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Pharmaceutical transparency: from resolution to reality

Snapshot of the implementation of WHA resolution 72.8 on transparency of pharmaceutical markets with country examples and recommendations

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HAI HEALTH ACTION INTERNATIONAL

Pharmaceutical transparency: from resolution to reality

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This report has been jointly written by Wemos and Health Action International.

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Executive summary

Transparency of the pharmaceutical sector is a critical issue. All over the world, policymakers, academics and civil society organizations are developing initiatives to increase pharmaceutical transparency to determine fair prices for health products and improve the overall accountability of the sector.

The global attention paid to the topic demonstrates the widespread understanding of the implications of decisions related to pricing and reimbursement of health products. These decisions must be made in a socially responsible manner.

This report highlights the steps taken in selected regions and countries to improve the transparency of medicine pricing since the adoption of World Health Organization's (WHO) transparency resolution in 2019. It also highlights what can be done next to translate commitments made in the resolution into reality, at the national, regional and global levels.

The report summarizes key developments at the global and European level and in Belgium, France, Germany, Italy, the Netherlands, Portugal, Spain, Switzerland, Brazil, Chile, Colombia, United States of America, and South Africa.

WHA resolution 72.8, a milestone

In 2019, growing calls for transparency of pharmaceutical markets resulted in a groundbreaking resolution at the 72nd World Health Assembly (WHA). After lengthy negotiations, WHA resolution 72.8 'Improving the transparency of markets for medicines, vaccines, and other health products' was adopted by consensus by the WHO Member States.

The resolution calls on governments to enhance the transparency of pharmaceutical markets. More specifically, it asks WHO Member States to ensure public disclosure of net prices of health products paid by national authorities, and to improve the reporting by suppliers on sales revenues, prices, units sold, marketing costs, subsidies and patent-related information.

Despite being a watered-down version of the original draft – for example by making disclosure of sensitive research and development (R&D) information voluntary rather than mandatory – this resolution acknowledges the importance of transparency of markets for medicines, vaccines and other health products. It also provides countries with direction on how to achieve this.

Good practices: implementing initiatives to improve transparency

Several countries have taken initiatives in line with the objectives of WHA resolution 72.8. Governments of other countries can learn from these actions to develop and implement effective and suitable national policies. View a selection of good practices below.

Harmful practices: protecting further price secrecy

While many countries are developing initiatives to increase pharmaceutical transparency, Germany and Switzerland are taking worrying steps in the opposite direction. Pushed by the pharmaceutical industry – which has a significant presence in these countries – both governments are adopting or proposing new legislation to protect and increase secrecy of the prices they pay for new medicines.

These examples show how much the pharmaceutical industry has a grip on government policy, rather than the other way around. The consequences extend beyond the country's borders. By legislating the secrecy surrounding the prices they pay to pharmaceutical companies, the German and Swiss governments sidestep accountability for how they spend taxpayers' money. In addition, they leave other countries without reference for their price negotiations with pharmaceutical companies.

Confidential price agreements go against the spirit of transparency and damage the interest of public health by hindering the effectiveness and efficacy of public spending. They affect price negotiations and prevent traceability between costs and prices.

The need to foster international collaboration

We see that individual countries can be reluctant to develop and implement transparency measures, arguing that they cannot change the system on their own. In addition, there may be a fear that pharmaceutical companies will not market their products in a country where they are heavily regulated or where price agreements will be disclosed.

Therefore, effective transparency policy does not only require national legislation but also – in parallel – international collaboration. Several countries in Europe have already set up alliances and platforms to exchange information and negotiate together, aiming to maximize their purchasing power thus lowering the prices of expensive medicines. These alliances should be strengthened and expanded and serve as examples for other regions of the world.

Summary of recommendations

The report provides recommendations for WHO Member States, the WHO and civil society organizations to effectively contribute to greater transparency of pharmaceutical markets.

WHO Member States should:

- Implement legislation to increase transparency of – at least – the net prices paid, R&D costs and public funding of R&D of health products.
- Review (or actively contribute to) national legal, administrative and regulatory frameworks governing access to data about prices, costs, clinical data and health technology assessments in order to ensure better informed price negotiations and provide relevant information for patients.
- Ensure that medicines selection procedures are open to public scrutiny, transparent on the evidence they are based on and allow for public engagement.
- Recognize that confidential price agreements with pharmaceutical manufacturers go against the interests of public health and good governance.
- Target excessively high prices and condemn infringements linked to anticompetitive practices such as the misuse and abuse of IP protection tools, in accordance with competition law and human rights treaties.
- Foster collaboration among public procurers and payers to share their data and publish them in a consolidated manner to inform the public.
- Invest in capacity building, including human resources and technology, to improve capabilities on price setting, cost assessments and information dissemination.
- Use the information obtained through transparency to apply a calculation model to determine the part of public share and a fair price.

WHO should support Member States in designing and implementing national legislation and policies, and facilitate initiatives for international collaboration.

Civil society organizations should monitor relevant political and legislative developments, as well as advocate and support positive steps towards greater transparency.

Selection of good practices

Chile

Combatting anticompetitive pharmaceutical practices

Chilean institutions responsible for ensuring free competition in markets have been advocating for increased transparency to enhance access to medicines. At the same time, executive and legislative branches proposed modifications to the healthcare legislation, aimed at preventing price collusion between manufacturers and sellers of medicines, and establishing a national observatory of medicines. This national observatory would enable price monitoring as well as oversight by the government and citizens.

Italy

Pioneering legislation for R&D cost disclosure

In 2020, Italy achieved a major milestone by enacting a decree with criteria and methods to determine prices of new medicines. The decree demands the disclosure of biomedical R&D costs and the amount of public funding of R&D of health products considered for reimbursement. It also requires pharmaceutical companies to provide a comparative evaluation of costs of therapeutic alternatives, and to annually report on sales, turnover, marketing costs and patent status of the reimbursed product. The decree still needs to complete the administrative process to enable implementation and enforcement.

The Netherlands

Citizen research into what is socially acceptable

The Dutch healthcare institutions and the national competition authority have started a programme to identify – in a transparent manner – which costs and prices for new medicines are socially accepted, which elements play a role in this and how these elements can be implemented. The programme entails interviews with relevant stakeholders and experts and citizen research. The citizen research will capture a public perspective on which prices are socially acceptable, and which elements are important in this regard, such as transparency. The programme will provide policy advice to the Ministry of Health.

Spain

Government push for transparency

To promote transparency and safeguard the right of access to public information, Spain has established a special institutional body: the High Transparency Council. Through this entity, citizens and entities can request access to government-related information, including on decisions regarding pricing and procurement of health products. Several civil society organizations have already successfully requested the disclosure of prices of certain expensive medicines. In addition, the Ministry of Health is currently working on two decrees aimed at obliging laboratories to declare the costs of research, development and production of a product.

South Africa

Transparency enshrined in the Constitution

South Africa acknowledged the importance of transparency by enshrining it in the country's Constitution, back in 1997. All institutional bodies that enter into contracts for goods or services, "must do so in accordance with a system that is fair, equitable, transparent, competitive and cost-effective." After an appeal to the Constitution, all contracts and negotiation-related documents for the procurement of Covid-19 vaccines were made public in 2023.

Glossary of terms

External reference pricing

External reference pricing, also known as international reference pricing, is the practice of comparing the price of pharmaceutical products in different countries to set a benchmark price.[1] It is an approach in which prices are set according to the benchmark prices for the same or similar medicines in comparable countries. This benchmarking mechanism is a pricing tool used to contain cost and ensure that the medicine price paid in a given country remains reasonable compared to the prices paid in other countries. It is often used together with other pricing approaches, such as negotiation. External reference pricing is used by many OECD (Organisation for Economic Co-operation and Development) countries to regulate medicine prices. However, the proliferation of confidential pricing agreements raises concerns regarding the effectiveness and reliability of this pricing mechanism.

Internal reference pricing

Internal reference pricing compares the prices of pharmaceutical products that are therapeutically similar and can be substituted for one another within a particular country.[2] Internal reference pricing tries to ensure that prices of comparable and interchangeable products are set at the same or a similar level.

Reference country

A reference country is part of a basket of countries whose prices can be compared as part of external reference pricing. The basket of reference countries should be chosen in accordance with the objective of the national pharmaceutical policy.

Fair pricing

The concept of fair pricing is the subject of a long-running discussion. It could be briefly defined as the price which is "affordable to the buyer while covering the seller's costs and providing a reasonable profit margin."[3] According to the definition given by the World Health Organization (WHO) for the purposes of the Fair Pricing Forum,[4] "a 'fair' price is one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines. In other words, fairness here implies positive incentives and/or benefits for all stakeholders – i.e. those who purchase and use medicines, and those involved in the R&D and manufacture of medicines."

According to the definition given by the European Cancer League in their paper on the issue,[5] a 'fair price' is justifiable, predictable and cost-effective within the aims and priorities of the healthcare systems and the available budget.

1 World Health Organization. (2021). External Reference Pricing. WHO Guideline on Country Pharmaceutical Pricing Policies: A plain language summary. https://iris.who.int/bitstream/handle/10665/341894/9789240024083-eng.pdf.

2 World Health Organization. (2021). Internal Reference Pricing. WHO Guideline on Country Pharmaceutical Pricing Policies: A plain language summary. https://iris.who.int/bitstream/handle/10665/341895/9789240024571-eng.pdf.

3 Moon S, Mariat S, Kamae I, Pedersen H B. (2020). Defining the concept of fair pricing for medicines. BMJ. 368. https://www.bmj.com/content/368/bmj.l4726.

4 World Health Organization. (2019). Medicines: Fair pricing forum. https://www.who.int/news-room/questions-and-answers/item/medicines-fair-pricing-forum.

5 Association of European Cancer Leagues. (2020). What is a Fair Price?. https://www.cancer.eu/wp-content/uploads/ECL-What-is-a-Fair-Price-Paper_final.pdf.

Rebates

A rebate is the return of part of the purchase price by the seller to the buyer. In this context, rebates are price concessions that drug manufacturers provide to payers or pharmacies. They are negotiated based on various factors, including a drug's volume of sales, market competition, and therapeutic added value. They impact pricing strategies and profit margins, especially in the context of high drug prices. Rebates directly affect the net price of drugs: the actual amount paid after subtracting these rebates. Manufacturers use rebates to attract more buyers and increase their market share by making products cheaper. Rebates are negotiated on a case-by-case basis in the greatest secrecy.

Confidential agreements

Confidential agreements are mutual written agreements between two parties concerning the confidentiality of provided information. These agreements protect research results and what is termed business information from being disclosed or used by third parties.

Non-disclosure agreements

A non-disclosure agreement means both parties maintain strict confidentiality and do not disclose, or cause or permit to be disclosed, to any person or entity, any information covered by the agreement.

Managed entry agreements

According to the OECD, managed entry agreements (MEAs) can be broadly understood as arrangements between a manufacturer and payer or provider for a certain health technology subject to specific conditions.[6] These agreements may include confidential rebates or discounts.

Value-based pricing

According to WHO, value-based pricing sets prices according to the benefits of a product to health systems and patients when compared to other available treatments for the same condition.[7] It must include an analysis of budget impact and affordability.

6 OECD. (2019). Performance-based managed entry agreements for new medicines in OECD countries and EU member states: How they work and possible improvements going forward. https://health.ec.europa.eu/system/files/2020-01/2019_entryagreements_newmedicines_oecdeu_en_0.pdf.

7 World Health Organization. (2021). Value-based pricing. WHO Guideline on Country Pharmaceutical Pricing Policies: A plain language summary. https://iris.who.int/bitstream/handle/10665/341896/9789240024595-eng.pdf.

Introduction

Since the rise of the commercial pharmaceutical industry in the 20th century – and the associated increase in expensive new medicines – the lack of transparency in the sector has been the subject of debate among stakeholders. Advocates state that transparency is essential for more equitable access to affordable medicines.[8] The secrecy surrounding costs, prices and contracts for Covid-19 vaccines during the last pandemic has once again put the issue high on the international agenda.

In 2019, the World Health Assembly (WHA) adopted resolution 72.8, 'Improving the transparency of markets for medicines, vaccines, and other health products', aimed at enhancing transparency in global markets. This report presents a snapshot of the state of implementation of this WHA resolution in selected countries in Europe, the Americas and Africa. It also contains recommendations for World Health Organization (WHO) Member States, the WHO itself and civil society organizations on next steps and strategies to improve implementation or adaptation of the resolution in national and regional settings.

Why transparency is a critical starting point for sustainable pharmaceutical markets

Health is a fundamental need and therefore a universal human right.[9] Access to medicines is critical for its fulfilment. Pharmaceutical companies have disproportionate power in this area: they largely determine which medicines are developed and produced, where these products are marketed and at what price.

Excessive prices

The pharmaceutical industry exerts considerable influence on public health, yet its actions remain largely opaque. In the absence of appropriate laws and regulations, there is no obligation for companies to be transparent about, for example, the development costs of medicines, the (net) prices they charge for their medicines and relevant data from clinical trials. This enables companies to charge any price for new products without proper accountability.

This lack of transparency has major consequences on a government's bargaining power during negotiations. Public purchasers negotiate, as it were, blindfolded with pharmaceutical companies on the price of new medicines. They often end up paying excessive prices, leading to financial pressure on public health systems and displacement of resources from other care.[10] For many countries, new medicines are often simply unaffordable and thus inaccessible.[11]

Information asymmetry

Excessive medicine prices are fuelled by a persistent information asymmetry between pharmaceutical companies and purchasers.

8 Perehudoff, K. (2022). European governments should align medicines pricing practices with global transparency norms and legal principles. The Lancet Regional Health–Europe. https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(22)00068-0/fulltext.

9 World Health Organization. (2023). Human Rights. https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health.

10 Pharmaceutical Accountability Foundation. Issue #3 Poor Enabling Environment. https://www.pharmaceuticalaccountability.org/issues/poor-enabling-environment/.

11 Vallano, A., Pontes, C., Agustí, A. (2023). The challenges of access to innovative medicines with limited evidence in the European Union. Front Pharmacol. https://pmc.ncbi.nlm.nih.gov/articles/PMC10500193/.

While companies have a strong negotiating position, they keep public buyers in a position of insufficient or incomplete information, leading to weak negotiating power. This hinders their delivery of socially responsible policies for procurement and reimbursement of medicines. More transparency on prices and pricing can remedy the imbalances and lead to lower, fairer prices of medicines.

Accountability

Besides enhancing excessive prices, a lack of transparency also undermines the important democratic principle of accountability – an essential condition for good governance. Governments serve the public, and pharmaceutical companies fulfil a pivotal social function as well. Both must therefore be trustworthy, function well and comply with ethical standards. It is crucial that the public can assess their actions and keep them accountable. This also applies to pricing and price negotiations for medical products.[12]

What to expect in this report

This report focuses on developments at the global level, followed by policy frameworks and initiatives developed at the European level. Special attention to relevant developments in Europe is granted because the continent has seen a strong public and political mobilization around skyrocketing medicine prices in recent years, mainly due to the high prices of newly marketed oncological medicines and those for rare diseases.[13]

Next, the report presents examples from Europe, the Americas, and Africa, describing each featured country's position on the WHA resolution, the latest political and legislative developments, and how prices of medicines are set nationally. Key stakeholders, such as civil society organizations and academics, were consulted to support the analyses for each country. The aim is not to provide an exhaustive overview of transparency in pharmaceutical markets, but rather to track the steps some countries have taken towards greater transparency and learn from them. Moreover, it is important that the issue remains at the core of WHO Member States' priorities and policies at national, regional and global levels.

After the conclusion, the report ends with recommendations to policymakers and other relevant stakeholders, such as WHO Member States, pharmaceutical companies, and civil society organizations. These offer guidance on how these actors can effectively contribute to improving transparency in the pharmaceutical system and markets.

12 Transparency in the pharmaceutical industry reaches beyond pricing. For example, it also relates to clinical trials (such as results, protocols and costs) in which new medicines or formulations are tested on human volunteers. However, this present report focuses on transparency of prices and pricing.

13 See for example Eccles, M. (2024, 14 October). Drug prices in Europe are soaring — and are only expected to rise. Politico. https://www.politico.eu/article/drug-medicine-price-europe-rising-big-pharma-europe/#:~:text=In%20France%2C%20for%20example%2C%20reimbursed,8%20billion%20over%20this%20period.

Global developments

WHO has played a key role in setting up global frameworks, norms and policies regarding transparency. Transparency around strategies for measuring, monitoring and managing prices are critical for promoting access to medicines while strengthening health services.

WHA resolution 72.8 is one of several WHA resolutions and WHO initiatives taken on transparency. Another is the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property (WHA resolution 61.21), dealing with the need for greater transparency in prices of pharmaceutical products as well as R&D costs and clinical trials results. Resolution 72.8 represents a significant advancement in terms of transparency within the pharmaceutical market on a global scale.

Since the adoption of resolution 72.8, WHO has launched several initiatives, such as the Novel Medicines Platform under the umbrella of WHO/Europe, provided recommendations updating the Guideline on Country Pharmaceutical Pricing Policies, and developed a few technological tools such as the Market Information Source database and Essential Medicines and Health Products Price and Availability Monitoring Mobile Application (MedMon).

WHA resolution 72.8 drives consensus on pharmaceutical transparency

In 2019, Italy brought the discussions on transparency in the pharmaceutical markets to a global level by proposing a resolution on this matter to the 72nd World Health Assembly (WHA). The proposal, based on a draft prepared by the Italian Medicines Agency (AIFA), explicitly demanded transparency on net prices, clinical trials data, patent status information and marketing approval status of health products.

The resolution was initially supported by Portugal, Spain and Greece, followed by a geographically diverse list of countries, including Malaysia, Egypt, South Africa, Uganda, Turkey, Serbia and Slovenia.

Germany and the UK, supported by Japan, Denmark and Sweden – all countries with major pharmaceutical manufacturing sectors – attempted to weaken the resolution during the deliberation stages, particularly in connection to the language on transparency on R&D costs. The UK and Germany ultimately disassociated themselves from the resolution, which was adopted by consensus.[14]

Despite being a watered-down version of the original document, for example by making disclosure of sensitive R&D information not mandatory but voluntary, this resolution reframed and highlighted the issue of transparency in several respects.

First, it emphasized the need for national governments to "enhance the publicly available information on the net prices applied in different countries." Second, it called for greater transparency around patent-related information, allowing payers and other relevant authorities to better assess the product and its price and barriers to generic entry. Lastly, it recognized the importance of public sector funding for research and development of health products, seeking to improve the transparency of both public and private funding across the value chain.

14 Zarocostas, J. (2019). UK, Germany, dissociate from WHO drug pricing resolution. The Lancet. Vol 393, Issue 10188. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)31329-7/abstract.

Overall, the resolution set out a mandate for Member States and WHO to create or improve systems to collect and share information about (listed and net) prices, sales revenues, units sold, marketing costs, subsidies and incentives.

However, several key elements are still missing from the resolution, such as the disclosure of full R&D costs, including production costs, the terms and conditions of intellectual property (IP) and technologies' licensing agreements, the full IP status (not limited to patents), the terms and conditions of public funding and public procurement agreements.[15]

Despite the remaining differences in views and interpretations on transparency, the WHA resolution provides a basis for an emerging global consensus on what information should be disclosed. However, the vagueness over definitions and objectives affects the way the debate on transparency is maintained, to some extent prolonging the status quo and the lack of concrete action. The adoption of the resolution thus marks the beginning rather than the end of a process.

WHO's overarching role

WHO has been producing evidence-based materials that can guide governments and other stakeholders in the design, formulation and implementation of policies and public interventions regarding greater transparency. Improving access to essential medicines has long been the focus of many international development programmes and projects focusing mainly on developing countries. However, until recently, very few health programmes have given high priority to improving transparency and governance within the health system and specifically the pharmaceutical sector.[16]

A review of the two former global initiatives aimed at improving transparency and accountability in the pharmaceutical system – the Medicines Transparency Alliance (2008)[17] and Good Governance for Medicines programmes (2014)[18] – revealed that at that time there was no uniform concept or understanding of transparency, either across countries or among stakeholders within countries. In many countries, it was unclear what transparency and accountability meant and how they should be implemented. Unfortunately, this lack of clarity continues today.

The WHO Guideline on Country Pharmaceutical Pricing Policies (hereafter the Guideline) states that, for the design and implementation of effective pricing policies, all relevant stakeholders should be enabled to know the prices of medicines and how those prices were set.[19]

According to the Guideline, transparency around prices and pricing includes the sharing, disclosure and dissemination of:

15 MSF Access Campaign. (2024). Secrets Cost Lives: Transparency and Access to Medical Products. https://www.msfaccess.org/secrets-cost-lives-transparency-and-access-medical-products.

16 World Health Organization. (2016). The Medicines Transparency Alliance Programmatic Review of MeTA Phase II Final Report – March 2016. https://iris.who.int/bitstream/handle/10665/246256/9789241565387-eng.pdf?sequence=1&isAllowed=y.

17 Ibid.

18 World Health Organization. (2014). Good governance for medicines: model framework, Updated version 2014. https://iris.who.int/bitstream/handle/10665/129495/9789241507516_eng.pdf.

19 World Health Organization. (2021). Promoting Price Transparency: WHO Guideline on Country Pharmaceutical Pricing Policies. https://iris.who.int/bitstream/handle/10665/341898/9789240024632-eng.pdf.

- the net transaction prices (i.e. prices including discounts and rebates) paid by purchasers, such as governments;
- all prices along the supply and distribution chain;
- a public report about the research and development (R&D) contributions from all sources;
- pricing arrangements between companies and purchasers;
- the details of pricing arrangements such as managed entry agreements, and patent status and licensing arrangements (legal contracts where a company grants another company the rights to sell its product);
- pricing and reimbursement decisions of the government; and
- relevant price components, such as production costs, R&D costs, added therapeutic value and profit margin.[20]

In 2020, WHO published an updated version of the Guideline on Country Pharmaceutical Pricing Policies.[21] It has been revised to reflect the years of country experiences and the evidence on existing pricing policies. It contains recommendations on pricing policies commonly considered in countries to manage medicine prices, as well as pragmatic considerations for what is required to implement these policies according to the objectives and context of individual health systems.

The revised Guideline suggests that countries improve the transparency of pricing and prices through the following mechanisms:

1 sharing the net transaction prices of pharmaceutical products to relevant stakeholders, within and external to the country;
2 disclosing prices along the supply and distribution chain;
3 publicly reporting research and development (R&D) contributions from all sources; and
4 communicating pricing and reimbursement decisions to the public.

WHO also suggests that countries improve the transparency of pricing and prices through a clear description of pricing approaches and their technical requirements.

To support data and information sharing, WHO completed a study on the transparency of medicine price information sources and published the resulting Market Information Source database as a first step to understanding the feasibility of developing a global market intelligence platform.22 The database contains a list of publicly available information on national and global sources related to pharmaceutical prices, pharmaceutical registries, clinical trials, and medicine shortages across the 194 Member States. Although much information is still lacking in many countries, efforts to bring together all publicly available information in one place are contributing to the use and dissemination of relevant public knowledge.

