Oslo Medicines Initiative

Established in 2020, the Oslo Medicines Initiative (OMI) is a collaboration between the WHO Regional Office for Europe, the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency. The OMI aims to provide a neutral 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.

In line with the Regional Office’s European Programme of Work 2020–2025 – “United Action for Better Health”, equitable and sustainable access to quality medicines is critical for universal health coverage and for achieving the Sustainable Development Goals. The OMI provides a strong focus on equity and on leaving no one behind, and is underpinned by three pillars; solidarity, transparency and sustainability.

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 World Health Assembly resolutions, in particular, resolution WHA72.8 on improving the transparency of markets for medicines, vaccines, and other health products.
ACCESS TO INFORMATION IN MARKETS FOR MEDICINES IN THE WHO EUROPEAN REGION

OSLO MEDICINES INITIATIVE TECHNICAL REPORT

Sabine Vogler
Abstract

Transparency is important for good governance and evidence-informed policy-making for access to medicines. Based on a document review and validation of findings by national authorities, this report examines whether the public authorities, and in some cases, the public in Member States in the WHO European Region can access information about medicine prices, R&D costs and results, volumes, patent status and marketing authorization status, as outlined in World Health Assembly resolution WHA72.8 of 2019 on improving the transparency of markets for medicines, vaccines, and other health products. Across the 48 countries studied, high transparency exists for marketing authorization status and, in several countries, for list prices and volume data. Transparency was low for net prices, input costs, patent expiry dates and clinical trial results and costs. Measures to improve transparency in these areas were also identified. Price regulation, capacity-building and collaboration between public authorities were identified as key to improving transparency, and thus to informing decision-making to ensure sustainable access to medicines.

Keywords

TRANSPARENCY, WORLD HEALTH ASSEMBLY RESOLUTION WHA72.8, MEDICINES PRICES, ACCESS TO INFORMATION, ACCESS TO DATA, PATENTS, R&D


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Suggested citation: Vogler S. Access to information in markets for medicines in the WHO European Region. Oslo Medicines Initiative technical report. Copenhagen: WHO Regional Office for Europe; 2022. Licence: CC BY-NC-SA 3.0 IGO.

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Designed by: Imprimerie Centrale Luxembourg
Acknowledgements

This report was authored by Sabine Vogler (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmacoeconomics Department, Gesundheit Österreich [Austrian National Public Health Institute]).

The WHO Regional Office for Europe is grateful to Dimitra Panteli (European Observatory on Health Systems and Policies) and Zaheer-Ud-Din Babar (Department of Pharmacy, University of Huddersfield) for their review and feedback on the draft report.

The author would like to thank members of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network of competent authorities, who validated country-specific findings about access to information, which are reported in an accompanying web-annex.

The author is also grateful to Manuel Alexander Haasis and Katharina Habimana (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmacoeconomics Department, Gesundheit Österreich [Austrian National Public Health Institute]) for their collaboration in developing the study protocol and to Katharina Habimana for contributing to the development of Fig. 1. The author would like to also thank Marcela Vieira (Global Health Centre, Graduate Institute of International and Development Studies) for her comments on the study protocol. Valentin Kandler and Yuliya Pashkevych (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmacoeconomics Department, Gesundheit Österreich [Austrian National Public Health Institute]) are also gratefully acknowledged for their support in reviewing data sources used for this report.

The WHO Regional Office for Europe produced and managed the development and editorial process for this series of Oslo Medicines Initiative (OMI) technical reports. Sarah Garner, Krista Kruja, Rachelle Harris, Stanislav Kniazkov, Govin Permanand, Natasha Azzopardi Muscat and Rachael Crockett of the Regional Office, listed in order of contribution level, conceptualized and strategically developed this report and provided inputs regarding the revision of various drafts.

This publication was developed as part of the OMI. This report was produced with the financial support of the Norwegian Ministry of Health and Care Services, which has contributed to this series of technical reports through funding for the OMI.
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIM</td>
<td>International Association of Mutual Benefit Societies</td>
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<tr>
<td>ATC</td>
<td>Anatomic, Therapeutic and Chemical classification system</td>
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<tr>
<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<tr>
<td>ERP</td>
<td>external reference pricing</td>
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<td>EU</td>
<td>European Union</td>
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<td>EURIPID</td>
<td>European Integrated Price Information Database</td>
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<td>MEA</td>
<td>managed entry agreement</td>
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<td>OMI</td>
<td>Oslo Medicines Initiative</td>
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<td>Pat-INFORMED</td>
<td>Patent Information Initiative for Medicines</td>
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<tr>
<td>PPRI</td>
<td>Pharmaceutical Pricing and Reimbursement Information [network]</td>
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<tr>
<td>R&amp;D</td>
<td>research and development</td>
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Executive summary

Background

In 2019, the Seventy-second World Health Assembly endorsed resolution WHA72.8 on improving the transparency of markets for medicines, vaccines, and other health products, which called on Member States to:

- take appropriate measures to publicly share information on net prices (the amount received by manufacturers after subtraction of all rebates, discounts and other incentives);
- take the necessary steps to support dissemination and enhance availability of costs of clinical trials and their results, regardless of outcomes;
- work collaboratively to improve reporting by suppliers, such as on cost inputs, sales revenues, subsidies and incentives; and
- facilitate public reporting of the patent and marketing authorization status of health products.

Objectives and approach

Limited information is available about the extent of data accessibility in the areas listed above. This Oslo Medicines Initiative technical report maps whether the general public – or at least public authorities – in Member States in the WHO European Region can access such information.

In May and June 2021, relevant data sources from national regulatory authorities, public payers, patent offices, and pricing and reimbursement authorities were reviewed for 48 of the 53 countries in the Region to examine whether the relevant information was accessible, and by whom. The literature was also searched to identify whether governments had taken action to improve transparency. Country-specific fact sheets (in English and in Russian) reporting the findings in detail were shared with the national authorities for validation.

Findings and policy considerations

Across the 48 countries studied, high transparency exists for market authorization status and, in several countries, for list prices and volume data.

- **Marketing authorization status** information is publicly accessible in all countries through marketing authorization registers. These registers contain information
about whether a medicine has been authorized. In some countries they also include the date of authorization and information on commercialization status (whether the medicine has been launched on the national market or has been withdrawn).

- **List prices** are usually publicly accessible – at least for medicines that are publicly funded. Information about list prices is, however, lacking in countries with no price regulation, such as some countries in central Asia.

- **Volume and sales data** are publicly accessible in several countries, although sometimes only for publicly funded medicines. In some countries public authorities have established reporting systems (such as interactive websites and publication of annual reports) to share the data with the public – usually at an aggregated level. In a few countries, however (particularly those with a fragmented health-care system and those without a reimbursement system), no aggregated data on medicines consumed and sold are accessible – including for publicly-funded medicines. The lack of access to these data by policy-makers hinders decision-making and diminishes negotiating power.

Low transparency was identified for net prices, patent expiry dates, clinical trial results and costs, and input costs. Some measures to improve transparency in line with resolution WHA72.8 were also identified.

- When public payers conclude a confidential agreement to manage the entry of medicines with high price tags and limited evidence to the publicly-funded health system, information on the negotiated discounts and resulting **net prices** is usually not accessible for any external parties. Authorities may ask manufacturers to provide information on net prices in other countries as part of their application for funding, but this is done in very few countries.

- While most countries in the WHO European Region have a publicly accessible patent register, for medicines which carry several patents, various dates may be listed, making **patent expiration dates** – when a medicine will become off-patent – difficult to decipher.

- Most countries in the Region in which clinical trials are conducted have a national publicly accessible clinical trials register that provides general information about the trials but rarely report **clinical trial results**. While some results are published, there is publication bias when it comes to negative results. An important measure for European Union (EU) member states was the launch of the EU Clinical Trials Information System, based on the EU Clinical Trials Regulation (Regulation (EU) No. 536/2014), which aims to increase transparency of clinical trials information.

- **Research and development (R&D), production and marketing costs** are also very opaque, including the share of public funding involved. Costs for clinical trials and further R&D-related activities conducted by pharmaceutical companies are not publicly accessible in any country in the Region; nor are input cost data for R&D per medicine accessible to governments. In a few countries authorities require these data from the companies as background information for pricing and reimbursement decisions.
Transparency is important for good governance and accountability, and to support evidence-based policy-making. For instance, **harnessing generic and biosimilar competition** requires access to patent expiry dates of the originator medicines to facilitate preparation and implementation of generic and biosimilar policies.

