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## Exploring the consequences of greater price transparency on the dynamics of pharmaceutical markets

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## Abstract

For some time, governments, stakeholders and civil society have been voicing the need for greater transparency in pharmaceutical pricing. The 2018 OECD report *Pharmaceutical Innovation and Access to Medicines* suggested that increased price transparency could promote public accountability, while potentially delivering efficiencies to health systems by including economic considerations in coverage decisions, treatment guidelines, and budget allocation. Despite this, precisely what should (and indeed, could) be made more transparent, and how greater transparency would affect the functioning of markets, have been poorly characterised. Various published commentaries and analyses discussing the benefits and drawbacks of greater price transparency have not been grounded in empirical evidence. To help frame the policy debate, in late 2021 the OECD undertook an exploration of the potential consequences of greater price transparency on market dynamics. The work included a roundtable and a series of semi-structured interviews, with overall participation by 19 experts in pharmaceutical pricing, economics of pharmaceutical markets, competition, and law. With an extensive review of the current practice and relevant literature as a preface, this Working Paper presents the key findings from those consultations.

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## **Executive Summary**

Price opacity has become commonplace in pharmaceutical markets as actual transaction prices paid by purchasers are increasingly disconnected from public or "list" prices, in part the result of the proliferation of confidential agreements between manufacturers and health care payers. It can be argued that confidentiality assists payers in achieving more favourable net prices, and companies in price discriminating between countries, which promotes equitable access and which can be efficient in an economic sense. At the same time, however, confidentiality is undermining the confidence of both payers and patients about the industry, and further challenging policy makers in attempting to find a balance between rewarding innovation, delivering affordable access, and maintaining the sustainability of health systems. Confidential prices prevent the general public from scrutinising public expenditure, and undermine the accountability of reimbursement and coverage decisions.

Growing public pressure for coordinated international action on price transparency culminated in 2019 with the adoption of a 72nd World Health Assembly resolution on "Improving the transparency of markets for medicines, vaccines, and other health products". Despite this, precisely what should be made more transparent, and how greater transparency would affect the functioning of markets, has been poorly characterised. This paper presents a review of the relevant literature and evidence and outlines four key findings resulting from a series of consultations with experts who shared their insights on how price transparency could affect the dynamics of pharmaceutical markets:

- Current efforts toward greater price transparency are "hastening slowly". To date, despite the establishment of a number of national and international databases and mechanisms for sharing pricing information either publicly or among competent authorities, there is little evidence to support the effectiveness of these initiatives in advancing transparency in pharmaceutical information. Some OECD countries have adopted national legal provisions moving towards greater disclosure of information on negotiated prices, revenues, or public funding of pharmaceutical research and development (R&D). Several countries have established public databases with information on pharmaceutical pricing, or have implemented mechanisms for data sharing between competent authorities in order to facilitate joint price negotiations. However, internationally, despite 30 cross-country initiatives that share some pricing information, few disclose actual transaction prices.
- There is neither clarity nor consensus among countries and stakeholders about the
  objectives of greater price transparency, or about precisely what information should be
  disclosed. Deliberations about price transparency are often coupled with discussions of
  transparency of other sorts of pharmaceutical information including industry revenues and costs,
  clinical trial data, patents and exclusivity rights, and public funding of R&D. Transparency is viewed
  both as "a means to an end" in achieving lower prices and/or expanded access, and an end in
  itself, reflecting its intrinsic value for public accountability. Among different countries, motives and
  objectives for seeking greater price transparency vary according to national wealth; the size of the
  pharmaceutical market; and the capacity and negotiating power of national competent authorities.

Objectives also vary significantly among the stakeholders – the industry, payers and pricing authorities, policy makers, and civil society.

- The literature exploring the likely consequences of greater price transparency across countries is sparse. Current literature examines the impact of government initiatives mandating greater price transparency on prices within countries, but is poor to consider any potential spillover effects across countries. Evidence to date has been drawn from modelling theoretically the impact of simplified simulated scenarios drawing on list prices and making assumptions about discounts and rebates that cannot be verified. Moreover, evidence from within individual countries is inconclusive, with some studies suggesting no clear effect of greater price transparency on price levels, while others show price movements in both directions. There is no evidence of transnational effects of greater price transparency on pharmaceutical market dynamics, including the potential impact on external reference pricing, and on differential pricing and parallel trade between countries.
- There was substantial disagreement among the experts consulted on how greater • transparency could impact the functioning of markets. Some were confident that greater price transparency could render significant benefits, namely stronger bargaining power for public payers in price negotiations with industry, greater public accountability and legitimacy of coverage decisions. Others saw greater price transparency as introducing new risks to the functioning of markets, for example, through price convergence, with the potential for higher prices and/or reduced patient access in countries with lesser ability to pay, unclear effects on differential pricing and parallel trade, and uncertain consequences for long term commercial decisions regarding both market participation and investment in R&D. Neither perspective is supported by the existing evidence, arguably suggesting a need for caution in moving the agenda forward. Coordinated international action on fully disclosing data on net prices is not necessarily desirable or sustainable as it would require extraordinary political commitment to overcome dominant national self-interest. Moreover, with transparent net prices, some experts suggested that some payers would be likely to resile from cooperating-in-transparency agreements and re-engage in confidential negotiations. Also, companies might be less willing to agree to lower prices in low and middle income countries (LMICs), and would adjust their pricing and launch strategies accordingly. Overall, there would be winners and losers, with unclear impact on differential pricing and equity of access. Greater price transparency might evolve as a hybrid regime, with agreement on a formal tiered pricing framework in which countries could, for example, commit to disclosing net prices within pre-specified ranges, rather than agreeing to a regime of complete transparency per se.