20 Ibid.

21 World Health Organization. (2020). WHO Guideline on Country Pharmaceutical Pricing Policies. https://www.who.int/publications/i/item/9789240011878.

22 World Health Organization. (2025). Medicine Prices and Other Market Information Sources. https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/affordability-pricing/med-price-info-source.

WHO Essential Medicines and Health Products Price and Availability Monitoring Mobile Application (MedMon)

Part of WHO's follow-up actions from the Fair Pricing Forum was to launch an update of its electronic tool MedMon, designed to monitor availability and prices of health products in countries. This multi-language tool aims to rapidly collect and analyse data on the price and availability of medicines in health facilities and procurement centres.[23] As part of the latest update provided, WHO completed studies in Europe, namely in Ukraine in 2019, and in Uzbekistan and Tajikistan in 2021. As of 2023, WHO completed the development of the Country Assessment Platform (CAP), the larger survey platform built to host MedMon as well as other facility-based and household surveys.

WHO piloted the platform in three countries: Kenya, Tajikistan and Ghana. In Kenya, the London School of Hygiene & Tropical Medicine (LSHTM) used the platform to collect data on the price and availability of fixed-dose combinations of medicines for hypertension. In Tajikistan, WHO developed a new survey within CAP to assess the availability of laboratory equipment and diagnostic tools related to bacterial identification, in support of the country's antimicrobial resistance priorities. In Ghana, WHO collected data on the price and availability of medicines for non-communicable diseases and developed a new module to collect data on the price and availability of medical devices and diagnostics. This tool is a useful additional resource for publishing the data. Unfortunately, the CAP and MedMon tools were put on hold in 2024 due to resource constraints within WHO division.

WHO Fair Pricing Forum

Following approval of WHA resolution 67.22 ('Access to essential medicines', 2014[24]), and as part of measures undertaken to assist countries to "ensure access to safe, effective and quality-assured essential medicines, including high price essential medicines", WHO convened the first edition of the WHO Fair Pricing Forum in 2017, in the Netherlands.[25] With the Forum, the WHO aims to bring together stakeholders to improve access to all essential medicines and essential health technologies as part of quality and effective health services.[26]

The Forum's goal is to facilitate discussion on existing approaches and emerging policies to address issues pertaining to pharmaceutical markets' transparency and the affordability of essential medicines and health products. It provides a platform for all relevant stakeholders to exchange and share ideas on the developments, risks and challenges related to transparency and pricing issues. Consideration of the need to achieve price and pricing transparency has been a recurring theme across all the forums and topics discussed.

23 World Health Organization. (2018). MedMon - WHO Essential Medicines and Health Products Price and Availability Monitoring Mobile Application. https://www.who.int/news/item/18-02-2018-medmon-mobile-application.

24 World Health Assembly. (2014). Access to Essential Medicines (WHA67.22). World Health Organization. https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R22-en.pdf.

25 See World Health Organization. (2017). Fair pricing forum 2017 meeting report. https://www.who.int/publications/i/item/WHO-EMP-IAU-2017-10.

26 World Health Organization. (n.d.). Affordability and pricing. https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/affordability-pricing.

WHA resolution 72.8 requested the WHO Director-General, among other demands, "to continue WHO's efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products."

The second Forum was held in Johannesburg, South Africa, in 2019. The proposal for the transparency resolution was endorsed by a number of participants at this Forum, reaffirming the commitment to promote the transparency of R&D costs, production costs, prices, and profit margins of pharmaceuticals, vaccines and health technologies.[27] The third Forum was held virtually (co-hosted with Argentina) in 2021, and the latest edition took place online in February 2024.
In the third Forum in 2021, transparency of pricing and markets for health products dominated most of the sessions as an overarching issue. Transparency was seen as critical for informing effective government policymaking and decision-making to increase access. When governments know and understand the cost of R&D and have visibility of the production and supply chain processes, they are better equipped to put a value on health products and to negotiate fairer prices.[28] The importance of improving the transparency of both public and private sector funding across the value chain was also highlighted.[29]

The Oslo Medicines Initiative

Established in 2020, the Oslo Medicines Initiative (OMI) is a collaboration between the WHO Regional Office for Europe (WHO/Europe), the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency. The OMI aims to provide a platform for the public and the private sectors to jointly outline a vision for equitable and sustainable access to, and affordability of, effective, novel and high-priced medicines. The OMI has commissioned a series of technical reports to summarize relevant evidence and provide policy considerations as a basis for discussion to inform its work. These reports are also in line with the implementation of WHA resolutions, in particular, WHA resolution 72.8. In this framework, a report entitled 'Access to information in markets for medicines in the WHO European Region'[30] has been published. This acknowledges the fact that some countries have implemented transparency policies, and that their experience can allow other countries to benefit from the lessons learned.

Mandated by WHO/Europe, a scoping review[31] was performed in 2021 to support policymakers in the WHO European region who seek to develop policies related to market transparency by summarizing the current evidence on the legal implementation of measures to improve the transparency of markets for medicines, vaccines and other health products. The review identified various legal and regulatory mechanisms that have been used in the WHO European region and beyond to achieve disclosure. These mechanisms

27 Fletcher, E. R. (2019, 11 April). WHO-led Fair Pricing Forum Gathers Diverse Groups To Improve Drug Access. Health Policy Watch. https://healthpolicy-watch.news/who-led-fair-pricing-forum-gathers-diverse-groups-to-improve-drug-access.

28 World Health Organization. (2021). Fair Pricing Forum ends with good intentions and new undertakings from WHO. https://www.who.int/news/item/23-04-2021-fair-pricing-forum-ends-with-good-intentions-and-new-undertakings-from-who.

29 World Health Organization. (2021). Forum Discussion Paper: Pricing approaches sensitive to health systems' ability to pay and the need for accelerating towards Health Sustainable Development Goal. https://iris.who.int/bitstream/handle/10665/348288/WHO-MHP-HPS-MIA-2021.02-eng.pdf.

30 Volger, S. (2021). Access to information in markets for medicines in the WHO European Region. https://iris.who.int/bitstream/handle/10665/361757/9789289058322-eng.pdf?sequence=1.

31 Perehudoff, K., Mara, K., 't Hoen, E. (2021). What is the evidence on legal measures to improve the transparency of markets for medicines, vaccines and other health products (World Health Assembly resolution WHA72.8)?. World Health Organization. Regional Office for Europe. https://iris.who.int/handle/10665/342474.

include legislation and regulations on reporting, pricing and reimbursement (and pooled procurement legislation), as well as laws that are not directly relevant to medicine pricing but can impact price transparency, such as access to public information laws.

At the 72nd session of the WHO Regional Committee for Europe in Tel Aviv, Israel, in September 2022, a WHO statement gave WHO/Europe the mandate to continue to act as a neutral convenor, host and facilitator by creating a formal stakeholder collaboration platform – the WHO/Europe Access to Novel Medicines Platform (NMP) – to improve affordable and equitable access to effective, novel, high-priced medicines in the European region.[32]

The Novel Medicines Platform

The aim of the Novel Medicines Platform is to identify concrete actions to improve affordable and equitable patient access to effective, novel, high-cost medicines in the European region.[33] Four working groups have been set up on the themes of 1) transparency, 2) solidarity, 3) sustainability and 4) novel antimicrobials.

Working groups, including government representatives, the pharmaceutical sector, academia and public interest civil society, meet regularly to agree on a new paradigm that would allow governments to negotiate prices more effectively, leading to lower and fairer prices. The working group on transparency focuses on two aspects: 1) agreement on what information can be made more transparent in accordance with the framework set out in WHA resolution 72.8; and 2) identification of indicators to assess patient access to effective, novel, high-cost medicines, and exploration of approaches to improve and standardize their collection, analysis and use.

WHO/Europe addressing access conditions to novel medicines, which are often highly priced and out of reach for many, is a significant step forward. It highlights the urgent need for closer cooperation among governments to tackle excessive prices and the lack of transparency affecting the sector across Europe.

The chair of the working group on transparency, Francis Arickx, stated: "Transparency requires openness, communication, and accountability from and towards the patients, stakeholders, industry and society. We need [to] not only ask for transparency from the pharmaceutical industry regarding how they set prices, how much they want to gain and how much was invested in drugs development; we also need to ask for transparency from the buyer's side – their needs and expectations, and how much funds are available and can be invested."[34]

Since the set-up of the platform is consensus-based, it has been challenging to look at bigger steps that could improve transparency of the pharmaceutical markets as the focus was about agreeing on terms and sharing existing data. The NMP was also structured in a controversial way as the pharmaceutical industry co-chairs various working groups, thereby potentially influencing the direction and outcomes.

32 World Health Organization. (2022). 72nd session of the WHO Regional Committee for Europe. https://www.who.int/europe/about-us/governance/regional-committee/session-archives/72nd-session-of-the-who-regional-committee-for-europe.

33 World Health Organization. (n.d.). The Novel Medicines Platform. https://www.who.int/europe/groups/the-novel-medicines-platform.

34 World Health Organization. (2024). WHO/Europe's Novel Medicines Platform launches working group on transparency to improve access to medicines. https://www.who.int/europe/news-room/03-01-2024-who-europe-s-novel-medicines-platform-launches-working-group-on-transparency-to-improve-access-to-medicines.

As next steps, WHO/Europe is looking for sustainable funding, which could come from the private sector, to finance selected proposals, some of which may be industry-led. This raises concerns about WHO's ability to continue to run such a process effectively and autonomously.

Overall, it seems to be a missed opportunity for the NMP to take the much-needed steps that can support WHO Member States from Europe to increase price transparency and public accountability in the pharmaceutical sector.

Developments at the European level

As consistently recalled by the European Commission, pursuant to Article 168(7) of the Treaty on the Functioning of the European Union (TFEU),[35] European Union (EU) Member States are responsible for the organization of their healthcare system and for the delivery of health services and medical care, including the allocation of resources assigned to them. In this framework, each EU Member State can take measures to regulate the prices of medicinal products and establish the conditions of their public funding. However, as an international organization, the EU is founded and empowered by its Member States to discharge certain functions outlined in its treaties. EU Member States should work towards aligning the pharmaceutical policies of different international bodies they are members of – e.g. World Health Organization (WHO) and World Trade Organization (WTO) – with human rights standards.[36]

EU Transparency Directive

The issue of transparency in healthcare at the EU level was addressed in 1989 with what was termed the Transparency Directive (Directive 89/105/EEC on the transparency of measures regulating the prices of medicines for human use and their inclusion in the scope of national health insurance systems). This directive aims to ensure that any measures taken by EU countries to set the prices of and to reimburse medicinal products are transparent. To achieve this, it sets out the procedures that EU countries must follow so that their decisions and policies do not create obstacles to EU pharmaceutical trade. Often confused with price transparency, Directive 89/105/EEC aims to obtain transparency around decision-making on pricing and reimbursement, but not transparency with regards to the product prices themselves.

After conducting a review of the legislation, the Commission proposed amendments through a new directive,[37] in March 2012. Its objective was to streamline procedures and reduce the time taken by national authorities in making decisions on the pricing and reimbursement of medicines. The proposed directive intended to improve legal clarity and certainty for all interested parties. As mentioned in the explanatory memorandum, "negotiations in the Council Working Party on Pharmaceuticals and Medical Devices proved to be difficult, given the politically sensitive nature of the file." Finally amended and adopted, the implementation of the directive is mentioned in the new EU Pharmaceutical Strategy proposed by the Commission in April 2023 (more on this below), which aims to ensure that the transparency of national decisions on medicine prices and reimbursement is in line with the

35 European Union. (2008). Consolidated version of the Treaty on the Functioning of the European Union - PART THREE: UNION POLICIES AND INTERNAL ACTIONS - TITLE XIV: PUBLIC HEALTH - Article 168 (ex Article 152 TEC). https://eur-lex.europa.eu/eli/treaty/tfeu_2008/art_168/oj/eng.

36 University of Amsterdam. (2025, 31 January). Dr Katrina Perehudoff intervention. OHCHR 2025 workshop on 'Expert workshop on new developments in ensuring access to medicines, vaccines and other health products'. https://www.ohchr.org/sites/default/files/documents/issues/health/medicines/kperehudoff-ohchr-intervention-january-2025.pdf.

37 European Union. (2013). Proposal for a Directive relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52013PC0168.

updated Transparency Directive, while respecting EU countries' competence to set their own prices for medicines, as long as they comply with (procedural) requirements.

In September 2024, the European Commission published a report on the functioning of the directive.[38] Although the Commission reiterates its objective of promoting transparency of pricing information in order to help Member States make better pricing and reimbursement decisions, there is general agreement that the directive is outdated and no longer responds to the challenges and realities of the pharmaceutical system in place 30 years on. The lack of transparency on net prices, including discounts and rebates, is mentioned as a major obstacle to the effectiveness of the directive. Some are calling to include regulation on confidential and voluntary agreements in the scope of a revised directive.

Transparency crisis during the Covid-19 pandemic

The lack of transparency was particularly decried during the European Commission's management of the Covid-19 crisis and around the joint procurement agreements. The European Commission's pre-purchase contracts for the Covid-19 vaccines set a worrying precedent in terms of opacity and loss of democratic control over public spending. According to the European Court of Auditors, the price of these contracts amounted to 71 billion euros.39 Nevertheless, the content of these contracts remains inaccessible to the public. It is currently impossible to ascertain the precise amounts received by each party, the intended purposes, or the specific terms of the liability and compensation clauses agreed upon between the governments and the companies.

In reaction to this, the European Parliament adopted a resolution on 'Covid-19 pandemic: lessons learned and recommendations for the future'40 in 2023, underlining "the need for better EU practices on transparency and democratic accountability in relation to crisis countermeasures in order to strengthen citizens' support and trust." Transparency is at the heart of the resolution, mentioned more than 70 times.

Aligned with the need for greater transparency of public funding, the resolution "recommends attaching better conditions to public funding for the future, regarding transparency standards on the use of public funds, know-how transfers and affordability" (point 100). It also "reaffirms the need for greater transparency in biomedical R&D to independently establish well-targeted financial investments and reduce duplication by ensuring clinical trial data and outcomes are reported and accessible" (point 297).

The European Parliament recalled expressly WHA resolution 72.8 "which calls for the enhanced dissemination of and access to costs from clinical trials" (point 125). It recalled the core principle of solidarity on pricing sharing (point 200), and stressed that transparency is the fundamental principle on which the work of the EU institutions should be based, namely to guarantee democratic oversight and enhance citizens' trust in public institutions. It insisted "on principles of fair pricing, transparency and a fair return on public investment for advance purchases" (point 278). Any form of support from public authorities should be conditional upon accessibility, affordability, availability, safety and transparency clauses. Since the beginning of 2021, at the instigation of the Green MEP Michèle Rivasi, a few Greens/

38 European Commission. (2024). Final report, Functioning of Directive 89/105/EEC relating to the transparency of measures regulating the prices and reimbursement of medicinal products ('Transparency Directive'). https://research-portal.uu.nl/ws/files/245634245/functioning_of_directive_89105eec_relating_to_the-HW0124003ENN.pdf.

39 European Court of Auditors. (2022). Upcoming audit report on the EU's COVID-19 vaccines procurement. https://www.eca.europa.eu/en/news/ANNOUNCEMENT2209_06.

40 European Parliament. (2023). European Parliament resolution of 12 July 2023 on the COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI)). https://www.europarl.europa.eu/doceo/document/TA-9-2023-0282_EN.pdf.

EFA members of the European Parliament[41] have initiated proceedings before the European Court of Justice (ECJ) to obtain transparency in the Covid-19 vaccine purchase contracts.

In July 2024, the ECJ issued its ruling on the lawsuit filed by the five Greens/EFA MEPs requesting access to documents related to the joint purchases of Covid-19 vaccines.[42] The Court annulled the Commission's decision and found that the Commission did not sufficiently demonstrate, inter alia, why access to key provisions such as on indemnification for any vaccine-related damages and on donations and resales of vaccines would undermine commercial interests. This decision was welcomed by many, including Kim van Sparrentak, a Greens/EFA MEP who underlined the rejection of the Commission's automatism to claim confidentiality and commercial interests over public access.[43]

Even if not directly linked to price transparency or the WHA resolution as such, this outcome should lead towards greater transparency on the use of public funding in the EU. The confidentiality required to protect commercial interests can no longer be invoked as the ultimate justification to the detriment of the public interest.

'Deadly prices'

Recently, the journal Investigate Europe published an in-depth investigative piece entitled 'Deadly prices: how big pharma feeds inequality in Europe' on Europe's secret drug pricing system, revealing a world of opaque deals and unequal access.[44] The research demonstrated that prices and access vary widely across European countries. According to the pharmaceutical industry, countries should pay according to their means, so that the rich pay more than the less well off. The reality seems different: the journalists' scrutiny of the breakthrough drugs of one pharmaceutical producer indicates that the company charges much more in some low-income countries than in some well-to-do economies. But only industry has all the facts. For the past 15 years, a blanket of secrecy has been laid over the vast European pharmaceutical market. Companies approach countries separately to offer new drugs with a discount, provided they never tell any other country what that rebate is.

41 Greens/EFA MEPs Kim van Sparrentak, Tilly Metz, Jutta Paulus, Margrete Auken and Michele Rivasi.

42 Curia, T-689/21, Auken and Others v Commission, Judgement 18.06.204. https://curia.europa.eu/juris/documents.jsf?num=T-689/21; https://curia.europa.eu/juris/documents.jsf?num=T-761/21.

43 The Greens/EFA in the European Parliament. (2024, 17 July). Greens/EFA welcomes ECJ ruling on access to COVID vaccine contracts. Press release. https://www.greens-efa.eu/en/article/press/greens-efa-welcomes-ecj-ruling-on-access-to-covid-vaccine-contracts.

44 Investigate Europe. (2024). Deadly Prices. https://www.investigate-europe.eu/themes/investigations/deadly-prices-europe-big-pharma-medicines.

Cross-country initiatives flourishing

Several European countries are gathering around joint initiatives to share information and negotiate together in view of maximizing their purchasing power and lowering the prices of medicines.

The Beneluxa Initiative

Launched to explore wider collaborative opportunities and to foster patients' access to innovative medicines at an affordable cost, Beneluxa is a purchasing alliance bringing together the following European countries: Belgium, the Netherlands, Luxembourg, Austria and Ireland.[45]

During the informal meeting of European Ministers for Employment, Social Policy, Health and Consumer Affairs in Riga, in April 2015, the health ministers of Belgium and the Netherlands announced their initiative to explore possible collaboration on pharmaceutical policy. This included price negotiations with pharmaceutical companies for orphan medicinal products. In September 2015, the Grand Duchy of Luxembourg joined the Belgium-Netherlands project. Austria joined the cooperation initiative in June 2016 and Ireland in 2018. Since then, this project has been named Beneluxa.

One of the areas of cooperation is information-sharing on medicine prices. By working closely together, these countries believe that it will be easier to negotiate medicine prices with the industry. Collaboration also allows them to share more data and demand more transparency on the cost build-up of pharmaceutical products.

In May 2019, the initiative's countries highlighted the importance of price transparency among countries in a statement: "The members of the Beneluxa Initiative highly value transparency as a key contributor to achieving sustainability of access to medicines. Transparency will assist in improving insight into the inner workings of the pharmaceutical value chain. We strongly support access to data generated by clinical research, including negative and inconclusive outcomes. We welcome a wide debate on these topics and further discussion at international level. The first concrete step should be to create price transparency among countries."[46]

The first agreement was made jointly with the Netherlands, Belgium and Ireland on the price of Zolgensma (onasemnogene abeparvovec), a gene therapy used to treat spinal muscular atrophy, in October 2021.[47] The initiative has jointly negotiated on the price of a therapy four times in total, the latest agreement being on the price of Libmeldy (atidarsagene autotemcel) in April 2023.

Beneluxa is a positive step forward, recognizing the advantages of joint and concerted negotiation to increase purchasing power and bring down the price of expensive medicines. It also strengthens collaboration between Health Technology Assessment (HTA) agencies via joint assessments, sharing of data and evidence, alignment with national HTA procedures and facilitating agreement on reimbursement terms.

45 Beneluxa. (n.d.). Initiative on Pharmaceutical Policy. https://beneluxa.org/.

46 Beneluxa. (2019). Statement 16 May 2019: Transparency of prices. https://beneluxa.org/statements#toc-16-may-2019-transparency-of-prices.

47 Beneluxa. (2021). Statement 08 October 2021: Outcome of joint negotiations for Zolgensma. https://beneluxa.org/statements#toc-08-october-2021-outcome-of-joint-negotiations-for-zolgensma.

However, despite all the good intentions to promote greater transparency, none of the joint agreements has published the final negotiated price. This means that other countries and ultimately patients cannot benefit from these agreements. Agreements have also been limited in number and scope.

The Valletta Declaration

Another regional initiative is the Valletta Declaration. In 2017, health ministers from several European countries launched this initiative with the aim of exploring different methods of negotiating prices with the pharmaceutical industry. The group comprised Malta, Cyprus, Greece, Italy, Spain and Portugal, with Ireland, Slovenia and Romania joining in 2018. The joint key activities of the declaration include horizon scanning, information sharing, and joint negotiation for selected medicines. Compared to other initiatives such as Beneluxa, the Valletta Declaration Group (VDG) focuses on drug pricing information-sharing. Ultimately the group advocates for greater transparency in medicine prices to ensure accessibility and affordability for all citizens.[48]

The group is clearly aligned with the objectives of the WHA resolution, although the initiative needs to be broadened, strengthened and given greater visibility.

The Fair and Affordable Pricing Initiative

Another cross-country initiative emerged in 2019 called the Fair and Affordable Pricing Initiative (FaAP), a regional cooperation of Eastern European countries – the Czech Republic, Hungary, Lithuania, Poland and Slovakia – aiming to improve and facilitate access to effective and affordable medicinal products by developing methods and modalities of cooperation and negotiations.[49] The latest information available is that a sharing workshop "to facilitate voluntary cooperation" took place in 2020. To ensure the initiative's continued success, it is essential that it is reinforced and made more effective in the future.

EURIPID project

The European Integrated Price Information Database (EURIPID) was established in 2010 as a voluntary non-profit collaboration of national pricing and reimbursement authorities in European countries. These authorities have committed themselves to providing national data and fostering information and data exchange between EU countries, thereby enhancing price transparency.[50] It mainly comprises European countries that are part of the EU, as well as a few others such as Israel, Switzerland and the UK.[51]

Under this EU-funded project, countries work together to build and maintain a database of national medicine prices and pricing regulations. The purpose is to prevent negative effects on access to medicines and medical tools created by international price benchmarking rules.

