HEALTH SYSTEMS AND POLICY ANALYSIS

POLICY BRIEF 45

What are the implications of policies increasing transparency of prices paid for pharmaceuticals?

A primer for understanding the policy perspective in light of the empirical evidence

Erin Webb Erica Richardson Sabine Vogler Dimitra Panteli



GOVERNMENT OF MALTA OFFICE OF THE DEPUTY PRIME MINISTER MINISTRY FOR HEALTH



Pharmaceutical Research Technology, Pharmaceutical Drug Industry Health Services Accessibility Health Policy

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What are the implications of policies increasing transparency of prices paid for pharmaceuticals?

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Authors

Erin Webb – Department of Healthcare Management, Technical University of Berlin; European Observatory on Health Systems and Policies

Erica Richardson – European Observatory on Health Systems and Policies

Sabine Vogler – Pharmacoeconomics Department, Austrian National Public Health Institute

Dimitra Panteli – European Observatory on Health Systems and Policies

Editor

Dimitra Panteli

Series Editor

Anna Sagan

Associate Editors

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List of abbreviations

AAI	Accelerating Access Initiative	
APA	advanced purchasing agreements	
ART	anti-retroviral therapy	
BPS	Banco de Preços em Saúde	
EFPIA	European Federation of Pharmaceutical Industries and Associations	
ERP	external reference pricing	
EU	European Union	
EURIPID	European Integrated Price Information Database	
GDP	gross domestic product	
GPRM	Global Price Reporting Mechanism	
HIV	human immunodeficiency virus	
HTA	health technology assessment	
JPA	joint procurement agreement	
LMIC	low- and middle-income countries	
MEA	managed entry agreement	
MI4A	Market Information for Access to Vaccines	
NPT	net price transparency	
R&D	research and development	
UNAIDS	Joint United Nations Programme on HIV/AIDS	
WHO	World Health Organization	

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Key messages

- Public payers and pharmaceutical manufacturers have a shared interest in enabling timely access to necessary and innovative medicines. At the same time, there is a tension between the interests of purchasers (to contain costs) and of manufacturers (to provide return on investment and maximize profits).
- The most common pricing mechanisms in Europe such as external reference pricing (ERP) and managed entry agreements (MEAs) – tend to create incentives for pharmaceutical companies to give confidential discounts on the official list prices. This obscures the actual prices paid for medicines.
- Net price transparency (NPT) for pharmaceuticals the public disclosure of prices paid to manufacturers – is seen by many as key to overcoming the opacity of pharmaceutical systems and to addressing the imbalance between countries with different levels of negotiating power (as larger or smaller purchasers, or richer or poorer countries). It is also regarded as a means of ensuring that public payers purchasing pharmaceuticals for their populations can be held accountable.
- However, policy action on NPT is not straightforward:
 - Empirical evidence on the effect of NPT is extremely limited. Economic simulations do not provide a clear answer and evidence from natural experiments only comes from very specific settings, not least because NPT policies have never been fully implemented.
 - Some policy-makers are concerned that moves towards increased price transparency would have a negative impact on accessibility, because pharmaceutical companies may then withdraw from markets or set prices at unaffordable levels, in particular in cases of less attractive (e.g. smaller) markets.
 - Payers in different health systems may consider measures to increase price transparency for pharmaceuticals as more or less necessary to increase affordable access to medicines.
- Any movement towards NPT requires a re-examination of the established trade-offs in pharmaceutical policy in Europe and worldwide. It is important to consider:
 - the differing needs and negotiating capacities across countries
 - the complexities of the interactions between stakeholders
 - the particularities of specific market segments
 - the way the process of implementation may shape the policy's impact

- the consequences for different countries and the 'knock on' implications of these effects for availability and affordability in other (national) health systems
- the likely implications for innovation.
- Increasing transparency in the pharmaceutical system will require greater European and international collaboration

 strengthening and going beyond existing initiatives. It also demands a clear focus on maintaining access, innovation and sustainability. Recent experience with joint purchasing, such as in the case of the COVID-19 vaccines, may bolster similar initiatives in future.

Executive summary

Actual prices paid for medicines by public payers have traditionally been obscured because of confidential discounts given by pharmaceutical companies. However, the arrival of very expensive medicines has created a push towards improving transparency.

Health systems in Europe employ a range of policies to determine what they will pay for pharmaceuticals. External reference pricing (ERP) and managed entry agreements (MEAs) are among the most common pricing mechanisms in Europe. These create incentives for pharmaceutical companies to keep any discounts on the official list prices confidential, to ensure that referenced list prices are kept as high as possible. MEAs often contain confidential terms too. There are many other dimensions along the pharmaceutical life cycle that are non-transparent, including the costs of research and development (R&D) for new medicines, the results of clinical trials, the process for determining what public payers will pay, as well as the profit margins of pharmaceutical companies and other actors in the supply chain (such as wholesalers and pharmacists).

The arrival of an increasing number of very expensive medicines in recent years has led to a push towards improving transparency in the pharmaceutical system, with a 2019 World Health Assembly Resolution calling on countries to "take appropriate measures to publicly share information on the net prices of health products". The two primary motivations behind calls to disclose actual prices paid for medicines are: 1) ensuring access to affordable medicines, especially for countries with weaker negotiating positions; and 2) safeguarding accountability of public payers who purchase medicines on behalf of their populations.

This brief aims to provide an understanding of the issue of net price transparency (NPT) and how it fits within the complex pharmaceutical system, particularly in the European setting. It presents an overview of existing empirical evidence on the effect of NPT on access and affordability, and unpacks the potential implications of implementing policies to increase NPT.

While NPT has the potential to support affordability and accountability, there are concerns that introducing NPT within the existing pricing system may reduce access.

Theoretically, if countries use ERP and know exactly what is paid elsewhere, they might set prices according to the lowest net price in other countries. This would tend to compress prices. Although the resulting uniform price may be cheaper for countries with a higher ability to pay, it could be less affordable for those with a lower ability to pay, potentially reducing access. However, this assumes that under ERP higher income countries already pay more for medicines than lower income countries, which is not always the case.

Empirical evidence on the effect of NPT on access and affordability for pharmaceuticals is extremely limited.

Recent scoping and systematic reviews confirm the dearth of robust evidence to answer the guestion of how NPT would affect price. Evidence from natural experiments with pharmaceuticals is limited to specific settings. Some price transparency policies have been introduced in low- and middle-income countries (LMICs), but results have been mixed and do not have complete equivalency with NPT considerations in Europe. Economic simulations do not provide a clear answer to the effects of NPT either. Evidence from other types of health services and other industries also shows mixed results and has limited transferability: case studies from US health care mostly focus on consumer-based 'shoppable' services, and the empirical examples of NPT in other industries that are cited most frequently largely pertain to commodities (such as raw materials or agricultural produce) rather than complex manufactured products like medicines.

Experience from international collaboration highlights both successes and challenges with increasing transparency.

The recent experience with COVID-19 vaccine procurement prompted an unprecedented cross-country agreement. These initiatives are not generally set up with the explicit goal of sharing information about net prices, but in the case of joint procurement, net price information is available, at least among participating payers. Platforms for sharing pricing information have had some success, but do not disclose confidential information on price discounts or the terms of MEAs.

In the past, models for international pricing agreements have been challenging to implement. Equity pricing, for example, would provide a structure to differentiate the price of medicines based on a country's ability to pay, but would require a fully transparent pricing mechanism, international collaboration and solidarity.

Any action on NPT requires a re-examination of the established trade-offs in pharmaceutical policy in Europe and worldwide, and careful design and implementation.

Given the lack of 'natural experiments' and inherent opacity of the current pharmaceutical system, the consequences of policies to increase NPT remain unclear. The introduction of such policies is further hampered by their interconnectedness with contextual factors that determine equity in access to medicines. There are large differences between the types of pharmaceutical manufacturers and the types of purchasers and the relative power they have in negotiations. Preexisting contracts, policies and agreements introduce additional complexity as there are legal implications for NPT policies that may conflict with existing confidentiality agreements. • Depending on the prevailing mechanisms for price setting, payers in different health systems may regard measures to increase price transparency for pharmaceuticals as more or less necessary.

Accurate information about the prices paid in other settings may be particularly valuable for countries with less experience using different negotiating strategies. Countries in this position may have less bargaining power due to market size or a more limited ability to pay or because their pharmaceutical policy framework is still being developed. Other countries may have an interest in introducing transparency policies to improve accountability.

• Movement towards greater transparency can be expected and should be accompanied by ongoing monitoring of potential effects.

Movement towards NPT should adopt a nuanced approach, for instance considering differences in the structure of the market for on-patent and off-patent medicines, and the potential consequences of increased parallel trade. There may also be a new appetite for collaboration in Europe, particularly following the experience of vaccine procurement in the COVID-19 pandemic. However, the interconnectedness described in this brief means that decision-makers may want to consider the consequences for other countries as well as for availability and affordability in their own system as a result of effects in other countries. The element of fairness of pricing across countries would also certainly arise with increased NPT and should be considered as part of the policy implementation process. • Discussions focusing solely on NPT risk overshadowing other necessary considerations for equitable access to affordable medicines.

Countries with weaker negotiating positions, whether due to their population size and/or ability to pay, have more limited capacity in procuring medicines and providing access to patients, and may define 'value for money' differently based on their wealth or development. Some non-EU countries have begun to move towards confidential MEAs as part of efforts to control pharmaceutical spending. However, these agreements come with additional complexities, and their role in ensuring equitable and affordable access is not uncontested.

Manufacturers could choose to cut investment in R&D if their revenues fall, particularly if they anticipate prices for future products will be lower.

Providing equitable access to affordable medicines is more important than ever.

Ultimately, reforms in pharmaceutical policy are best evaluated in the context of the triple aims of: 1) providing timely and affordable access to safe and effective medicines; 2) fostering innovation by providing incentives to support research for the ongoing development of truly innovative treatments; and 3) safeguarding financial sustainability by pricing publicly funded medicines at an appropriate level for future health and pharmaceutical budgets. These three aims operate against a background of different payer needs and highlight the importance of effective governance, including at the international level. Thus, any movement towards increasing NPT will require greater European and international collaboration both within and beyond existing initiatives such as joint procurement and equity-based pricing.

POLICY BRIEF

1. Introduction: why this brief?

Policy-makers in all health systems in Europe must balance limited resources with providing the best possible care for their populations. Ensuring universal access to affordable, necessary pharmaceuticals is a frequent challenge in this context, as resources spent on purchasing pharmaceuticals constitute a substantial share of health expenditure in most health systems. Countries employ a variety of mechanisms to determine what their health systems will pay for medicines, including pricing and reimbursement policies, regulations on distribution margins and measures influencing consumption (see also previous European Observatory on Health Systems and Policies work: Panteli et al., 2016; Vogler, Paris & Panteli, 2018). This policy brief focuses on the potential effects of increasing NPT, meaning the transparency of prices paid to pharmaceutical manufacturers as a result of pricing or reimbursement policies.