Transparency can also support **pricing policies**. Both cost-based and value-based pricing approaches need data: clinical outcome data are required for value-based pricing policies, and R&D and further input cost data are needed for cost-based pricing policies. Countries applying external reference pricing – which determines prices based on the price of that medicine in other countries – risk overpaying, since the policies relate to **list prices** rather than actual prices after any discounts.

Limited transparency can be detrimental to **effective policy decision-making**. For example, price data may be required to determine the reimbursement amount, or aggregate volume data may be needed to assess the budget impact of publicly funded medicines. The mapping exercise conducted for this report demonstrated varying access to information across countries. Lower-income countries in the Region and those with less mature pharmaceutical regulation and policy frameworks tend to have lower levels of access to information. Policy-makers might consider the following conclusions and approaches to improve transparency in the pharmaceutical sector.

- **Transparency is not binary – varying degrees of transparency are possible.** Even if full transparency to the public is currently not feasible for some elements mentioned in resolution WHA72.8, partial accessibility – for example, among public authorities for some dimensions – can be achieved to support more informed health policies.

- **Publication of list prices is enabled by price regulation.** Where price regulation exists, the list prices are uniform across a country. Without price regulation, list prices – which are set by pharmaceutical companies and distributors – vary for the same medicine across pharmacies in a country. Countries without price regulation have limited access to list prices: even public authorities lack this information.

- **Approaches may be available to public authorities to address information gaps presented by list prices.** When authorities reference other countries’ prices to set their own, they could take into account officially published statutory discounts, or they could oblige manufacturers to provide net price information. Enforcing and validating these actions is challenging.

- **Health system strengthening and capacity building are needed, as is collaboration between public authorities.** In some cases, limited transparency could be addressed if public sector bodies (such as public procurers and payers) in the outpatient and hospital sectors and from different ministries (including ministries of health and finance) worked together more closely to generate and share data needed by other public authorities.
Introduction

Equitable and sustainable access to safe, effective, affordable and quality-assured medicines and health products is critical to achieving universal health coverage and the Sustainable Development Goals – in particular, target 3.8.1 (1). WHO Member States, including high-income countries, have increasingly expressed concern that the high prices of some medicines hinder access (2–4). In addition to demonstrated high-value medicines being high-priced, those with limited evidence of therapeutic value may also be high-priced. While recognizing that the pharmaceutical sector is a for-profit industry that accrues risks for research and development (R&D), evidence increasingly shows that the prices of innovative medicines substantially exceed the R&D costs (5). Transparency about the extent of investment in medicines R&D and supply is lacking (6,7); this hinders understanding of whether prices are justified, and erodes trust (8).

Public authorities’ limited knowledge of the costs incurred by the industry for development of a specific medicine is exacerbated by missing information on further input costs – such as production costs – of pharmaceutical companies and revenues received, including tax incentives and sales data. Overall estimates of R&D costs exist, with variable findings (6,7,9–11), but product-specific information – which public authorities need to make decisions about requests for pricing and reimbursement – is lacking.

Limited transparency also results from the common practice of payers and pharmaceutical companies agreeing to keep negotiated net prices confidential. For example, a company may offer a payer a discount on the list price for a medicine on the condition that the discount and resulting net price paid will be kept confidential (12–19). This creates information asymmetries and an imbalance in negotiating power, since a company will know the net prices across countries for their products, while public payers will not (20).

Many countries apply external reference pricing (ERP), in which medicine prices are set based on their prices in other reference countries (21). With ERP, health authorities refer to official list prices in the reference countries, but these are often higher than the confidential net prices the reference countries have negotiated (22). As a result, payers are incentivized to negotiate confidential deals (20). The practice of ERP also incentivizes companies to launch medicines strategically in markets where prices are likely to be highest, leading to negative spill-over effects, such as delayed access to medicines for lower-income countries (23–27).

Recently, industry stakeholders have taken steps to address these delays in access. In spring 2022, the European Federation of Pharmaceutical Industries and Associations (EFPIA) pledged that its members would file pricing and reimbursement applications for European Union (EU) authorized medicines in all 27 EU member states within two years of being granted EU marketing authorization. To support this objective, the EFPIA also set out plans to create the European Access Portal. This would enable marketing authorization holders for innovative medicines or biosimilars to provide information voluntarily about
the status of pricing and reimbursement applications in various EU countries. They could thus set out any reasons a marketing authorization holder had not filed in a particular market, or explain a delay in pricing and reimbursement decisions (28). The Portal is expected to improve transparency of the root causes of unavailability and delays to medicines entering the market to enable solutions to be identified and implemented jointly by government and industry stakeholders. The EFPIA plans to disclose information from the Portal via six-monthly publications at the aggregated or therapeutic level, but it is not yet clear whether data from the Portal will be publicly accessible.

Transparency is important for good governance and accountability, and for building trust. Access to information is also crucial for ensuring evidence-based decision-making. Additional examples that highlight the need for data in pricing decisions include the following.

- Assessing the value of a potentially innovative medicine relies on an understanding of its (added) therapeutic benefit. All clinical trial results, including negative ones, and other evidence – such as post-marketing real-world data – are relevant to informing pricing and reimbursement decisions.

- Cost input factors – including R&D and production costs and marketing expenses – are instructive background information that public authorities can consider in their appraisals of pricing and reimbursement requests from pharmaceutical companies, as they contextualize the data provided.

- To optimize policies in the off-patent sector, knowledge of patent expiry of originator medicines and subsequent launch of generic and biosimilar medicines allows public authorities to plan appropriate implementation measures. These might include building clusters of medicines and creating educational measures for doctors to inform them about upcoming opportunities to switch to biosimilar medicines, for instance.

- Authorities need to have the capacity to generate reliable information on current and expected volumes (such as the number of patients) to be able to estimate the future budget impact of a medicine.

On 28 May 2019, the Seventy-second World Health Assembly endorsed resolution WHA72.8 on improving the transparency of markets for medicines, vaccines, and other health products (29). This resolution urges Member States to take appropriate measures to publicly share information on the net prices of health products and to support dissemination of clinical trial costs and results, regardless of their outcomes. In addition, it calls for public reporting of patent status and marketing authorization status of health products to be facilitated, and requests improved reporting of information by suppliers on registered medicines – such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives. Fig. 1 visualizes the four main areas of information for which greater transparency is requested.
Fig. 1. The four areas in which resolution WHA72.8 requests greater transparency

Resolution WHA72.8 urges improved transparency on:

- Net prices
- Results and costs of clinical trials
- Supplier information (sales, revenues, prices, units sold, marketing costs, investments and subsidies)
- Patent status and marketing approval status

To date, little information is available about which countries have improved transparency in these areas, and to what extent. This report sets out to start closing the gap on what has been done to date.
Methods

This Oslo Medicines Initiative (OMI) technical report presents the results of a study that reviewed whether information related to medicines as outlined in resolution WHA72.8 is accessible by the public – or at least by public authorities – in countries in the WHO European Region. In cases of full or partial accessibility, the scope of the accessible data (including possible gaps and limitations, as well as prerequisites) was explored.

2.1 Scope of the study

Resolution WHA72.8 of 2019 relates to health products, which include “medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies” (29). The mapping exercise for this study was conducted for medicines – no specific investigation was undertaken for vaccines. Other health technologies were outside the scope of this study.

The study focused on information about the four main areas for which resolution WHA72.8 requests greater transparency (see Fig. 1). It expanded these areas into the following four strands, which formed the outline of the data collection exercise.

- Strand 1: access to data on medicine prices – this included all medicine price data, mapping not only the net prices and price data provided by suppliers set out in resolution WHA72.8 but also official list prices, which were not mentioned in the resolution.
- Strand 2: access to data on R&D – this included not only the results and costs of clinical trials set out in resolution WHA72.8 but also R&D costs in general, which were not mentioned in the resolution.
- Strand 3: access to data other than price information from suppliers – this included volume and sales data, aggregated at the country level, since (list) price information provided by suppliers is covered in strand 1. As the resolution only relates to suppliers (manufacturers) and does not include the supply chain (for example, possible discounts among distributors), the supply chain is outside the scope of this study.
- Strand 4: access to data on regulatory information – this included information on patent status and marketing authorization status.