Five actions were identified as necessary to move the agenda on price transparency forward:

- Investing in evidence generation of the impact of existing cross-country initiatives that share price information in order to inform future action on price transparency. This report outlines the main features of the cross-country initiatives currently sharing price data and highlights the insufficient evidence to date demonstrating the effectiveness of efforts to increase medicine price transparency;
- <u>Greater clarity about the issues that greater price transparency is expected to address</u>, and consideration of whether other policy options might be more effective/less risk prone. The motives for greater price transparency vary across countries and between stakeholders, some of whom view transparency as essential to addressing a number of critical policy challenges, despite the lack of empirical evidence of effectiveness. The OECD is currently undertaking a country survey to understand the willingness, expectations, and motives of governments and payers in sharing information on medicine prices;</u>
- <u>Modelling of the spillover effects of greater price transparency</u> to anticipate the behaviour of stakeholders and the effects on prices and markets. Modelling would facilitate a better

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understanding of the complex interactions between the multiple stakeholders and countries in the global pharmaceutical market, and allow the consideration of a number of parameters, including interconnections, uncertainties, information opacities, and static and dynamic mechanisms. Modelling should accommodate different scenarios since the implications of price transparency are expected to differ quite substantially across markets, e.g. comparing consequences among high income countries (HICs); versus between HICs and LMICs; across the European Union (EU), or between the EU and the United States; as well as consider the various strategic reactions of companies under price transparency considering the different number of competitors and type of market exclusivity rights granted;

- Agreement on those elements of transparency that should be prioritised, as calls for greater transparency include *inter alia* transparency of pricing, patent information, public funding of R&D, and clinical trial data. Information available in the public domain on industry revenues, R&D costs, and marketing expenditure is often unreliable or incomplete, with data and methods often not disclosed and sources subject to controversy. Patent data are publicly available but can require specialised expertise for interpretation, while data on public funding are biased towards publicly listed companies, and are not structured in a way that facilitates policy analysis. Greater clarity about the objectives as well as the data and analytical frameworks to be used is needed to move towards some (or all) forms of transparency; and
- Understanding what price information countries could share and how, and the conditions under which they would agree to do so. The OECD has undertaken a country survey to determine the information (i.e. which prices, and for which medicines) that could be shared, and by what mechanisms, taking into account existing legal frameworks and technical barriers. An analysis of the results of this survey will be presented in a subsequent report. Various arrangements for sharing data could be considered, for example, groups of countries could agree to share confidential pricing information on a reciprocal basis between competent authorities in a closed network, but without public disclosure.

## Résumé et points saillants

L'opacité des prix est devenue monnaie courante sur les marchés pharmaceutiques, les prix de transaction réels payés par les acheteurs étant de plus en plus déconnectés des prix publics ou "de liste", en partie à cause de la prolifération d'accords confidentiels entre les fabricants et les payeurs de soins de santé. On peut faire valoir que la confidentialité aide les payeurs à obtenir des prix nets plus favorables et les entreprises à pratiquer une discrimination par les prix entre les pays, ce qui favorise un accès équitable et peut être efficace d'un point de vue économique. Dans le même temps, cependant, la confidentialité sape la confiance des payeurs et des patients à l'égard de l'industrie, et pose un défi supplémentaire aux décideurs politiques qui tentent de trouver un équilibre entre la récompense de l'innovation, la fourniture d'un accès abordable et le maintien de la durabilité des systèmes de santé. La confidentialité des prix empêche le grand public de contrôler les dépenses publiques et compromet la responsabilité des décisions de remboursement et de couverture.