While a wide range of mechanisms are employed to determine the amounts health systems will pay for pharmaceuticals, decision-makers in Europe often rely on published list prices in other countries to guide them in this process. Using list prices in other countries as benchmarks to set the price a health system will pay is known as ERP. This practice incentivizes manufacturers to provide confidential discounts on the official list prices to payers to ensure that referenced prices across countries remain as high as possible. In turn, the widespread use of such discounts means that list prices do not accurately reflect what is in fact paid for pharmaceuticals (the 'net' prices). This difference between list prices and net prices does not allow countries to know whether they are 'getting a good deal' and complicates holding public payers accountable for the resources they devote to pharmaceuticals (and the extent to which their spending represents value for money). However, many policy-makers consider ERP easier to implement than other policies, such as value-based pricing, which require a lot of capacity for decision-making and negotiations (Kanavos et al., 2010; Paris & Belloni, 2013; WHO, 2020b).

The arrival of an increasing number of new medicines with very high price tags in the past decade, such as the costly hepatitis C medicines that entered the market in 2014, has led to a push towards improving transparency in pharmaceutical markets, not least regarding net prices. The 2017 European Parliament Resolution on options for improving access to medicines, which built on multiple preceding initiatives, includes several calls for increased transparency (European Parliament, 2017). The subsequent 2019 World Health Assembly Resolution 72.8 on "Improving the transparency of markets for medicines, vaccines, and other health products" calls on countries to "take appropriate measures to publicly share information on the net prices of health products", where net prices are defined as "the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives" (World Health Assembly, 72, 2019).

The two primary motivations behind calls to disclose actual prices paid for pharmaceuticals include: 1) ensuring access to affordable medicines, especially for countries with weaker negotiating positions; and 2) safeguarding accountability of public payers who purchase medicines on behalf of their populations. However, the call for increased NPT is often also met with resistance, not least due to the assertion by the industry that publishing the prices actually paid for pharmaceuticals would lead to price inflation, particularly for countries with lower ability to pay and, as a result, hamper access to medicines (EFPIA, 2017). Further, because of the complexity of pharmaceutical markets, policies to increase NPT would have wider implications, for instance regarding parallel trade, and would impact countries beyond the ones implementing them. Concerns about ensuring affordability and access in an equitable and sustainable manner while simultaneously fostering a robust innovation system delivering new treatments to meet population needs further complicate the implementation of NPT.

Nevertheless, limited empirical evidence exists to support assertions about NPT either improving or limiting affordability and access. Due to the uncertainty about the implications of price transparency policies, policy-makers have generally been reluctant to introduce related measures. To make new, very high-priced medicines more affordable, payers have rather tended towards concluding confidential MEAs with manufacturers, which have a high administrative burden and remain largely opaque.

This brief aims to provide a solid foundation for understanding the issue of NPT and how it fits within the complex pharmaceutical system, particularly in the European setting. It presents an overview of existing empirical evidence on the effect of NPT on access and affordability, and unpacks the potential implications of implementing price transparency policies with a focus on considerations for policy-makers.

How is this brief structured?

The brief begins by introducing the fundamentals of how pharmaceutical prices are determined in the European setting (Section 2). It proceeds by providing a wider reflection on the ways that the pharmaceutical system currently lacks transparency, including NPT (Section 3). Section 4 continues by describing the possible implications of price transparency policies based on the limited evidence from previous experience both within and outside pharmaceuticals, while Section 5 discusses what we can learn from existing collaborative initiatives in pharmaceuticals. The brief then presents considerations for policy-makers before implementing price transparency policies (Section 6) and concludes with a future outlook (Section 7).

2. What shapes prices for pharmaceuticals in Europe?

Public payers have to balance access for their populations with the budgets they have available. Over the years, several mechanisms have developed to determine the prices public payers pay for pharmaceuticals in their respective reimbursement schemes. A previous policy brief, 'Ensuring access to medicines: How to redesign pricing, reimbursement and procurement?', provides a more comprehensive description of the policy instruments used to regulate prices and determine reimbursement of medicines (Vogler, Paris & Panteli, 2018).

When setting prices, manufacturers consider existing market prices for equivalent alternatives as well as anticipating payer priorities, for instance regarding value-based pricing. Pricing strategies used in one country can have effects reaching beyond the national borders; manufacturers avoid launching in markets with price controls and after entering one price-controlled country are less likely to launch in additional markets (Kyle, 2007).

This section looks at relevant policies and practices on the payer and manufacturer sides, as well as the relative negotiating power. These are not comprehensive, but set some needed context for considering NPT policies.

Health systems employ a range of policies to determine what they will pay for pharmaceuticals

Box 1 provides an overview of some of the key policy mechanisms and payer practices that shape pharmaceutical prices in Europe, especially for high-priced innovative medicines. ERP (also called international price referencing), and MEAs are two of the most common pricing policies in Europe for high-priced on-patent medicines (Vogler, 2018). Tendering and bundled purchasing may apply to both onpatent and off-patent medicines, for which internal reference pricing is also commonly applied (Panteli et al., 2016). Some countries have only recently begun, or have little capacity to implement, complex pricing strategies, so more commonly use ERP or tendering rather than MEAs. Advanced purchasing agreements (APAs) and cross-national joint procurement were used in the context of the COVID-19 vaccines, and could conceivably be considered for further areas in the future. Several of these mechanisms can be linked to health technology assessment (HTA), which determines the (comparative) value of a medicine based on clinical evidence (Panteli et al., 2016; Vogler, Paris & Panteli, 2018) and entails negotiations between payers and the pharmaceutical company. Figure 1 visualizes the payer approach for each of these mechanisms.

Box 1: Key mechanisms to determine what health systems will pay for high-priced medicines

(1) External reference pricing

ERP entails looking at prices in other countries where the medicine in question has already been launched and is available on the market. A country uses the prices paid in other countries as a benchmark to determine their own price. The specifics of price setting using ERP vary, but can include referencing the average price across a basket of comparator countries, or the lowest price, or the average of the three lowest prices. However, ERP is usually based on the list prices of medicines, which does not include negotiated confidential discounts. Almost all EU Members use ERP to inform prices for at least some pharmaceuticals (Rémuzat et al., 2015). Manufacturers are thus incentivized to provide confidential discounts on the official list prices to public payers to ensure that referenced list prices remain as high as possible.

The use of confidential discounts is widespread and well documented (Rémuzat et al., 2015), and often relates to the terms of MEAs described below. This means that individual payers, who only have the official prices at their disposal, do not have a reliable benchmark to assess what they can expect to pay when they negotiate with manufacturers. Furthermore, using ERP incentivizes payers to delay their pricing decisions (and any related negotiations) until prices in other markets are available, and incentivizes manufacturers to launch their pharmaceuticals in a sequence that protects their prices (Riccaboni et al., 2020).

The level of opacity with ERP and confidential discounts directly affects countries that use ERP to determine their own prices and indirectly affects countries whose prices are being referenced. When high-price countries reference low-price countries, this contributes to launch delays and higher launch prices in low-price countries (Danzon & Epstein, 2012). The prices used for ERP also require continuous updating to avoid referencing an outdated (and higher) price (Vogler, Schneider & Zimmermann, 2019). Perhaps most crucially, the existence of confidential discounts makes payers uncertain whether they have secured a 'good deal' with their own confidential discount, given the contractual obligation to not disclose price information, and also incentivizes manufacturers to set high list prices (Gamba, Pertile & Vogler, 2020).

(2) Managed entry agreements

MEAs are agreements between the pharmaceutical manufacturer and payer that enable coverage or reimbursement based on certain criteria (Ferrario & Kanavos, 2013). This often supports access to high-priced medicines with limited data on clinical efficacy and outcomes when there are concerns about realized patient benefits and cost impact (Ferrario et al., 2017). The existence and especially the terms of MEAs are largely confidential, and have become increasingly complex over time (OECD, 2018). The conditions of MEAs can be financially driven (e.g. free doses, discounts, rebates) or health outcomes driven (e.g. payment by result, coverage with evidence development) (Ferrario & Kanavos, 2015). Depending on the terms of the MEA, determining a net unit price can be difficult (see Section 3).

(3) Tendering

Public tendering, where purchasers use a formal and competitive process to solicit bids from manufacturers, has historically been more common in hospital settings for high-priced medicines but has also been used for outpatient medicines for some specific pharmaceuticals (Vogler, Paris & Panteli, 2018). As it is a competitive procedure, it only can be used for pharmaceuticals with substitutes, so is generally not applied to on-patent innovative medicines.

(4) Bundled purchasing

Bundled purchasing, or portfolio discounts, combine the purchase of multiple medicines from the same manufacturer/seller into one deal as part of the negotiation process, further obscuring price

information for an individual medicine (see Section 3). However, bundled pricing arrangements are not possible in all countries due to national legal frameworks.

(5) Advanced purchasing agreements

APAs (also known as advance(d) purchase agreements and advance(d) purchase mechanisms) require payers to determine their treatment areas of priority and willingness to pay. They can be used to incentivize development of new pharmaceuticals in areas with high unmet needs and have been employed successfully in the development and launch of the COVID-19 vaccines (see Section 5). However, in order to set up these agreements, countries must have a pre-existing understanding of which treatment areas to prioritize and willingness to pay for various treatments, likely supported by a robust HTA process and payer experience. These prerequisites are challenging for many countries as these processes require a high amount of capacity.

(6) Joint procurement

Joint procurement, where a group of payers come together to purchase pharmaceuticals, can facilitate transparency and affordability. It is intuitive that payers/purchasers joining together to negotiate for their populations collectively with pharmaceutical manufactures increases market size and strengthens their negotiating position. In Europe, both EU-level and narrower cross-country collaborations are in place, although joint procurement is not without its challenges (see Section 5).

Figure 1: Various mechanisms are used for pricing and/or purchasing pharmaceuticals



Source: Author illustration.

Industrial practices and pricing policies emphasize profit maximization

While payers (as public agents) are responsible for acting on behalf of their populations, pharmaceutical companies operate as private economic agents, whose main objective is to maximize profits. Several industrial practices shape prices within the pharmaceutical system, which are described in this section.

The market power of pharmaceutical companies differs between on-patent and off-patent medicines

Pharmaceutical producers operating in different markets have distinct market dynamics for on-patent and off-patent medicines. In the market for on-patent pharmaceuticals, the sellers (pharmaceutical companies) have market power because they are the only company that is legally allowed to produce a particular medicine within a certain time period. Additionally, the buyers (payers) operate in an oligopsony, which means only a small number of payers exist for the product. The off-patent market for pharmaceuticals also has oligopsony purchasers, but the pharmaceutical producer does not have the same market power as there are multiple competing products. These differences in the market structure within the pharmaceutical system correspond to different reactions to NPT policies (see Section 4).