In addition, the study identified measures to implement the resolution and improve transparency in the areas listed.
2.2 Data collection and validation

In May and June 2021, relevant data sources (from national regulatory authorities, public payers, patent offices, and pricing and reimbursement authorities) for countries in the Region were reviewed to examine whether the relevant information was accessible, and by whom. The literature was also searched to identify measures and approaches taken by governments to contribute to improved transparency, as envisaged by the resolution.

The study author developed a template for country-specific fact sheets. For each country, the extent of accessibility of the defined elements was examined through a search of main websites and literature. Key data sources included the websites of medicines agencies, ministries of health, national health services, social health insurance funds and public health institutes. A targeted literature review was also conducted to identify measures to improve transparency.

The findings were used to populate fact sheets in English, reporting the findings in detail. For some eastern European and central Asian countries the fact sheets were translated into Russian to support validation. These fact sheets are available in the web-annex.

In June 2021, the completed fact sheets were validated by public authorities for pharmaceutical pricing and reimbursement that were also members of the Pharmaceutical Pricing and Reimbursement Information (PPRI) networks. Government officials were tasked with validation, clarification of open issues and completion of the forms in cases of missing information. At the time of the validation exercise, the PPRI network comprised public authorities responsible for pharmaceutical pricing and reimbursement in 52 countries or areas, including 43 Member States of the WHO European Region; five additional countries were reached through the PPRI eastern Europe and central Asia network. Of the 53 countries in the Region, 48 were contacted to validate data; five countries which were not members of PPRI networks (Andorra, Bosnia and Herzegovina, Monaco, Montenegro and San Marino) were not included in the fact sheets since data regarding public authorities’ access to information would not be feasible to verify in a manner consistent with included countries. In July 2022, all included countries were contacted once again to validate the data in their country fact sheets as presented in the web-annex.

The fact sheets were validated by 33 countries in at least one of the validation rounds (19 countries were validated twice), although not all requested information could be confirmed or provided. In cases of a lack of clarity or differences in understanding between the author and the country representatives that could not be resolved through follow-up conversations, the author decided which information to include and how to present it.

1 Albania, Armenia, Austria, Belarus, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, North Macedonia, Norway, Poland, Portugal, Republic of Moldova, Romania, Russian Federation, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom
2 Azerbaijan, Georgia, Tajikistan, Turkmenistan, Uzbekistan
Results

The findings of the mapping exercise relate to 48 countries in the WHO European Region: Albania, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, North Macedonia, Norway, Poland, Portugal, Republic of Moldova, Romania, Russian Federation, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tajikistan, Türkiye, Turkmenistan, Ukraine, the United Kingdom and Uzbekistan. This section summarizes the key findings; the full country fact sheets, which also list data sources for the information identified, are provided in the web-annex.

3.1 Information on medicines prices

3.1.1 Access to list prices

In most countries in the WHO European Region (42 of the 48 included countries) official price data are – at least in part – publicly accessible (see Fig. 2). Public accessibility relates to the official list prices: the ex-factory/manufacturer price, wholesale price and/or pharmacy retail price, with or without value-added tax. The scope of the price types published varies across countries, however. For instance, all price types are reported in accessible data sources in very few countries (including Hungary), whereas only one or two price types (typically the ex-factory price and the pharmacy retail price) are published in several other countries. Another price type that is frequently published, as stipulated by public procurement regulations, is the procurement/tender price. The procurement price is typically published as part of the contract award note; it usually presents the total value of the procurement contract but does not set out the price per unit of the medicine.

In particular, EU member states tend to have high public accessibility of list prices – at least for reimbursed medicines. This is attributable to the EU Transparency Directive 89/105/EC of 1989 (33), which obliges Member States to publish the prices of medicines included in national health systems. It does not, however, specify any details – for example, which price type should be published, the form or conditions of publication or the sector (whether the hospital sector is also included, for instance).

In six countries, primarily in central Asia, list prices are not publicly available and in a few of these cases, prices are not even known to the public authorities. This results from a lack of price regulation: the manufacturers or distributors determine the prices, which frequently differ across pharmacies and dispensaries within the country. This can pose challenges for medicine reimbursement and can lead to inequitable prices across the country. For example, in Kyrgyzstan a lack of price regulation complicates reimbursement-processes (34). Public authorities have limited knowledge of prices. This limits their ability to set reimbursement prices (which represent a defined fraction of the wholesale price), and they
depend on wholesalers to provide this information. Additionally, public authorities can only gather retail price information through onsite price surveys. Reports also indicated that medicine prices were higher in pharmacies in remote areas than in chain pharmacies in urban areas.

Access to list prices may be limited for the public as a result of subscription fees for medicine price databases, which are typically maintained by private providers. This is the case in Germany, for instance, where access to price data is only possible for a fee, except for defined health care professionals. In Austria, reimbursement prices of medicines used in the outpatient sector are made publicly accessible by the social health insurance fund, but to gain a complete picture of all price types of most medicines marketed in Austria a subscription fee is required to access a database managed by the Publication House of the Austrian Chamber of Pharmacists.

It is possible to indirectly access price types that are not published if the add-ons for distributors in the supply chain – such as wholesale and pharmacy mark-ups – are regulated (for example, through linear mark-ups or a regressive margin scheme). For instance, if the pharmacy retail price is published, a statutory wholesale and pharmacy mark-up scheme facilitates calculation of the wholesale and ex-factory price. The ex-factory price is not known even by the pricing authority (30) in some countries in the Region (including Denmark, Finland, the Netherlands, Sweden and the United Kingdom) where prices are set at the wholesale price level and the ex-factory price is negotiated on commercial terms between the manufacturer and the wholesaler.

Notes: Data are partly accessible in Austria, where apart from the reimbursement prices in the outpatient sector published by the social health insurance fund, the other list price types (including the ex-factory price) are only accessible for a fee; in Germany, where access to a price database is only available free of charge to defined health professionals, while third parties pay a fee for access; and in Malta, where no list of medicine prices is publicly accessible, but some price data are published from time to time on the Malta Competition and Consumer Affairs website (for example, following a reduction in price). Data were not publicly accessible in Kyrgyzstan, which had no accessible list price at the time of the validation exercise, but reform of publication of list prices was ongoing.
3.1.2 Access to net prices

Resolution WHA72.8 of 2019 calls on WHO Member States to take appropriate measures to share information publicly on net prices. It defines these as “the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives” (29).

One of the reasons for this call to improve transparency of net prices is the growing controversy over “secret deals”. These have increasingly been concluded for some medicines with high price tags and possibly low evidence on their (added) therapeutic value (2,35–37), in countries in the Region and globally (14–17,19,38). Such arrangements are known by several names; in Europe the umbrella term “managed entry agreements” (MEAs) is usually used. Typically, MEAs are classified as financial MEAs (such as capping the number of treatments or patients, for example, price–volume agreements and simple flat discounts) and performance-based MEAs (such as risk-sharing, conditional reimbursement, coverage with evidence, pay-for-performance and payment-at-results schemes) (14,16,17,19,27,39,40). In some countries, it is not known which type of MEA is applied, or in some cases even which medicines are subject to an MEA (18). What all MEAs have in common is that the conditions – and especially the discounted price – are to be kept confidential between the manufacturer and the pricing authority or public payer (12,18,19).

Net price accessibility appears to be based on the accessibility of list prices that are statutorily determined. Six of the countries in which data was validated have no list price accessibility; in these countries, net prices appear not to be applicable, since payers do not conclude MEAs but purchase medicines for the public sector through public procurement, while other medicines have free pricing. Fig. 3 highlights which of the 42 countries that publish list prices (see Fig. 2) also make net prices publicly accessible.

Fig. 3. Access to net price data in 42 countries that have publicly accessible list prices

![Figure 3: Access to net price data in 42 countries](image)

- Publicly accessible
- Partly accessible
- Not accessible
- Not applicable/not known

Notes: Data were partly accessible in Germany, Norway, Poland and Switzerland, where some agreements of negotiated prices are not confidential.