The database constitutes more than 30 million data points on prices of medicinal products and since 2019 also information on volumes and the existence of managed entry agreements (MEA) in EURIPID member states. Although EURIPID is a valuable source of information for national authorities beyond external reference prices, the lack of information on net prices, negotiated rebates and discounts as well as the low level of commitment and political support from EU Member States make its effectiveness questionable.

48 Health Action International. (2020). Cross-Country Cooperation Schemes: a fair-weather solution to the issue of access to medicines in Europe?. https://haiweb.org/wp-content/uploads/2020/12/Report-Cross-Country-Cooperation.pdf.

49 The Fair and Affordable Pricing Initiative. (n.d.). https://fairandaffordable.github.io/.

50 EURIPID. (n.d.). https://euripid.eu/.

51 EURIPID. (n.d.). Participating countries. https://euripid.eu/participating-countries/.

An OECD (Organisation for Economic Co-operation and Development) report[52] highlights countries' interest in a pilot mechanism for sharing pharmaceutical net prices, although they disagree on practicalities and the potential impact on prices, access and negotiations. According to key findings of the 2024 report entitled 'Exploring the feasibility of sharing information on medicine prices across countries', a significant number of OECD countries would like to share information on net prices of pharmaceuticals with other countries, with a preference for doing so within a closed network. Despite the broad consensus among countries that disclosing net prices would increase or not affect the negotiation powers for payers, the usefulness of external reference pricing, and the sustainability of pharmaceutical spending, they also expressed substantial disagreement regarding the impact of greater price transparency on overall price levels, access to medicines, and the intricacy of price negotiations between payers and manufacturers. Most respondent countries expressed interest in participating in a pilot mechanism for sharing net prices with their peers. As noted, however, achieving this objective would necessitate legislative and contractual adjustments in several countries.[53]

As proposed in the EU Pharmaceutical Strategy for Europe, establishing new ways of sharing information about new pharmaceuticals across countries is a priority area to complement cross-country collaborations for joint medicines pricing and reimbursement negotiations.[54]

EU pharmaceutical package

Some efforts to include transparency can be observed in the reform of the EU pharmaceutical legislation launched in April 2023 by the European Commission. The revision aims to make health products more available, accessible and affordable. One of the key elements of the proposals was to introduce measures for greater transparency of public funding of medicine development.

The Explanatory Memorandum of the Directive proposal states the following:[55]

Increased transparency on the contribution of public funding to research & development costs

Marketing authorization holders will be required to publish a report listing all direct financial support received from any public authority or publicly funded body for the research and development of the medicinal product, whether successful or not successful. Such information will be easily accessible to the public on a dedicated webpage of the marketing authorization holder and in the database of all medicinal products for human use authorized in the EU. Greater transparency around public funding for medicinal products development is expected to help maintain or improve access to affordable medicinal products.

52 OECD. (2024). Exploring the feasibility of sharing information on medicine prices across countries. https://www.oecd.org/en/publications/exploring-the-feasibility-of-sharing-information-on-medicine-prices-across-countries_5e4a7a47-en.html.

53 Ibid.

54 Perehudoff, K., Mara, K., 't Hoen, E. (2021). What is the evidence on legal measures to improve the transparency of markets for medicines, vaccines and other health products (World Health Assembly resolution WHA72.8)?. World Health Organization. Regional Office for Europe. https://iris.who.int/handle/10665/342474.

55 European Commission. (2023). Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192.

This key aspect is featured in Article 57 of the proposed directive. This article would establish the obligation for manufacturers to declare public funding of R&D. The European Parliament has proposed amendments to this article, ensuring that the public disclosure obligation applies to "any direct financial support received from any public authority, publicly funded body or philanthropic or not-for-profit organization or fund, irrespective of its geographic location, and any indirect financial support received from any public authority or publicly funded body of the [European] Union or its Member States."

This was further reinforced in the preamble. The European Parliament tabled amendment 72, recital 131 to the preamble of the directive.[56] The Commission's original proposal states that reporting obligations should only concern direct public financial support such as contracts or grants as there is a practical difficulty in identifying how indirect public funding instruments support the development of a particular product. However, the EP's amendment states that these practical difficulties only arise in third countries, implying a reporting obligation on all public funding.

In the proposal for a new regulation,[57] the preamble directly refers to the need for transparency. The EP's amendment 5 recital 3 to the preamble highlights the need for transparency in the process of development of medicinal products tailored to unmet medical needs in order to address unequal patient access.[58]

New text was also proposed in the context of the threat of antimicrobial resistance and misalignment between R&D priorities and public health needs of citizens. Language in amendment 50 recital 78b (new paragraph to the preamble) proposes that the regulation addresses market failures inter alia through increasing transparency on R&D expenditure "to better deliver on the objectives of affordability, accessibility and availability of medicinal products in the Union." Increased transparency on expenditure would enable Member States to identify the extent to which gaps remain in the development of new antibiotics, for example, as well as avoid blanket market exclusivity protection.[59]

56 European Parliament. (2024). European Parliament legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)). https://www.europarl.europa.eu/doceo/document/TA-9-2024-0220_EN.pdf.

57 European Commission. (2023). Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52023PC0193.

58 European Parliament. (2024). REPORT on the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006. https://www.europarl.europa.eu/doceo/document/A-9-2024-0141_EN.html.

59 Ibid.

At the time of writing, the dossier (containing the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and the proposal for a Regulation of the European Parliament and of the Council on the Union code relating to medicinal products for human use) is in the hands of the Council. It remains to be seen whether the above-mentioned amendments will remain in the final approved text.

If adopted, these provisions would introduce legally binding obligations on pharmaceutical manufacturers marketing their products in the EU to disclose any direct public financial support received, in furtherance of WHA resolution 72.8. Additionally, the proposal to require manufacturers to disclose public contributions to R&D as a condition for EU market authorization could set an important global precedent. Such an EU-wide rule could inspire foreign regulators to adopt similar regulations and signal growing international acceptance of stricter disclosure norms in the pharmaceutical sector.[60]

60 Perehudoff, K. (2024). From Brussels to the World: The Diffusion of EU Pharmaceutical Legislation towards Developing Economies. European Journal of Risk Regulation. Advance online publication. https://doi.org/10.1017/err.2024.89.

Europe

Belgium

In Belgium, the number of confidential managed entry agreements – arrangements between a manufacturer and payer or provider for a health technology subject to specific conditions – has increased. This development, together with the high prices of medicines, have led to initiatives to enhance the transparency of drug prices. These include establishing fair prices of medicines, using AIM's fair pricing calculator. Other European countries are also looking at and using this model.

Role in the WHA transparency resolution

Ahead of the adoption of WHA resolution 72.8, numerous organizations in Belgium including Médecins sans Frontières, Test Achats and Médecins du Monde released a statement calling on Belgium to support the resolution. They argued that the resolution would enable authorities to have the information they need to make responsible decisions on the price of a medicine and its reimbursement.[61] They highlighted the exorbitant prices impacting patients' access to treatment, as well as the related threats to the financial viability of the health system.
Belgium is also a member of the Beneluxa initiative, as detailed in the chapter 'Developments at the European level'.

Political and legislative developments

Managed entry agreements

On the procurement of medicines and other health products, a majority of contracts between pharmaceutical companies and the government remain secret: this is the case for eight of the ten most expensive drugs bought by Belgium,[62] as well as 22 out of 25 drugs most dispensed by hospital pharmacies.[63]

Managed entry agreements (MEAs) were extensively criticized by the Belgian Healthcare Knowledge Centre (KCE) in their 2017 report on such MEAs, as well as their 2021 report on oncology medicines.[64] Challenges identified by

61 Médecins sans Frontières. (2019). La Belgique doit s'engager pour plus de transparence sur les prix et l'efficacité des médicaments. Press release. https://press.msf-azg.be/la-belgique-doit-sengager-pour-plus-de-transparence-sur-les-prix-et-lefficacite-des-medicaments.

62 Amies, N. (2023, 23 September). Belgian Government faces soaring medical bill as drug costs skyrocket. Brussels Times. https://www.brusselstimes.com/704440/belgian-government-faces-soaring-medical-bill-as-drug-costs-skyrocket.

63 Groupe de Recherche et d'Action pour la Santé. (2024). Dépenses de l'assurance-maladie pour des médicaments délivrés par des pharmacies hospitalières, Belgique, 2022: une analyse du GRAS. http://gras-asbl.be/2024/05/23/depenses-de-lassurance-maladie-pour-des-medicaments-delivres-par-des-pharmacies-hospitalieres-belgique-2022-une-analyse-du-gras/.

64 KCE. (2017). How to improve the Belgian process for Managed Entry Agreements? An analysis of the Belgian and international experience. https://kce.fgov.be/sites/default/files/2021-11/KCE_288_Improve_Belgian_process_managed_entry_agreements_Report.pdf; and KCE. (2021). Benefits and costs of innovative oncology drugs in Belgium (2004-2017). https://kce.fgov.be/sites/default/files/2021-11/KCE_343_Innovative_oncology_drugs_in_Belgium_Report_0.pdf.

KCE include the risk that manufacturers may ask for a higher departing price in expecting an MEA, as well as the difficulties to de-list a drug from reimbursement if established by an MEA.[65]

The 2024 MORSE (Monitoring Of Reimbursement Significant Expenses) report produced by the Belgian National Institute for Health and Disability Insurance (NIHDI) found that a majority of the medicines acquired through MEAs are oncological medicines.[66]

As part of the greater transparency of agreements provided for in the roadmap for modernizing drug reimbursement procedures, the new MORSE report includes for the first time data on the difference between the initially estimated turnover (i.e. volume of sales) and the actual turnover, which to a large extent forms the basis for determining the level of compensation.
Despite the prevalence of MEAs in Belgium, some changes have been proposed which seek to enhance transparency overall.[67] Back in 2020, a new act was adopted by the Belgian parliament seeking to enhance transparency for MEAs concluded by the NIHDI.[68] It appears in practice that the Court of Audit has yet to be granted full disclosure of financial information within MEAs.

Medicine reimbursement procedure

Belgium is currently considering a reform of its medicine reimbursement procedure. The roadmap, presented by NIHDI to the government in March 2023, includes a reform of managed entry agreements, i.e. a change in their duration (reform 32) to a limit of six years (two contracts of three years).[69] As part of the roadmap, the parties to the contract have now been rendered public by NIHDI since October 2024.[70] The stated aim of this reform is to ensure fewer confidential contracts and more transparency in this process. However, the proposed increased transparency does not explicitly refer to price transparency. The proposal was approved by the Federal Council of Ministers in January 2024. Parts of the proposal were reflected in two legislative proposals, both introduced in April 2024 and adopted through the urgency procedure. The first aims to adapt existing laws in line with the new roadmap, which include measures on the harmonization, simplification and increased efficiency and transparency of procedures relating to the reimbursement of medicines.[71] Certain groups express regret that the proposal does not go further on the transparency of MEAs.[72]

65 See KCE. (2017). How to improve the Belgian process for Managed Entry Agreements? An analysis of the Belgian and international experience. https://kce.fgov.be/sites/default/files/2021-11/KCE_288_Improve_Belgian_process_managed_entry_agreements_Report.pdf.

66 See INAMI. (2024). Nouveau rapport MORSE : Transparence sur le coût des médicaments pour l'INAMI et sur les médicaments innovants sous « contrats ». https://www.inami.fgov.be/fr/presse/nouveau-rapport-morse-transparence-sur-le-cout-des-medicaments-pour-l-inami-et-sur-les-medicaments-innovants-sous-contrats.

67 Ibid.

68 Loi du 4 Mai 2020. Loi modifiant des dispositions législatives en ce qui concerne la transparence des conventions en matière de spécialités remboursables. https://etaamb.openjustice.be/fr/loi-du-04-mai-2020_n2020202642.html.

69 NIHDI. (2023). Annexe à la proposition de feuille de route pour la modernisation des procédures de remboursement. https://www.inami.fgov.be/SiteCollectionDocuments/medicaments_modernisation_procedure_tableau_synthese.pdf.

70 See INAMI. (2024). Médicaments innovants sous « contrat Article 81/111 » : les parties publiques des conventions désormais disponibles en ligne. https://www.inami.fgov.be/fr/actualites/medicaments-innovants-sous-contrat-article-81-les-parties-publiques-des-conventions-desormais-disponibles-en-ligne.

71 Chambre des Représentants de Belgique. (2024, 2 April). Projet de loi modifiant la loi relative à l'assurance obligatoire soins de santé et indemnités coordonnée le 14 juillet 1994 en ce qui concerne la modernisation des procédures de remboursement en vue d'un accès rapide et durable aux médicaments. https://www.dekamer.be/FLWB/PDF/55/3953/55K3953001.pdf.

72 Chambres des Représentants de Belgique. (2024, 29 April). Rapport fait au nom de la commission de la Santé et de l'Egalité des chances par Mme Gitta Vanpeborgh. https://www.dekamer.be/FLWB/PDF/55/3953/55K3953004.pdf.

Fair pricing calculator

In 2021, the International Association of Mutual Benefit Societies (AIM) proposed a fair pricing calculator as a complement to its fair pricing model (from 2019), to improve access to innovative medicines. AIM is an umbrella organization of federations of health mutuals and health insurance bodies from over 26 countries, also outside of Europe. Founded in 1950, all members are not-for-profit organizations providing health coverage. Its aims are to provide universal health coverage on the basis of solidarity and democracy.[73] This model formed part of a wider campaign to, inter alia, "foster a comprehensive, open and transparent debate for a paradigm shift in the pricing of medicines."[74]

This calculator has been referred to multiple times in practice. For example, it is used by default by the so-called Clean Team, a joint purchasing association of several Dutch health insurers, when negotiating with pharmaceutical companies.[75]

Mutual insurance association Solidaris also launched an initiative for fair pricing, in which they refer to secret negotiations between the payers and the pharmaceutical companies.[76] The petition led to a discussion in parliament in April 2024. The initiative uses the AIM model for fair pricing as a base.[77] Following on from this, two new legislation proposals were put forward referring to the AIM model for fair pricing and echoing the Solidaris initiative.[78] The asking price of medicines is often completely disconnected by pharmaceutical companies from the costs associated with the research, development, production and commercialization of the medicine. Instead, pharmaceutical companies ask for the maximum amount that society is prepared to pay. This puts an unjustified pressure on social security. In order to put a stop to this bad form of pricing and the lack of transparency, this bill aims to re-establish the prices of medicines using objective and transparent criteria. The aim is to include transparent criteria in Belgian legislation to determine the price of medicines on an objective basis, taking into account the costs, reasonable

73 AIM Mutual. (n.d.). Our Goals. https://www.aim-mutual.org/our-goals/.

74 AIM Mutual. (2021). AIM offers a tool to calculate fair and transparent European prices for accessible pharmaceutical innovations. https://www.aim-mutual.org/wp-content/uploads/2021/06/AIMs-fair-pricing-model-Accompanying-paper-to-the-fair-pricing-calculator_June2021.pdf.

75 AIM Mutual. (2024). Petra van Holst, CEO of Zorgverzekeraars Nederland (ZN) "Dutch insurers apply AIM's fair pricing calculator by default when negotiating drug prices with companies". https://www.aim-mutual.org/mediaroom/petra-van-holst-ceo-of-zorgverzekeraars-nederland-zn-dutch-insurers-apply-aims-fair-pricing-calculator-by-default-when-negotiating-drug-prices-with-companies/.

76 SOLIDARIS. (2024). Et si on payait le juste prix des médicaments?. https://lejusteprixdesmedicaments.be/.

77 AIM Mutual. (2024). Solidaris discusses the Belgian Parliament's legislative proposal on fair prices. https://www.aim-mutual.org/mediaroom/solidaris-discusses-its-legislative-proposal-on-fair-prices-in-the-belgian-parliament/.

78 Chambre des Représentants de Belgique. (2024, 25 September). PROPOSITION DE LOI modifiant la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994, en ce qui concerne la justification et l'objectivité des prix des médicaments. https://www.dekamer.be/flwb/pdf/56/0268/56K0268001.pdf; and Chambre des Représentants de Belgique. (2024, 4 October). PROPOSITION DE LOI modifiant la loi coordonnée du 14 juillet 1994 relative à l'assurance obligatoire soins de santé et indemnités afin que le prix des médicaments ou des spécialités pharmaceutiques puisse être déterminé sur la base de critères transparents et objectifs. https://www.dekamer.be/flwb/pdf/56/0307/56K0307001.pdf.

benefits and additional revenues depending on the innovativeness of the medicine.

Although it is uncertain in the current political context that these proposals will make it through parliament – the industry lobby continues to play a big role in Belgium and is actively working to impede any transparency developments[79] – it demonstrates the timely discussions ongoing on price confidentiality in the country.

Concerns about high prices

Several associations have launched initiatives against high prices. In 2021, consumer association Test Achats launched a petition against high medicine prices. They had previously criticized the lack of transparency in the Covid-19 vaccine contracts. In their petition, Test Achats highlight that patients may be paying multiple times for their medicines.[80]

From the political party perspective, the Socialist manifesto ahead of the June 2024 elections in Belgium explicitly referred to the need for transparency in how drug prices are calculated.[81]

In summary, concerns about high prices and access to medicines remain at the forefront of discussions in Belgium. Several efforts have been undertaken to increase transparency, even if more needs to be done to align with WHA resolution 72.8.

Medicine pricing procedure

The pricing procedure of medicines is covered by the Minister of Economic Affairs who determines the maximum ex-factory price. The maximum public price is determined by the sum of the ex-factory price, the margin for the wholesalers and pharmacists, the pharmacist fee for delivery of the reimbursable products and 6% VAT. These prices are subject to price control by the Price Department of the Federal Public Service for Economic Affairs.[82]

The Royal Decree of 10 April 2014 regulates modalities such as pricing, price increase requests, notifications and communications. As with other European countries, the pricing procedure runs parallel to the reimbursement procedure.

79 Bersi, E., Rico, M. (2024). From transparency to public research: how to make medicines a right not just a business. Investigate Europe. https://www.investigate-europe.eu/posts/deadly-prices-from-transparency-to-public-research-how-to-make-medicines-a-right-not-just-business.

80 Test Achats. (2021). Test Achats lance une campagne contre le prix exorbitant des médicaments. Press release. https://www.test-achats.be/sante/maladies-et-medicaments/medicaments/presse/test-achats-lance-une-campagne-contre-le-prix-exorbitant-des-medicaments.

81 Parti Socialiste Belge. (2024). Réduire les prix des médicaments. https://www.ps.be/sante-prix-medicaments-medecine-traitement-maladie.

82 Global Legal Insights. (2023). Belgium: Pricing & Reimbursements Laws and Regulations 2023. https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/belgium/.

Europe

France

Largely supported by civil society, France passed a legislative act requiring pharmaceutical companies to disclose the amount of public investment they have received for their R&D for the development of medical products. Currently, the pharmaceutical industry's under-reporting is impeding full implementation. Additional measures are needed to make the legislation effective.

Role in the WHA transparency resolution

The initial proposal of WHA resolution 72.8 was more ambitious, aiming to shed light on the R&D investments and marketing costs made throughout the development chain and on the status of patents. However, some countries, including France, voiced their opposition. The French delegates expressed doubts as to the applicability of the resolution, which had initially been proposed and supported by France and Greece, among other European countries.[83]

Political and legislative developments

In the wake of the WHO resolution on transparency, Olivier Véran, then General Rapporteur of the French National Assembly's Social Affairs Committee, defended an amendment to the Social Security Financing Bill for 2020, requiring pharmaceutical companies to declare to the Economic Committee for Health Products (CEPS) the amounts of public investment in research and development from which they had benefited, for publication. Ultimately censured by the Constitutional Council on procedural grounds, the provision was reintroduced the following year, even though the person who had tabled it, Mr Véran, had in the meantime become the Minister of Health.

Following a question from the Member of Parliament Caroline Fiat to the Minister of Health on the political engagement of the government on price transparency in January 2020, the Minister replied in July that the government remained committed to greater transparency, that several initiatives had taken place (such as the publication of data on medicines reimbursed by the social security system) and that it seemed "desirable" for the public authorities and the general public to have access to information on public investment in the development of a drug. Nevertheless, the Minister added that "the possibility of accurately tracking the impact of the various sources of public investment on the development of a drug raises a number of practical questions, such as the distribution of amounts between different drugs, whether or not to take into account development failures or transfer of intellectual property. In view of these issues, it is unwise to take this uncertain factor into account when setting the price of a drug. It would also be contrary to the principle of setting the price according to the therapeutic value of the drug."[84]

83 Sidaction. (2019). Prix des médicaments : la transparence totale est urgente. Press release. https://www.sidaction.org/communique/prix-des-medicaments-la-transparence-totale-est-une-urgence/.

84 Pappers politique. (2020). Transparence sur le prix des médicaments : Question écrite de Mme Caroline Fiat – Ministère des solidarités et de la santé. https://politique.pappers.fr/question/transparence-prix-medicaments-QANR5L15QE25829?q=.

However, the above-mentioned amendment, in article 79 of the LFSS (*Loi de financement de la sécurité sociale*, i.e. the Social Security Financing Act) for 2021, finally passed, mainly thanks to the strong mobilization of many civil society organizations. A coalition of 70 organizations and individuals asked for more transparency in medicine policies in an open letter to the Minister of Health, Agnès Buzyn, and Prime Minister, Edouard Philippe.[85] The association OTMeds (*Observatoire de la transparence dans les politiques du médicament*, which is the Observatory for Transparency in Pharmaceutical Policies) was created in June 2019, just after the adoption of WHA resolution 72.8, to push for its concrete implementation. OTMeds published the 'National transparency checklist for medicines and health products', listing detailed steps to promote transparency on eight subjects in the health product production and supply chain.[86]

Article 79 of the LFSS

The adopted article 79 of the LFSS stipulates that companies must make available to the CEPS the amount of public investment in R&D from which they have benefited for the development of medicinal products registered or intended to be registered on the lists of reimbursed medicinal products, and that this amount must be made public. Regulatory texts specify the nature of the public investments concerned (these are direct investments, thus excluding subsidies, etc.) By way of symmetry, a contractual article relating to the application of this obligation requires that the contributions paid by pharmaceutical laboratories to the various public R&D bodies are also made public.

However, the implementation of this article has been largely disappointing. For 2022, the situation is worrying: the CEPS report shows that only two pharmaceutical laboratories declared amounts, totalling 194,202 euros.[87]

A group of joint civil society organizations (AIDES, Action Santé Mondiale, Médecins du Monde, and UAEM) criticized the 2023 annual report of the CEPS[88] as (only seven) pharmaceutical companies declared that they had received only 3 million euros of public aid.[89] While transparency about public support for the pharmaceutical sector would enable the government to address a skewed balance of power in negotiations with the industry, these initial figures run counter to the expected effect. "They are proof of significant under-reporting, which calls for a political response so that the public authorities can play their role as guarantor of the general interest and the right to health", as mentioned in the communiqué referred above. For example, Sanofi alone receives 150 million euros in research tax credits, but did not declare any aid from France in this report, since tax exemptions have been excluded from the reporting requirements.