Pharmaceutical companies develop their market launch sequence to maximize profitability

Companies have a variety of sales strategies, including the launch sequence across countries, in order to meet their shareholder commitments and determine which markets to enter to meet profitability and revenue targets. Specifically, firms often prioritize market launches in countries that can both support higher prices and are referenced by other countries, and then enter other markets at a later time. In this way, the price set during the first country launch has spill-over effects to countries that use ERP.

Additionally, in relation to the time elapsing from marketing approval to reimbursement (see also Panteli et al., 2016), it is said that confidential agreements on price - most often for new, high-priced medicines – may enable payers to provide faster access to medicines. This occurs when manufacturers are able to meet willingness-to-pay thresholds at an earlier stage by using discounts. Based on the list price, the cost in relation to benefit may be too high to justify reimbursement, meaning that it could take companies multiple applications for reimbursement with different prices or more robust evidence before sufficient value-for-money criteria are met. With a confidential discount on price from the beginning, these steps can be avoided. In this context, the producer may still choose to enter a market even if profitability may be lower than in another country if the price is higher than the marginal cost of production.

Country-specific differences in industrial focus influence price setting

Some countries are both buyers and suppliers in the pharmaceutical system, so industry considerations may play a role in prices paid for pharmaceuticals. In other words, countries that have a large pharmaceutical industry, such as Germany and Switzerland, produce many of the pharmaceuticals supplied on their own market and those of other countries. The governments of these countries have an incentive to support the pharmaceutical industry as it creates employment and export revenue for the economy. Other countries that do not have a large pharmaceutical industry have different incentives and hold a different position in the global market.

The bargaining power of public payers and pharmaceutical producers shape price negotiations

Differences in the bargaining power of payers based on ability and willingness to pay, access to information, disease burden and population size, also mean that not all transactions between payers and manufacturers are based on the same principles and that payers may have different perspectives and priorities (see Section 6). These elements may come into play in many of the pricing mechanisms illustrated in Figure 1. Additionally, representatives of pharmaceutical companies are trained in price negotiations and some payers may not receive equivalent training. Other payers have become more comfortable with negotiations over time and aspire to pricing that reflects the needs and values within the population. In general, countries with smaller target populations and/or a lower ability to pay are at a relative disadvantage during negotiations.

Additional factors in the country context include personal relationships between representatives of pharmaceutical companies and procurers, and political stability as a determinant for manufacturers to enter the market and be willing to negotiate. Overall, the heterogeneous levels of negotiating experience and specific contexts across countries affect whether policy-makers support a move towards price transparency policies. Payers in countries with more developed pricing strategies and stronger negotiating positions may be likely to focus on other measures to ensure affordability of medicines for their citizens.

3. How does the current pharmaceutical system lack transparency?

In the European Union (EU), for pricing and reimbursement authorities, transparency of process is regulated in the 1989 'Transparency Directive' 89/105/EEC (European Union, 1988). Following this Directive, national purchasers within the EU are required to clearly identify the methods they use to control pharmaceutical prices, to provide the reasons for reimbursement decisions in this area, and comply with defined timetables for arriving at such decisions. The Directive relates to the transparency of measures regulating the pricing of pharmaceuticals for human use and their inclusion in the scope of the national health system. The Directive mainly defines procedural obligations on the Member States to ensure that pharmaceutical companies benefit from timely, motivated and appealable decisions as regards the pricing and reimbursement of their products by national authorities. The Directive requires EU Member States to publish the list prices of medicines (co-)funded by the health system. However, confidential discounts, which are outside the scope of this Directive, mask what is actually paid for pharmaceuticals (Section 2).

The 2019 WHA Resolution supports the introduction of measures to enable the publication of "net prices", which it

defines as "the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives" (World Health Assembly, 72, 2019). However, the pharmaceutical system also lacks transparency in other aspects relevant to the costs of pharmaceuticals for health systems, such as the costs of the pharmaceutical development process.

The focus of this brief is on NPT, or the prices actually paid for pharmaceuticals by public payers. This section unpacks some of these dimensions of non-transparency that also increase the complexity of policies supporting NPT.

The pharmaceutical life cycle contains multiple non-transparent dimensions

The process of bringing a medicine to market and enabling its safe, efficient and effective use by those who need it contains several steps, which can be simplified into three phases: pre-launch (or pre-market, e.g. R&D, patenting and registration), peri-launch and post-launch. The process for determining what health systems will pay largely occurs in the peri-market phase, i.e. in the period shortly before and after a product is launched. NPT is relevant in the peri-market and post-market phases, but there are several dimensions of opacity to consider that lead up to or influence NPT (Figure 2, see also Vogler, Paris & Panteli, 2018). These are largely

Figure 2: Many steps in the pharmaceutical life cycle are not fully transparent beyond NPT



Source: Author illustration.

related to information asymmetries within the pharmaceutical market (see Box 2). This section covers these not fully transparent steps within the pharmaceutical life cycle, from R&D costs to profit margins.

Box 2: Information asymmetry influences the process of pricing medicines

Information asymmetry, where one stakeholder has more or better information than the other, introduces an imbalance in the pharmaceutical system. In pharmaceutical purchasing, information asymmetries can occur between the payer and pharmaceutical company, between the payer from Country A and the payer from Country B, between payers and distributors (wholesalers and community pharmacies), and between the payer and the public.

With the first information asymmetry, better-informed payers might be able to more effectively negotiate prices with pharmaceutical companies if they knew, for example, the comparative benefit of a new medicine against the existing standard of care. The lack of knowledge on R&D and production costs also creates information asymmetry between payers and pharmaceutical companies. Public authorities have no way to verify the costs brought forward by manufacturers, which provides an imbalance in the negotiation, especially as investments in R&D are a key factor cited by manufacturers to justify their pricing for medicines (Vogler, Paris & Panteli, 2018).

Information asymmetry between countries, where Country A receives a confidential discount and Country B does not, or where both countries receive discounts of different magnitudes, prevents meaningful price comparisons between countries. There is thus no guarantee in the current system that countries are purchasing medicines in line with their ability to pay, for instance that lowincome countries procure medicines at lower prices than high-income countries (OECD, 2018). A further point of information asymmetry occurs between the payer and the public. Without full information, the public is not able to evaluate coverage and pricing decisions made by authorities or to have accurate figures for pharmaceutical prices in order to assess net prices and price trends (OECD, 2018), impeding accountability.

(1) Research and development

The costs of developing a new medicine, or R&D costs, are known to manufacturers, but not to policy-makers or the public. If this information were more transparent, it would help with understanding the true magnitude of investment required to bring a medicine to market. Additionally, knowing where this investment comes from (i.e. public support or private funds) could avoid the public sector paying twice – for both R&D costs and the cost of the pharmaceutical (Government of the Netherlands, 2016). It has been argued that disclosing R&D costs would encourage cost-plus approaches in pharmaceutical pricing, which is considered disadvantageous by manufacturers (Riccaboni et al., 2020) and some payers, but has been suggested by other stakeholders as a way to curb profiteering (AIM, 2019).

(2) Clinical trials

Despite progress in recent years, many clinical trials still do not make all their results publicly available (Borysowski, Wnukiewicz-Kozłowska & Górski, 2020). A full overview of clinical trial results is a crucial foundation for pricing and reimbursement decisions for new medicines, which are increasingly guided by value considerations and based on HTA in European countries. The EU Clinical Trials Regulation, which came into full application at the end of January 2022, aims to improve transparency of results from clinical trials through the EU Clinical Trials Information System (EMA, 2022).

(3) Pricing process

The process for determining prices, including the criteria considered during negotiations, the positions of different stakeholders, as well as the reasons for and stakeholders' contribution to delays, are not always public knowledge. Even though it is in the public interest to know how taxpayers' money is spent to help keep payers accountable, the procedures for determining the price of pharmaceuticals are often not transparent.

(4) Pricing, purchasing and funding arrangements

The result of the pricing process described above is a pricing and purchasing arrangement. These arrangements might include confidential elements. They may also include mechanisms such as MEAs that provide reimbursement based on outcomes and introduce a level of monitoring and oversight. How these arrangements further complicate transparency of prices paid for pharmaceuticals is explained further below.

(5) Profit margins of pharmaceutical firms

While aggregated profit margins of pharmaceutical firms can be accessed through financial reporting documents, the profit margin of individual medicines is not transparent. While some may not see this as problematic because pharmaceutical manufacturers are private companies, it does represent an additional gap in transparency in the pharmaceutical system and contribute to information asymmetry (Box 2).

(6) Interactions among private actors along the supply chain

In addition to the transparency along the phases of pharmaceutical development described above, there is also a lack of transparency around prices set by private actors along the supply chain, concerning the transactions between wholesalers, pharmacies and manufacturers (Figure 3).

Mark-ups and margins for wholesalers and retail pharmacies are regulated to varying degrees within countries and, as a consequence, can vary between suppliers and distributors/dispensers (e.g. pharmacies). In addition to the impact on public health expenditure, a lack of margin regulation also impacts patient spending, since out-of-pocket spending on pharmaceuticals is considerable





Source: Author illustration adapted from Ryan & Sood, 2019.

in many countries. Furthermore, even with regulated distribution mark-up and published retail/consumer prices, confidential discounts between supply-chain actors may be possible (and allowed in some countries), and may allow earnings for private actors while they charge higher prices to public payers. In addition, while EU countries are mandated to publish list prices, not all countries have this requirement.

Although private-sector price incentives, discounts and arrangements between them may affect price transparency, these have largely been considered as in the commercial domain and within the remit of confidential arrangements between private parties. However, some initiatives, such as the Margins Survey in the UK undertaken by the Department of Health (PSNC, 2021), aim to calculate the margins at various levels in the distribution chain, to better understand data on prices and margins. This can eventually have an impact on the price paid by the public sector.

Parallel trade introduces further pricing complexities

Parallel trade is possible within the EU context due to the free movement of goods within the EU internal market. In parallel trade, a medicine that is sold at a lower price in Country A than Country B is purchased by a distributor in

Country A for resale in Country B. While this enables access to lower cost medicines in importing countries, countries with high volumes of exported pharmaceuticals due to parallel trade activity have reported shortages, and some countries have introduced legislation to limit the export of pharmaceuticals (Panteli et al., 2016; Vogler & Fischer, 2020). The existence of parallel trade creates another level of complexity in understanding NPT. Currently, parallel traders collate non-public data on prices across countries, which might change if transparency policies were to be implemented (see Section 6).

Purchasing strategies such as MEAs, bundled purchasing and volume discounts complicate the concept of a single net price

The net price might not be easy to determine even if all components of negotiated contracts are disclosed. In some cases (procurement) arrangements, particularly performance-based MEAs, are designed in a way that a determination of the price (or rather the cost) for the public payer is only possible ex-post, and with some difficulty given the conditions attached.

