which set out new criteria and procedures for the negotiation of the price of medicine and reimbursement decisions, entered into force after publication in the official journal in July 2020. Meanwhile, the Netherlands announced a set of measures in 2017, such as an amendment to the Medicine Prices Act by, inter alia, replacing Germany with Norway as reference country and the reform of the reimbursement system. It also placed conditions on the coverage of expensive medicines. In 2019 Dutch authorities proceed to amend Patent Act to allow pharmacies to prepare, under certain conditions, medicines regardless their patent status.

Pursuing Initiatives at the Regional and Global Level

Although pricing and reimbursement decisions remain essentially a sovereign matter, as long as pharmaceutical companies continue imposing confidentiality clauses in procurement contracts that so seriously hinder governments’ ability to negotiate, only international cooperation can ultimately tackle the challenges of high prices.

As mentioned above, both Italy (2014) and Netherlands (2016) used their pro-tempore EU Presidencies to address the topic of high prices of medicines at the highest EU institutional level, asking for greater transparency, more fluid collaboration among countries and a review of incentives mechanisms, among other measures. At the same time, both are leading members in sub-regional voluntary cooperation initiatives (Valletta Declaration and Beneluxai) laying the ground for an enhanced inter-country cooperation beyond the institutional constraints of EU treaties.

Italy was a leading proponent for the transparency resolution at the World Health Assembly in 2019, even clashing with other EU Members States, including Germany and Denmark, with the Netherlands adding its name to the list of co-sponsors in the final stages. The Netherlands was instrumental in setting up the first edition of the WHO Fair Pricing Forum, held in Amsterdam in 2017, and has supported and participated in subsequent meetings in Johannesburg, South Africa (2019) and a virtual meeting hosted by the Argentinian government (2021).
Reinforcing Role of Competition Authorities

Confronted by cases of price hikes and misuse of orphan drug designation, both Italy and the Netherlands successfully used competition rules and institutions to reign in excesses, on occasion paving the way for the EU competition watchdog to open diligences and imposing economic fines and other sanctions\textsuperscript{iii}.

Abusing a position of market dominance, hindering supply of a given product and unjustified price hikes are among the most common activities authorities seek to root out and end, both at the EU and national levels. Investigations can be lengthy and complex, initiated ex-officio or following a complaint. The role of civil society, media and healthcare professionals is critical\textsuperscript{iv}.

The Leadiant Case

In 2018, the Authority for Consumers and Markets in the Netherlands began looking into prices of prescription drugs and, in early 2019, opened an investigation into the pricing practices of Leadiant, manufacturer of chenodeoxycholic acid (CDCA)—a medicine for prescribed a rare metabolic disease cerebrotendineous xanthomatosis (CTX). The investigation resulted in a fine of 19.6 million as it was proved the company had unjustifiably inflated the price of the drug. The role of civil society, and in particular that of the Pharmaceutical Accountability Foundation, was critical in this investigation.

The Aspen Case

After purchasing the trading rights for a group of off-patent cancer medicines (known as Cosmos drugs and reimbursed by the Italian health service) from GlaxoSmithKline (GSK), generic pharmaceutical company Aspen entered negotiations with the Italian regulatory authority in 2013 to increase the price. Aspen asked for Cosmos drugs to be deemed non-reimbursable, which would mean that they would not be subject to price regulation. As part of the negotiation strategy, Aspen deliberately caused a shortage of Cosmos drugs in the Italian market. The decision by the regulatory authority to allow for a price increase of 1500% was revoked by the Italian competition authority based on European jurisprudence.

Sources:
RECOMMENDATIONS

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 Instances
• 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.

HAI Resources and Contributions
WHO/HAI Pricing Manual and Methodology
Database of Medicine Pricing Surveys
Statement on the Oslo Medicines Initiative, March 2021
Report: How EU governments respond to the challenges of sustainable access
Report: Realities of access to medicines in the Netherlands
1 With initial support of other Member States Italy, Greece, Portugal, Slovenia and Spain, the document asks governments to share information on net prices and demands that WHO continues convening the Fair Pricing Forum in order to “to discuss the affordability and transparency of prices and costs relating to health products”. See World Health Organization (WHO) Seventy-second World Health Assembly Resolution WHA72.8 on improving the transparency of markets for medicines, vaccines, and other health products, 28 May 2019. Available at //apps.who.int/gb/ebwha/pdf_files/WHA72/A72_8-en.pdf Accessed 1 October 2021.


6 Affordability of medicines is mentioned in several of the flagship initiatives of the document both in connection to patients access to medicines and economic sustainability of public health systems. See EUR-LEX communication from the Commission to the European Parlia-ment, the Council, the European Economic and Social Committee and the Committee of the Regions Pharmaceutical Strategy for Europe COM/2020/761 final. Available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0761&from=EN Accessed on 12 October 2021.


10 Also of interest are the Baltic Procurement Initiative, initiated in May 2012 comprised of Estonia, Lithuania and Latvia, and the Nordic Pharmaceutical Forum created in May 2015 with the participation of Denmark, Iceland, Norway and Sweden (Finland as an observer). Both instances engage in information sharing and joint procurement. Like Valletta and Beneluxa, the Nordic Pharmaceutical Forum includes Horizon Scanning as part of joint activities of members. See WHO- EURO Cross-country collaborations to improve access to medicines and vaccines in the WHO European Region. WHO, 2020, pp. 5-9. Available at. https://apps.who.int/iris/bitstream/handle/10665/332933/978928055031-eng.pdf Accessed on 13 October 2021.

Oncological treatments such as Pertuzumab (breast cancer) and Nivolumab (lung cancer), priced respectively at €54,000 and €50,000 per patient, per year were among the excessively high-priced medicines singled out by the “Our medicines, our right” campaign led by HAI with the support of over 10 Civil Society organisations ahead of the legislative elections of March 2017. See HAI Soaring Medicine Prices the Target of New Public Campaign Ahead Of 15 March Election. 7 March 2017. Available at https://haiweb.org/media-resource/media-release-soaring-medicine-prices-target-new-public-campaign-ahead-15-march-election/. Accessed on 12 October 2021.


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