The adoption of the article as such can be seen as a positive step towards greater transparency, but its terms and applicability remain largely restrictive and ineffective. To ensure full transparency, the data published should include and detail direct and indirect public financial support, such as tax credits. In addition, the lack of sanctions means that there is no guarantee that the legislation will effectively be enforced.

85 Londeix, P. (2019). Lettre ouverte au gouvernement sur la transparence dans les politiques du médicament. https://blogs.mediapart.fr/edition/transparence-dans-les-politiques-du-medicament/article/051119/lettre-ouverte-au-gouvernement-sur-la-transparence-da.

86 Observatoire de la transparence dans les politiques du médicament. (2019). Check-List de la transparence des médicaments. https://otmeds.org/publications/check-list-de-la-transparence-sur-les-medicaments/.

87 Comité Economique des Produits de la Santé. (2023). Rapport d'activité 2022. https://sante.gouv.fr/IMG/pdf/ra_ceps_2022.pdf.

88 Comité Economique des Produits de la Santé. (2022). Rapport d'activité 2021. https://sante.gouv.fr/IMG/pdf/ra_ceps_2021_versionprovisoire_dec22.pdf.

89 AIDES. (2023). Quand la France demande aux entreprises pharmaceutiques plus de transparence, la réponse est toujours plus d'opacité. Press release. https://www.aides.org/communique/quand-la-france-demande-aux-entreprises-pharmaceutiques-plus-de-transparence-la-reponse.

As raised by a French public health advocate, Gaëlle Krikorian, it is reasonable for citizens to inquire about the resources and advantages the government provides to private companies. Accepting the opacity sought by multinationals, obtained by abusing the argument of trade secrets and commercial confidential information, directly contravenes the safeguards that are supposed to ensure democratic control over public finances.[90]

In May 2024, a dozen major public health nonprofit organizations published civil society's prescription for a new drugs policy (*L'ordonnance de la société civile pour une nouvelle politique du médicament*), renewing their claim for access to affordable medicines and transparency. For instance, the healthcare nonprofit organization France-Assos-Santé, an umbrella organization of one hundred national and regional organizations, believes that 1) the traceability and proper use of public money must be guaranteed by total transparency and a rule of non-cumulation of European and national aid; 2) the public aid granted must be subject to public evaluation; and 3) national legislation must be amended to ensure that all aid given for the development and production of a medicine is effectively declared. Transparency should address the biased balance of power with pharmaceutical companies and reduce the asymmetry of information that makes it more difficult for the public authorities to estimate a fair price.

Medicine pricing procedure

The CEPS, a body under the authority of the ministers for health, social security and economy, is responsible by law for setting the prices of medicines covered by compulsory health insurance.

If a pharmaceutical company wishes a drug to be reimbursed by the French Social Security system, it submits an application to the French National Authority for Health for review by the Transparency Commission (CT). If no application is made, the drug cannot be reimbursed.

If, however, the company wishes to market the drug, it is authorized to do so once marketing authorization has been obtained from the European Medicines Agency. The price of the drug is then set freely by the pharmaceutical company. The final decision on reimbursement is taken by the Ministers of Health and Social Security and published in the Official Journal.

After studying the dossier submitted by the pharmaceutical company and the scientific data available, the Transparency Commission of the French National Authority for Health issues a scientific opinion in which it assesses the medical service rendered (SMR) and the improvement in medical service rendered (ASMR) by the drug. It is given a score from 1 to 5. A drug that represents a 'major' therapeutic advance will be given a score of 1. Conversely, a product that offers nothing new will be given a score of 5. Between these two extremes, the National Authority for Health may judge the medical advance to be 'significant', 'moderate' or 'minor'. It also assesses the number of potential patients.

The price of the drug is then negotiated with the manufacturers under the umbrella of the CEPS. This brings together the payers (health insurance, mutual insurance companies) as well as the Ministry of Industry, and takes place behind closed doors.

90 Krikorian, G. (2024). Industrie pharmaceutique: des financements publics sans transparence ni contrôle. https://www.alternatives-economiques.fr/gaelle-krikorian/industrie-pharmaceutique-financements-publics-transparence-contr/00109551.

For the most innovative drugs – rated 1 to 3 – the CEPS sets a price close to the average charged in the major European countries (Germany, Italy, the United Kingdom, Spain). France mainly uses external reference pricing (ERP) to set the price of publicly reimbursed medicines using these four countries in its basket. The CEPS also asks the laboratory to commit to a sales volume. This selling price will be the same for all pharmacies in France. Hospitals and clinics can negotiate directly with manufacturers to try to obtain a discount.

It should be noted that France, being historically a low-price country, is the most referenced country using the ERP-based system. Since the actual net price is not public, it could neither be used by competitors for benchmarking, nor by foreign countries to establish ERP-related drug prices, leading to one of the common ERP counter-effects on pricing. Germany and the UK are the second most referenced countries. They are both known to be high-priced countries due to their free pricing systems.[91]

91 European Commission. (2014). External reference pricing of medicinal products: simulation based considerations for cross country coordination. https://health.ec.europa.eu/system/files/2016-11/erp_reimbursement_medicinal_products_en_2.pdf.

Europe

Germany

Germany is one of the main opponents of the transparency resolution. The government recently amended its regulation on pharmaceutical pricing and reimbursement to protect confidential agreements in price negotiations. The new law allows pharmaceutical companies to have two different prices for their products – the official list price and the real net price paid – creating further confusion and opacity.

Role in the WHA transparency resolution

Germany has taken a firm public stance by dissociating itself from the WHA resolution on transparency.

During the negotiation process, Germany and the United Kingdom, backed by Japan, Switzerland, Denmark and Sweden – all countries with major pharmaceutical manufacturing sectors – attempted to water down the resolution, particularly when it came to the language relating to transparency for R&D costs.

In an open letter dated 24 May 2019 addressed to Jens Spahn, Germany's Minister of Health, a group of 66 civil society organizations called on Berlin to abandon "its obstruction" of the resolution.[92] An identical public letter was addressed to Mathew Hancock, the British Secretary of State for Health and Social Care, and to Rory Stewart, the Secretary of State for International Development. "The German government's opposition to this resolution is in sharp contrast to its claim to act as a leader in global health", asserted the letter.

After public leaks on individual countries' negotiating positions and the targeted campaign by health advocacy groups, Germany walked out of the negotiating session.

Germany's exit from the negotiations coincided with the timely entry of a group of countries as co-sponsors of the resolution, which included India, Brazil, Kenya, Uganda and Sri Lanka.

After the adoption of the resolution by consensus, Germany, the UK and Hungary went on the record saying they were dissociating themselves from the resolution, blaming "serious governance concerns" and arguing that it "was rushed through".[93]

92 HealthGap. (2019). Open Letter from 36 civil society organisations working in sub Saharan Africa regarding the German government's opposition to increased transparency in research costs and prices for medicines. https://healthgap.org/wp-content/uploads/2019/05/Open-Letter-to-Germany.pdf.

93 Zarocostas, J. (2019). UK, Germany, dissociate from WHO drug pricing resolution. The Lancet. Vol 393, Issue 10188. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)31329-7/abstract.

Political and legislative developments

Unlike most European countries, Germany, the continent's largest economy, has taken a step backwards in terms of price transparency, protecting more opacity and secrecy for the benefit of the pharmaceutical companies operating on its territory.

Germany has reformed its regulation of pharmaceutical pricing and reimbursement laws with confidential reimbursement prices. Officially to avoid market withdrawals from the country, and effectively to impede international reference pricing, the German government offered pharmaceutical companies the ability to keep the reimbursement price confidential. This reform was passed on 4 July 2024 by the German parliament (Bundestag).[94]

The new draft of the Medical Research Act (*Medizinforschungsgesetz*) came out in January 2024. In it, the German government planned to add some amendments to its regulation on pharmaceutical pricing and reimbursement. The Medical Research Act is part of Germany's new National Pharma Strategy which aims to make the country more attractive for pharmaceutical R&D and manufacturing. A draft of this new Pharma Strategy was announced by the government on 13 December 2023 in a strategy paper,[95] which proposed several measures to boost the nation's pharmaceutical sector, its competitiveness and growth.

The Medical Research Act was first presented to stakeholders in late January 2024. After an initial consultation, the government revised the draft and initiated the legislative process at the end of May 2024.[96] Overall, the government has worked at an unusually fast pace and was successful with its plan to get the bill through parliament before the summer break. The adopted Act includes legislative changes in several areas. On price confidentiality, the new law introduces the option for pharmaceutical companies to agree on confidentiality of the reimbursement amounts for their new medicine. This can be subject to negotiations of the AMNOG (*Arzneimittelmarktneuordnungsgesetz*, i.e. the law on the restructuring of the pharmaceutical market) with the federal health insurance association (*GKV-Spitzenverband*). The confidentiality would apply until the expiry of the product's regulatory data exclusivity. Consequently, the agreed reimbursement price would not be listed in public sources and not even be told to pharmacies. The product will be sold with the (higher) price that the company determines and not with the agreed reimbursement price.[97]

Therefore, the new law allows pharmaceutical companies to have two prices: the 'public price' on the product package and the 'real price' as agreed in the AMNOG process. In return, the companies are required to reimburse the health insurance funds the overpaid difference between the public price and real price. To give healthcare insurers a control mechanism for this compensation claim,

94 Deutscher Bundestag. (2024). Beschlussempfehlung und Bericht des Ausschusses für Gesundheit (14. Ausschuss) zu dem Gesetzentwurf der Bundesregierung – Entwurf eines Medizinforschungsgesetzes. https://dserver.bundestag.de/btd/20/121/2012149.pdf.

95 Die Bundesregierung. (2023). Strategie Paper, Verbesserung der Rahmenbedingungen für den Pharmabereich in Deutschland Handlungskonzepte für den Forschungs- und Produktionsstandort. https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/P/Pharmastrategie/231213_Kabinett_Strategiepapier.pdf.

96 Gesetzentwurf der Bundesregierung Entwurf eines Medizinforschungsgesetzes. (2024). https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/M/Kabinettsbeschluss_Entwurf_eines_Medizinforschungsgesetzes.pdf.

97 Inside EU Life Science. (2024). Germany again to reform drug pricing and reimbursement laws – With "confidential reimbursements prices" that impede international reference pricing. https://www.insideeulifesciences.com/2024/02/16/germany-again-to-reform-drug-pricing-and-reimbursement-laws-with-confidential-reimbursements-prices-that-impede-international-reference-pricing/.

the pharmaceutical companies need to notify the real price to a limited group of stakeholders. In return for greater confidentiality, the agreed reimbursement price will be reduced by 9%.[98]

The option to keep the reimbursement amount confidential has long been a request of pharmaceutical companies, as Germany is often used as a reference price country. Several companies that came out of the AMNOG process with a low reimbursement price withdrew their products (mostly with no or little additional therapeutic benefits) from the German market to avoid a subsequent price erosion in other countries.

In addition, in connection with the possibility of confidentiality of the German reimbursement price, the Medical Research Act sets out that the prices of healthcare products in other European countries should no longer be taken into account in German price negotiations. The Act also states that pharmacies should no longer replace medicines with a confidential reimbursement price with cheaper (parallel) imported medicines. In order to reduce costs, current German legislation stipulates that, in certain cases, pharmacies must dispense cheaper imported drugs instead of more expensive drugs. However, as pharmacies do not know the exact price, they cannot determine the price difference compared with imported medicines. As a result, the substitution obligation is lifted for drugs for which the reimbursement amounts are confidential.

Over the last decade many pharmaceutical companies with innovative medical products chose Germany as their first launch country in the EU. One suggested reason is that the timelines of the AMNOG process are strictly regulated and offer predictability. Germany is also still a high-price country for new drugs and offers an initial free pricing period of 6 months (until recently, 12 months), meaning that companies are free to set the price of their product once it is launched on the German market.

Additionally, and separate from the confidential reimbursement price option, the Medical Research Act introduces a new legal tool that creates a link between drug pricing and local clinical trial activities. A new provision provides pricing incentives for pharmaceutical companies that can demonstrate that a "relevant part" of the clinical trials for their new medicine was conducted in Germany. Drugs for which a relevant portion of clinical trials were conducted in Germany will be given more leeway in reimbursement negotiations. If the pharmaceutical company can prove that at least 5% of the clinical trial participants for the new product were enrolled in Germany, that product's pricing will benefit from a newly introduced legal relaxation of certain pricing safeguards.

The Medical Research Act passed the German Federal Council (Bundesrat) on 27 September 2024.[99] There is a 'sunset clause' for the confidentiality option: the option only applies to medicines whose AMNOG reimbursement pricing procedure is concluded by 30 June 2028. This time limitation was implemented to allow an evaluation of its effects on the German healthcare system. The confidential reimbursement prices come not only with a high entry barrier (local R&D activities and infrastructures) but also at a high price (9% additional markdown).

This new piece of legislation represents a clear blow to the principle of international reference pricing and to European health insurance systems based on solidarity and universal access. Secret prices in Germany will exacerbate the access

98 Inside EU Life Science. (2024). Germany amends drug pricing and reimbursement laws with "Medical Research Act" – Drug pricing becomes intertwined with local clinical research expectations. https://www.insideeulifesciences.com/2024/07/12/germany-amends-drug-pricing-and-reimbursement-laws-with-medical-research-act-drug-pricing-becomes-intertwined-with-local-clinical-research-expectations/.

99 Bundesrat. (2024). Medizinforschungsgesetz. https://dserver.bundestag.de/brd/2024/0416-24B.pdf.

issue, as even higher prices charged by the manufacturers will be even more difficult for many European countries to afford.[100] There is a risk of massive collateral damage for patients in the EU. According to recent research by Investigate Europe, internal documents from the German Ministry of Health substantiate the suspicion that the US-based pharmaceutical company, Eli Lily, may have linked its settlement in Germany to a change in the German law, demanding the discounts be kept secret in the future.[101] According to documents obtained by journalists from WDR, NDR, Süddeutsche Zeiting and Investigate Europe, with the help of the Freedom of Information Act, the company could have used its billion-dollar investment to enforce the desired secret prices in a new law. Almost all healthcare experts consider the regulation to be harmful – even health insurance companies fear drastic price increases. The head of the Federal Joint Committee, the former Saarland Health Minister Josef Hecken (CDU), criticized that the secret prices "unnecessarily weaken a previously effective and good instrument in favour of the pharmaceutical industry." If the price is to remain secret for only 10% of all new drugs, "additional costs of up to 840 million euros would be conceivable in the first year", the National Association of Statutory Health Insurance Funds (GKV) has calculated.[102]

Medicine pricing procedure

The German healthcare financing system features 110 'Sickness Funds' or health plans that collectively cover healthcare expenses for 90% of the population. 48 indemnity insurance firms cover the remainder. The pharmaceutical pricing system builds on this multi-payer insurance system.[103] Drug manufacturers are permitted to establish an initial list price for their products after EMA authorization, and they are paid these prices for the first year after launch. During this first year, however, the Institute for Efficiency and Quality in Healthcare (IQWiG) and the Joint Federal Committee (GBA) conduct their assessment and, for those drugs demonstrating some extent of added benefit, turn it over to the umbrella organization of Sickness Funds to negotiate a new price.

Price negotiations in Germany are structured as a bilateral monopoly, with a single buyer, the umbrella organization of Sickness Funds, facing a single seller, the drug maker. If no agreement can be negotiated, the drug's price is established by an arbitration panel consisting of representatives of each side plus an appointed chair.

If the German pharmaceutical assessment process considers a drug not to offer an incremental benefit over existing treatments, it usually assigns it to one of the therapeutic classes covered by reference pricing. Manufacturers are permitted to set whichever price they feel is appropriate for drugs falling into these classes, but the umbrella organization of health insurers establishes a limit to what individual insurers will contribute towards payment.

Patients must pay out of pocket the difference between the price set by the manufacturer and the reference-based reimbursement limit set by the purchaser organization.

100 https://www.iqwig.de/en/presse/iqwig-in-the-media/2024-06-14.html.

101 Investigate Europe. (2024). Wunsch von Eli Lily. https://www.investigate-europe.eu/de/posts/wunsch-von-eli-lilly.

102 Tageschau. (2024). Change in the law in favour of US pharmaceutical companies?. https://www.tagesschau.de/investigativ/ndr-wdr/gesundheitssystem-medikamente-pharmaunternehmen-104.html.

103 Drug Assessment and Pricing in Germany. (n.d.). https://bcht.berkeley.edu/drug-assessment-and-pricing-germany.

Europe

Italy

Italy was one of the initiators of the resolution with a key role in drafting and negotiating its text. After the adoption of the resolution, the government followed up with an interministerial decree mandating manufacturers to disclose certain R&D costs. They must share biomedical R&D costs during negotiations, and indicate the annual sales, turnover, marketing costs, and patent status of the reimbursed product in reimbursement agreements. The decree still needs to complete the administrative process to enable implementation and enforcement.

Role in the WHA transparency resolution

Italy played an essential role in drafting and negotiating the text of WHA resolution 72.8. A first ambitious proposal for a resolution to enhance the "transparency of markets for drugs, vaccines and other health-related technologies" was submitted by the Italian Minister of Health Giulia Grillo to the WHO Director General in February 2019.[104] A reviewed text was later presented for discussion to the 72nd World Health Assembly. The text was co-sponsored by Greece, Egypt, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Tunisia, Turkey and Uganda.[105]

The initial proposal for the resolution was much sharper, and contained clear-cut recommendations for Member States, with a strong emphasis on ensuring transparency of R&D costs and manufacturing know-how. As already mentioned, such focus was watered down in the final text and replaced by a more general approach to price transparency.

Behind the resolution lay a significant political momentum driven by Luca Li Bassi, General Director of the Italian Medicines Agency (AIFA, Agenzia Italiana del Farmaco), and Giulia Grillo, Italian Minister of Health. Li Bassi, who led the long, closed-door negotiations of the WHA drafting group, acknowledged that there had been "hiccups" in talks over the "sensitive" proposals. "We had to build constructive dialogue around sensitive topics", he said, adding that he was ultimately satisfied "to see how many countries and member states around the world have gathered around these important topics with an open mind and willingness to identify [a] way forward." Li Bassi added he had been "pleased and surprised" with the interest generated by the resolution – "not only [among] policymakers, regulators and government officials but also [in]

104 Ministero della Salute. (2019). Attachment 1: Improving the transparency of markets for drugs, vaccines and other health-related technologies. https://www.salute.gov.it/imgs/C_17_notizie_3670_listaFile_itemName_1_file.pdf.

105 World Health Organization. (2019). Improving the transparency of markets for medicines, vaccines, and other health-related products and other technologies to be discussed at the 72nd session of the WHA to be held on 20-28 May 2019. Draft resolution proposed by Italy, Greece, Egypt, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Tunisia, Turkey, Uganda, version 20 May 2019. https://www.keionline.org/wp-content/uploads/WHA-Resolution_DRAFT_20-05-2019.pdf.

the academic world, science, medical doctors, and health professionals all around the world." He acknowledged this topic is also considered important for "normal people", for patients and for civil society groups, which also desire to participate in dialogue.[106] For his tenacious efforts in negotiating the resolution, Li Bassi was awarded the 2019 International Transparency in Medicines Policies Awards by the French civil society organization OTMeds.

Political and legislative developments

Following the adoption of the resolution in May 2019, the Italian government contributed to domestic implementation by enacting an interministerial decree, adopted by the Minister of Health in accordance with the Minister of Economy and Finance on 2 August 2019. The decree was named 'Criteria and methods by which the Italian Medicines Agency determines, through negotiation, the prices of medicines reimbursed by the National Health Service' (GU no. 185 of 24 July 2020).[107]

This decree, together with an amendment to the French Bill on Social Security Funding for 2020, is considered a milestone accomplishment in mandating manufacturers to disclose R&D costs. Both the Italian decree and the amendment to the French Bill on Social Security Funding aim to impose transparency on the extent of public funding allocated for R&D costs of medical products considered for reimbursement. Moreover, the Italian decree requires the disclosure of biomedical R&D costs during negotiations and requires that reimbursement agreements indicate the annual reporting of sales, turnover, marketing costs, and patent status of the reimbursed product.
The decree regulates the procedure for price negotiation and reimbursement between pharmaceutical companies and AIFA. The interministerial decree calls for pharmaceutical companies to compile a dossier with relevant information on: added therapeutic value of the product when compared to therapeutic alternatives used in national clinical practice; comparative evaluation of costs with therapeutic alternatives; data on marketing, sales and reimbursement in other countries, including details on price and reimbursement conditions; data on public contributions and incentives acquired to perform R&D; and other details, including the patent status of the product.

As for the procedure, the interministerial decree assigns responsibility to two main committees within AIFA: the Scientific-Technical Committee (CTS) and the Pricing and Reimbursement Committee (CPR). These two committees have now been merged into a new Scientific and Economic Committee for Medicines (CSE), incorporating the functions of former committees, combining expertise in technical-scientific evaluation and pricing.

The former CTS (now CSE) is first called to evaluate the clinical and added therapeutic value of the product. If the comparative evaluation of the added therapeutic value results in a negative decision, the negotiation is automatically considered concluded. However, the procedure may continue in the event that the company offers an equal or lower therapeutic cost than therapeutic alternatives.

Following this first step, the CPR (now CSE) is responsible for the continuation of the procedure. It is during this phase that AIFA is called to negotiate the price on the basis of the evidence previously gathered by the CTS. For the agreement to be finalized, a company must disclose, among

106 Fletcher, E. R. (2019, 28 May). World Health Assembly Approves Milestone Resolution On Price Transparency. Health Policy Watch. https://healthpolicy-watch.news/world-health-assembly-approves-milestone-resolution-on-price-transparency/.

107 Gazzetta Ufficiale, MINISTERO DELLA SALUTE DECRETO. (2019, 2 August). Criteri e modalita' con cui l'Agenzia italiana del farmaco determina, mediante negoziazione, i prezzi dei farmaci rimborsati dal Servizio sanitario nazional. https://www.gazzettaufficiale.it/eli/id/2020/07/24/20A03810/sg.

other things, data on public contributions acquired to perform R&D. According to Pierluigi Russo, technical-scientific director of AIFA, discussions are also taking place with pharmaceutical industry associations to identify simplified procedures that will not require all processes to go through the CSE.[108] Once identified, these processes will be evaluated by the Committee and then approved by AIFA's Board of Directors.

Through this milestone progress, we look forward to collecting further information on the current implementation of the interministerial decree in Italy.

Medicine pricing procedure

AIFA is responsible for negotiating the price of medicinal products borne by the National Health Service (Servizio Sanitario Nazionale, or SSN) and decides on the eligibility for reimbursement and supply. As observed, the Italian interministerial degree of 2 August 2019 regulates the procedure, substituting the existing framework (Delibera CIPE no. 3, 1 February 2001). The criteria established by the interministerial decree from 2019 apply to all medicinal products classified under the category A as established by Italian law, including all products reimbursed by SSN, and some specific products from category C,[109] whose cost is borne by citizens.