Both financially driven and health outcomes driven MEAs may complicate price transparency, especially at the unit level. For example, MEAs that offer free doses or set the payment based on the clinical outcome delink price and product. Even if MEAs were fully transparent, for some performance-based MEAs with complex mechanisms, it would be very difficult to ascertain the unit price. Therefore, if stakeholders seek a single net price, this value is not readily discernible.

Bundled pricing arrangements with multiple pharmaceuticals from the same manufacturer/seller as part of the negotiation process may not be possible everywhere, and particularly for new medicines. The overall discount awarded on the contract is not necessarily bound to all or any of the individual items within it. Therefore, even if public procurement is transparent by publishing the overall cost of the contract, it may not show the whole picture of prices paid for individual medicines if it does not also include the volume purchased. This makes it impossible to determine an actual unit price paid for each pharmaceutical.

Mechanisms used by payers such as clawbacks and tax deductions affect pharmaceutical price transparency as well

Clawbacks also complicate the understanding about how much is paid for individual medicines. They apply to manufacturers, pharmacists and/or wholesalers and return a portion of pharmaceutical expenditure if manufacturers' revenues or public spending reach a certain level. This overestimates the level of spending because payers may receive some money back from pharmaceutical expenditures (Panteli et al., 2016). Other mechanisms that include more than one product also complicate understanding of net prices. For example, tax breaks may underestimate spending on medicines, as pharmaceutical companies are able to keep more of the profits. Neither of these mechanisms occur at the level of individual medicines, but they still muddle the information about prices paid for pharmaceuticals as a whole.

Box 3: Price transparency can exist at several levels ranging from no disclosure to full public disclosure

Different degrees of transparency are possible aside from full public disclosure as advocated in the 2019 WHA Resolution (World Health Assembly, 72, 2019); net prices paid in other sectors or countries can be disclosed to individual payers or among a group of payers purchasing together (Figure 4). It is also possible that only the fact of a deviation from the official list price is shared, but not the amount or specific terms contained in confidential agreements (see Section 6).

Four conceivable levels of disclosure among stakeholders can be classified, starting with no disclosure. This means that no entity has access to pricing information aside from the data owner (e.g. R&D information known only to manufacturers). The second level of disclosure is data owners that disclose information to selected individual parties in a contractual relationship, such as between a payer and a pharmaceutical company (e.g. confidential agreements based on results of clinical trials). The third level involves disclosure to selected others who are not in the contractual relationship (e.g. net prices among payers). Finally, the most disclosure to the public (this is supported for net prices paid to manufacturers in the WHA Transparency Resolution of 2019). These levels of disclosure effect the possible policy options for price transparency initiatives (see Section 6).

4. What do we know about the impact of price transparency on access and affordability?

The research behind this brief did not identify any major empirical studies that answer the question of how price transparency policies impact pharmaceutical prices. Most of the literature with direct links to European health systems is argumentative rather than empirical in nature. Even the limited empirical evidence on the effects of price transparency on prices is not sufficient to categorically predict the implications of potential NPT policies on pharmaceutical expenditure and medicines affordability. The dearth of robust evidence to answer this question has been confirmed by a recently published scoping review (Ahmad, Makmor-Bakry & Hatah, 2020) as well as a WHOcoordinated systematic review (Tordup et al., 2020).

Despite the lack of empirical evidence, there are some insights on the impact of price transparency on access and affordability. These include insights from theory, evidence from other industries and international initiatives including recent experiences with joint procurement in the EU for the COVID-19 vaccines. Box 3 presents a range of options from no disclosure to full public availability of net prices.





The theoretical basis for NPT in pharmaceuticals

Price transparency among payers would enable all payers to see the price offered in each transaction. Moving towards NPT, at least with disclosure to other payers, one theoretical perspective suggests that this would result in lower prices, particularly through more effective negotiations that are able to reach the defined policy goals. International prices act as a benchmark for both ERP and price negotiations between payers and pharmaceutical companies, and if these prices do not reflect the true price of the product, this may lead to poor negotiation outcomes – particularly for those with limited negotiating power (OECD, 2018). Other economic theorists argue that price transparency would increase prices and/or stall innovation and further jeopardize access, particularly for low-resource settings (e.g. Ridley, 2005; Berdud et al., 2019).

Some theorize that the combination of NPT and ERP practices may decrease access and R&D investments

As ERP is commonly used as a tool to inform pharmaceutical prices in Europe, NPT could incentivize public authorities (at national level) to set prices according to the actual price level in other countries. Over time, this could theoretically compress prices and lead to uniform pharmaceutical prices across countries (Ridley, 2005). This means that some countries have a higher ability and/or willingness to pay, which means that the compressed price would be lower than what they would pay otherwise. Conversely, countries with a lower ability to pay may not be able to afford the new price for the pharmaceuticals that is set by the market. This may decrease access to on-patent, high-priced medicines in lower income countries (Berdud et al., 2019). However, this theory assumes that higher income countries pay more for medicines than lower income countries, which is demonstrably not always the case (Babar et al., 2019; Silverman et al., 2019; Moye-Holz & Vogler, 2022), and that they would seek to substantially decrease what they pay based on information from lower income settings.

Price compression may also lead to lower R&D funding, if industry revenues decrease because of lower prices in highincome countries, and manufacturers choose to make cuts to the R&D part of their budget. If pharmaceutical companies anticipate prices for future products to be lower, it is rational for them to invest less in R&D. This could be more likely for large pharmaceutical companies seeking to maintain consistent profit margins than smaller companies, which increasingly make up a larger share of pharmaceutical product launches (Vaughan & Ledley, 2021) and would reflect strategic decisions regarding the balance between R&D investment and other types of expenditure, such as shareholder buybacks and dividends (US House Oversight Committee, 2021).

Economic simulations do not provide a clear answer to the effects of NPT

Economic simulations to predict the results of NPT have varied outcomes depending on the underlying assumptions (Hahn, Klovers & Singer, 2008; Brown, 2019; Van Dyck,

Riccaboni & Swoboda, 2020). One found that price transparency should lead to lower prices if firms were not forward-looking; however, when firms were assumed to be forward-looking, the result depended on the relative strength of the transparency signal against the speed to close the deal (Ettinger & Sidartha, 2016).

Evidence from natural experiments with pharmaceuticals is limited to specific settings

Overall, there are very few publications that report net prices of pharmaceuticals (Mardetko, Kos & Vogler, 2019). In one of the few pieces of research in the European setting, price differences were compared for nine cancer drugs from 15 countries (van Harten et al., 2016). A reply from the Belgian Minister of Health stated that for some medicines both official as well as formal prices for Belgium were incorrect, which highlighted the difficulty of price comparisons in general and the need for collaboration also in other areas aside from prices (de Block, 2016).

In the US context, it has been suggested that the reliance on confidential discounts contributes to high pharmaceutical costs, because net prices closely correlated with third-party estimates of changes in pharmaceutical net prices (Wineinger, Zhang & Topol, 2019). In Europe as well, the current pricing system with confidential discounts has been considered as undermining efforts for pragmatic pricing decisions towards ensuring access to affordable medicines (Vogler et al., 2017).

Some price transparency policies have been introduced in LMICs, but with mixed results

There is some evidence (empirical but not substantial) to suggest mechanisms incorporating transparency features in LMICs lead to more favourable contract terms after negotiations, even if not lower prices (Vacca, Acosta & Rodriguez, 2011; Hinsch, Kaddar & Schmitt, 2014; Paschke et al., 2018). In 1998, Brazil established a free and open information system available online (Banco de Precos em Saúde, BPS) that shows the prices of medicines and health products. Federal public institutions in Brazil are required by law to publish purchasing information, including the quantity, unit price, form of bidding, and more, while other public and private institutions do so voluntarily (Kohler et al., 2015). However, the increased transparency was not shown to lead to consistent reductions in pharmaceutical purchase prices, possibly due to local supply conditions, health system inefficiencies, or corruption (Kohler et al., 2015). Argentina, Colombia and Peru have also taken steps to increase transparency, for example in Argentina, where public-sector tender bids have been published online (Ministry of Health Argentina, 2010). Currently, as in Brazil, the outcomes of these price transparency efforts are mixed (Kohler et al., 2015). Price transparency was also introduced as a result of the involvement of international organizations in joint procurement of anti-retroviral therapy (ART) to treat human immunodeficiency virus (HIV) in LMICs (Box 4). However, these transparency policies largely targeted transparent prices for consumers after tendering and/or negotiation processes, rather than NPT at the health system level.

Box 4: The case of HIV medications in LMICs

Where transnational organizations have been central to the procurement of specific products to broaden access to health services in LMICs, one of the results has been a de facto introduction of price transparency for those products. This has been the case for HIV medications since 1998.

Access to ART for people with HIV was a source of global inequality, where the burden of HIV infection was felt most acutely in the Global South, but the high price of pharmaceuticals meant treatment was only widely accessible in the Global North. In 1998, the Joint United Nations Programme on HIV/AIDS (UNAIDS) introduced the Drug Access Initiative, which explored the feasibility of a structured introduction of price-reduced ART in a range of LMICs. The Drug Access Initiative led to the first differential pricing for ART in LMICs and demonstrated that diversion of price-reduced drugs from LMICs to high-income countries could be limited. However, the price of the drugs remained the main obstacle to expanding access to ART. Therefore, UNAIDS and the managers of the Drug Access Initiative in Uganda and Côte d'Ivoire explored whether the drugs could be obtained more cheaply, first from the research-based companies that were partners in the initiative, and later from generic manufacturers. Further action was also prompted by public information about prices of locally produced ART in Brazil and Thailand (where the threat of compulsory licensing had been used to push down prices). In May 2000, five transnational organizations (UNFPA, UNICEF, WHO, UNAIDS and the World Bank) announced a partnership with five pharmaceutical companies to address the lack of affordable HIV medicines in resource-poor settings – the Accelerating Access Initiative (AAI). They set up a preferential pricing mechanism at the country level, to offer ART at about 10% of the list price to the public sector and nongovernmental organizations that complied with three conditions (correct use, no mark-up, no backflow of pharmaceuticals to markets in high-income countries). Competition from lower-priced generic manufacturers added to the pressure on high prices, particularly as the manufacturers involved were transparent in their offers (Hein & Moon, 2013).

Transparency as part of this initiative has meant net prices were made publicly available and this has become standard practice for the international procurement of a wider range of medicines. From 2008–2013, the prices paid by international donors for both proprietary and generic pharmaceuticals when procuring them for national programmes in LMICs have been made public through the Global Price Reporting Mechanism (GPRM). The GPRM focuses on HIV, tuberculosis and malaria treatments and publishes information about the procurement transactions including: volume, prices, international commercial terms, country of destination and procurement date in an open access database (https://apps.who.int/hiv/amds/price/hdd). The Global Fund is still fully transparent in the prices it pays when procuring pharmaceuticals for its programmes (https://www.theglobalfund.org/en/sourcingmanagement/price-quality-reporting).