“Not applicable” relates to some countries in eastern Europe and central Asia that have not negotiated MEAs.
In most countries net price data are not accessible: only Iceland has net price accessibility (see Box 1).

**Box 1. Price transparency in Iceland**

Iceland was identified as the sole country with transparent discounts granted by the companies. Pharmaceutical representatives can offer a discount on the wholesale price, which results in the price type “wholesale discount price to pharmacy”. This is published in the price catalogue, and is used to determine the pharmacy retail price.

Pharmaceutical companies are incentivized to offer high discounts, since if alternatives are available, the pharmacist must dispense the lowest-priced medicine (generic substitution). This discount is fixed per medicine and may not differ between pharmacies. The social health insurance fund calculates the reimbursement amount based on the wholesale discount price. Apart from these discounts on the wholesale price, no other arrangements or MEAs are in place.

*Source: Information provided by the country representative from Iceland; the example was also presented in a WHO Health Evidence Network synthesis report (41).*

In a few countries, net prices are accessible for some medicines in specific settings. For example, Switzerland reported having net price transparency for most medicines, in principle, but some confidential MEAs have been concluded, as confirmed by the literature (38).

In general, limited net price accessibility usually concerns novel medicines for which MEAs are negotiated. However, there are also several cases from countries such as Germany, of off-patent medicines also being subject to confidential discounts.

### 3.1.3 Measures to promote price transparency

#### 3.1.3.1 Transparency in list prices

Some central Asian countries have been working on improving price transparency. Armenia’s representative informed the study author about draft legislation that aims to make a list of negotiated prices publicly accessible. In Kyrgyzstan, price regulation is being introduced, and an electronic catalogue with list price data has been developed to inform patients about maximum wholesale and retail prices of registered medicines in the country, with a planned implementation date of October 2021.

In line with the EU Transparency Directive (33) (see section 3.1.1), the European Integrated Price Information Database (EURIPID) contains list prices of publicly funded medicines. EURIPID is not a source offering data that would not be accessible elsewhere, as it contains national list prices that are already published (see Box 2). Competent authorities can access list price data of other countries and they, in return, contribute to EURIPID by providing price data for their own countries.
3.1.4.2 Transparency of net prices

One of the main motivations behind resolution WHA72.8 (29) was concern from several countries about high prices and the lack of net price transparency impeding access to medicines. Over the last decade, governments and authorities have become increasingly aware of unintended implications of confidential discounts negotiated in MEAs, for example at the detriment of equity objectives. These arrangements have failed to achieve equitable access across European countries: some lower-income countries and small markets do not have access to high-priced medicines, even if they are willing to agree to a secret deal. If supplied, they tend to pay higher list prices (analysed in terms of purchasing power parity) and/or they are granted no discounts (47,48). Governments, even in high-income countries, feel pressured into accepting conditions and prices they consider unfavourable. With the loss of knowledge resulting from non-transparent deals, they are no longer on a level playing field with the industry, and are also not transparent about public spending. By striving for improved transparency, governments are also seeking to strengthen the balance in pharmaceutical systems, as requested by the Council of the EU under the Dutch Presidency in 2016 (43).

Some countries had already introduced measures to improve net price transparency before resolution WHA72.8 was endorsed by the World Health Assembly in 2019. Without disclosing any confidential price data or discounts, the Austrian Social Health Insurance labelled medicines for which an MEA was concluded in the reimbursement code – the positive list for the outpatient sector – by adding an abbreviation next to their listings (49). This flags the existence of an MEA to public authorities of other countries when referring to Austrian price data while applying ERP (a pricing policy based on prices in other countries). Only authorities that provide price data for their own country are eligible to access EURIPID (25). As of 2021, EURIPID members comprised 26 countries (all in the WHO European Region) (42).

EURIPID provides an example of a value-adding initiative for countries to voluntarily participate in data sharing that promotes price transparency (43,44). In 2017, the European Parliament requested that net prices could also be listed in EURIPID (45), but this has not yet been implemented. Information on whether a medicine was subject to an MEA was included in the EURIPID database for some countries, but others are hesitant even to flag the existence of an MEA (46).
MEAs provided in a separate list rather than in price lists risks being disregarded: ERP-applying payers may not be aware of this information, or may not check it because of time constraints. Thus, the decision to flag medicines with an MEA in the EURIPID database, if participating countries agree (see Box 2), is a beneficial and pragmatic approach.

Collaboration between countries is one way to fill the gaps in necessary information resulting from non-transparent structures. One option is a “clearing house” mechanism to facilitate exchange of information – such as net prices – through a trusted third party, which would aggregate and anonymize information. This mechanism is applied across hospitals in the Netherlands, for example, but the practice relates only to net prices of medical devices, not to medicines (51). In Austria, the introduction of a clearing house for information exchange between public purchasers (social insurance and hospital owners) was planned, with the option of an extension at the European level at a later stage (52,53), but the project was put on hold (54). Countries that are members of the cross-country Valletta Declaration collaboration share information about prices but do not associate specific countries with the net prices paid: they make the range of prices paid visible without linking each price to a country. Thus, they do not break confidential agreements (46).

Overall, few measures to improve net price transparency have been implemented since the adoption of resolution WHA72.8, but one example is Italy’s move to request net price data from the manufacturer as part of the pricing and reimbursement dossier (41) (see Box 3).

Box 3. Implementation of resolution WHA72.8 in Italy

Negotiations take place between the Italian Medicines Agency and pharmaceutical companies over whether a medicine will be included in funding at the expense of the national health service, and at what price. In preparation, companies have to provide defined data in their dossiers when requesting reimbursement. Information on list prices in other countries used to be requested, since this serves as one criterion in the pricing and reimbursement decision, in addition to data on costs incurred for R&D and for production – also provided by the company (39).

As a follow-up to resolution WHA72.8 in 2019, Italy changed its legislation on price and reimbursement negotiations (55). Companies are now required to provide additional information on the launch of a medicine, its consumption and its reimbursement status in other countries. Data should specify the price and reimbursement conditions, including any negotiated contracts.

To implement this change in legislation, the Italian Medicines Agency updated its guidelines for companies when compiling their dossiers (56), which entered into force on 1 March 2021. The updated guidelines ask companies to report the medicine price in other EU member states and in the United Kingdom, if applicable. They also request information on whether prices and/or any discounts or MEAs are subject to confidentiality agreements and, if so, the counterparts with whom the agreements were signed, the date of conclusion and duration of the contract, as well as the type of MEA (financial or performance-based). If the agreement is not confidential, the company is asked to specify the size of the negotiated discounts and the number of packs sold. If the price was the outcome of a negotiation with a collaboration (the guideline explicitly mentions the Beneluxa Initiative, the Valletta Declaration and the Visegrad Group), this should also be reported (55).
In addition, German legislation, which has been in place for several years, requires consideration of net prices when applying ERP (25). Limited information is available, however, about how this provision has been implemented during negotiations.

3.2 Information on R&D

3.2.1 Access to clinical trial results

Clinical trials are conducted in many but not all countries in the WHO European Region. In some small countries (such as Cyprus) the number of clinical trials conducted is limited, and in some countries (such as Azerbaijan) the first clinical trials started only recently (for COVID-19 vaccines).

Sponsors can include information on clinical trials in registers maintained by countries – such as the United States clinical trials database (57), which offers information on privately- and publicly-funded clinical studies conducted around the world – and international registers. The WHO International Clinical Trials Registry Platform aims to ensure that a complete view of research is accessible to decision-makers in health care globally (58). For EU member states, the EU Clinical Trials Register (59) has played an increasingly important role in accessing information (see section 3.2.3 for details).

In 42 of the 48 included countries, one or more clinical trials registers – or at least a published summary of conducted clinical trials – was identified (see Fig. 4). Germany has one register for clinical trials conducted in Germany and one for both national and international clinical trials. In 60% of the countries with clinical trials registers (25 countries) they are publicly accessible. If published, this is usually done in the form of a list or a searchable database on a website. Countries without a clinical trials register include those in which no clinical trials have yet been conducted (such as Kyrgyzstan) and a few EU member states that do not maintain a national register but oblige companies to enter clinical trials data directly into the EU Clinical Trials Register (59).