In Italy, the list prices of all reimbursed medicines are published. Net prices of the 5% or 5%+5% discount imposed by national law are also published. However, net ex-factory prices remain confidential if a confidential agreement has been signed between AIFA and manufacturers. Moreover, there are legal provisions mandating public disclosure of medicine price information obtained through public tenders at the local level.[110]

108 Russo, P. (AIFA). (2024, June). Ecco la strategia nazionale per governare l'innovazione. AboutPharma. https://www.aboutpharma.com.

109 Also category C is part of the scope of the interministerial Decree. This category includes those products that have been approved by EMA but not negotiated by AIFA for reimbursement.

110 OECD. (2024). Exploring the feasibility of sharing information on medicine prices across countries. https://www.oecd.org/en/publications/exploring-the-feasibility-of-sharing-information-on-medicine-prices-across-countries_5e4a7a47-en.html.

Europe

The Netherlands

The Netherlands has been at the forefront of promoting improvement of access to medicines by tackling high prices and creating greater transparency. The parliament supports this goal, and the government remains committed to moving forward. The programme on socially acceptable drug expenditure (MAUG) might be a promising collaborative way to advance towards a transparent method of identifying costs that are socially acceptable.

Role in the WHA transparency resolution

Traditionally, the Netherlands has been at the forefront of medicines policy debates, both at the EU and national level. The country held the Presidency of the European Council in 2016, with then Minister of Health, Edith Schippers, putting the issue of access to medicines and transparency high on the political agenda for the first time. The adoption of the Council conclusions[111] at the end of the Presidency established the need to find a balance between intellectual property (IP) rights and innovation, raised the challenges of high prices for both health systems and patients ("patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels"), and stressed the need to improve transparency.

A joint article by the Minister of Health, Edith Schippers, and the Minister of Foreign Trade and Development Cooperation, Lilianne Ploumen, entitled 'Better life through medicine -let's leave no one behind',[112] published in The Lancet in November 2016, demonstrated the prominence of the Netherlands on this topic. In this article, coinciding with the publication of the Lancet Commission on Essential Medicines Policies,[113] both ministers agreed on the need to change the pharmaceutical business model based on monopolies: "We cannot achieve any real progress without acknowledging that the current patent-based business model and the way we apply international patent rules need to change. The system is broken."

In the same year, the Netherlands also took on the organization of the first Fair Pricing Forum, which was held in Amsterdam in May 2017. In his opening speech, State Secretary Martin van Rijn recalled the global issue of affordable care.

111 Council of the European Union. (2016). Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States. Press release. https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/.

112 Ploumen, L., Schippers, E. (2016). Better life through medicine—let's leave no one behind. The Lancet. Vol 389, Issue 10067. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31905-5/abstract.

113 Wirtz, V. J., et al. (2017). Essential medicines for universal health coverage. The Lancet. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31599-9/fulltext.

"Increasing prices of medicines and medical technologies are of major concern to all of us", he noted. As a way forward, he mentioned: "Together we can explore new routes in the development of medicines. This is focusing on specific needs, but also on decent profit margins and socially responsible licensing beforehand. We should also align as countries when it comes to fair pricing. Together we will have a stronger voice at the negotiating table. And a stronger voice is what we need!" Furthermore, Van Rijn stated "We also need a stronger voice to get insight into the real costs of research and development for new products that come to the market. And yes, we do want better insight into the profit margins of the pharmaceutical industry as well."[114]

The Netherlands is an active member of the Beneluxa Initiative, a purchasing alliance with Belgium, Luxembourg, Austria and Ireland, to explore wider collaborative opportunities and to foster patients' access to innovative medicines at an affordable cost (more information in the chapter 'Developments at the European level').

Political and legislative developments

Transparency in the government agreement

In the Rutte 4 government (2021-2024), transparency was a key part of the coalition agreement. The coalition programme stated: "We will increase the grip on rising healthcare costs of expensive medicines and aids and want these to be marketed at a fair price. We will focus on transparency in price structure and negotiation, partly through European cooperation."[115] Unfortunately, the programme has not been further developed and implemented, often with the argument that the Netherlands cannot do everything on its own and referring to the need for an EU-wide approach.

Motions in parliament

In a motion unanimously adopted by the Dutch Parliament on 12 April 2023,[116] the Dutch government was requested to determine whether transparency on medicine costs and profits can be required from pharmaceutical companies. It is expected that the results of this evaluation will form part of the new medicines reimbursement system on which the new Minister of Health was supposed to report in autumn 2024.[117]

On 30 May 2024, the Minister of Medical Care, Pia Dijkstra, promised to further analyse the Italian legislation on transparency for expensive medicines and share her findings with parliament.[118]

Both the motion and the question to the Minister were raised by the Member of Parliament Julian Bushoff, from the Labour/Greens party. All political parties from left to right indicated their interest in transparency – especially the liberal MP Tielen (VVD) and MP Jansen (NSC) have asked and written extensively on the topic.[119]

114 Government of the Netherlands. (2017). Speech by State Secretary for Health, Welfare and Sport Martin van Rijn on innovation and affordable prices for medicines at the Fair Pricing Forum in Amsterdam. https://www.government.nl/documents/speeches/2017/05/11/speech-state-secretary-martin-van-rijn-at-%E2%80%98fair-pricing-forum%E2%80%99.

115 Coalitieakkoord 2021-2025. (2021, 15 December). Omzien naar elkaar, vooruitkijken naar de toekomst. https://www.kabinetsformatie2023.nl/binaries/kabinetsformatie/documenten/publicaties/2021/12/15/coalitieakkoord-omzien-naar-elkaar-vooruitkijken-naar-de-toekomst/coalitieakkoord-2021-2025.pdf.

116 Tweede Kamer. (2023, 12 April). Motie van het lid Bushoff over het afdwingen van transparantie over kosten en winstmarges van geneesmiddelenfabrikanten. https://www.tweedekamer.nl/kamerstukken/moties/detail?id=2023Z06545&did=2023D15502.

117 Tweede Kamer. (2024, 19 June). Stand van zaken moties en toezeggingen zomer 2024. https://www.tweedekamer.nl/kamerstukken/brieven_regering/detail?id=2024D25716&did=2024D25716.

118 Tweede Kamer. (2024, 30 May). Hulp- en geneesmiddelenbeleid. https://www.tweedekamer.nl/debat_en_vergadering/commissievergaderingen/details?id=2023A07269.

119 Tweede Kamer. (2024, 27 May). Hoorzitting Dure geneesmiddelen. https://debatdirect.tweedekamer.nl/2024-05-27/zorg-gezondheid/troelstrazaal/dure-geneesmiddelen-10-00/onderwerp.

In response to a motion from Labour MP Kuiken on 8 July 2021, which stated the need for intensified cooperation and dialogue between relevant institutes to curb the costs of highly priced medicines,[120] a new programme has been set up, *Programma Maatschappelijk aanvaardbare uitgaven geneesmiddelen* (MAUG), which translates as 'Programme for socially acceptable drugs expenditure'. The MAUG programme seeks to enhance collaboration between the National Health Care Institute (ZIN), the Dutch Health Care Authority (NZA) and the Netherlands Authority for Consumers and Market (ACM). The Ministry of Health is also involved in the MAUG programme, as the Ministry asked for advice and will facilitate the efforts and communication about the progress with parliament. The aim of this cooperation is to ensure that medical care adds value to people's health and is available at reasonable prices. The programme is looking for a transparent way to identify which costs are socially accepted. It aims at objectively assessing the added value of a medicine to society and stimulating competition between pharmaceutical companies.[121] In May 2024, an update on the MAUG programme was shared with the Minister of Medical Care.[122] The final recommendation is expected to be published later in 2025. To inform that, they will do a market analysis, conduct interviews with experts, and consult citizens.

Although no concrete legislative proposal is yet on the table, a number of initiatives and political stakeholders are expressing their interests and concerns and are looking for ideas on how to improve further transparency.

Medicine pricing procedure

When a new medicine is registered on the market, the Dutch National Health Care Institute (*Zorginstituut Nederland*, or ZIN) assesses whether it should be reimbursed by the government. Based on the assessment of various factors, for example the seriousness of the disease, the effectiveness of the medicine, and the availability of other drugs, it will formulate a recommendation for the Minister of Medical Care. If the medicine is very expensive, ZIN can also advise the minister to negotiate a lower price.

In the Netherlands, this procedure is called *De Sluis* ('airlock' in English) for very expensive medicines.[123] The criteria for using De Sluis are laid down by law. A drug can become a candidate for De Sluis if:

- → It costs 20 million euros or more per year to use the drug nationwide for one or more new indications. The drug then enters De Sluis for each new indication.
- → The cost of a medicine for one indication is 10 million euros or more per year and the use per patient per year is 50,000 euros or more.

Only the costs for the medicine itself are included in these criteria. The other parts of the treatment, such as hospitalization, are not.

Once a medicine is placed in De Sluis, the registration holder (usually the manufacturer) needs to hand in a complete dossier so they can start the assessment. There are four criteria listed: 1) need, 2) effectivity, 3) cost-effectivity, and 4) feasibility.

120 Tweede Kamer. (2021, 9 July). Geneesmiddelenbeleid. https://zoek.officielebekendmakingen.nl/kst-29477-722.html.

121 De Autoriteit Markt en Consument (ACM), de Nederlandse Zorgautoriteit (NZa) en het Zorginstituut Nederland (ZINL). (2023). Op weg naar maatschappelijk aanvaardbare prijzen en uitgaven van geneesmiddelen in het basispakket – werkagenda. https://open.overheid.nl/documenten/ronl-44f1e3da96f5fe6fc54e199446b26c3a49f6d2e1/pdf.

122 NZA. (2024, May). Brief voortgang programma Maatschappelijk Aanvaardbare Uitgaven Geneesmiddelen. https://puc.overheid.nl/nza/doc/PUC_765846_22/.

123 Zorginstituut Nederland. (n.d.). Sluis voor dure geneesmiddelen. https://www.zorginstituutnederland.nl/over-ons/programmas-en-samenwerkingsverbanden/horizonscan-geneesmiddelen/sluis-voor-dure-geneesmiddelen.

In this process, the ZIN gets advice from independent committees: the Scientific Advisory Council and the Insured Package Advisory Committee (ACP). After this process, ZIN provides a recommendation to the Minister of Medical Care whether to take up the new medicine in the basic package for reimbursement, or to negotiate lower prices. Once it has been established that a medicine is worth the cost, it can be reimbursed in the basic health insurance package. This is up to the Minister of Medical Care to decide.

This De Sluis procedure is often part of discussions in the Netherlands between pharmaceutical companies, patients, politicians and government bodies. This procedure can take a long time, and sometimes the Minister decides not to reimburse the medicines, which impacts their availability. However, with the rising costs of expensive new medicines, the government cannot pay the full requested prices for all new medicines.

Moreover, one of the bottlenecks of De Sluis is that it requires manufacturers to share reports and information on their products. If those are not available, it will take longer to assess and form a recommendation to the Minister. Transparency of the asked price and clinical data would significantly help to speed up the process.

Europe

Portugal

An initial co-sponsor of the transparency resolution, Portugal has since not made much progress to operationalize it. Legislative proposals have sought to limit the burden that high-priced medicines place on citizens, but these have been rejected. Although some political parties are pushing for improved access to healthcare, they currently do not appear to focus on the need for greater transparency.

Role in the WHA transparency resolution

Portugal put itself forward as one of the main co-sponsors of WHA resolution 72.8 at the 72nd World Health Assembly, with the then Minister of Health Marta Temido emphasizing the need for guaranteeing "equitable access to new and innovative medicines".[124] She underscored the prevailing lack of transparency in the pharmaceutical and health technologies' markets and her support for measures and tools to increase transparency. Minister Temido also highlighted that "promoting transparency throughout the value chain, strengthening pricing policies, cross-sector and cross-border collaboration for information-sharing, regulation and joint procurement of medicines are paramount to enhance affordability and accessibility of medicines."[125]

During this same speech, the Minister recalled Portugal's participation in and support of the Valletta Declaration that focuses on price negotiations and drug pricing information-sharing (more information in the chapter 'Developments at the European level'). The WHA transparency resolution can be considered as a tangible output from the Valletta Declaration Group.[126]

Political and legislative developments

In the last few years, there have been various debates and proposals in the Portuguese parliament seeking to address the challenges of access to high-priced medicines.

In 2023, the political party Left Bloc (*Bloco de Esquerda*) presented two bills to parliament seeking to respond to these challenges. One bill proposed that the National Medicines Laboratory (*Laboratório Nacional do Medicamento*) must be authorized to produce medicines without

124 Knowledge Ecology International. (2019). WHA72: Portuguese Minister of Health, Marta Temido, underscores strong support for the WHO transparency resolution. https://www.keionline.org/30805.

125 Ibid.

126 Magri, G. (2019, 12 July). Valletta Declaration tackling medicine price transparency issue. The Independent. https://www.independent.com.mt/articles/2019-07-12/local-news/Valletta-Deceleration-tackling-the-issue-of-transparency-on-medicine-prices-6736210821.

therapeutic alternatives in case of persistent shortages or sharp price variations.[127] Another proposal aimed to ensure access to medicines and medical devices such as glasses, hearing aids and dental protheses, due to the high price burden on patients in accessing such health products.[128]

In addition to these parliamentary proposals, increased access to healthcare featured in several political parties' manifestos ahead of the 2024 March legislative election. Parties called for a range of measures, including reforms of the health system, to ensure better efficiency and access to healthcare. Two major political parties (Left Bloc and Liberal Initiative) called for a 100% reimbursement for those who cannot afford medicines.[129]

Of special relevance are legal and administrative amendments regarding the national regulatory authority, *Autoridade Nacional do Medicamento e Produtos de Saúde* (INFARMED). Since 2023, the amended Decree Law No. 176/2006 provides that "INFARMED shall ensure that information on the price of medicinal products is made available through media accessible from its website and other digital tools."[130] According to the government, the rationale behind this amendment is to provide further transparency on the pricing information. However, the information referred to has already been made available by INFARMED for the last 15 years, but the tools to access this information were – and remain – hard to use. Further, this amendment stipulates that medicine prices are removed from the packaging. Instead, the retail price and reference price (if applicable) are only stated on invoices and prescriptions. According to consumer group DECO, information is an essential right for consumers, particularly regarding price. Removing the prices from packaging and forcing users to refer to INFARMED's website alienates parts of the population, e.g. those with low digital literacy or the elderly population.[131]

Medicine pricing procedure

Concerning the price of health products and their transparency, Portugal's INFOMED[132] human medicinal products database is hosted and managed by INFARMED. For each product, the database provides the maximum retail price, the reference price, as well as the reimbursement rate (in %). The prices of medicines are dictated by the Decree Law No. 97/2015 from 1 June,[133] revised in 2017, using reference countries (Spain, France, Italy and Slovenia from 2023) and including other variables such as marketing margins, marketing rate and VAT.[134]

High prices of medicines remain a challenge in Portugal when it comes to accessing medicines and other health products. The use of reference

127 Bloco de Esquerda. (2023). Mitigar a rutura de medicamentos em portugal através de Produção feita pelo laboratório nacional do medicamento: Exposição de motivos.

128 Bloco de Esquerda. (2022). Assegurao acesso a medicamentos, óculos, aparelhos auditivos e próteses dentárias através da sua comparticipação : Exposição de motivos.

129 See Iniciativa Liberal. (2024). Sumario do Programa Eleitoral 2024. https://iniciativaliberal.pt/wp-content/uploads/2024/02/Sumario-do-Programa-Eleitoral-2024.pdf; and Bloco de Esquerda. (2024). Programa eleitoral do Bloco de Esquerda : Legislativas 2024. https://www.bloco.org/media/PROGRAMA_BLOCO_2024.pdf.

130 Diário da República. (2023, 26 December). Decreto-Lei n.º 128/2023. https://diariodarepublica.pt/dr/detalhe/decreto-lei/128-2023-835674293.

131 DECO. (2024). Novas medidas de informação para os medicamentos. https://deco.pt/direitos-dos-consumidores/novas-medidas-de-informacao-para-os-medicamentos/.

132 INFOMED. (n.d.). https://extranet.INFARMED.pt/INFOMED-fo/.

133 INFARMED. (n.d.). Regulamentação de preços. https://www.INFARMED.pt/web/INFARMED/entidades/medicamentos-uso-humano/avaliacao-tecnologias-saude/regulamentacao-de-precos.

134 INFARMED. (n.d.). Atribuição de preços. https://www.INFARMED.pt/web/INFARMED/entidades/medicamentos-uso-humano/avaliacao-economica/regulamentacao-preco-medicamentos/atribuicao_precos.

pricing has been criticized for basing itself on countries with higher GDP rates than Portugal, thus distorting the prices.[135] The lack of pricing transparency and access remains a major issue despite the fact that Portugal ratified WHA resolution 72.8 in 2019. Since then, there have been no changes to its legislation on medicine pricing.

Access challenges and high prices remain a major concern in Portugal. However, despite its political support at European and international level, the country has not implemented concrete measures to improve transparency. Even though the issue of access to medicines (especially availability and pricing) is part of the political agenda, there is a need for further political will to effectively address these issues.

135 See Debates Parlamentares. (2023, 14 February). PROJETO DE LEI N.º 568/XV/1.ª. https://debates.parlamento.pt/catalogo/r3/dar/s2a/15/01/165/2023-02-14?sft=true&pgs=2-4&org=PLC&plcdf=true#p1.

Europe

Spain

Spain has made some strides in implementing the transparency resolution. In recent years, the Ministry of Health has spoken out in favour of increasing transparency during discussions on the reform of the Law on Guarantees and Rational Use of Medicines and the new Royal Decree on Health Technology Assessments. This stance is also demonstrated by the Ministry's disclosure of prices of certain medicines, following challenges from civil society through the newly created Transparency Council.

Role in the WHA transparency resolution

Spain was one of the early promoters and co-sponsors of the draft transparency resolution,[136] with the aim of increasing transparency in pharmaceutical policy issues both domestically and at a global level.

Following its adoption, the Spanish representative described the resolution as a "reasonable step forward" on a widespread issue. As co-sponsor, he expressed his wish to see a reduction in reservations and greater clarity on R&D costs and clinical trials. He also warned the industry that the way forward must be unwavering because it is fair, necessary and democratic.[137]

Political and legislative developments

The country's own legislation on the matter, namely the Law on Transparency, Access to Public Information and Good Governance[138] enacted in 2013, set out a mechanism whereby citizens and entities may request that government-related information be disclosed. It is used by civil society organizations to access information on R&D costs and other relevant matters in the price-setting and reimbursement process.[139]

136 Perehudoff, K., Mara, K., 't Hoen, E. (2021). What is the evidence on legal measures to improve the transparency of markets for medicines, vaccines and other health products (World Health Assembly resolution WHA72.8)?. World Health Organization. Regional Office for Europe. https://iris.who.int/handle/10665/342474.

137 Fletcher, E. R. (2019, 28 May). World Health Assembly Approves Milestone Resolution On Price Transparency. Health Policy Watch. https://healthpolicy-watch.news/world-health-assembly-approves-milestone-resolution-on-price-transparency/.

138 GOBIERNO DE ESPANA, Ministerio de la Presidencia, Justicia y Relaciones con las Cortes. (2013). Boletin Oficial del Estado Ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno. https://www.boe.es/eli/es/l/2013/12/09/19/con.

139 See Case Study 2, Perehudoff, K., Mara, K., 't Hoen, E. (2021). What is the evidence on legal measures to improve the transparency of markets for medicines, vaccines and other health products (World Health Assembly resolution WHA72.8)?. World Health Organization. Regional Office for Europe. https://iris.who.int/handle/10665/342474.

This unique mechanism is part of the functions of the High Transparency Council, an institutional body "whose purpose is to promote transparency in public."[140]

In 2019, a group of 19 public interest organizations and health professionals' associations launched a legislative initiative to be discussed in the Spanish parliament called 'A fair price for medicines'. The aim of this initiative was to convey to members of parliament the need to "change the current system of setting prices for medicines, promote transparency measures in health, as well as the creation of an independent research and education fund."[141] The proposal highlighted the impact of the lack of transparency and accountability in the public investments made in biomedical research and negotiations with the pharmaceutical industry regarding pricing and reimbursement decisions which in turn can lead to conflicts of interest. The initiative did not gather enough signatures to be formally presented in parliament.

The Transparency Council

The Transparency Council is an independent administrative authority in Spain, responsible for promoting transparency and safeguarding the right of access to public information. It has its own legal personality and capacity to act publicly and privately.[142] Its statutes were approved by Royal Decree 919/2014 of 31 October 2014. The competencies for the Council include adopting recommendations for better compliance with the Law on Transparency, advising on transparency, and evaluating the degree of applicability of the Law on Transparency. Its new statute (enacted in August 2014) confirms its role as an independent administrative authority and regulates in detail the purposes, functions and guarantees of autonomy and independence.[143]

140 Gobierno de Espana. (n.d.) Portal de la transparencia. https://transparencia.gob.es/transparencia/en/transparencia_Home/index/MasInformacion/InformacionCTBG.html#:~:text=The%20Council%20for%20Transparency%20and%20Good%20Governance%20is%20the%20body,the%20provisions%20of%20good%20governance; and Gobierno de Espana. (n.d.). Portal de la transparencia. https://transparencia.gob.es/transparencia/en/transparencia_Home/index/MasInformacion/InformacionCTBG.html#:~:text=The%20Council%20for%20Transparency%20and%20Good%20Governance%20is%20the%20body,the%20provisions%20of%20good%20governance.

141 Salud por Derecho. (2019). Presentamos en el Congreso de los Diputados la iniciativa legislativa popular 'Medicamentos a un precio justo'. https://saludporderecho.org/se-presenta-en-el-congreso-de-los-diputados-la-iniciativa-legislativa-popular-medicamentos-a-un-precio-justo/.

142 Consejo de Transparencia y Buen Gobierno. (n.d.). https://www.consejodetransparencia.es/ct_Home/consejo/que-es.html.

143 See CONSEJO DE TRANSPARENCIA. (2024). El Consejo de Transparencia da la bienvenida a su nuevo Estatuto. https://www.consejodetransparencia.es/ct_Home/comunicacion/actualidadynoticias/hemeroteca/2024/20240802.html.