Every year, more than 140 countries report details of their vaccine purchases to the World Health Organization (WHO). Building on existing efforts, since January 2018 the Market Information for Access to Vaccines (MI4A) conducts the collection and reporting of vaccine purchase data (WHO, 2019b). For countries covered by GAVI, a vaccine alliance to improve access to vaccines for children in low-income countries, price information was 100% complete, but for high-income countries which procure their own vaccines, only 52% of countries provided full information (WHO,

2018). Nevertheless, where countries used MI4A data, they were able to negotiate lower prices, not just in LMICs, but also in smaller countries in Europe (Chernuschi, 2020). Price transparency has therefore proved a useful tool in vaccine procurement, but for price reduction the key factor seems to be the use of pooled procurement which does not rely on price transparency per se (WHO, 2019a).

Evidence from other types of health services is not fully transferrable to pharmaceuticals in the European setting

The empirical evidence from other types of health care goods and services is almost exclusively from the USA and focuses on the effect of price transparency on consumer (i.e. patient) behaviour (primarily for 'shoppable' services). For example, increased price transparency for implantable medical devices, as proposed in the US Congress' Transparency in Medical Device Pricing Act of 2007, would likely not provide sufficient benefits for the cost of implementation, and may even encourage collusion by medical device suppliers (Hahn, Klovers & Singer, 2008). Ultimately, this Act was not adopted into law. Transparency of medical imaging prices in the USA was seen to reduce total prices in one state, albeit largely due to patients choosing a lower-cost provider to minimize their out-ofpocket costs (Brown, 2019). Indeed, those with higher service coverage are less likely to look for price information (Lieber, 2017). More recent developments in the USA have occurred in the hospital setting, where hospitals have been required to publish prices since 1 January 2021. The legislation requires hospitals to publish the prices of the 300 most shoppable services for consumer awareness, defining the price information as: 1) gross charge; 2) discounted cash prices; 3) payer-specific negotiated charges; 4) minimum rates; and 5) maximum rates (Wheeler & Taylor, 2021). Hospitals challenged this new regulation in court and lost, so are now finding alternative ways to make this information less accessible (Gondi et al., 2021). While these examples might provide insights for European countries on the impact of transparency of medicines purchased directly by patients, it falls outside the focus of this brief.

Evidence from other industries shows mixed results and has limited transferability

While evidence on transparency policies from other industries is available, its transferability to pharmaceuticals markets is questionable. A few examples could be used as the basis for forecasting potential implications of price transparency regulations in pharmaceuticals, but there are no direct empirical parallels. Examples of other industries where price transparency has been introduced or parallels to the pharmaceutical industry have been drawn, and which have been identified in this exercise, include the defence industry, the concrete industry and the lithium, barge, gasoline, supermarket and meatpacking markets. All case studies have limited transferability to the pharmaceutical system.

The defence industry has several parallels to the pharmaceutical system, including its lack of price transparency

The defence industry (Box 5) is perhaps the most comparable in terms of payer characteristics ('governments'), R&D set-up, the impact of producing and non-producing countries, joint procurement pathways, as well as confidential discounts. At the same time, it is different in terms of the nature of product and government buy-in into R&D and production. Nevertheless, considering the market dynamics of the defence industry does provide insights into how discussions of price transparency have to consider the wider contextual features of both purchasers and suppliers in the system, including some interests on both sides to keep information non-transparent.

Box 5: Defence industry

The defence industry and the pharmaceutical industry have many common features. Governments are the dominant buyers for both industries. Both industries cover a wide range of products, from wellestablished technologies that have long been in use, to innovative and high technology products that require access to extensive R&D capacity. In view of these similarities (and the high prices of innovative arms and pharmaceuticals), joint procurement for both has been discussed at the EU level (Garcia-Alonso & Levine, 2008). As in the pharmaceutical system, in defence, confidential discounts are widespread. In the defence industry, the given price is often not what is actually paid, as allies of producer countries are frequently given discounts, or even free weapons; often the real value can be in the maintenance contracts (Levine & Smith, 1997a). Accurate data on net prices only exists between the producers and the purchasers. This lack of transparency with the potential for big profits increases the potential for corruption in the system (Levine & Smith, 1997b).

The defence industry (as with some aspects of the pharmaceutical industry) is strategically important and in producer countries it is often a big employer that is important to the national economy. This means there is an incentive to maintain high prices for domestically produced arms (even where the government is the main purchaser) through 'home bias' – to ensure that the domestic arms industry remains profitable. Producer countries may therefore pay higher prices than non-producer countries, but for national economic interests (Garcia-Alonso & Levine, 2008).

Unlike the pharmaceutical industry, national price controls for arms are not an issue, but export controls are. The defence industry covers five broad categories of arms (from weapons of mass destruction to services) and these are subject to different types and levels of control at the global level. Prices, like export controls, are considered a 'strategic variable'. For example, raising prices might push importing countries to find a peaceful solution to hostile situations to avoid the escalating costs of an 'arms race' (Levine & Smith, 1997a). Foreign governments cooperating on procurement may also drive down prices and encourage consolidation in the industry through increased purchasing power.

The scale of R&D capacity needed for the development of new weapons and weapon systems means there is a relatively small number of producer countries globally, and they can interact strategically to keep the industry profitable and shape market structure. Producer and non-producer countries have very different positions in the market (Levine & Smith, 1997a). As with the pharmaceutical industry, defence industry R&D is frequently co-produced with government money and this privileges countries with established defence industries (Garcia-Alonso & Levine, 2008). For governments, the incentive is to retain a slice of future monopoly

position profits from domestic enterprises, particularly as big profits can only be made where there is a monopoly on the technology (Levine & Smith, 1997b). Government is therefore the main purchaser of defence industry outputs and the main funder of R&D in this branch of the economy, but this is seen as a worthwhile investment in both the economy and national security.

An experience from the Danish concrete industry is often posited as a warning against NPT, but the transferability is limited

The concrete industry (Box 6) is a case study frequently cited in the context of debates on NPT in pharmaceuticals. In this case, Denmark pushed price transparency to keep the prices for ready-made concrete in check in light of routine confidential discounts. The push led to the ready-made concrete oligopoly just 'accepting' a uniform higher price and removing the secret discounts. This led to an overhaul of antitrust legislation in Denmark.

Box 6: Concrete industry in Denmark

A natural experiment in the Danish ready-mixed concrete market is commonly cited as an example of how introducing NPT to bring down prices can have the opposite effect. Because ready-mixed concrete cannot be transported far (or it would set in transit), there are de facto local monopolies and oligopsony purchasers. The lack of transparency in the market meant that many purchasers had secret discounts and policy-makers in Denmark pushed for price transparency to allow for more competition to drive down prices. The policy unintentionally had the opposite effect as the local concrete manufacturers accepted the same price and removed the secret discounts, thereby increasing prices overall. The policy outcome was to drop the obligated price transparency and overhaul antitrust legislation in Denmark, so market transparency was no longer emphasized.

The research conducted on this case study concluded that price transparency can push price convergence in a market with too few providers and that secret discounts and price-shading are natural (if not essential) features of an effectively competitive oligopoly (Albæk, Møllgaard & Overgaard, 1997). However, it is not clear that this research is directly relevant to the pharmaceuticals industry as concrete is more akin to a commodity than an innovative technology. This means that the market structure is very different, and may not be so useful for forecasting the effects of greater price transparency on the pharmaceutical system which deals in manufactured products and government purchasers, especially regarding on-patent products.

Empirical evidence on the effects of policies to increase NPT in commodity markets do not translate to pharmaceuticals

The other industries identified in the literature describe commodity products, and therefore have limited comparability to pharmaceuticals. Empirical evidence on NPT exists in the lithium, barge, gasoline, supermarket and meatpacking markets, but in these cases price transparency policies were introduced to protect the seller rather than the purchaser (Box 7), which is generally the opposite in discussions of NPT in the pharmaceutical system.

Box 7: Meatpacking markets and agriculture

In some agricultural markets, price transparency was introduced as a way of protecting the interests of producers rather than purchasers. Meatpackers exert oligopsony powers when purchasing live cattle for slaughter from cattle farmers. The Livestock Mandatory Price Reporting Act (1999) sought to increase price transparency in the USA to protect the interests of cattle farmers (as the producers). However, econometric modelling of the impact found the oligopsony power of the meatpacking industry still increased despite the new price transparency rules, due to other factors such as information asymmetry (Cai, Stiegert & Koontz, 2011). In this model, price transparency did not push up prices and cattle farmers did not see their profits rise. However, in a different model, a price transparency policy enabled farmers to implement an accurate reserve price at auction, thereby protecting their interests (Boyer & Brorson, 2013). A similar effect was found in Ghana where maize and groundnut farmers provided with price information were able to compare buyers and sell for the highest price (Courtois & Subervie, 2014). In Hessen, Germany, the CASH model sought to share information on prices paid for both agricultural outputs and inputs (Landesbetrieb Landwirtschaft Hessen, 2011). However, in these agricultural cases, price transparency is seen as a way of ensuring fair prices for farmers because historically they had been too low.

5. What can we learn from existing collaborative initiatives on pharmaceutical pricing?

Previous attempts at international pricing agreements have been challenging to implement

Next to the empirical evidence presented above, and in light of the continuing challenge of ensuring sustainable access to affordable medicines, a number of proposals have introduced pricing concepts that entail some degree of transparency of paid prices, primarily among payers. However, none have found their way into (full) implementation. This section considers two of these proposals: equity and cost-plus pricing.

Equity pricing would provide a structure to price medicines based on ability to pay

Tiered pricing allows for different prices across countries based on their ability to pay (Vogler et al., 2016). It can be done in the form of price discrimination by private-sector representatives (which is currently done by industry via confidential discounts) or equity pricing, with the public sector determining price differentials between countries. Both types of tiered pricing allow pharmaceutical companies to charge a relatively lower price in low-income countries to enable affordability of high-priced medicines, while maximizing profits from high-income countries (Berdud et al., 2019). However, in case of price discrimination, it may allow suppliers to capture a larger share of the surplus than purchasers. Further, tiered pricing policies initiated by the private sector use profit maximization practices that do not always correlate with need or ability to pay (Moon et al., 2011).

Under an equity pricing approach, policy-makers would work together (possibly with the support of an international institution) to establish a benchmark price and then differentiate the prices paid by each country based on income level and ability to pay. Countries in Europe have no experience with equity-based pricing. A proposal on how to organize such a full transparent pricing mechanism was prepared in a technical study (Vogler et al., 2016) but it was not considered politically feasible at the time since it would require the collaboration and solidarity of ideally all EU Member States. However, with the COVID-19 experience, this approach, at least for a few medicines, might be reconsidered.