The accessible information on clinical trials does not offer complete results data in any of the countries examined, however. In a few countries (including Germany, Switzerland and the United Kingdom) some study results are accessible in the registers, but it is up to the sponsor of the trial to include this information. Measures have been launched at the EU and national levels to improve transparency in this area (see section 3.2.3).
3.2.2 Access to R&D cost data

Several publications on assumed R&D costs are available (6,7,9–11), but R&D costs for specific medicines are not officially disclosed. An important part of these costs is spending on clinical trials. Further R&D costs include expenditure on basic research, fees for applications, subsidies to support and incentivize R&D (typically granted by the public sector to the private sector) and investment in research infrastructure, including costs associated with early phase R&D processes.

Information on costs of clinical trials is not accessible to the public in any of the included 48 countries. Public authorities can request the data, but normally they do not know these costs. Information provided to public authorities is frequently limited to the taxes and fees charged for clinical trials applications. Greece reported that the pricing authority receives an estimate of national trial costs as part of the documentation included in pricing applications; the National Ethics Committee reviews these costs.

Expenditure on further R&D by the private sector is not accessible. In addition, the shares of public funding for R&D per medicine are not known. Germany provides a publicly accessible database to report government investment in R&D in various fields of scientific research (60). This has limited usefulness, however, for determining the cost of or subsidies for specific clinical research per medicine, which would be relevant information for public authorities deciding on pricing and reimbursement at the level of individual medicines (see also section 3.2.3.2).
3.2.3 Measures to promote transparency in R&D data

3.2.3.1 Transparency in clinical trial results

Non-reporting of negative results of clinical trials is considered ethically and morally inappropriate (61,62). Publication of well conducted trials with negative results can avoid waste (such as repetition of trials) and can protect future trial participants and patients from receiving therapy that is unlikely to cure (63). For authorities, having access only to positive findings can be misleading for their decision-making on marketing authorization, as well as on pricing and reimbursement when the (therapeutic) benefit of a medicine is considered for value-based pricing approaches. Although researchers and sponsors have a responsibility to report results of clinical trials – including negative ones – reporting gaps and biases exist.

A major advance has been made in the EU with the Clinical Trials Regulation (Regulation (EU) No. 536/2014) (64). This aims to increase transparency of information on clinical trials, including their results, to be provided through the EU clinical trials portal and database, which will be publicly accessible (unless for justified cases of confidentiality) (see Box 4).

Box 4. EU clinical trials portal and database

The goal of the EU Clinical Trials Regulation (64) is to create an environment favourable to conducting clinical trials in the EU, with the highest standards of safety for participants and increased transparency of trial information.

The Regulation aims to make data on the authorization, conduct and results of all clinical trials in the EU publicly accessible. It also sets out consistent rules for conducting clinical trials to increase their efficiency and to foster innovation and research, while helping avoid unnecessary duplication of or repetition of unsuccessful trials.

The Clinical Trials Regulation, which replaces previous EU legislation (65), entered into force on 16 April 2014, but its application was dependent on development of a fully functional EU clinical trials portal and database. After several postponements, the portal went live on 31 January 2022, so sponsors can now enter data in the new system, which is publicly accessible. A transition period is in place until the end of 2025; after that, clinical trials launched under the previous legislation must also be transferred to the new system (66,67).

The Clinical Trials Regulation aims to ensure transparency through publication of all clinical trials data in the database, unless justified in cases of commercially confidential information, protection of personal data, confidential communication between EU member states and ensuring effective supervision of the conduct of clinical trials.
Some countries have also been working individually on improving transparency in results of clinical trials. For instance, the National Institute for Health and Care Research in the United Kingdom commissions researchers, offering them part or full funding. It stipulates that trial findings should be published – as early as possible, but at most within 24 months of primary study completion – in a peer-reviewed, open-access journal or platform. Responsibility for timely publication of findings resides with the principal investigator in receipt of funds from the Institute

3.2.3.2 Transparency of clinical trial costs

The study found evidence of measures to work towards disclosure of the costs of clinical trials from two countries: a legislative change in France (see Box 5) and legal enforcement in a specific case in Spain. In the latter, the Council of Transparency and Good Governance, an independent administrative authority based on federal law, supported the Spanish Government’s request for a company to publicly disclose the price of a cellular immunotherapy and the therapeutic and financial criteria used. The aim was to obtain some indication indirectly of R&D costs. The request was filed using the law on access to public information

Box 5. French legal initiative to support disclosure of public funding

In response to resolution WHA72.8, the French Parliament adopted an amendment to the 2021 Social Health Insurance Budget Law to oblige pharmaceutical companies to report the amount of public investment in R&D they had received to the Pricing Committee (the interministerial body responsible for negotiating medicine prices with companies). The information is intended to be published.

According to a subamendment, however, the disclosure should only be a total amount; it is not specific to the medicine for which the price is negotiated.

Source: Perehudoff et al. (41).

3.3 Input cost data

3.3.1 Access to input cost data

Resolution WHA72.8 urges Member States to work collaboratively to improve reporting of information by suppliers. Some of the elements of supplier information it lists concern data of key importance for decision-making and are addressed in other sections (see section 3.1 on medicines prices and section 3.4 on volume and sales data). Depending on the organization of the health-care system, these data may not be owned exclusively by suppliers in countries in the WHO European Region but may also be known to the
authorities (such as price data in the case of statutory price setting, and volume data in the cases of joint procurement and monitoring of sales).

The resolution also mentions marketing costs for suppliers and any subsidies and incentives they receive. No input costs, such as production or marketing costs were publicly accessible in any of the included 48 countries. In nearly all countries in the WHO European Region, authorities do not know these inputs. A few countries (including Armenia, Cyprus, Greece and Spain) reported that they may gain access to parts of this information on request, but the scope and quality of any data received are not known. It is also unclear whether this information can be requested by other actors, despite the potential for the information to have global benefit.

Such information would provide valuable background information to price negotiations, even if medicine prices are not based solely on cost data but mainly on (added) therapeutic value considerations. The 2019 legislation in Italy (see Box 3) stipulates an obligation for the company to communicate marketing costs and any discrepancies with what had previously been defined (55). In Ireland, input cost data can be requested by the Health Service Executive in cases where viability and sustainability of supply is a concern. The data are not made publicly accessible by the Health Service Executive, according to information provided by the country representative.

3.3.2 Measures to promote transparency in input cost data

No national initiatives to improve transparency of input cost data were identified. Interest in input cost data has increased recently, however. Some policy-makers have argued for moving towards a more cost-based approach considering input data, rather than value-based pricing – considering the added therapeutic value of medicines, determined through health technology assessment.

The International Association of Mutual Benefit Societies (AIM) proposed a cost-based pricing model in which medicines should be considered a public good, and prices should be more aligned with the R&D costs, while taking the added therapeutic value into account appropriately. AIM suggested a transparent framework for determining the price of medicines based on the costs of R&D, production and sales, as well as a profit margin and a bonus for medicines that offer added therapeutic value. With the intention of creating a system that encourages transparency but does not depend on it, the model proposed to allow a lump sum of €250 million that the sponsor and developers would invest in R&D. Alternatively, sponsors would be allowed to charge real incurred cost but would have to document it (69). This is a proposal for discussion; it has not yet been piloted.
3.4 Volume and sales data

3.4.1 Access to volume and sales data

Volume data relate to the number of medicines prescribed, dispensed, sold or consumed. Volumes multiplied by prices result in expenditure data (from payers’ and procurers’ perspectives) and sales/revenue data (from pharmaceutical companies’ perspectives).

Public access to volume and sales data is mixed (see Fig. 5). In more than half of the included 48 countries (27 countries), the public has access to volume data for at least some medicines, and in more than two thirds of these countries some sales or expenditure data are also accessible.

Fig. 5. Access to volume and sales data in 48 countries

- Volume and sales data not accessible
- Publicly accessible volume and sales data
- Publicly accessible volume data; sales data not accessible

The scope of data to which the public and public authorities have access to may be limited, however. Usually, while the company has volume and sales data for all the medicines it sells, access of public payers and procurers can be limited to data on the specific medicines they purchase and (co-)fund. Authorities can also only offer public access to the information they can access. In fragmented health-care systems with several payers and purchasers (for example, where each hospital or health insurer procures on its own), public payers do not have access to aggregated volume and sales data per medicine or therapeutic group. In such systems, overall aggregated data are not accessible as a matter of routine but may require sometimes burdensome collection – either from individual purchasers or via data reporting by suppliers.