Examples of requests to the Spanish Transparency Council:

- In 2019, civil society organization Civio requested access to procurement and reimbursement conditions of Yescarta (axicabtagene ciloleucel), a blood cancer treatment, with a maximum price set in Spain at EUR 327,000 per personalized treatment. The Council upheld the principle that the costs of medicines must not be secret.[144] However, the Council in this case ruled that negotiations between pharmaceutical companies and States cannot be integrated within the limits established in article 14 of the Law on Transparency.[145]
- In 2021, Civio enquired about the net price for Zolgensma (onasemnogene abeparvovec), a gene therapy used to reduce the symptoms related to spinal atrophy in young children, with a maximum price in Spain set at 1,945,000 euros,[146] one of the most expensive medicines available for reimbursement. An initial ruling by Madrid's administrative court number 4 found in favour of Civio's and the Transparency Council's arguments, rejecting the appeal by the market authorization holder, Novartis.[147]
- Civil society organization *Salud por Derecho* and consumer association *Organizacion de Consumidores y Usuarios* (OCU), on behalf of the *No Es Sano* coalition, petitioned the Ministry of Health in 2022 for information on real prices of Gilead's Veklury (Remdesivir) via the Transparency Council. The marketing authorization holder had argued against revealing prices, stating that it would "entail a loss of negotiating and competitive capacity in prices, which would entail damage to the public interest."[148] The Council ultimately upheld the petitioner's claim, stating that the restrictions in accessing the information lacked sufficient and proportionate justification.[149] The Ministry of Health and the marketing authorization holder appealed this decision to the Courts, with civil society supporting the Transparency Board. In a landmark decision, the judge ruled that the disclosure of prices of medicines was not prejudicial to trade or economic interests.[150]

144 Civio. (n.d.). Que los precios de los nuevos medicamentos dejen de ser secretos. https://civio.es/precios-medicamentos-transparencia/.

145 Consejo de Transparencia. (n.d.). RCA282. Condiciones de financiación y precio del medicamento Yescarta. https://www.consejodetransparencia.es/ct_Home/Actividad/recursos_jurisprudencia/Recursos_AGE/2023/RecursosMinisterios/282-MSanidad1.html.

146 Civio. (n.d.). Que los precios de los nuevos medicamentos dejen de ser secretos. https://civio.es/precios-medicamentos-transparencia/.

147 This marked the second ruling in favour of the right to know the real price and financing conditions of a drug. Civio. (2023). Un juzgado vuelve a dar la razón a Civio frente a Novartis para que el precio de los medicamentos sea público. https://civio.es/novedades/2023/09/12/transparencia-precios-medicamentos-zolgensma-novartis/.

148 Noriega, D. (2024, 18 January). La Justicia allana el camino para que Sanidad y los laboratorios revelen los precios de los medicamentos más caros. El Diario. https://www.eldiario.es/sociedad/justicia-allana-camino-sanidad-laboratorios-revelen-precios-medicamentos-caros_1_10841710.html.

149 Consejo de Transparencia. (n.d.). RCA285. Condiciones de financiación y precio del medicamento Remdesivir. https://www.consejodetransparencia.es/ct_Home/Actividad/recursos_jurisprudencia/Recursos_AGE/2023/RecursosMinisterios/285-MSanidad2.html.

150 Salud por Derecho. (2024, 12 January). La justicia nos da la razón: los precios de los medicamentos debe ser públicos. https://saludporderecho.org/sentencia-veklury-transparencia/.

The appointment of a new Minister of Health in late 2023 seems to have changed the Ministry's position; recent cases concerning the treatments Yescarta and Veklury show a different approach by the executive. Rather than continuing to appeal and take the cases to Court, the Minister of Health was willing for the first time to disclose the prices of the treatments and did not appeal the judicial resolution.[151] In addition, the Ministry of Health has committed to place transparency at the heart of the ongoing reform of the Law on Guarantees and Rational Use of Medicines, currently under discussion in parliament.[152] In parallel, in the midst of discussions on the new Royal Decree on Health Technology Assessment, officials from the Ministry of Health have publicly called for increased transparency in R&D and production costs of medicines, while stating that the Ministry itself is making changes to improve transparency of its public information.[153] The Ministry of Health is willing to increase transparency of these aspects.[154]

Salud Por Derecho argues that the current draft should be strengthened to avoid broad and vague language. Instead, they suggest the inclusion of clear obligations for pharmaceutical companies, including tax incentives received, public subsidies, direct or indirect financial support, and more.[155] Nevertheless, the draft decree is another sign of a continuing move towards further transparency on behalf of the Spanish Ministry of Health.

On the legislative side, as mentioned above, the government is currently considering the Royal Decree on Health Technology Assessment that would seek to oblige laboratories to declare how much it costs to research, develop and produce a product.

Medicine pricing procedure

Pricing of medicines and other pharmaceutical products is regulated through Royal Decree 271/1990 of 23 February 1990 which uses a 'complete cost' system.[156] This system reportedly seeks to avoid unnecessary costs, such as those arising from overvaluation of active substances, and excessive payments for trademarks.

151 Organización de Consumidores y Usuarios (OCU). (2024). Caso Veklury: triunfa la transparencia. https://www.ocu.org/salud/medicamentos/noticias/precio-veklury-transparencia.

152 Arganda, C. (2024, 28 January). Sanidad aprobará la reforma de la Ley de Garantías y los RD de precio y ETS en 2024. DiarioFarma. https://diariofarma.com/2024/01/28/sanidad-quiere-aprobar-en-2024-la-reforma-de-la-ley-de-garantias-y-los-rd-de-precio-y-ets.

153 Arganda, C. (2024, 1 July). Padilla plantea información, transparencia y predictibilidad como claves de la evaluación. DiarioFarma. https://diariofarma.com/2024/07/01/padilla-plantea-informacion-transparencia-y-predictibilidad-como-claves-de-la-evaluacion.

154 Pérez Mendoza, S. (2024, 10 September). Sanidad obligará a los laboratorios a desvelar cuánto les cuesta producir los medicamentos. El Diario. https://www.eldiario.es/sociedad/sanidad-obligara-laboratorios-desvelar-les-cuesta-producir-medicamentos_1_11641918.amp.html.

155 Salud Por Derecho. (2024). Salud por Derecho calls on the Ministry of Health for more transparency in the assessments of medicines and other health technologies. https://saludporderecho.org/en/salud-por-derecho-calls-on-the-ministry-of-health-for-more-transparency-in-the-assessments-of-medicines-and-other-health-technologies/.

156 See art. 3, Real Decreto 271/1990, de 23 de febrero, sobre la reorganización de la intervención de precios de las especialidades farmacéuticas de uso humano. https ://www.boe.es/buscar/doc.php?id=BOE-A-1990-5368.

The maximum industrial price (PVL) is set by the Interministerial Price Commission, attached to the General Secretariat of Health and Consumer Affairs within the Ministry of Health.[157] The authorized prices of medicines dispensed in pharmacies and included in the National Health Service are available on the Ministry of Health website.[158] It is estimated that around 43 countries indirectly base their medicines prices on Spain, making Spain the third most referenced country.[159]

157 Ministerio de Sanidad. (n.d.). Comisión interministerial de precios. https://www.sanidad.gob.es/areas/farmacia/precios/home.htm.

158 See Sanidad. (n.d.). Conoce el precio del medicamento. https://www.sanidad.gob.es/campannas/campanas10/medicamentosGenericosEFG/conoce-precio-medicamento.html.

159 Simon Kucher. (2024, 10 June). Drug price transparency in Spain: Are pharma innovations in the Spanish market at risk?. https://www.simon-kucher.com/en/insights/drug-price-transparency-spain-are-pharma-innovations-spanish-market-risk.

Europe

Switzerland

Since the adoption of the transparency resolution, the Swiss government has pushed for increasing secrecy. Managed entry agreements now have a legal basis in Switzerland and their contents may be excluded from public disclosure possibilities via Switzerland's transparency legislation. These are clear moves against WHA resolution 72.8 and greater price transparency.

Role in the WHA transparency resolution

During the negotiations on the WHA transparency resolution, Switzerland, among other Member States such as Germany, contributed to watering down the text of the resolution. In particular, the Swiss delegation was openly opposed to the mandatory disclosure of costs associated with R&D, including clinical trials, by the pharmaceutical industry,[160] despite having previously expressed support for the public exchange of net prices of health products. This opposition was closely followed by the announcement of the introduction of secret rebates in Switzerland.[161]

Political and legislative developments

Several national initiatives are a cause for concern in the pursuit of further transparency and the implementation of WHA resolution 72.8.
As part of a package of measures intended to bring down the costs of healthcare, the federal government is currently considering a reform of the federal law on health insurance ('LAMal' in French, 'KVG' in German). Among the proposed amendments, two address key aspects of the existing framework.

Firstly, the amendments would codify into law managed entry agreements (MEAs).[162] According to government sources, the legal adoption of MEAs is necessary to afford increasingly expensive medicines as they may lead to 20% to 30% discounts and ensure access for patients.[163] Secondly, the amendments foresee that MEAs would be excluded from the Law on Transparency,

160 David Plüss, J. (2019, 28 May). WHO adopts watered-down resolution on drug transparency. SwissInfo. https://www.swissinfo.ch/eng/business/world-health-organization_who-adopts-watered-down-resolution-on-drug-transparency/44995340.

161 Public Eye. (n.d.). Des modèles de prix qui font le jeu de la pharma. https://www.publiceye.ch/fr/hématiques/pharma/pas-de-rabais-secrets/des-modeles-de-prix-qui-font-le-jeu-de-la-pharma; and Albrecht, P. (2024, September 23). Der Pharmaplan. Republik. https://www.republik.ch/2024/09/23/der-pharmaplan.

162 Which would now be under art. 52b as explained in the FOPH's information sheet from 19 August 2020. See Confédération Suisse, OFSP. (2020). Fiche d'Information : Modèle de prix pour médicaments. https://www.newsd.admin.ch/newsd/message/attachments/62454.pdf.

163 Swiss Confederation. (2022, 7 September). Message concernant la modification de la loi fédérale sur l'assurance-maladie (Mesures visant à freiner la hausse des coûts, 2e volet). https://www.fedlex.admin.ch/eli/fga/2022/2427/fr.

the government justifying this exception in order to maintain confidentiality over MEAs.[164] Usually, the Law on Transparency enables public access to official documents,[165] but this would no longer be the case for the contents of MEAs.

During parliamentary deliberations in June 2024, the Council of States (upper house in parliament representing the cantons) joined the Federal government and the National Council (lower house in parliament representing the people) in agreeing to the use of MEAs and their exclusion from the above-mentioned Law on Transparency.[166]

Evidence gathered by the Swiss NGO Public Eye indicates that costs are not reduced, and patient access is not increased, through the use of MEAs.[167] It is argued that this amended law would completely exclude the possibility of discovering the net prices of treatments from the scope of Switzerland's federal Law on Transparency.[168] Currently, documents are still accessible, albeit heavily redacted. If this amendment is accepted, there will be no possibility of receiving or disclosing any documents.[169]

In June 2024, the health commission of the Council of Nations recommended deleting provisions relating to MEAs.[170] After extensive debates between the Council of States and the Council of Nations, the reforms were adopted in March 2025. Although the legislation still enshrines secrecy into law, the language is slightly softer, using the term 'may' rather than 'shall'.[171]

An additional concerning development is the proposal to include a day 0-type reimbursement process, such as is currently the case in Germany, pushed for by the pharmaceutical industry. Essentially, reimbursement from day 0 allows the pharmaceutical industry to enter into the system as early as possible and with a high price,[172] with price negotiations continuing after. The industry argues that this enables faster and more equitable access to innovative medicines.[173] However, this process means that although prices can be reviewed and lowered later on, the initial high prices are set as reference ones,[174] and it may be harder to lower the price or ultimately remove the drug from the speciality list. Further, there will be no transparency on any price lowering

164 Swiss Confederation. (2022, 7 September). Message concernant la modification de la loi fédérale sur l'assurance-maladie (Mesures visant à freiner la hausse des coûts, 2e volet). https://www.fedlex.admin.ch/eli/fga/2022/2427/fr.

165 Swiss Confederation. (2006). Loi sur la Transparence. https ://www.fedlex.admin.ch/eli/oc/2006/355/fr.

166 Swiss Parliament. (2022). LAMal. Modification (Mesures visant à freiner la hausse des coûts – 2e volet), https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20220062.

167 See Public Eye. (n.d.). Des modèles de prix qui font le jeu de la pharma. https://www.publiceye.ch/fr/thematiques/pharma/pas-de-rabais-secrets/des-modeles-de-prix-qui-font-le-jeu-de-la-pharma.

168 Ibid.

169 Public Eye. (2023, 28 September). Le Parlement doit défendre le principe de transparence sur les prix des médicaments. Press release. https://www.publiceye.ch/fr/coin-medias/communiques-de-presse/detail/le-parlement-doit-defendre-le-principe-de-transparence-sur-les-prix-des-medicaments.

170 Swiss Parliament. (2024, 21 June). Réseaux de Soins Coordonnés : La Commission maintient son rejet. Press release. https://www.parlament.ch/press-releases/Pages/mm-sgk-n-2024-06-21.aspx; see also Albrecht, P. (2024, September 23). Der Pharmaplan. Republik. https://www.republik.ch/2024/09/23/der-pharmaplan.

171 For the original proposal, see Confédération Suisse. (2022). (Mesures visant à freiner la hausse des coûts, 2e volet). https://www.fedlex.admin.ch/eli/fga/2022/2428/fr. For the negotiated version, see Parlement Suisse. (2025). Modification du 21 mars 2025.

172 Albrecht, P. (2024, 23 September). Der Pharmaplan. Republik. https://www.republik.ch/2024/09/23/der-pharmaplan.

173 Sierro, M. (2022, 3 May). Communiqué de presse : Interpharma propose un remboursement de l'accès des patient-e-se à l'innovation. Interpharma. https://www.interpharma.ch/blog/medienmitteilung-interpharma-schlaegt-einen-rueckvergueteten-innovationszugang-fuer-patientinnen-und-patienten-vor/?lang=fr.

174 Bersi, E., Buzzoni, L., Peigné, M. (2024, 12 June). Medicine dealers: Europe's secret drug negotiations. Investigate Europe. https://www.investigate-europe.eu/posts/deadly-prices-medicine-dealers-europe-secret-drug-negotiations.

negotiations following the introduction of the medicine to the market.

On top of these amendments, several questions have been put forward in the Swiss parliament on transparency-related matters, thanks to the advocacy work undertaken by Public Eye and other civil society organizations.

In 2022, the government was asked whether they would consider making the pharmaceutical industry's investments transparent, as is the case in Italy. The government's answer was to refer to their continued engagement with the WHO and OECD.[175]

The government has also been requested to explain the increase in MEAs concluded in the period from 2019 to 2023. Here again, the government in its answer refers to the necessity to engage in confidential negotiations when trying to procure costly medicines quickly and at more affordable prices.[176]

Many other interventions and questions in parliament from different political groupings relate to transparency and the price of pharmaceuticals. Ultimately, civil society has attempted to 1) ask for alternatives to the proposed reform, such as making R&D costs transparent so that a 'fair price' can be negotiated with an empowered Federal Office of Public Health (OFSP); 2) demonstrate that the Federal Council already uses MEAs and that increasingly these are not transparent on the speciality list (see below), and; 3) ask what evidence the Federal Council has for reduced costs and quicker access to medicines.[177]

Medicine pricing procedure

The Swiss health system is divided across cantonal and federal competency. The federal government is responsible for the compulsory health insurance scheme, while cantons are primarily responsible for healthcare provision and hospital care.

Individuals residing in Switzerland are responsible for seeking out basic health insurance with an insurer of their choice. They may also choose to take out supplementary health insurance.[178] Medicines prices are set in Switzerland by the OFSP. This is based on the cost-effective analysis: first, there is a therapeutic cross-comparison with medicine already available on the market to treat the same disease. Second, the price of the product is compared with the prices of the product in the external reference countries (ex-factory prices). Reference countries for Switzerland include Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Sweden and the United Kingdom.[179] It is in the pharmaceutical industry's interest to set a high visible price,[180] and according to the Federal Council, up to 60 countries directly and indirectly refer to the Swiss prices,[181] which can also explain why secrecy remains so important for the pharmaceutical industry in Switzerland. High prices set in Switzerland will mean high prices

175 Swiss Parliament. (2022, 19 September). Heure des questions. Question Porchet Léonore. Prix des médicaments. A quand la transparence sur les investissements des entreprises pharmaceutiques?. https://www.parlament.ch/fr/ratsbetrieb/amtliches-bulletin/amtliches-bulletin-die-verhandlungen?SubjectId=57972.

176 Swiss Parliament. (2023, 5 June). Comment expliquer l'augmentation des modèles de prix secrets pour les médicaments?. https://www.parlament.ch/fr/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20237324.

177 Feedback received from Dr. Gabriela Hertig, Public Eye.

178 Swiss Confederation. (n.d.). Healthcare system. https://www.eda.admin.ch/aboutswitzerland/en/home/wirtschaft/soziale-aspekte/gesundheitssystem.html.

179 Swiss Confederation. (n.d.). Information related to the specialities list. https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Mitteilungen-zur-Spezialitaetenliste.html.

180 See Albrecht, P. (2024, 23 September). Der Pharmaplan. Republik. https://www.republik.ch/2024/09/23/der-pharmaplan.

181 See Federal Council. (2022, 7 September). Message concernant la modification de la loi fédérale sur l'assurance-maladie (Mesures visant à freiner la hausse des coûts, 2e volet). https://www.fedlex.admin.ch/eli/fga/2022/2427/fr.

for any of the countries who refer to the Swiss one. In conclusion, initiatives put forward at a national level are a concerning development. These may lead to the codification of confidentiality or drug pricing in Switzerland, in direct opposition to the transparency resolution and despite strong civil society engagement.

South America

Brazil

In line with some of the requirements of the transparency resolution, Brazil applies a pricing policy with agreements on the disclosure of information and the setting of prices. Besides fostering accountability, transparency benefits other countries that use drug prices in Brazil as an external reference. However, once on the market, prices are adjusted for inflation, which means that they rise. This has led to questions about the efficacy of price regulation in Brazil in reducing prices.

Role in the WHA transparency resolution

Brazil supported WHA resolution 72.8 throughout the 2019 World Health Assembly. In reference to the original proposal for the resolution, Brazil's representative affirmed that "the draft roadmap outlined a comprehensive and balanced approach, across the entire value chain" and hoped that "the draft resolution would further efforts to improve access to medicines."[182] During the drafting stage, the Brazilian delegation positioned itself in favour of transparency and public access to data, including the price (including rebates and discounts), costs, medical benefits and therapeutic value of medical products.[183]

According to a member of the Brazilian delegation to the 72nd WHA, "transparency of negotiations and research and development costs was identified as the solution to ensure that all governments can have an informed understanding of the costs involved and, thus, be in a better position to decide what should constitute a fair price. Only with full transparency can governments engage in fair negotiations over treatment prices." Another member declared that "working towards fair pricing also means building a system where not only wealthier nations or those with greater purchasing power have access to the treatments they need."[184]

Brazil also endorsed the resolution in other international forums. In a 2019 meeting with the health authorities of the BRICS – an intergovernmental organization consisting

182 World Health Organization. (2019). Seventy-Second World Health Assembly: Summary Records of Committees, Reports of Committees. https://apps.who.int/gb/ebwha/pdf_files/WHA72-REC3/A72_2019_REC3-en.pdf.

183 World Health Organization. (2019). Improving the transparency of markets for medicines, vaccines, and other health-related products and other technologies to be discussed at the Seventh-second session of the World Health Assembly to be held on 20-28 May 2019. Draft resolution proposed by Egypt, Greece, Italy, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Turkey. https://www.keionline.org/wp-content/uploads/A72_ACONF2-en-May22.pdf.

184 Comissão Nacional de Incorporação de Tecnologias No Sistema Único de Saúde - CONITEC. (2019). Nações reunidas para discutir negociações mais justas na compra de medicamentos. https://www.gov.br/conitec/pt-br/assuntos/noticias/2019/abril/nacoes-reunidas-para-discutir-negociacoes-mais-justas-na-compra-de-medicamentos.

of emerging economies[185] – the Brazilian representative invited the other countries to discuss the strategies for implementing WHA resolution 72.8. On 16 June 2021, during the Covid-19 pandemic, the health ministries of the MERCOSUR – a regional trade agreement between Argentina, Brazil, Paraguay and Uruguay – issued a statement affirming that WHA resolution 72.8 urged countries to reveal the real price their health systems pay for drugs and that the WHO had committed to work towards more transparency about the real costs across the supply chain, from basic research to commercialization.[186]

Brazil's support for WHA resolution 72.8 and its international position on the issue of transparency and public access to data is coherent with its domestic legislation, as will be discussed below.

Political and legislative developments

The Brazilian legislation is aligned with some provisions of WHA resolution 72.8. However, there are increasing calls for changes to the price transparency legislation.

A draft bill (PL 5591/2020) introduced in the Senate in December 2020 aims to modify Federal Law no. 10742/2003, which, as mentioned above, sets the rules for the regulation of drug prices in Brazil. The draft bill proposes that the prices practiced in countries that are socioeconomically comparable to Brazil may be used for external price refencing. Additionally, it proposes that prices from countries without a universal public healthcare system or without a drug price regulation policy shall not be used as reference.

This draft bill also proposes amendments to Federal Law no. 6360/1976 to oblige pharmaceutical companies applying for marketing authorization to also disclose information on: 1) the discount policies applied by the manufacturer in other countries; 2) the R&D costs (including pre-clinical research and clinical trials) involved in the development of the drug, including a breakdown of public and private funding; and 3) all patent rights and pending patent applications that the company holds for the drug.

On the other hand, there have been calls for less transparency, with the argument that it creates obstacles for price negotiation. Accordingly, price transparency makes pharmaceutical companies hesitant to offer Brazil lower prices that will be used as international references for other countries to regulate and negotiate prices. For instance, a director of Sindusfarma – the largest association representing the interests of the pharmaceutical industry in Brazil – affirmed in a public event that "one advantage that European countries have is that they [...] can conduct confidential negotiations. They have a public list price, but they also have the price practiced in confidential contracts. This might be an issue we need to discuss in Brazil, to ensure confidentiality for one, two, or three years in the contract."[187] The European trend towards greater protection of confidential information is a cause for concern, reminding us of the importance of acting within the framework of global and concerted action. Recently, the body responsible for drug price regulation in Brazil opened a public hearing to discuss the pricing of advanced therapies, which has fuelled a debate on pricing.

185 BRICS. (n.d.). https://infobrics.org/.

186 MERCOSUR. (2021). Declaração dos Ministros da Saúde do MERCOSUL e o estado plurinacional da Bolívia sobre a pandemia COVID-19. https://documentos.mercosur.int/simfiles/declaraciones/84909_DECLARACION%20RMS_PT_COVID19.pdf.

187 Unified Portal of the Federal Justice of the 4th Region. (2024). Fórum da Saúde debate acessibilidade a tratamentos médicos no SUS e na Saúde Complementar. https://www.trf4.jus.br/trf4/controlador.php?acao=noticia_visualizar&id_noticia=28517.

Medicine pricing procedure

The health system in Brazil

In Brazil, a universal national public health system (*Sistema Único de Saúde*, or SUS) free at the point of use coexists with a large voluntary private health insurance sector. The national health system covers primary, secondary and tertiary care, and offers a comprehensive package that includes drugs. The public health system, and the federal government in particular, is the main single buyer of prescription drugs in Brazil.[188] Insurance companies are not obliged to cover outpatient prescription drugs, except cancer drugs.