Cost-plus proposals aim at limiting excess profit margins but information on costs is not readily available

In line with price transparency and equity pricing, a proposal from the payer perspective has suggested a transparent framework for calculating prices paid for pharmaceuticals in Europe based on a combination of factors (Figure 5). These include the costs of research, production and sales as well as a profit margin and a bonus for pharmaceuticals offering added therapeutic value. To account for differences between the ability of countries to pay, the framework suggests adapting the price based on GDP. For example, a pharmaceutical with an average 'fair price' of $\leq 10,000$ would cost $\leq 2,300$ in Bulgaria and $\leq 20,500$ in Ireland (AIM, 2019). While such novel



Figure 5: AIM's proposal for calculating an average fair price in Europe

Source: Author illustration based on AIM, 2019.

cost-plus approaches considering different factors have been proposed, they have not been implemented in practice, in part due to the difficulty in obtaining information on costs (see Section 3) as well as concerns about impeding innovation.

In Europe, platforms to share pricing information have encountered obstacles

Given the assumed non-feasibility of government-led equitybased tiered pricing, alternative initiatives, such as the provision of reliable information on prices, have been proposed as options to increase transparency of net prices. In Europe, the European Integrated Price Information Database (EURIPID) shares some pricing and volume information, and clearing houses may also be able to share information without breaching contractual obligations.

EURIPID shares some information but has limitations

EURIPID is considered a good practice example for sharing pharmaceutical information. EURIPID is primarily a database which provides national list prices of reimbursable medicines from mainly European countries that are willing to participate in this project by sharing their own data. EURIPID started as an initiative of experts working at the Hungarian Social Insurance Fund in collaboration with public authorities in a small group of countries, and was then turned into an EU project. The key inputs are the published prices of reimbursed medicines, the publication of which is mandated by the EU Transparency Directive. The database has developed in such a way that information shared complies with applicable national and contractual confidentiality regulations (Habl et al., 2018). EURIPID has been exploring inclusion of further information elements such as volume data and confidential prices. The latter was requested by the European Parliament (European Parliament, 2017), but it has not been possible to implement. However, some countries report whether a pharmaceutical falls under a MEA, but not the agreement's terms. Even without further information about the set-up of the MEA, some countries remain hesitant to flag the existence of MEAs due to the confidentiality agreements in place.

Clearing houses provide an option for sharing anonymized net price information

Clearing houses are mechanisms that anonymously collect information, which a trusted third party collates and shares (Vogler, Paris & Panteli, 2018). In the context of pharmaceutical prices, clearing houses could collect data from payers on net prices after confidential discounts. As described above, the WHO collects pricing information about vaccines without disclosing the country that provided the data (WHO, 2019b), and some research projects have collected this information as well (Morgan, Vogler & Wagner, 2017). In the Netherlands, hospitals established a voluntary collaboration to share actual prices of medical devices (den Ambtman et al., 2020). For a clearing house to be successful, it is essential to identify the appropriate data steward and ensure participation among those sharing the data.

Several cross-country collaborations have arisen in Europe

Collaborations within Europe related to pharmaceutical procurement have occurred at both the EU level and between smaller groups of countries. The recent experience with COVID-19 vaccine procurement prompted an unprecedented cross-country agreement. These initiatives are generally not set up with the explicit goal of sharing information about net prices, but in the case of joint procurement, net price information is available.

The EU Joint Procurement Agreement has been mobilized a few times, but is not yet widely used

At the EU level, a joint procurement agreement framework for medical countermeasures was introduced in 2014 in response to the 2009 H1N1 influenza pandemic (European Commission, 2014). During the H1N1 pandemic, countries paid relatively high prices in order to stockpile influenza vaccines and antiviral medications, but these stockpiles were not fully used. In response, the EU adopted the voluntary joint procurement agreement (JPA) with the goals to increase solidarity, ensure equitable access and strengthen the purchasing power of Member States when procuring medical countermeasures in public health emergencies. Under this agreement, the European Commission coordinates the procurement process, while individual countries conduct the purchasing. At the time of its launch in June 2014, 14 countries joined the JPA, while as of August 2021, 37 countries have signed the agreement (European Commission, 2021b). During the COVID-19 pandemic, multiple calls for tender on personal protective equipment, ventilators, medicines, and more were facilitated under the JPA. However, for the procurement of COVID-19 vaccines, a different mechanism was used (Box 8).

Box 8: Procurement of vaccines during COVID-19 using advance purchasing agreements

One of the largest efforts for joint procurement in the EU has been for COVID-19 vaccines. The European Commission mobilized funds from the Emergency Support Instrument to set up a wide portfolio of vaccines from different manufacturers using APAs (European Commission, 2021a). In this experience, both EU countries and vaccine manufacturers accepted a single price within the terms of each agreement. However, some of the content of the APAs is redacted (European Commission, 2020a) and certain terms remain confidential. Based on available information, the price adopted in Europe differed from prices in other countries, such as the USA. This case challenges the notion of price convergence: although a fair amount of information was available, there was still price differentiation. In Europe, small countries such as Malta benefited from the European collaboration, and without the centralized procurement through the EU they might not have had access to the vaccines at the same speed or price. The COVID-19 experience shows that collaboration and political commitment can facilitate agreements with the industry that enable faster access for more people, although the industry suggests that complex cross-border agreements should be limited to emergency situations (EFPIA, 2022). Given the price increases for some vaccine products announced in August 2021 (Mancini, Kuchler & Khan, 2021), for the European context it is important that provisions in such agreements do not compromise sustained affordability.

Several cross-national collaborations in pharmaceutical purchasing have developed

Several joint initiatives among groups of countries have emerged in the European Region (Figure 6), potentially in response to the narrow scope of the JPA (limited to medical countermeasures) and the interest of some countries of similar income in collaborating technically, as there was a perceived need to collaborate to ensure access to cancer medicines, orphan medicines and other medicines with high price tags. However, most of these collaborations do not focus on procurement, but rather support networking, knowledge sharing, horizon scanning, HTA and negotiations (WHO, 2020a), all of which can still produce synergies and learnings. Countries that have signed the Valletta Declaration share information about prices, but do not associate specific countries with the net prices paid for pharmaceuticals, for example making the range of prices paid visible without linking one price to one country. This is necessary when individual public payers have signed nondisclosure agreements with the manufacturers.

In some cases, cross-country collaborative initiatives do include joint procurement. For the Baltic Procurement Initiative, Estonia, Latvia and Lithuania successfully concluded several joint tenders for vaccines. In this case, the tender prices that the collaboration reached reflect net prices of vaccines, de facto introducing price transparency for the payers from these countries. In 2020, the Nordic Pharmaceutical Forum between Denmark, Norway and Sweden published a call for a joint tender for undersupplied older hospital medicines, resulting in nine signed contracts (with Iceland abstaining from the first negotiation due to legal challenges), and a second call was launched in 2021 (Vogler et al., 2021b). This second round included Denmark, Norway and Iceland, and the joint tender received offers for all 13 products, mostly for generic antibiotics and essential medicines. Stakeholders noted strengthened competition due to more suppliers bidding, and a representative from Iceland indicated that more products became available in the market at significantly lower prices (AMGROS, 2022). However, every country has a different legal framework and way of setting up contracts, which is a challenge when establishing collaborative purchasing initiatives.

Figure 6: Examples of collaborative pharmaceutical initiatives in the EU





Source: Author illustration based on WHO, 2020a.

6. What should policy-makers consider in the context of NPT initiatives?

Given the lack of 'natural experiments' and inherent opacity of pricing data, the consequences of price transparency remain unclear. The introduction of policies to increase transparency of paid prices for pharmaceuticals is further hampered by their interconnectedness with several contextual factors that determine the pursuit of better access to medicines. This is particularly relevant from the perspective of equitable access at the European or global level. As described below, large differences exist between the types of pharmaceutical manufacturers and the types of purchasers, and the relative power they have in negotiations. Further, pre-existing contracts, policies and agreements introduce additional complexity. Policy-makers have a necessity to address linked issues that impact access and affordability, such as parallel trade, while considering the implications for accountability.

Who should consider policies to increase transparency of paid prices?

Since pharmaceutical provision in most health systems is at least partly funded from public money, an important aspect of price transparency relates to accountability for public payers, as greater transparency might enable the public to understand why some medicines are unaffordable and to scrutinize how public funds are invested. Public accountability varies depending on the political context of the country. Nevertheless, making available accurate information about how much public payers spend on pharmaceuticals provides important information from an accountability perspective.

Depending on the prevailing mechanisms for price setting, payers in different health systems may consider measures to increase price transparency for pharmaceuticals as more or less necessary. Countries with less experience using different negotiating strategies (due to a developing pharmaceutical policy framework or a less strong negotiating position because of market size or more limited ability to pay), may be keener to ensure they have accurate information about the prices paid in other settings. Other countries may have an interest in introducing transparency policies in order to inform pricing along the pharmaceutical distribution chain.

A differentiated approach would be required for on-patent and off-patent medicines

From the perspective of manufacturers of single source novel medicines, transparency is not desirable and they predict that it would lead to price convergence and overall lower prices, which may compromise access and reduce R&D investment (EFPIA, 2017). Manufacturers worry that the increased use of value-based pricing mechanisms linked to HTA may be replaced under price transparency with increased use of ERP (Riccaboni et al., 2020). The knock-on effects and feedback loops of ERP and strict pricing rules may exacerbate the issue and contribute to companies deciding not to launch in certain countries, or launching at a later date (Danzon & Epstein, 2012; Kyle, 2007). Within

Europe, if a pharmaceutical company is unable to meet its revenue targets in countries with the largest markets, it may look to increase prices in countries with lower volumes to maintain profit revenues. At the same time, payers may choose to wait for a product to come to market, as it might lower the price paid, because the level of confidential discount may increase and/or list price might decrease over time. This may expand (but delay) access to the product without the potential need for rationing as the lower price means a greater volume can be purchased, and may be particularly meaningful for countries with a lower ability to pay for high-cost medicines.

For generic medicines, some price transparency already exists in the market, for instance where tendering prices are known to other payers within a system, or list prices are published in line with reporting requirements. Policies such as internal reference pricing for generic products aim to lower the amounts paid by public payers (see Panteli et al., 2016), and some countries also use ERP for generics to seek further price reductions. If ERP continues and even accelerates due to transparency policies, it may lead to unsustainably low prices for generics in some countries, while simultaneously higher prices in others related to price convergence, which could result in generic providers pulling out of the market and lower generic penetration rates.