Overall, data accessibility appears to be better for the outpatient sector, which usually has centralized reimbursement systems, than for the hospital sector, which is organized in a decentralized manner in several countries. In countries with a reimbursement system that only covers the outpatient sector, authorities at the national level tend to have more limited
access to information (and no access to hospital volume and sales data), which eventually also limits accessibility for the public. Limited knowledge about (expected) volumes and spending can weaken the negotiation power of individual payers and purchasers, and this adds to the limited transparency concerning net prices (see section 3.1.2). It should be noted that the hospital sector, which frequently has a fragmented structure in countries in the Region, is also the setting in which specialized medicines with very high price tags tend to be introduced.

In several countries, public authorities publish medicine volume and sales data for the whole country, or at least for the outpatient sector. While the private sector does not publish volume and sales data, confidential agreements enable commercial data providers (such as some consultancy firms) to sell volume and sales data of high-income countries in the Region.

3.4.2 Measures to promote transparency in volume and sales

In some countries (such as Denmark and Hungary) reporting obligations have been imposed so that suppliers have to submit information on volume and sales in the full market (including for non-funded medicines) to the authorities.

To improve transparency and to ensure accountability towards citizens, several countries have taken initiatives to publish volume and sales data (see the example from Germany in Box 6). The format for publication of volume and/or sales data differs across countries (for details and links, see the web-annex). Several public institutions have been publishing annual statistical reports— in some cases for more than 15–20 years. These reports vary in length and are publicly accessible on the websites of medicines agencies, social

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**Box 6. Comprehensive annual consumption and spending reports in Italy and Germany**

In 2001, the Italian Medicines Observatory published its first 145-page report about medicines consumption and expenditure (70). This was followed by annual publications, which have expanded over the years (to over 800 pages for the 2020 report (71)). They include detailed analyses for therapeutic groups and information on regulation and policies. They are also accompanied by a report in English. Further specific consumption and spending reports (such as on medicines used in pregnancy, antibiotics and medicines used during the COVID-19 pandemic) have also been published.

Consumption and spending data from the statutory social health insurance has been published in Germany on an annual basis since 1985. This has also expanded to a very large volume, as detailed statistics on prescriptions and social health insurance expenditure are accompanied by sections on current topics (such as biosimilar medicines) (72). While some leading authors of the series are from the academic sector, the endeavour is also supported by the Scientific Institute of the Social Health Insurance, which also provides the data.

The German report gained high public attention in the late 1990s after a court ruling. An appeal by 19 pharmaceutical companies meant that the 1997 edition had to be published in a censored version. Several passages had to be redacted because they suggested that a number of medicines were of questionable value (73).
insurance institutions or other relevant public organizations. Some countries offer bilingual publications, or include a separate report translated into English.

Instead of – or in addition to – such reports, public authorities in an increasing number of countries provide interactive tools on their websites, which offer free access to volume and/or sales data. The Nordic countries launched publicly accessible databases more than two decades ago. For instance, the Danish Health Data Authority manages a publicly accessible web platform which contains statistics on total sales of medicines in Denmark from 1996 to 2020 (74). Information is fed by the data reported to the Register of Medicinal Product Statistics of the Danish Medicines Agency. All pharmacies and non-pharmacy dispensaries are obliged to report medicines sales; thus, the outpatient data cover all sales in Denmark, including those of non-funded and non-prescription medicines. Medicine sales to hospitals are also reported and publicly accessible in the web platform. The data can be searched by therapeutic group, Anatomic, Therapeutic and Chemical (ATC) classification fifth level (which defines the active substance) and product name; further use of retrieved data is allowed provided it is correctly cited.

Information at the level of individual products or active substances (ATC fifth level) can support policy-makers to make informed pricing and reimbursement decisions and carry out monitoring. It can also be used by scientists for analyses and by the public to trace public spending and hold public authorities accountable. Where products are marketed by one or few manufacturers, industry representatives have raised concerns that such publication may disclose commercially sensitive information. As a result, some companies have taken legal action against public authorities.

Box 7. Challenges in ensuring accessibility to volume and sales data in Sweden and Iceland

The National Board of Health and Welfare – a government agency under the Swedish Ministry of Health and Social Affairs – manages a publicly accessible database that contains information on medicines dispensed in community pharmacies from 2006 to 2020 (no data are available for non-prescription medicines and hospital volumes) (75). Search is possible by ATC classification (down to ATC fifth level) and for medicine groups, by region, gender, age group and date (year/month).

Since January 2019, however, it is no longer possible to request statistics that describe sales if there is only one manufacturer in the relevant ATC group. Furthermore, the publicly accessible database no longer shows results in defined daily doses – the common measurement for reporting volume and sales data. Data are now only displayed per number of patients and prescriptions. The National Board of Health and Welfare decided to make this change following a court ruling against a similar authority – the eHealth authority – in which the court rejected submission of a statistical report containing volume and sales data to a logistic provider for confidentiality reasons (76–77).

In Iceland, the Medicines Agency used to compile consumption and sales data of authorized medicines in the country, collected from wholesalers, and publish them in a database. Following a ruling by the Ministry of Welfare on 16 January 2015, however, publication of the data was suspended “at least for the time being” (78).
3.5 Patent status information

3.5.1 Access to patent status and expiry information

Medicines may be subject to numerous patents with different expiry dates. If applied strategically by pharmaceutical companies, these may ensure intellectual property protection for several years (80). Public payers and procurers have a key interest in the expiry dates of medicine patents, as this helps them to prepare and encourage swift entry of generic and biosimilar medicines into the health-care system. Equivalent to originator or reference medicines that were under patent protection, generic and biosimilar medicines offer the same therapeutic benefits at more affordable costs for patients and/or the health system. They make an important contribution to equitable patient access to affordable medicines (3).

Information on patent status is provided by patent registers, which are accessible at the national level and regionally. In Europe, for instance, the European Patent Office – an intergovernmental organization with 38 participating countries – maintains the European Patent Register (81). The Eurasian Patent Organization’s pharmaceutical register was established based on the Eurasian Patent Convention, and is of relevance for eight eastern European and central Asian countries (82).
In at least 44 of the 48 countries, national patent registers are publicly accessible on the Internet (see Fig. 6). Information is usually provided only in national languages. The level of user-friendliness of the registers varies, but they facilitate quick searches of patent documents in several countries, based on consultation of the registers by the author. Similarly, the European Patent Office website, Espacenet, offers patent search with free access to over 130 million patent documents (83).

While patent documents can be accessed, however, the date of (complete) patent expiry of a medicine – on which generic or biosimilar medicines are allowed to be marketed – cannot be identified easily as many medicines have multiple patents. This challenge was reported by most responding countries.

Fig. 6. Access to information on national patent registers in 48 countries

![Chart showing access to information on national patent registers in 48 countries]

Note: In three of the four countries with non-accessible patent registers, the study information was not validated by the country.

3.5.2 Measures to promote transparency in patent status information

The Patent Information Initiative for Medicines (Pat-INFORMED) is an international initiative to promote transparency in patent status, which offers public access to medicine patent information (84). Pat-INFORMED is a collaborative project of the World Intellectual Property Organization, which hosts the database, the International Federation of Pharmaceutical Manufacturers and Associations and 20 research-based biopharmaceutical companies that provide the data. The database is gradually being expanded; it currently contains six therapeutic areas (HIV/AIDS, cardiovascular diseases, diabetes, hepatitis C, oncology and respiratory conditions) and the medicines in WHO’s Essential Medicines List (85). A disclaimer in the Pat-INFORMED database flags the possibility of errors in the data, which are provided directly by pharmaceutical companies without third-party validation. As an additional limitation, the data provide information about the patent filing and grant dates (if available), but not about the patent expiry dates of medicines, which would be of interest for policy-makers.
Another valuable tool is MedsPaL, the medicines patents and licences database of the Medicines Patent Pool (86). It contains the patent and licensing statuses of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low- and middle-income countries; few countries in the WHO European Region are included. Despite its benefits, this database is of limited use for countries in the Region, as the scope of its data on medicines and countries is limited, and the issue of multiple patents per medicine remains.