As a rule, drugs considered to receive public funding are first evaluated by Conitec, the National Health System's health technology assessment body. Conitec's appraisals must evaluate treatments' cost-effectiveness and budget impact. Cost-effectiveness is a mechanism for value-based pricing, which is particularly important when the international prices paid by other health systems are unknown. It is not uncommon for Conitec to recommend that the government lists a treatment for funding, provided that price negotiations and price reductions are undertaken to ensure cost-effectiveness and reduce its budgetary impact on the healthcare system. In the case of the drug Zolgensma, Conitec recommended its funding under a risk-shared agreement.

The principle of publicity established in the Federal Constitution and in the Public Procurement Law (Federal Law no. 14133/2021) requires that the price of the drugs procured by the public health system must be made public. The federal government maintains a system – the Integrated System for General Services Administration (*Sistema Integrado de Administração de Serviços Gerais*, or SIASG) – that allows public access to information over the drugs procured by the federal government, including the price paid.

For a drug to enter the market in Brazil, the legislation requires two steps. First, the drug needs to receive marketing authorization from the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, or ANVISA). Federal Law no. 6360/1976 (as modified by Federal Law no. 10742/2003) establishes that applications for marketing authorization should inform, among other things:

- The company's price for the product in other countries;
- The acquisition cost of the product's active ingredient;
- The treatment cost per patient using the product;
- The potential number of patients to be treated;
- The list of prices intended to be charged in the domestic market, with a breakdown of its tax burden;
- The breakdown of the proposed commercialization plan for the product, including estimated expenses for sales efforts and advertising;
- The price of the product that has been modified, in the case of changes in formula or form; and
- A list of all substitute products available on the market, accompanied by their respective prices.

After receiving marketing authorization, a pharmaceutical company seeking to commercialize its product shall apply to the Chamber of the Regulation of the Medicines Market (*Câmara de Regulação do Mercado de Medicamentos*, or CMED) to establish a maximum sale price. The norms regarding price regulation were established by Federal Law no. 10742/2003 and further detailed by CMED. CMED will receive the information already provided to ANVISA. Moreover, according to CMED Resolution 04/2002, the pharmaceutical company's application for price registration needs to inform, among other things:

188 Da Silva, L.P.A. (2019). Access to medicines thematic budget: analysis of federal resources allocated to pharmaceutical assistance over 10 years – Assessment of Ministry of Health Medicines Budget execution from 2008 to 2018. Institute for Socioeconomic Studies (INESC). https://inesc.org.br/wp-content/uploads/2019/12/OTMED-2019_ING_WEB.pdf?x12453.

- The price at which the company intends to commercialize each pharmaceutical form, with a breakdown of applicable taxes and commercialization margins;
- The manufacturer price practiced in Australia, Canada, Spain, the United States of America, France, Greece, Italy, New Zealand, Portugal, and the manufacturer price practiced in the product's country of origin, excluding applicable taxes;
- The comparative cost-effectiveness analysis between the medication and existing therapeutic alternatives;
- The information regarding the product's patent, including the number of the first international patent filing, filing date, and country where it was filed; the number of the patent filing at the Brazilian National Institute of Industrial Property; and the innovation presented by the product on which the patent application was based;
- The published economic evaluation studies, when available;
- The Phase III clinical trials conducted that are relevant for the comparison between the new medication and those existing in the country for the same therapeutic indication, if applicable; and
- The new therapeutic indications for the same medication under study, in the process of approval, or approved in other countries, if applicable.

The price of new products that do not provide benefits compared to alternative therapies is set based on the maximum price of the alternative therapies in Brazil and cannot exceed the lowest price in the list of countries mentioned above. For new products that offer health gains (safer, more effective or more cost-effective) and that are already being commercialized in at least three of the countries in the list above, their list price in Brazil cannot exceed the lowest list price for the same product in this basket of countries. If it is not yet commercialized in at least three of these countries, then a provisional price will be established and subject to periodic review.

Despite the robustness of the regulation on paper, which is in line with the WHO Guideline on Country Pharmaceutical Pricing Policies,[189] there is growing concern that the use of external reference pricing is limiting the impact of the regulation because of the gap between list prices and the actual prices paid by countries' healthcare systems. In addition, given that GDP per capita in these reference countries is much higher than in Brazil, a drug with the same or similar nominal price in these countries will be less affordable for Brazilian consumers and the Brazilian healthcare system.

189 Zucoloto, G. F., Hasenclever, L., Negri, F., Miranda, C. (2024). Políticas de preços e acesso a medicamentos: o Brasil ante as recomendações da Organização Mundial da Saúde. In Tecnologias e preços no mercado de medicamentos (1, 1, 309). Brazil. Instituto de Pesquisa Econômica Aplicada (Ipea). https://repositorio.ipea.gov.br/bitstream/11058/14588/10/Cap_7_Politica_de_precos_acesso_a_medicamentos.pdf.

South America

Chile

Chile supported the transparency resolution and has often discussed the topic of transparency in past and current legislative proposals. Moreover, the country is concerned about high drug prices. It has yet to formally adopt new legislation to implement the resolution domestically. The Drug Law 2, proposed in 2015, contains a proposal for the National Health Service System (CENABAST) to establish a national observatory of medicines which would monitor prices and make price and market information publicly available. This law has yet to be approved.

Role in the WHA transparency resolution

Chile participated actively in the 72nd World Health Assembly. Their representative publicly emphasized the importance of transparency, notably through prioritizing the development of an information-sharing mechanism. She also supported strategies to facilitate public-private collaboration that would provide access to price negotiations on national and subregional levels.[190]

Political and legislative developments

Meanwhile, Chilean institutions responsible for ensuring free competition have been advocating for increased transparency. In 2019, the National Economic Prosecutor's Office proposed 14 measures to enhance access to medicines in Chile. These suggested measures, which included promoting price transparency, have the potential to significantly improve the efficiency and effectiveness of the State's medicine purchases, as well as encourage pharmacies to dispense the most affordable medicines.[191] Although the proposed measures were not mandatory, they did contribute to raising awareness among authorities and legislators, who later proposed amendments to Chile's legislation.

Simultaneously, the legislative and executive branches proposed a series of modifications to Chile's healthcare legislation, called the Health Code, to promote greater access to medicines. Among the measures was the generation of price transparency for medicines. The bill that "modifies the Health Code to regulate generic bioequivalent medicines and prevent the vertical integration of laboratories and pharmacies" or

190 72nd World Health Assembly. (2019). Provisional Summary Record of the Eleventh Meeting. https://apps.who.int/gb/ebwha/pdf_files/WHA72-A-B-PSR/A72_APSR11-en.pdf.

191 Instituto de Salud Pública de Chile. (2017). ISP encabeza observatorio de medicamentos para poner en marcha aplicación que compara precios. https://www.ispch.gob.cl/noticia/isp-encabeza-observatorio-de-medicamentos-para-poner-en-marcha-aplicacion-que-compara-precios.

the Drug Law 2 (Bulletin 9914-11),[192] presented in 2015, seeks to amend the Health Code to regulate generic bioequivalent medicines and prohibit vertical integration between laboratories and pharmacies which in practice generates distribution monopolies. This prohibition implies that manufacturers cannot be the same entities as sellers, in order to prevent price collusion on medicines. This practice had previously enabled price manipulation and market concentration. The bill emerged following the collusion scandal involving Chile's major pharmaceutical chains[193] and aims to ensure access to quality medicines at fair prices while promoting greater independence among market actors.

A central element of this bill is the creation of the National Observatory of Medicines, whose purpose is to monitor prices, propose measures to improve access to medicines and publish critical market information, such as price differences compared to other markets. By publishing this information, the Observatory would ensure more citizen and governmental oversight, contributing to transparency and preventing abusive practices. After nine years of contentious debate, the bill has stalled due to a lack of governmental momentum, lobbying by laboratories and pharmacies, and controversies over price controls and medicine interchangeability.[194], [195] If this bill were to be adopted, it would reportedly incorporate the transparency obligations outlined in WHA resolution 72.8.[196]

Previous to the Drug Law 2 bill, one of the most notable pieces of law approved is Law 20.724 (also known as Drug Law 1), amending the Health Code regarding pharmacy and medicine regulation, which was introduced in 2008 and approved in 2014.[197] It aimed to promote transparency and competition in the pharmaceutical market. This law imposed the obligation on pharmacies to provide patients with updated information on listed prices, discounts and actual prices charged. In addition, the law required that the National Health Service System must make drug prices publicly available electronically to enable consumer comparison.[198]

192 Senado de Chile. (2024). Modifica el Código Sanitario para regular los medicamentos bioequivalentes genéricos y evitar la integración vertical de laboratorios y farmacias. https://tramitacion.senado.cl/appsenado/templates/tramitacion/index.php?boletin_ini=13310-11.

193 In Chile, the pharmacy chains were convicted of colluding between 2007 and 2008 to artificially raise the prices of at least 206 medicines, harming consumers. Tribunal de Defensa de la Libre Competencia. (2025, 5 March). TDLC condena a Farmacias Cruz Verde S.A. y Salcobrand S.A. por colusión en el mercado de distribución de productos farmacéuticos. https://www.tdlc.cl/tdlc-condena-a-farmacias-cruz-verde-s-a-y-salcobrand-s-a-por-colusion-en-el-mercado-de-distribuion-de-productos-farmaceuticos/.

194 Libertad y Desarrollo. (2022, March). Fármacos II en la recta final. https://lyd.org/centro-de-prensa/noticias/2022/03/farmacos-ii-en-la-recta-final.

195 Diario Financiero. (2020). Ley de fármacos II en etapa final. https://www.df.cl/opinion/cartas/ley-de-farmacos-ii-en-etapa-final.

196 Senado de Chile. (2021). Ley de Fármacos 2: en su recta final. https://www.senado.cl/comunicaciones/noticias/ley-de-farmacos-2-en-su-recta-final.

197 Biblioteca Nacional Del Congreso Chile. (2014). Ley 2074. https://www.bcn.cl/leychile/navegar?idNorma=1058373&buscar=20.724.

198 For the law which amends the Health Code regarding the regulation of pharmacies and medicines, see Biblioteca Nacional Del Congreso Chile. (2014). Ley 2-724. https://www.bcn.cl/leychile/navegar?idNorma=1058373&buscar=20.724.

Other legislative proposals such as Law No. 21.198 (the CENABAST[199] Law) also demonstrate the focus on increasing transparency.[200] This was apparent through the discussions surrounding this law, which emphasized the importance of establishing transparency standards by creating a consultative body responsible for monitoring and setting medicine prices. CENABAST's mediation in purchasing medicines for private pharmacies would contribute to greater clarity and equity. As part of transparency measures, the law would require CENABAST to publish all mediation operations, including medicine prices, on its website, allowing greater public oversight of its activities.

Medicine pricing procedure

Like in many other countries, high medicine prices are a matter of concern in Chile. These costs significantly impact household expenses, with medicines comprising 35.8% of out-of-pocket healthcare costs in 2016.[201] To address this, programmes like FONASA[202] and CENABAST provide financial support, with FONASA offering discounts and the High-Cost Medicines Programme covering 100% of medicines for certain conditions.[203] CENABAST also negotiates lower prices for public and private pharmacies, setting maximum prices to reduce costs. In 2023, it generated 11.34 billion Chilean pesos (13 million US dollars) for private pharmacy supplies.[204]

CENABAST currently provides multiple sources of information on purchases, including purchasers and distributors. One of the most valuable databases is the CENABAST Observatory. The CENABAST Observatory is a transparent platform for information, from purchase orders and delivery compliance to current contracts with each supplier.[205] The observatory also contains an international price observatory that compares the prices of medicines purchased by CENABAST with those of similar products in other countries.[206]

Additionally, interested parties can access relevant information through the active transparency portal. This portal contains contracts and agreements signed by CENABAST. Furthermore, specific information, particularly related to medicine prices, can be requested electronically from the entity.[207] While CENABAST plays a crucial role in negotiating better prices for the public sector, its impact on the private market remains limited.

Role in the WHA transparency resolution

Colombia participated actively in the negotiations running up to the approval of WHA resolution 72.8. Together with most of the early promoters of the motion, it co-organized a side event at the 72nd World Health Assembly on the need for a multidimensional approach to transparency as key to achieving universal health coverage (UHC).[208]

199 CENABAST (Central de Abastecimiento del Sistema Nacional de Servicios de Salud) is Chile's public agency responsible for purchasing and distributing medicines, medical supplies, and equipment for the public healthcare system. CENABAST. (n.d.). Quiénes somos. https://www.cenabast.cl/institucion/quienes-somos/.

200 Biblioteca Nacional del Congreso de Chile. (2024). Ley 21198. https://www.bcn.cl/leychile/navegar?idNorma=1140791.

201 Centro de Estudios Públicos (CEP). (2019). Gasto de bolsillo en salud: una mirada al gasto en medicamentos. https://www.cepchile.cl/investigacion/gasto-de-bolsillo-en-salud-una-mirada-al-gasto-en-medicamentos/.

202 FONASA (Fondo Nacional de Salud) is Chile's public health insurance system, managed by the Ministry of Health (MINSAL). It is the financial entity entrusted to collect, manage and distribute state funds for health in Chile. FONASA. (n.d.) Conoce FONASA. https://www.fonasa.cl/sites/fonasa/conoce-fonasa.

203 Biblioteca del Congreso Nacional de Chile. (2015). Ley 20850. https://www.bcn.cl/leychile/navegar?idNorma=1078148.

204 CENABAST. (n.d.). Gestión de abastecimiento a farmacias privadas: Ley Cenabast. https://www.cenabast.cl/gestion-de-abastecimiento-farmacias-privadas-ley-cenabast.

205 CENABAST. (n.d.). Acceso al Observatorio. https://www.cenabast.cl/accesos-a-observatorio.

206 Ibid.

207 Portal de Transparencia. (n.d.). Ingreso de Solicitud de Acceso a la Información. https://www.portaltransparencia.cl/PortalPdT/ingreso-sai-v2?idOrg=1050.

208 Third World Network. (2019). WHO: Consensus on transparency resolution still elusive. https://twn.my/title2/intellectual_property/info.service/2019/ip190506.htm.

South America

Colombia

Although the country currently has no binding obligation to increase transparency, institutions could enhance it through collaborative agreements and deliberations that establish standard practices for data accessibility, portability and use. Despite advances in price regulation and public access to medicine price-related information, Colombia faces challenges in achieving full transparency in the health sector. The lack of detailed information about data exclusivity, for example, undermines public trust.

Political and legislative developments

The concern for transparency in Colombia is part of wider efforts to enhance market transparency and prevent corruption at the domestic level. To such end, Colombian authorities had previously undertaken various initiatives, such as the Rules on Priority Measures for Transparency and Integrity in the regulation of medicine prices and the definition of the benefits plan in Colombia[209] or the Register of Transfers of Value between actors in the health sector and the pharmaceutical industry (RTVSS).[210]

Resolution 2881 of 2018 from the Ministry of Health and Social Protection established the RTVSS to promote transparency in relationships between actors in the health sector and the pharmaceutical and health technology industries by mandating the reporting and publication of transfers of value, such as money, goods or services. This initiative sought to enhance visibility of interactions, prevent undue influence and potential conflicts of interest, and help protect equity and integrity in medical care. Furthermore, the register was based on specific reporting rules and sanctions for non-compliance, fostering an ethical and transparent environment within the sector.

209 See Gobierno de Colombia. (2015). Decálogo de medidas prioritarias de transparenci a e integridad para la regulación de precios de medicamentos y la definición del plan de beneficios en Colombia. https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/decalogo-transparencia-integridad-sectorsalud.pdf.

210 Ministerio de Salud de Colombia. (2018). Resolucion 2881. https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/resolucion-2881-de-2018.pdf.

Since the approval of WHA resolution 72.8, Colombian authorities have remained committed to securing greater transparency in pharmaceutical markets through interventions in the legal and regulatory framework. Not all attempts have been successful, and some proposals have not been finally approved.

Circular 18 of 2024 defines the methodology by which the National Commission on Prices of Medicines and Medical Devices identifies the medications that should enter the regime of direct price control and determines their maximum sale price or exclusion from such control. This methodology is established through the creation of 'relevant markets' based on criteria such as active ingredients, grouped pharmaceutical forms (GPF), and the international non-proprietary name (INN).[211], [212]

Medicine pricing procedure

The health system in Colombia

The Colombian health system is based on the General System of Social Security in Health (SGSSS), which includes two main regimes: the contributory regime (CR) for individuals with the ability to pay, such as those with formal employment or independent workers, pensioners, and their families; and the subsidized regime (SR) for people without the capacity to pay for the full cost of contributions required for affiliation to the contributory regime. There are also exceptional regimes (ER), such as those for the military forces, national police, and those who are part of the teaching profession. Enrolment in social security is mandatory through Health Promotion Entities (EPS), which register affiliates and collect their contributions. The private sector is mainly used by the upper class and some middle-income individuals, who turn to private services due to lack of timely access to the SGSSS.

The Ministry of Health and Social Protection manages medicine pricing and reimbursement policies in Colombia.[213] Available data includes the average price over three months, maximum sale prices, quantities and the number of medicines-related contracts. This information is categorized as open data, allowing public access and transparency.

The Medicine Price Information System (SISMED) collects data on purchasing, selling and reimbursing marketed medicines.[214] It aims to provide a reliable, timely, publicly accessible data source on medicine prices and the units sold. The primary purpose of SISMED is to register medicine prices within the market. The data includes average prices and maximum and minimum sale prices, all categorized as open data for public accessibility and transparency.

Medicines Human Product Database

The National Institute for Food and Drug Surveillance (INVIMA) serves as Colombia's surveillance authority for medicines and food. Its primary purpose is to ensure regulatory oversight in these areas. The institute provides information such as registration numbers, medicine names, manufacturer details and patient safety information. Access to this information can

211 See Ministerio de Salud de Colombia. (2024). Comisión Nacional de precios de medicamentos y dispositivos médicos Circular 18 de 2024. https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/circular-018-de-2024.pdf.

212 The methodology involves defining relevant markets in pharmaceuticals by grouping products based on criteria such as active ingredients, which identify therapeutic substances; grouped pharmaceutical forms (GPF), which categorize medicines by their mode of administration or dosage form; and the international non-proprietary name (INN), a globally standardized name assigned by the WHO for clarity and consistency across different brands and markets.

213 Sistema Integrado de Información de la Salud (SISPRO). (n.d.). Sistema de Información de Precios de Medicamentos. https://www.sispro.gov.co/central-prestadores-de-servicios/Pages/SISMED-Sistema-de-Informacion-de-Precios-de-Medicamentos.aspx.

214 inisterio de Salud de Colombia. (n.d.). Regulacion de precios de medicamentos. https://www.minsalud.gov.co/salud/MT/paginas/medicamentos-regulacion-precios.aspx.

be categorized as open data or restricted data, depending on the nature of the request and data sensitivity.

Colombia grants five years of data exclusivity for new medicines containing new chemical entities, as established by Decree 2085 of 2002. However, no official public online database in the country provides updated information on preclinical studies, including specific data, methodology, pharmacology or toxicology. While Colombia makes clinical trial data IDs publicly accessible, other critical information about early-stage research remains inaccessible, limiting transparency.

North America

United States of America

Although several US states have passed drug transparency laws, and despite the support for the transparency resolution and an active civil society, the US lags behind in successfully implementing the terms of WHA resolution 72.8 at the federal level. It also fails to take into account some of the demands in its access to public research policy initiatives. Moreover, the fact that the US is leaving the WHO raises questions about its commitment to international agreements in the coming years.

Role in the WHA transparency resolution

While the United States opposed certain language during the negotiation process and pushed back on terms such as requirements to disclose clinical trial costs, once adopted by the 72nd WHA in 2019, the resolution was ultimately supported by the country, including on pricing transparency.

Political and legislative developments

Although still voicing formal support for the implementation of WHA resolution 72.8, the United States has made very limited progress in implementing the transparency measures described in the resolution at national level.

Federal and state legislation

While a number of federal bills with language on drug price transparency have been introduced in Congress, those bills are yet to become federal laws. On the state level, however, there is more progress as individual states have passed laws concerning drug pricing transparency.

Previously, Vermont became the first state to pass a law on drug price transparency in 2016, with California following suit in 2017.[215] Nowadays more than 20 states have passed drug price transparency laws.[216]

Most state transparency laws require reporting from drug manufacturers when the companies raise the wholesale acquisition cost (WAC) of a drug above a certain threshold or introduce a new drug above a certain price. As these laws have been enacted on a state-by-state basis, the levels of price thresholds, what data is required to be reported, how that data is collected/reported, and whether that data is public varies significantly by state. Some notable state laws include:[217]

215 ASHP. (n.d.). Issue Brief: State Drug Pricing. https://www.ashp.org/advocacy-and-issues/key-issues/drug-pricing/issue-brief-state-drug-pricing.

216 Goodwin. (2023). 2023 State Drug Transparency Law Development Update. https://www.goodwinlaw.com/en/insights/publications/2023/11/alerts-lifesciences-state-drug-transparency-law-development-update.

217 National Academy for State Health Policy. (2022). Prescription Drug Pricing: State Strategy Implementation. https://nashp.org/prescription-drug-pricing-state-strategy-implementation/.

- **California**
  The drug transparency programme in California requires that launch price information and five-year schedules of price increases reported by manufacturers are publicly posted on its website.[218]
- **Oregon**
  Oregon's drug price transparency law includes provisions for an annual public hearing that includes analysis of data provided by relevant stakeholders on drug pricing, discussion with stakeholders, and policy recommendations.
- **Maine**
  Maine's drug transparency suite of legislation not only requires reporting by drug manufacturers, but also by insurers, pharmacy benefit managers, pharmacies, and distributors, in order to capture a more holistic view of drug prices across the supply chain.

The National Academy for State Health Policy provides a detailed table comparing the terms of state drug pricing laws.[219]

Other policy developments

Another example of the United States' failure to comply with the norms set out in WHA resolution 72.8 concerns the National Institutes of Health's (NIH) reporting and data tracking. The NIH is the primary agency of the United States' government responsible for biomedical and public health research.

The NIH is not in compliance with the norms on availability of reliable, comparable, transparent and sufficiently detailed data across the value chain, including the prices, units sold, costs, and subsidies and incentives, as set out by WHA resolution 72.8.