The health system actors involved in pharmaceutical pricing and procurement must be considered

Even countries with a national health system or single health insurance fund may have multiple purchasers of medicines. These purchasers may either be third-party payers, including insurers or other coverage schemes and reimbursement agencies, or public buyers within the health system, such as hospitals. The responsible agency for procurement varies across countries, from e.g. ministries of health to medicines agencies, a designated procurement agency owned by the federal state, or by regions. In some countries, public authorities in the pharmaceutical sector combine several competences along the value chain, which facilitates access to information. For example, if the medicines agency is responsible for both market authorization and price setting, there is access to clinical information that could be used to support reimbursement decisions. In some countries, the confidential discounts negotiated between the reimbursement agency and the industry are not shared with other public bodies, e.g. public procurement agencies, although this would be helpful for the preparation of a tender (Vogler et al., 2021b).

The impact of price transparency on parallel trade within the EU is uncertain

If the transparency of paid prices were to increase, parallel traders would have direct insight into the potential of different transaction routes without the need for cost comparison centres that currently exist to facilitate parallel trade. The influence of parallel trade varies across EU countries; parallel imports may curb costs in countries with high price levels but parallel exports can introduce or exacerbate shortages in countries with low price levels. It is difficult to predict how these dynamics might change if discounted prices became transparent, and what the knockon effects for the availability of medicines would be or whether countries would react by imposing export bans to avoid shortages (Nolen & Balling, 2021).

Transparency policies may conflict with existing confidential agreements

There are also legal considerations that create additional imbalance in the market and are relevant to the introduction of transparency policies (Government of the Netherlands, 2016). Measures that increase NPT as endorsed in the 2019 WHA resolution may run into obstacles from a contract law standpoint, especially with MEAs that include confidential non-disclosure clauses prohibiting signatories from sharing the terms of the agreement (World Health Assembly 72, 2019). It is possible that such clauses would be violated regardless of the degree of NPT, in terms of whether price information is publicly available or shared among designated actors within a group of countries. In some countries, this confidentiality is backed up by specific legislation (Russo et al., 2021).

Further legal perspectives that may have a bearing on the issue include, for instance, antitrust legislation, and the extent to which payers working together violates such principles. Pharmaceutical companies are subject to EU antitrust rules under TFEU Articles 101 and 102. TFEU Article 101 prohibits agreements between multiple companies, while TFEU Article 102 prohibits abuse of monopoly power (European Commission, 2008; 2012). Unlike pharmaceutical companies, payers are not subject to EU antitrust rules and competition law. However, public authorities are subject to the EU Transparency Directive (EU Transparency Directive Council Directive 89/105/EEC; European Union, 1988), while the private sector is not – and this has also been subject to criticism and discussions.

Increasing transparency of what is paid for pharmaceuticals can take different forms

An alternative to NPT would be to reveal the existence – but not the magnitude - of confidential discounts to mitigate the risks associated with full transparency (OECD, 2018). Transparency in public spending can also be achieved in aggregated ways beyond disclosing net prices of individual pharmaceutical productsmedicinesaccountability. For example, since 2020, the French Pricing Committee has published the average discounts per indication group in its annual activity reports (CEPS, 2020; 2021). Where confidential MEAs are in place for originator medicines, pricing information could be made available to follow-on (generic or biosimilar) manufacturers to enable them to enter the market competitively at patent expiry. However, from the perspective of the industry, this could affect market access, as one manufacturer determined not to launch the generic of a product in Italy because publicly available prices suggested that it was uneconomical (EFPIA, 2022).

Finally, increasing the transparency of the pricing, procurement and reimbursement processes, which could lower prices by encouraging bidders and enhancing accountability, has been frequently advocated alongside or instead of transparency of paid prices (Paschke et al., 2018; Berdud et al., 2019; Shaw & Mestre-Ferrandiz, 2020). Such steps, while not leading to full price transparency, may allow payers to increase their level of accountability. However, they would still not enable payers in countries with limited negotiating power to have a credible benchmark indicating what is being paid elsewhere.

Action on price transparency would need to be carefully designed and implemented

The complexities outlined above explain why transparency measures remain difficult to implement. For example, while payers desire information about net prices, they are wary to be the first to disclose, given the risks of breaking confidentiality agreements and taking unilateral action to provide information to other payers without a clear incentive. However, this would be alleviated as more payers provided information about net prices and realize possible benefits, as there are currently no examples.

The design of related measures should be carefully thought through; for instance, it might be easier to introduce policies that impact only future pricing agreements, as opposed to disclosing all existing discounts in a given country. The implementation process, necessary governance mechanisms and oversight for price transparency policies would also be crucial. Depending on the motivation for introducing transparency policies, it is important to have clear and transparent criteria for the upkeep and/or adaptation of underlying mechanisms (i.e. if price transparency is introduced in the hope of lowering expenditure, but these measure(s) do not lead to cost-containment, the goal of accountability alone may not be sufficient to maintain them).

Furthermore, policy-makers aiming to introduce transparency measures should account for ways in which policies could be circumvented, as the industry has different interests and objectives to those of public bodies. For instance, to reward confidentiality, manufacturers may promise individual procurers a much 'better deal' compared to the one they would achieve through collective purchasing. In all cases, trusted brokers such as international organizations and political will would be needed to support the policy development and implementation process.

7. The way forward? Discussion and conclusions

Is full NPT feasible? Is it desirable?

In combination, the complexity of the pharmaceutical system and the variety of negotiating strategies present barriers to implementing the WHA Resolution 72.8 on transparency as envisioned (World Health Assembly, 72, 2019). Nevertheless, movement towards price transparency can be expected. Especially after the experience of negotiating EUwide prices for COVID-19 vaccines, policy-makers may have a new appetite for collaboration (including joint procurement) led by governments or by a supranational institution, which could be designed to enhance price transparency, at least among those in a group.

At the same time, some payers develop new approaches to meet other priorities, such as pricing based on explicit value frameworks or steering medicines development towards unmet needs. Arrangements such as APAs would demonstrate willingness to pay for specific medicines to treat designated disease areas. However, countries have different capacity in terms of established pricing strategies and means of assessing value, measuring outcomes, technical know-how and negotiating position, all of which creates an uneven landscape across Europe and beyond. Some policies may even require collaborative action since they may be too large an undertaking for a single country. Policies supporting NPT might therefore be higher on the reform agenda for some countries than others, and might be addressed in cross-country collaborative action, but the interconnectedness described in this brief means that a perspective incorporating consequences for other countries and consequences for availability and affordability in one's own system due to effects in other countries should be considered.

Providing equitable access to affordable medicines is more important than ever

Ultimately, reforms in pharmaceutical policy are best evaluated in the context of the triple aim: 1) providing timely and affordable access to safe and effective medicines; 2) continually focusing on innovation by providing incentives to support research for the development of truly innovative treatments; and 3) safeguarding financial sustainability by pricing publicly funded medicines at an appropriate level for future health and pharmaceutical budgets. These three aims operate against a background of payer needs and highlight the importance of effective governance, including at the international level.

Discussions focusing solely on price transparency risk overshadowing the significance of equitable access to affordable medicines. Countries with weaker negotiating positions, whether due to their population size and/or ability to pay, have more limited capacity in procuring medicines and providing access to patients, and may define 'value for money' differently based on their wealth or development. Outside the EU framework, countries with a limited budget for pharmaceuticals, and thus likely fewer medicines in reimbursement, tend to have less transparency of list prices as they do not have to adhere to the provisions of the EU Transparency Directive (European Union, 1988). As some non-EU countries start to introduce price regulation, some have begun moving towards confidential MEAs. Yet, as described earlier in this brief, such agreements come with additional complexities, and their role in ensuring equitable and affordable access is not uncontested.

Ensuring that the incentives system supports innovation

Pharmaceutical advancements have supported longer and healthier lives, and innovation requires continued investments in research and development. This R&D is funded based on the revenue of pharmaceutical companies as well as public-sector investment, particularly in the earlier stages in the life cycle of a medicine. From the industry's perspective, NPT may be viewed as a cost-cutting measure leading to a race-to-the-bottom on price across countries, which could not only impact negatively on affordability and availability as discussed above, but also endanger the sustainability of future R&D. However, this does not have to be the case, as discussed earlier in this brief. The current business model incentivizes the private sector to seek maximum shareholder profits, which may reward 'quick wins' rather than long-term investments in innovation. Alternative incentive strategies, such as APAs linked to public health needs, may provide a way forward to incentivize innovation over the longer term and more closely align with the ultimate health-system goal of improved health (see also Panteli & Edwards, 2018).

Strong political commitment and recognizing that payers have different priorities and capacities is paramount for any movement towards increased price transparency

Payers seek to make the best use of available resources and thus achieve the most affordable prices for medicines for their populations, but different countries and payers have different negotiating positions. This needs to be factored in during international discussions on price transparency policies. Pricing approaches that account for these differences, such as taking gross domestic product (GDP) into account (e.g. price paid for a pharmaceutical depends on GDP per capita) or incorporate subsidy assistance, could be used to ensure access to medicines in countries with a lower ability to pay. Alternatively, joint negotiations could cluster countries to pool together middle-income and highincome countries. Either of these strategies requires international collaboration supported by guidance or action on the international level to operationalize.

The 2019 WHA Resolution on NPT in pharmaceuticals, as well as other efforts that would alter the pharmaceutical system, require strong political support to come to fruition (World Health Assembly, 72, 2019). However, payers and procurers are not homogenous and have different incentives in their interactions with pharmaceutical companies. Moreover, even though current practices such as ERP are widely criticized, they are perhaps more feasible for policy-

makers with more limited experience and know-how to implement than a value framework for purchasing innovative pharmaceuticals or ministerial agreements for joint procurement. In the EU, the economic background and context of solidarity might enable more transparency. However, any movement towards price transparency requires effective governance at multiple levels, as well as sustained government will to implement the reform. Ongoing discussions as part of the Oslo Medicines Initiative (WHO, 2021b) within Europe and the Fair Pricing Forum (WHO, 2021a) more globally represent opportunities to continue these efforts. The Pharmaceutical Strategy for Europe, adopted in November 2020, also aims to create a regulatory framework for the EU (European Commission, 2020b).

Does a transparent price equal a fair price?

Price transparency is often (although not necessarily) linked to discussions about cost containment, with the assumption that increased price transparency would lead to lower prices, as discussed above. If price transparency led to price compression, pharmaceutical companies might have lower revenues from the countries with high willingness to pay. This anticipated result is based on another assumption, namely that if countries realize they are paying more for a medicine than others, they will use this as an argument to demand lower prices because they would consider their price paid unfair. Yet, this may not be the case, as highincome countries may not demand or expect to achieve prices paid in countries with a much lower ability to pay. The element of fairness of pricing across countries would certainly arise with increased NPT and should be considered as part of the policy implementation process.

Conclusions

Empirical evidence on the effects of policies to increase the transparency of prices paid for pharmaceuticals on prices and overall cost containment is scarce and/or with limited transferability to the current debate; this is largely due to a lack of such policies in pharmaceutical markets. The evidence that does exist points to the significance of the specific products for which such policies are enforced (e.g. on-patent versus off-patent medicines) as well as contextual factors. Policy action on pharmaceutical price transparency must consider the differing needs and capacities across countries as well as the complexities of the interactions between stakeholders, and recognize that the process of implementation may shape the policy's impact. However, based on discussions so far and in light of the new urgency caused by the COVID-19 pandemic, there is good reason to re-examine the established trade-offs in pharmaceutical policy in providing timely and affordable access to innovative medicines in Europe and worldwide.