Across the countries in the Region, a measure to improve transparency of patent expiry information was identified in Germany. The data validation exercise confirmed that following recent legislative amendments, manufacturers are now required to provide patent expiry dates at the request of the National Association of the Statutory Health Care Funds.

3.6 Marketing authorization status information

3.6.1 Access to marketing authorization status information

A high level of transparency is ensured for regulatory information on authorized medicines. In 47 of the 48 countries marketing authorization information is publicly accessible – usually published by the national medicines authority (see Fig. 7). In several countries (see the web-annex) information about authorized medicines – including their date of marketing authorization – is supplemented by information on their commercialization status: whether the medicine has been brought to the market and is, at that time, on the market. The additional data on commercialization status is valuable because it provides information about whether the medicine is actually available, whereas information on marketing authorization relates to the theoretical availability of medicines.

Fig. 7. Access to marketing authorization information in 48 countries

- No publicly accessible information on marketing authorization
- Publicly accessible information on marketing authorization plus information on commercialisation in the same source
- Publicly accessible information on marketing authorization

Note: For the sole country in which no publicly accessible information was identified, the information was not validated by the country.
In some countries, further data – such as on prescription status, price or reimbursement status – are provided in a regulatory database. Inclusion of further information in a single source facilitates data handling, and may reduce errors resulting from searching and connecting information from different sources.

Information is usually published in the form of lists that can be downloaded or as a searchable database on a website. Most databases provide links to essential information for patients and health professionals (such as the patient information leaflet and summary of product characteristics). In some countries the databases are also accessible in an English version, in addition to the national languages.

3.6.2 Measures to promote transparency in marketing authorization status information

Given the high level of transparency in this area, no further measures appear to be necessary. Databases, which were consulted for the purpose of this report, allow easy handling of and quick access to information in several countries.
Accessibility of data mentioned in resolution WHA72.8 of 2019 (29) for the public and public authorities varies across the WHO European Region and according to the four strands identified by the study (see section 2.1).

4.1 Mixed findings on access to information

Across the 48 countries, the public generally has access to information on the marketing authorization status of medicines in their country through registers managed by national regulatory authorities. In several countries the public also has access to clinical trials registers – although these rarely offer results of clinical trials. Patent registers are also available to the public in some countries, although in these it is practically impossible to determine the date when a medicine will be fully free from patent protection. Such information on patent expiry is also not accessible by public authorities.

Only the company knows how much it spent on R&D and any further costs incurred, such as for production, marketing and promotion of a medicine. Information on net prices – negotiated prices with discounts – is, as standard, kept confidential between the payer and the company. For official list price and for volume and sales (expenditure) data, the findings across the Region are mixed; these are publicly accessible in some countries (see Fig. 8 for an overview).

Fig. 8. Overview of mapping access to data in 48 countries

Access to data seems to be higher for regulatory data such as marketing authorization status and dates than for pricing and funding information resulting from negotiations (such as net prices). Furthermore, data ownership among public authorities (for example, of information on marketing authorization date, volumes and regulated prices) can support greater access to information for the public. Information in the hands of private sector representatives (such as input costs) is frequently not accessible, even for public authorities.
This report found that there appears to be greater transparency in countries with higher than average income in the Region and in countries with more advanced regulation and policy environments. Further details about access to information in each of the 48 reviewed countries can be found in the web-annex. It is important to highlight the relevance of a robust regulatory and policy framework: authorities that regulate list prices benefit from knowing the national prices across the country, and can publish these. In contrast, in countries with unregulated price settings, list prices – at least at the retail or consumer price level – vary within the country and are not even known to the authorities. Price regulation has proved crucial for greater transparency, as it serves as a prerequisite for publication of list prices. In addition, list price transparency also appears to foster net price transparency.

4.2 Implications of limited transparency on policy-making in the Region

The relevance of access to information as a prerequisite for evidence-based decision-making is known (see section 1). As the mapping exercise shows, however, information gaps exist across countries in the Region and limit robust decisions – particularly pricing decisions.

Apart from Iceland (a small market, which is rarely in the basket of reference countries when applying ERP), net prices of some medicines are kept confidential. The implications of this lack of transparency affect several countries that use ERP as at least a starting policy to determine medicine prices. These countries risk overpaying when they refer to the list prices, as they cannot access the net prices (22). In addition, the secrecy also affects payers in countries that have negotiated confidential discounts: there is evidence that in such cases list prices are probably higher, since the discounts are factored in (51).

In addition to ERP, many countries in the Region also apply value-based pricing approaches to set the publicly funded price of new medicines. To assess the value (the added therapeutic value in most cases), information on health outcomes is needed, however some negative results of clinical trials are not published. Thus, pricing and reimbursement decisions are sometimes taken based on a potentially overoptimistic assessments of the new medicine.

What a pharmaceutical company has spent on R&D of a medicine is not known, but public payers are expected to cover the industry's investment. In the light of these information gaps, governments risk paying twice (87) because basic research is frequently first conducted in universities and public research institutions, funded from taxpayer money, before promising start-up companies are bought up by Big Pharma (88). Thus, public funding and further public subsidies need to be accounted for when considering R&D costs in negotiations.

Off-patent medicines are promising solutions to ensure affordable and sustainable access. Timing is key: the earlier public authorities are aware of upcoming launches of generic and
biosimilar medicines, the better they can prepare for the implementation of measures. The findings show, however, that despite public accessibility of patent registers, necessary information about expiry dates of all relevant patents – and thus the opportunity for market entry of competitors – is not easily accessible.

4.3 Measures to improve transparency

Countries have worked to address the information asymmetry and data gaps in several of the areas mentioned in resolution WHA72.8, as the examples in Table 1 show. Ensuring public access to information is easy for public authorities when they own the data and have not concluded any confidentiality agreements, although some efforts may be required to work on technical solutions.

Gaining access to information owned by the private sector is more challenging. Companies may be obliged to report data, either on an ad hoc basis or systematically. Nevertheless, the challenge is enforcement: ensuring that the private sector provides the requested information correctly and completely. Legal approaches could be developed to allow validation of information provided by manufacturers with other countries (via information sharing and validation, supported by anonymization of data). In the case of data that are essentially only known by the companies (including money spent on R&D, investment to purchase start-ups, and aggregated data on patients treated, volumes and sales across countries), however, validation is hardly possible.

Table 1. Examples of measures to improve transparency in included countries

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Measures implemented</th>
<th>Measures proposed/under discussion</th>
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<tbody>
<tr>
<td>List prices</td>
<td>• Collaboration of European countries to share list prices through EURIPID</td>
<td>• Ongoing pricing reform in Kyrgyzstan: introduction of price regulation and planned launch of an electronic catalogue of list prices</td>
</tr>
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</table>
| Net prices               | • Public accessibility of lists/databases of MEAs in Italy and the United Kingdom – to show medicines subject to an MEA even if prices are not disclosed  
  • Flagging medicines with an MEA in the Austrian outpatient reimbursement list  
  • Requesting pharmaceutical companies to include information on negotiated discounts and packs sold in other countries as part of the pricing and reimbursement dossier in Italy | • A clearing house mechanism to facilitate exchange of net prices (or further relevant data) in an aggregated and anonymized manner through a trusted third party |
| Clinical trial results   | • Reform in EU legislation to strengthen reporting requirement for outcomes of clinical trials in a publicly accessible information system | –                                  |
| Clinical trial and further R&D cost data | • Obligations for companies to report public investment in R&D costs as part of requests for pricing and reimbursement in France | –                                  |
While some measures have been implemented, others have yet to demonstrate proof of concept. Relevant proposals in this context include the clearing house mechanism for anonymous sharing of confidential net prices through a trusted third party (see section 3.1.3) and the cost-based pricing calculation model developed by AIM (see section 3.3.2). Other measures have been launched but still need to be rolled out appropriately – such as the EU Clinical Trial Information System (see Box 4), which aims to ensure reports of all clinical trials outcomes – for which transition periods are still foreseen.

The study focuses on national measures implemented by countries in the Region, but it also highlighted the relevance of international governmental initiatives (such as EURIPID) and supranational action. For instance, the EU Transparency Directive (33) obliges EU member states to publish list prices of medicines funded by public payers. Even if the scope of accessible information is limited, European and international information systems and databases were helpful in adding some further information.