Intellectual property arising from federally funded research is dealt with by the Bayh-Dole Act. The Bayh-Dole Act is a 1980 federal law which stipulates that universities, non-profit organizations or businesses that receive federal funding can pursue ownership of an idea or product that they created rather than giving up those rights to the federal government.[220]

While there are challenges in adhering to those norms in the Bayh-Dole Act provisions that progressively limit the information a funding agency can require or disclose to the public (35 U.S.C. § 209(d)(2)), to obtain the type of information described in WHA resolution 72.8, the license has to require terms including reports on "the prices, units sold, costs and subsidies and incentives", and that the prices and units sold are reported "in different markets".[221]

On this, civil society organizations have lobbied NIH on the need for better reporting on the utilization of licensed inventions and access in developing countries.[222] As NIH routinely licenses technologies on an exclusive basis with a worldwide geographic scope, it is problematic that the NIH does not track any data on this but rather relies on pharmaceutical companies' assertions that worldwide rights are essential for them to invest in these technologies. On 8 December 2023,

218 California Health and Human Services Open Data Portal. (n.d.). Prescription Drug Wholesale Acquisition Cost Increases. https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases.

219 National Academy for State Health Policy. (2021). Prescription Drug Pricing Transparency Law Comparison Chart. https://nashp.org/state-tracker/prescription-drug-pricing-transparency-law-comparison-chart/.

220 Definition taken from Athanasia, G. (2022). The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today. Centre for Strategic and International Studies. https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today.

221 See Knowledge Ecology International. (2024). KEI letter to the NIH regarding need for better reporting on the utilization of licensed inventions and access in developing countries. https://www.keionline.org/40155.

222 Love, J. (2024). KEI Letter to the NIH regarding need for better reporting on the utilization of licensed inventions and access in developing countries. https://www.keionline.org/40155.

the National Institute of Standards and Technology (NIST) issued a Request for Information regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (88 FR 85593).[223] This is a tool to help agencies evaluate when it might be appropriate to require licensing of a patent developed with federal funding. The draft guidance will help agencies work through a range of policy considerations relevant to a potential march-in decision, including price.

The Draft Interagency Guidance Framework published by NIST included a footnote that states: "All portions of the march-in proceeding are closed to the public and are held confidential." This statement is at odds with the domestic governing statute, the regulation implementing the statute, WHA resolution 72.8, and widely accepted notions of good governance. Civil society pushed back on this language in the draft guidance. The final Interagency Guidance Framework for Considering the Exercise of March-In Rights has not yet been published.

Civil society's advocacy and litigation activities

In an effort to increase transparency at NIH and the government more broadly, civil society organizations, including Knowledge Ecology International (KEI), have engaged in advocacy as well as strategic litigation.

There are two ongoing lawsuits regarding Freedom of Information Act (FOIA) records.

One lawsuit concerned the release of Covid-19 technology-related contracts, wherein KEI filed numerous requests and then sued the Department of Health and Human Services (HHS) and the U.S. Army. In this suit, the government has produced all the Covid-19 contracts sought, and KEI is in negotiations with them regarding improperly redacted information in the contracts, such as contract amounts, government rights clauses and patent information. KEI has made the current versions of all the contracts publicly available.

The second lawsuit concerns records relating to several FOIA requests about NIH, including correspondence on the Accelerating Covid-19 Therapeutic Interventions + Vaccines (ACTIV) partnership, and former NIH Director Francis Collins' correspondence. The government has been ordered to produce the documents that are the subject of a review to assess its contracting practices, transparency, and how the information informs its approaches to other topics and negotiations, such as the pandemic treaty.

Additionally, in 2024, NIH announced that it was seeking input on a proposed policy to require that prospective licensees for its intramural research include an access plan in their agreement. The NIH published a 'Request for Information on the Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning'.[224] The policy would require organizations partnering with NIH through a patent licensing agreement, which succeed in bringing certain products to market, to submit a plan outlining steps they intend to take to promote patient access to any resulting drug, biologic, vaccine or device.

223 Federal Register. (2023). Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the.

224 National Institutes of Health. (2024). Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity in Access Planning. https://osp.od.nih.gov/request-for-information-on-draft-nih-intramural-research-program-policy-promoting-equity-in-access-planning/.

After consultation, in January 2025, NIH issued an Intramural Research Program (IRP) policy[225] to promote access to IRP-supported inventions resulting in drugs, biologics, vaccines or devices. As of 1 June 2025, organizations applying to NIH for certain commercial patent licenses will be required to also submit Access Plans outlining steps they intend to take to promote patient access to those licensed products. Once approved by NIH, those Access Plans will be incorporated into licenses granted by NIH as part of the licensee's development plan. As promoting transparency is at the core of such policy, the policy proposal suggested that, upon NIH's request, licensees would provide non-confidential versions or statements of Access Plans, to "the extent such Access Plan[s] include proprietary information", and that NIH may publish or share those versions with third parties. Unfortunately, the current US administration has decided to delay this access policy.

Medicine pricing procedure

The US healthcare system is complex, and the prescription drug component is no exception. There is no central negotiating authority, so the federal government cannot negotiate prices for any populations other than Medicaid beneficiaries and military veterans. Medicare and Medicaid are managed at the federal level by the Centers for Medicare and Medicaid Services (CMS). Medicine prices are set based on CMS' analysis of labour and resource input costs for different medical services based on recommendations by the American Medical Association. Since most Americans have health insurance, they do not directly pay for medical services. Insurance companies, as payors, negotiate healthcare pricing with providers on behalf of the insured.

In addition to drug manufacturers, the pharmacy supply chain can include wholesalers, pharmacy benefit managers (PBMs), physicians and hospitals, and retail and mail order pharmacies. The list price does not account for the additional areas that are acquired and negotiated by the PBMs.
A large disparity exists between the prices of drugs in the United States compared with other countries. The US pays more for prescription medicines than any other country.

225 National Institutes for Health. (2025). NIH Intramural Research Program Access Planning Policy. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-062.html.

Africa

South Africa

South Africa presents an interesting example of a country committed to improving access to medicines through greater transparency. The country attempts to improve transparency in relation to medicines pricing within legislative frameworks, and even at the highest level: its constitution. At the same time, it faces considerable challenges from an industry that is determined to maintain the existing disparities in access to information and therefore bargaining power.

Role in the WHA transparency resolution

South Africa's support for WHA resolution 72.8 was consistent with its pro-access agenda, as expounded in the National Drug Policy from 1996. The stance taken by South Africa would also have been informed by its own experience of litigation by the multinational pharmaceutical industry, which delayed the implementation of the legislation intended to give effect to the National Drug Policy.[226] It is also consistent with the later proposal, submitted by South Africa and India, for a waiver from certain provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to increase access to medical products against Covid-19, submitted to the WTO in 2020.[227] Although the eventual outcome of the waiver proposal was disappointing, it did underscore South Africa's diplomatic stance in relation to access to medicines.[228], [229]

Political and legislative developments

South Africa published a National Drug Policy in 1996, but this has never been revised and is now rather dated.[230], [231] South Africa's healthcare system is characterized by a stark contrast between an under-resourced and under-funded public sector catering for the majority of the

226 Pharmaceutical Manufacturers' Association v President of the Republic of South Africa. (1998). Case No. 4183/98; High Court of South Africa, Transvaal Provincial Division.

227 World Trade Organization. (2020). Waiver for Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

228 World Trade Organization. (2022). TRIPS Council welcomes MC12 TRIPS waiver decision, discusses possible extension. https://www.wto.org/english/news_e/news22_e/trip_08jul22_e.htm.

229 Health Justice Initiative. (2023). TRIPS Waiver Negotiations. https://healthjusticeinitiative.org.za/2023/09/28/trips-waiver-negotiations/#:~:text=On%2017%20June%202022%2C%20the,the%20face'%20for%20poor%20countries.

230 Government of South Africa. (1996). National Drug Policy for South Africa. https://www.gov.za/sites/default/files/gcis_document/201409/drugpol0.pdf.

231 Gray AL, Suleman F. (2024). Unpacking the process of developing South Africa's National Drug Policy - lessons for universal health coverage. Journal of Pharmaceutical Policy and Practice. Vol. 17 Issue 1.

population, and an expensive private sector catering for the minority, who are covered by private health insurance through medical schemes. Currently, less than 15% of the population are members or beneficiaries of medical schemes. Nonetheless, a proportion of the uninsured population purchases health services out of pocket from private sector providers, including pharmacies.

South Africa's 1996 national medicines policy included, as an economic objective, "lower[ing] the cost of drugs in both the private and public sectors." This was intended to be achieved "by monitoring and negotiating drug prices and by rationalizing the drug pricing system in the public and private sectors, and by promoting the use of generic drugs." However, while supporting the continued reliance on limited competitive bidding (tender) in the public sector, the policy focused to a far greater extent on the proposed intervention in the pricing of medicines in the private sector. The policy contained an unequivocal commitment to transparency, stating: "There will be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals."

The pricing intervention was addressed in national legislation passed in 1997, but only came into effect in 2004. Some elements were delayed by further litigation brought by private pharmacy groups, which were only resolved by the Constitutional Court in 2005.[232] A non-discriminatory single exit price (SEP) was introduced in the private sector, being the price paid by any final dispenser (pharmacy or licensed dispensing practitioner), regardless of the volume purchased. This means that no matter where a patient lives in the country or where they buy their medicines, they pay the same price for the medicine, with the exception of additional dispensing fees. The initial SEP was a cost-neutral effort, reflecting the weighted average of all discounts and rebates paid by manufacturers in the year before its introduction.[233] However, there is no transparency regarding the determination of the launch SEP. Each year, a maximum SEP adjustment is determined by the Minister of Health, on the recommendation of the Pricing Committee. The SEP also includes an undisclosed logistics fee paid to wholesalers and distributors.[234] While it is welcome that the declared SEPs are made publicly accessible [235] and are reflected in any invoice issued by a private sector provider, the fact remains that the SEP provisions do not meet the standard set by the WHO Guideline on Country Pharmaceutical Pricing Policies.[236] The SEP does not make "all prices along the supply and distribution chain" entirely transparent. More tellingly, it makes no attempt to disclose "financial contributions to the research and development (R&D) of products", whether from private or public sources.

Intrinsic to the design of the SEP intervention was a ban on any "bonus system, rebate system or any other incentive scheme" as well as a ban on sampling. However, despite having published draft regulations in this regard, the South African authorities have not managed to clearly designate

232 Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others [2005] ZACC 14. http://collections.concourt.org.za/bitstream/handle/20.500.12144/2222/Full%20judgment%20%282%20Mb%29-4786.pdf?sequence=11&isAllowed=y.

233 Suleman, F., Gray, A. (2017). Pharmaceutical Policies in South Africa. Pharmaceutical Policy in Countries with Developing Healthcare Systems. 285-302.

234 Bangalee, V., Suleman, F. (2018). Is there transparency in the pricing of medicines in the South African private sector? South African Medical Journal. 108 (2).

235 South Africa Department of Health. (n.d.). Pharmaceutical Economic Evaluation. https://www.health.gov.za/nhi-pee/.

236 World Health Organization. (2021). Promoting price transparency. WHO Guideline on Country Pharmaceutical Pricing Policies: A plain language summary. https://iris.who.int/bitstream/handle/10665/341898/9789240024632-eng.pdf.

what would be considered unacceptable marketing practices.[237] The WHO guideline recommendation that "pricing arrangements between companies and purchasers" should be transparent is therefore not sufficiently enforced in South Africa.[238]

No medicine pricing legislative changes have been made in South Africa since the adoption of WHA resolution 72.8. However, in one key regard, a court challenge has been successful in applying a key component of South Africa's Constitution.[239] Section 217 of the Constitution states: "When an organ of state in the national, provincial or local sphere of government, or any other institution identified in national legislation, contracts for goods or services, it must do so in accordance with a system which is fair, equitable, transparent, competitive and cost-effective." Like many countries, South Africa was coerced into signing non-disclosure agreements with Covid-19 vaccine manufacturers during the pandemic. In 2023, the High Court ruled on an application submitted by a non-governmental organization, Health Justice Initiative.[240] The court ordered that all Covid-19 vaccine contracts and negotiation-related documents be made public, in accordance with the constitutional obligation. The National Department of Health complied with the court order, allowing scrutiny of the prices paid and the conditions agreed to with vaccine suppliers. All other medicine prices paid by the state are routinely made public as the requests for tender and all tender awards are published on the website of the National Department of Health.[241]

There is, however, a growing concern about an area of medicine pricing that has not been addressed. South Africa's medicines law allows for individual patients to gain access to unregistered medicines required for an unmet clinical need. The same provision – section 21 of the Medicines and Related Substances Act, 1965 – is relied upon by the public sector when dealing with medicine shortages. Section 21 can also be invoked in managing a public health emergency. However, there is no mechanism for making the prices paid by individual patients visible to the public, including to other patients and their clinicians.[242] In 2024, the South African Competition Commission closed an investigation into the supply of treatments for cystic fibrosis, accepting that arrangements for supply had been secured.[243] The price to be charged by the supplier, Vertex Pharmaceuticals, was undisclosed, as the medicines in question had not been registered by the South African Health Products Regulatory Authority (SAHPRA) and no SEP could be applied. Individual patients and their insurers would have to rely on section 21 for approval to gain access, but no arrangement had been made for patients who are dependent on the public sector.

237 Minister of Health. (2014, 22 August). Medicines and Related Substances Act. General regulations relating to bonusing and sampling. Government Notice No. R.642. Government Gazette No. 37936.

238 Gray, A., Suleman, F., Pharasi, B. (2017). The National Drug Policy – 20 years and still going? South African Health Review 2017, 49-58. Health Systems Trust, Durban.

239 Constitutional Court of South Africa. (n.d.). The Constitution. https://www.concourt.org.za/index.php/constitution/the-text.

240 Health Justice Initiative v The Minister of Health and Information Officer, National Department of Health (Case No 10009/22). https://healthjusticeinitiative.org.za/2023/08/30/judgment-on-contract-transparency-in-the-public-procurement-of-covid-19-vaccines/.

241 South Africa Department of Health. (n.d.). Tenders. https://www.health.gov.za/tenders/.

242 Suleman, F., Jama, N., Meyer, S., Gray, A. (2023). Stakeholder perceptions of issues and possible solutions to access to oncology medicines – a case study of multi-stakeholder engagement. South African Health Review 2023: strengthening cancer services. Health Systems Trust, Durban.

243 Competition Commission South Africa. (2024). Access to Cystic Fibrosis Medication in South Africa Secured. https://www.compcom.co.za/wp-content/uploads/2024/12/Access-to-cystic-fibrosis-medication-in-South-Africa-secured.pdf.

Medicine pricing procedure

The current situation in South Africa can therefore be summarized as follows:

- all prices paid in the public sector are disclosed publicly and posted on the National Department of Health website;
- the constitutional obligation to make all public sector procurement transparent has been confirmed by the courts;
- although the SEPs charged in the private sector are similarly made public and posted on the National Department of Health website, there are concerns that undisclosed discounts and rebates are still being paid, despite existing legislative provisions; and
- section 21 of the Medicines and Related Substances Act provides a loophole to avoid making private sector prices transparent.

Other elements of WHA resolution 72.8 are covered to some extent, but not yet comprehensively. While SAHPRA has an online register of medicines, there is no publicly accessible source of data on sales revenues and units sold, let alone on marketing costs.[244] Tracking the patent status of medicines is also not easy, although the Companies and Intellectual Property Commission (CIPC) does provide a free search function.[245]

South Africa has embarked on comprehensive health systems reform in order to advance universal health coverage (UHC).[246] There are wide-ranging changes envisaged in relation to the development of benefit packages under National Health Insurance (NHI), the development of treatment guidelines and formularies, the application of health technology assessment (HTA), and the determination of prices for medicines and other health technologies. Existing efforts to improve the transparency of medicine selection processes are already making progress, and elements of HTA are already deployed.[247],[248] A comprehensive revision of the current medicines legislation is underway, though not intended to address the pricing component.

244 SAHRPA. (n.d.). Registered Health Products Database. https://medapps.sahpra.org.za:6006/.

245 CIPC Intellectual Property Online. (n.d.). https://iponline.cipc.co.za.

246 Republic of South Africa. (2023). National Health Insurance Act (Act 20 of 2023).

247 South Africa Department of Health. (n.d.). Essential Drugs Programme. https://www.health.gov.za/nhi-hpp-edp/.

248 Wilkinson, M., Gray, A. et al. (2022). Health technology assessment in support of National Health Insurance in South Africa. International Journal of Technology Assessment in Health Care. Vol 38, Issue 1.

Conclusion

Since the adoption of WHA resolution 72.8, 'Improving the transparency of markets for medicines, vaccines, and other health products', two countries have adopted specific legislation seeking to increase transparency. France requires pharmaceutical companies to declare public investments that have received and benefited from the R&D of medicinal products to the Economic Committee for Health Products (CEPS). Italy requests pharmaceutical companies to compile a dossier containing public contributions and incentives acquired for the R&D of the medicine.[249]

Disclosing the extent of public investment in the R&D of medicines and other health products is an effective way to prevent excessive profits as it allows overall costs to be assessed independently, rather than merely relying on industry estimates. In addition, making information on public investment available to the public could also prevent the public from paying twice for the same drug, first for the public investment in R&D and then for the high prices.[250] Although France and Italy were pioneers in this area, they still lag behind in the concrete implementation of their legislation.

Although some WHO Member States have not taken steps to enact legislation explicitly following WHA resolution 72.8, other pathways may contribute to increasing transparency, including on net prices of medicines.

In Spain, for example, civil society groups and coalitions play an increasingly important role in requesting greater transparency through Spain's newly created Transparency Council. Officials from the Ministry of Health have also increasingly called for more transparency, specifically in R&D and production costs of medicines.

Following a motion in parliament, the Dutch government was requested to determine whether it is possible to oblige pharmaceutical companies to be transparent about medicine costs and profits. This would answer the question of whether and how the government can adapt its legislative instrument.

In Belgium, the number of confidential entry management agreements has raised concerns. The payer and several political parties are trying to enhance greater transparency through roadmaps and legislative proposals, but these efforts are coming up against strong lobbying from the industry.

Some countries are joining forces through various voluntary initiatives that pave the way for greater transparency and further collaboration on prices, such as the Valletta Declaration Group and Beneluxa.

Despite the variety of steps towards more transparency being taken in many European countries, some are moving in the opposite direction. In Switzerland and Germany, there is pending or new legislation safeguarding secrecy and opacity of drug prices and managed entry agreements.

In the US, several states have passed drug transparency laws. However, despite the formal support for WHA resolution 72.8, an active civil

249 Presidenza del Consiglio dei Ministri. (2022). Disposizioni in materia di trasparenza dei rapporti tra le imprese produttrici, i soggetti che operano nel settore della salute e le organizzazioni sanitarie. https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2022;62.

250 World Health Organization. (2022). What are the implications of policies increasing transparency of prices paid for pharmaceuticals?. https://iris.who.int/bitstream/handle/10665/354271/Policy-brief-45-1997-8073-eng.pdf?sequence=2.

society on the issue and an access policy proposed by the National Institutes of Health (NIH), the federal government lags behind in successfully implementing greater price transparency.

In South America, countries have expressed strong interest in greater transparency, with both Colombia and Chile having sought to promote transparency in medicine pricing and reimbursement, with mixed success.

Brazil is a good example in terms of transparency implementation, despite pressure from the industry. For the time being, its disclosure policy is beneficial both for patients and neighbouring countries that use external reference pricing.

Finally, South Africa serves as a point of reference with the inclusion of price transparency for public sector procurement in its constitution.

Overall, six years after the adoption of WHA resolution 72.8, WHO Member States and other relevant parties have not done enough to sufficiently see the impact of greater transparency in the markets for medical products. Countries consistently ignored the transparency norms set out in the resolution during the ongoing negotiations for a WHO pandemic agreement, despite repeated calls from civil society.

Even if a few countries are taking some positive steps at the national level, concerted actions as well as strong political and financial support are needed both at European and global levels. All countries must ensure effective cooperation and data sharing.

The current lack of global coordination and effective implementation is hampering progress towards greater transparency. Global action requires the creation of harmonized standards and mechanisms to report and disclose information on biomedical R&D costs, units sold, sales revenue and net prices by country. This includes tools and mechanisms that can be adapted at the national level.

Enhanced transparency must be at the core of future global, regional and national policies and public interventions aimed at ensuring more affordable and equitable access to medicines and other health technologies. Transparency enables lower prices to be set, which has a positive impact on public health budgets.

In the absence of transparency, public accountability for public funding is significantly undermined. The current lack of transparency surrounding pharmaceutical markets must be addressed at the highest political levels. The pharmaceutical sector should not be an exception to the rule of good governance. All governments should consider taking national action to mandate increased information disclosure from an industry whose decisions have life-or-death consequences.

Recommendations

Improving transparency in the pharmaceutical system requires legal, contractual and policy changes, including a high level of national and global political commitment, coordination and cooperation. Many players have a role to play, and several approaches are possible. The recommendations below indicate possible steps to contribute towards greater transparency.

WHO Member States

- Implement legislation at the national and regional levels that will ensure greater transparency of costs and prices for medicines across the entire pharmaceutical value chain.
- Mandate the disclosure of R&D investments and any rebates and discounts at the point of reimbursement.
- Mandate the disclosure of any market entry agreement and the terms of that agreement when a medicine is purchased through such agreements.
- Implement legislation to improve the transparency of public investments and funding in R&D and associated public expenditures, drawing from examples of national legislation in France and Italy (both in terms of implementation and gaps).
- Similar to the bills proposed in Spain and the European Parliament, demand transparency on R&D costs through aggregated data.
- Review (or actively contribute to) national legal, administrative and regulatory frameworks governing access to data about prices, costs, clinical data and health technology assessments. This will ensure better informed price negotiations and provide relevant information for patients.
- Ensure that medicine selection procedures such as benefit packages, formulary or reimbursement rule design are open to public scrutiny, transparent on the evidence they are based on and allow for public engagement.
- Recognize that confidential (secrecy) price agreements with pharmaceutical manufacturers go against the interests of public health and good governance.
- Build on the example of South Africa which has enshrined transparency in its constitution: public contracts must be transparent and prices must be revealed, even after a price agreement has been signed.
- Target excessively high prices and condemn infringements linked to anticompetitive practices such as the misuse and abuse of IP protection tools, in accordance with competition law and human rights treaties.
- Implement a monitoring and surveillance system to intervene when there are excessive prices and/or anticompetitive behaviours.
- Foster collaboration among public procurers and payers to share their data and publish it in a consolidated manner to inform the public.
- Strengthen capacity and invest in human resources and technology related to the determination of price publication and cost data, as well as information dissemination.
- Use the information obtained through transparency to apply a calculation model to determine the part of public share and a fair price.

WHO

- Support Member States to design and implement national legislation and accompanying policies fostering transparency.
- Facilitate dialogue amongst stakeholders and provide the necessary user-friendly and easily accessible tools and platforms to exchange and collaborate further at the global level.
- Ensure Member States continue to report on progress made to the World Health Assembly.

Civil society organizations

- Actively monitor and support positive steps taken by policymakers and lawmakers to move towards greater transparency.
- Raise awareness of transparency issues and ensure democratic oversight, including citizen access to public spending data.
- Engage with all relevant stakeholders, including governments and the pharmaceutical industry, to foster dialogue and exchange best practices.
- Use litigation if necessary to enforce compliance with the law on public access to data.

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