8. Annex: Methods

To answer the research questions and arrive at useful policy lessons, this work uses three distinct steps:

- 1. Desk research in scientific and policy literature to identify empirical, but also other types of information, on the effect of price transparency on prices. An exploratory scoping search to identify available evidence was used as the basis for more targeted searches following initial results.
- 2. Expert review of the summary of evidence identified in Step 1.
- 3. Group interviews with various stakeholders from along the interest spectrum to further refine and contextualize findings and understand the real-world applicability and implications of related policy change.

The results of the exploratory scoping search identified few industries in the literature that had information about the effect of policies increasing transparency. The examples contained in this brief highlight key available examples, but should not be seen as an exhaustive literature review.

To accomplish Step 3, the Observatory conducted five group interviews with 25 stakeholders (Table 1). Each group interview was conducted virtually via Zoom for 90 minutes. The group interviews involved academic experts, pharmaceutical industry representatives and payer agents. This enabled access to a wide range of opinions, but the data collected cannot be considered representative of one or another group. Dimitra Panteli led the group interviews while Erin Webb and Erica Richardson took notes. The semistructured interviews roughly followed an interview guide, with active participation. The session was not recorded and used Chatham House Rules to ensure anonymity. After the session, the notes were compiled into a short summary and sent to all participants for validation. The notes were analyzed by hand and the key themes that ran through the interviews were identified by members of the research team working independently. These cross-cutting themes and findings are presented throughout this policy brief, but are not attributed in order to preserve the anonymity of group interview participants.

Table 1: Price transparency group interviews	
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DATE	GROUP	NUMBER OF PARTICIPANTS
27 April 2021, 16:30–18:00	Academic experts	6
28 April 2021, 16:00–17:30	Academic experts	3
29 April 2021, 14:00–15:30	Pharmaceutical industry representatives	4
07 May 2021, 13:00–14:30	Payer agents	6
26 May 2021, 12:00–13:30	Payer agents	6

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How do Policy Briefs bring the evidence together?

There is no one single way of collecting evidence to inform policymaking. Different approaches are appropriate for different policy issues, so the Observatory briefs draw on a mix of methodologies (see Figure A) and explain transparently the different methods used and how these have been combined. This allows users to understand the nature and limits of the evidence.

There are two main 'categories' of briefs that can be distinguished by method and further 'sub-sets' of briefs that can be mapped along a spectrum:

- A rapid evidence assessment: This is a targeted review of the available literature and requires authors to define key terms, set out explicit search strategies and be clear about what is excluded.
- Comparative country mapping: These use a case study approach and combine document reviews and consultation with appropriate technical and country experts. These fall into two groups depending on whether they prioritize depth or breadth.
- Introductory overview: These briefs have a different objective to the rapid evidence assessments but use a similar methodological approach. Literature is targeted and reviewed with the aim of explaining a subject to 'beginners'.

Most briefs, however, will draw upon a mix of methods and it is for this reason that a 'methods' box is included in the introduction to each brief, signalling transparently that methods are explicit, robust and replicable and showing how they are appropriate to the policy question.

Figure A: The policy brief spectrum



Source: Erica Richardson

The Policy Brief Series

- 1. How can European health systems support investment in and the implementation of population health strategies? David McDaid, Michael Drummond, Marc Suhrcke
- 2. How can the impact of health technology assessments be enhanced?
- Corinna Sorenson, Michael Drummond, Finn Børlum Kristensen, Reinhard Busse
- 3. Where are the patients in decision-making about their own care? Angela Coulter, Suzanne Parsons, Janet Askham
- 4. How can the settings used to provide care to older people be balanced? Peter C. Coyte, Nick Goodwin, Audrey Laporte
- When do vertical (stand-alone) programmes have a place in health systems? *Rifat A. Atun, Sara Bennett, Antonio Duran*
- How can chronic disease management programmes operate across care settings and providers? Debbie Singh
- 7. How can the migration of health service professionals be managed so as to reduce any negative effects on supply? *James Buchan*
- 8. How can optimal skill mix be effectively implemented and why? *Ivy Lynn Bourgeault, Ellen Kuhlmann, Elena Neiterman, Sirpa Wrede*
- 9. Do lifelong learning and revalidation ensure that physicians are fit to practise?

Sherry Merkur, Philipa Mladovsky, Elias Mossialos, Martin McKee

- 10. How can health systems respond to population ageing? Bernd Rechel, Yvonne Doyle, Emily Grundy, Martin McKee
- 11. How can European states design efficient, equitable and sustainable funding systems for long-term care for older people? José-Luis Fernández, Julien Forder, Birgit Trukeschitz,
- Martina Rokosová, David McDaid 12. How can gender equity be addressed through health systems? Sarah Payne
- 13. How can telehealth help in the provision of integrated care? Karl A. Stroetmann, Lutz Kubitschke, Simon Robinson, Veli Stroetmann, Kevin Cullen, David McDaid
- 14. How to create conditions for adapting physicians' skills to new needs and lifelong learning Tanya Horsley, Jeremy Grimshaw, Craig Campbell
- 15. How to create an attractive and supportive working environment for health professionals
- Christiane Wiskow, Tit Ålbreht, Carlo de Pietro
 16. How can knowledge brokering be better supported across European health systems?
- John N. Lavis, Govin Permanand, Cristina Catallo, BRIDGE Study Team 17. How can knowledge brokering be advanced in
- a country's health system? John. N Lavis, Govin Permanand, Cristina Catallo, BRIDGE Study Team
- How can countries address the efficiency and equity implications of health professional mobility in Europe? Adapting policies in the context of the WHO Code and EU freedom of movement *Irene A. Glinos, Matthias Wismar, James Buchan, Ivo Rakovac*
- 19. Investing in health literacy: What do we know about the co-benefits to the education sector of actions targeted at children and young people? *David McDaid*
- How can structured cooperation between countries address health workforce challenges related to highly specialized health care? Improving access to services through voluntary cooperation in the EU Marieke Kroezen, James Buchan, Gilles Dussault,
 - Irene Glinos, Matthias Wismar
- 21. How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe? Jaime Espín, Joan Rovira, Antoinette Calleja, Natasha Azzopardi-Muscat, Erica Richardson, Willy Palm, Dimitra Panteli
- 22. How to strengthen patient-centredness in caring for people with multimorbidity in Europe? Iris van der Heide, Sanne P Snoeijs, Wienke GW Boerma, François GW Schellevis, Mieke P Rijken. On behalf of the ICARE4EU consortium

- 23. How to improve care for people with multimorbidity in Europe? Mieke Rijken, Verena Struckmann, Iris van der Heide, Anneli Hujala, Francesco Barbabella, Ewout van Ginneken, François Schellevis. On behalf of the ICARE4EU consortium
- 24. How to strengthen financing mechanisms to promote care for people with multimorbidity in Europe? Verena Struckmann, Wilm Quentin, Reinhard Busse, Ewout van Ginneken. On behalf of the ICARE4EU consortium
- 25. How can eHealth improve care for people with multimorbidity in Europe? Francesco Barbabella, Maria Gabriella Melchiorre, Sabrina Quattrini, Roberta Papa, Giovanni Lamura. On behalf of the ICARE4EU consortium
- 26. How to support integration to promote care for people with multimorbidity in Europe? Anneli Hujala, Helena Taskinen, Sari Rissanen. On behalf of the ICARE4EU consortium
- 27. How to make sense of health system efficiency comparisons? Jonathan Cylus, Irene Papanicolas, Peter C Smith
- 28. What is the experience of decentralized hospital governance in Europe?
 - Bernd Rechel, Antonio Duran, Richard Saltman
- 29. Ensuring access to medicines: How to stimulate innovation to meet patients' needs? Dimitra Panteli, Suzanne Edwards
- 30. Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? Sabine Vogler, Valérie Paris, Dimitra Panteli
- 31. Connecting food systems for co-benefits: How can food systems combine diet-related health with environmental and economic policy goals? *Kelly Parsons, Corinna Hawkes*
- 32. Averting the AMR crisis: What are the avenues for policy action for countries in Europe? Michael Anderson, Charles Clift, Kai Schulze, Anna Sagan, Saskia Nahrgang, Driss Ait Ouakrim, Elias Mossialos
- 33. It's the governance, stupid! TAPIC: a governance framework to strengthen decision making and implementation Scott L. Greer, Nikolai Vasev, Holly Jarman, Matthias Wismar, Josep Figueras
- 34. How to enhance the integration of primary care and public health? Approaches, facilitating factors and policy options Bernd Rechel
- 35. Screening. When is it appropriate and how can we get it right? Anna Sagan, David McDaid, Selina Rajan, Jill Farrington, *Martin McKee*
- Strengthening health systems resilience: key concepts and strategies Steve Thomas, Anna Sagan, James Larkin, Jonathan Cylus, Josep Figueras, Marina Karanikolos
- Building on value-based health care Peter C Smith, Anna Sagan, Luigi Siciliani, Dimitra Panteli, Martin McKee, Agnès Soucat, Josep Figueras
- Regulating the unknown: A guide to regulating genomics for health policy-makers Gemma A Williams, Sandra Liede, Nick Fahy, Kristiina Aittomaki,
- Markus Perola, Tuula Helander, Martin McKee, Anna Sagan
 39. In the wake of the pandemic: Preparing for Long COVID Selina Rajan, Kamlesh Khunti, Nisreen Alwan, Claire Steves, Trish Greenhalgh, Nathalie MacDermott, Anna Sagan, Martin McKee
- 40. How can we transfer service and policy innovations between health systems?
- *Ellen Nolte, Peter Groenewegen* 41. What are the key priority areas where European health systems can
- learn from each other? Johan Hansen, Alexander Haarmann, Peter Groenewegen, Natasha Azzopardi Muscat, Gianpaolo Tomaselli, Mircha Poldrugovac
- Use of digital health tools in Europe: Before, during and after COVID-19 Nick Fahy, Gemma A Williams, COVID-19 Health System Response
- 43. European support for improving health and care systems
- European support for improving health and care system: Nick Fahy, Nicole Mauer, Dimitra Panteli
- 44. What are patient navigators and how can they improve integration of care? Hannah Budde, Gemma A Williams, Giada Scarpetti, Marieke Kroezen, Claudia B Maier

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World Health Organization Regional Office for Europe UN City, Marmorvej 51, DK-2100 Copenhagen Ø, Denmark Tel.: +45 45 33 70 00 Fax: +45 45 33 70 01 E-mail: eurocontact@who.int Website: www.euro.who.int

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