Proposals and initiatives of other stakeholders may also contribute to enhance transparency. Civil society has advocated public accessibility of information in the pharmaceutical sector. Net price transparency and information on R&D costs are core areas of this request, and accessibility is also considered useful for some further dimensions. The “national transparency check-list on medicines and health products” created by the French nongovernmental organization Observatoire de la transparence dans les politiques...
du médicament calls for public access to information on the dimensions of resolution WHA72.8 and also on medicine shortages, government positions in international forums and conflicts of interest (89).

Availability is also the focus of the European access database proposed by the European industry association EFPIA. The database aims to provide information about the timing and outcomes of the pricing and reimbursement processes of the medicines listed. These include whether the manufacturer has applied for reimbursement in a country – if not, the reasons for non-application; and if so, the reasons for the status of process (28). The published version of the proposal does not specify whether this information will be publicly accessible. If published, they may offer additional interesting information for the public and for public authorities in other countries; however, the proposal needs further evaluation to ensure that it addresses the areas highlighted in resolution WHA72.8.

4.5 The need for collaborative working

Ensuring meaningful information requires the commitment of both the public and private sectors, and cross-sector and cross-departmental collaboration. Resolution WHA72.8 calls for collaborative work on improved reporting by suppliers (such as on subsidies and incentives) and for publication of already publicly accessible or voluntarily provided costs of clinical trials. Policy-makers are thus responsible for obtaining access to such data and for publishing them, as appropriate. They need to address the private sector with clear requests for data that support their decision-making. For instance, information on total public subsidies is not useful for individual pricing and reimbursement decisions, as data need to be provided per product.

In some cases, data are held by the public sector but split among institutions. This is an issue in countries with fragmented health and pharmaceutical systems (as when different public payers and procurers fund a medicine and only have volume and spending data on the setting for which they are responsible). Moving forward towards enhanced transparency – potentially through reporting obligations for suppliers – countries may consider strengthening collaboration between public sector authorities. Examples may include the following.

- In cases of split funding responsibilities for outpatient and inpatient sectors, collaboration between procurers and payers for the different settings could be enhanced, including sharing and reporting of data to contribute to insights, and aggregated data (such as national monitoring of volume data).
- Net prices negotiated by one payer could be shared with other public sector bodies, such as payers or a procurement agency that could use the data to prepare appropriate tenders.
- Collaboration and information sharing between ministries would be beneficial (in particular between ministries of health and finance or trade, the latter being responsible for subsidies and incentives for R&D).

These approaches require capacity-strengthening in the public sector and greater coherence and alignment among public authorities.
4.6 Acknowledging different levels of accessibility while working towards transparency

While accessibility of information to the public is defined as the end goal of resolution WHA72.8, initial steps may involve improving access to data owned and managed by suppliers, or by single procurers or payers in a fragmented system, and making it available to all relevant public authorities in a country. Some limitations in transparency could be addressed through public sector collaboration, as highlighted by the examples above (for example, sharing net price information with public procurement bodies, and sharing data on financial support and subsidies to the private sector with pricing and reimbursement authorities).

Governments may also consider collaborating – for example, on cross-country joint procurement or joint pricing negotiations – and sharing anonymized national confidential information with partners.

4.7 Limitations of the mapping exercise

The study has some limitations. It is based on a review of country websites, which were considered relevant in this context, but may nevertheless be missing key information. In addition to possible gaps in completeness, errors resulting from possible misunderstandings of identified data – usually published in national languages – may have occurred in the review.

Country information was not validated by approximately one third of the countries included in the review. Even in cases of validated country fact sheets, it is acknowledged that country respondents – usually experts in pharmaceutical pricing and reimbursement – could not always respond to all questions (such as on challenges regarding patents or clinical trials). It was also observed that some concepts outlined in resolution WHA72.8 were prone to misunderstanding by country experts. This particularly concerned the term “net price”. Defined as “the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives” in the resolution (29), the net price relates to the discounted price negotiated and agreed between the manufacturer and the public payer. Nevertheless, in some cases the term was misunderstood as the final consumer retail price, or distribution margins were interpreted as discounts. Furthermore, the distinction between volume and sales data was not always clear in the terminology on websites and for country representatives.

While follow-up conversations between the author and the country respondents helped to generate greater clarity in several cases, in cases where no further responses were provided or where answers were not entirely clear, the author had to make decisions on how to interpret information provided during the validation. In view of these limitations, caution is required for interpreting the findings in this report. Further work will be taken forward to advance understandings of the state of transparency and value of various stakeholders’ access to information in the WHO European Region.
Public accessibility of pharmaceutical information reflects compliance with the principle of transparency – one of the key themes of the OMI – and contributes to good governance and accountability of the public sector to citizens. In addition, the four main areas for which resolution WHA72.8 of 2019 requests greater transparency (see Fig. 1) are of major importance for policy-makers: they support the design of effective policies that contribute to equitable access to affordable and cost-effective medicines. Some pricing and reimbursement policies are based on data listed in the resolution; for instance, ERP requires price data, value-based approaches and performance-based MEAs consider health outcomes demonstrated in clinical trials, and more cost-based policies need input data, including costs of R&D.

Some data are owned and managed by public authorities in the WHO European Region, and it is their responsibility to ensure public accessibility. Important efforts have been made in recent decades, such as publication of list price data and marketing authorization status information. Price regulation has played a major role: by setting national medicine prices, public authorities know the prices applicable throughout the country and can publish them. Some data (such as list prices of publicly funded medicines in EU member states) are publicly accessible in principle, but improvements in access and handling would support operational work. In this respect, collaborative initiatives such as EURIPID, which includes price information from several European countries, are useful for officials in public authorities when setting medicine prices based on prices in reference countries.

In other areas, information is only known by the pharmaceutical companies, such as all the results (including negative outcomes) of clinical trials conducted for a medicine, all patents and all cost data. To improve transparency and support evidence-based decision-making, sharing these data with at minimum the policy-makers who require them for their decisions could be a first step. To ensure implementation, legal or administrative changes may be needed, such as making reporting of such information mandatory in companies’ applications for pricing and reimbursement, and making public funding conditional on data sharing. A few countries have implemented transparency policies – before or after the endorsement of resolution WHA72.8; their experience can allow other countries to benefit from the lessons learned. Sharing of data would improve the quality of public decision-making and could facilitate a culture of trust between the public and private sectors. Nevertheless, validation of the data may be an issue, as this is not easily achieved.

Some data whose improved transparency is requested by the resolution are accessible only to the two parties to a negotiation: the public payer or institution and the company. Parties usually agree to keep information on net prices confidential, while for other dimensions, information gaps may be caused by fragmentation of the health system – for example, in the case of a lack of aggregated volume and expenditure data for medicines used in different hospitals or funded by different regions in a country. Addressing this requires collaboration among public procurers and payers to share their data initially and then publish them in a consolidated manner to inform the public. A coordinating structure,

Conclusions
potentially at the national level, could be supportive. Overall, capacity-strengthening is needed. National consumption and expenditure reports published by public authorities in several countries are good practice examples and may motivate other countries to implement similar publications.

Attempts to improve transparency in areas in which two parties have agreed confidentiality is a challenge. Options to move towards transparency without breach of contractual obligations are available, however, such an agreement between the public payer and the company to:

- share data with further public institutions in the country who need them (such as public procurement bodies);
- label the existence of MEAs in a price database; or
- work on clearing house solutions to share data while keeping the source anonymous.

While these models are far from granting full access to the public, they are solutions that may support policy-makers and contribute to improved access to high-priced medicines, while the work on improving transparency continues.

Access to information has different levels, ranging from no disclosure to full public transparency, and various initiatives and efforts can support a move towards higher levels. The mixed findings among included countries about the extent of accessibility among the main areas outlined in resolution WHA72.8 reflect the heterogeneity of approaches for different types of data. This may encourage policy-makers to be active and creative in their efforts to achieve greater transparency within the boundaries of contractual obligations. Nonetheless, changes in the extent of collaboration between the public and private sectors and mutual commitment to improved transparency are needed to ensure better access to novel, high-priced medicines.


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The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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