La pression publique croissante en faveur d'une action internationale coordonnée sur la transparence des prix a culminé en 2019 avec l'adoption d'une résolution de la 72e Assemblée mondiale de la santé sur « l'amélioration de la transparence des marchés des médicaments, vaccins et autres produits de santé ». Malgré cela, ce qui devrait précisément être rendu plus transparent, et de quelle manière une plus grande transparence affecterait le fonctionnement des marchés, a été mal caractérisé. Ce document présente un examen de la littérature et des preuves pertinentes et expose quatre conclusions clés résultant d'une série de consultations avec des experts qui ont partagé leurs idées sur la façon dont la transparence des prix pourrait affecter la dynamique des marchés pharmaceutiques :

- Les efforts actuels en faveur d'une plus grande transparence des prix « s'accélèrent lentement ». À ce jour, malgré la mise en place d'un certain nombre de bases de données nationales et internationales et de mécanismes de partage des informations sur les prix, soit publiquement, soit entre les autorités compétentes, peu de preuves attestent de l'efficacité de ces initiatives pour faire progresser la transparence de l'information pharmaceutique. Certains pays de l'OCDE ont adopté des dispositions juridiques nationales allant dans le sens d'une plus grande divulgation des informations sur les prix négociés, les recettes ou le financement public de la recherche et du développement pharmaceutiques. Plusieurs pays ont créé des bases de données publiques contenant des informations sur les prix des produits pharmaceutiques, ou ont mis en place des mécanismes de partage des données entre les autorités compétentes afin de faciliter les négociations conjointes sur les prix. Cependant, à l'échelle internationale, malgré 30 initiatives transnationales qui partagent certaines informations sur les prix de transaction réels.
- Il n'y a ni clarté ni consensus entre les pays et les parties prenantes sur les objectifs d'une plus grande transparence des prix, ou sur les informations précises qui devraient être divulguées. Les délibérations sur la transparence des prix sont souvent associées à des discussions sur la transparence d'autres types d'informations pharmaceutiques - notamment les revenus et les coûts de l'industrie, les données des essais cliniques, les brevets et les

droits d'exclusivité, ainsi que le financement public de la recherche et du développement (R&D). La transparence est considérée à la fois comme "un moyen d'arriver à une fin" en obtenant des prix plus bas et/ou un accès élargi, et comme une fin en soi, reflétant sa valeur intrinsèque pour la responsabilité publique. Dans les différents pays, les motifs et les objectifs de la recherche d'une plus grande transparence des prix varient en fonction de la richesse nationale, de la taille du marché pharmaceutique, ainsi que de la capacité et du pouvoir de négociation des autorités nationales compétentes. Les objectifs varient également de manière significative entre les parties prenantes - l'industrie, les payeurs et les autorités de tarification, les décideurs politiques et la société civile.

- La littérature explorant les conséquences probables d'une plus grande transparence des prix entre les pays est rare. La littérature actuelle examine l'impact des initiatives gouvernementales imposant une plus grande transparence des prix sur les prix à l'intérieur des pays, mais elle est pauvre en ce qui concerne les effets d'entraînement potentiels entre les pays. Jusqu'à présent, les preuves ont été tirées de la modélisation théorique de l'impact de scénarios simulés simplifiés s'appuyant sur les prix catalogue et faisant des hypothèses sur les remises et les rabais qui ne peuvent être vérifiées. En outre, les données recueillies dans les différents pays ne sont pas concluantes, certaines études ne suggérant aucun effet clair d'une plus grande transparence des prix sur les niveaux de prix, tandis que d'autres montrent des mouvements de prix dans les deux sens. Il n'existe aucune preuve des effets transnationaux d'une plus grande transparence des prix sur les prix sur la dynamique du marché pharmaceutique, y compris l'impact potentiel sur les prix de référence externes, ainsi que sur les prix différentiels et le commerce parallèle entre les pays.
- Les experts consultés n'étaient pas tous d'accord sur l'impact d'une plus grande transparence sur le fonctionnement des marchés. Certains étaient convaincus qu'une plus grande transparence des prix pourrait apporter des avantages significatifs, à savoir un pouvoir de négociation plus fort pour les payeurs publics dans les négociations de prix avec l'industrie, une plus grande responsabilité publique et la légitimité des décisions de couverture. D'autres considéraient qu'une plus grande transparence des prix introduisait de nouveaux risques pour le fonctionnement des marchés, par exemple, par la convergence des prix, avec le potentiel de prix plus élevés et/ou d'un accès réduit des patients dans les pays ayant une moindre capacité de paiement, des effets peu clairs sur la tarification différentielle et le commerce parallèle, et des conséquences incertaines sur les décisions commerciales à long terme concernant à la fois la participation au marché et l'investissement dans la recherche et le développement. Aucune des deux perspectives n'est étavée par les données existantes, ce qui incite à la prudence dans l'avancement de l'agenda. Une action internationale coordonnée sur la divulgation complète des données sur les prix nets n'est pas nécessairement souhaitable ou durable, car elle nécessiterait un engagement politique extraordinaire pour surmonter les intérêts nationaux dominants. De plus, avec des prix nets transparents, certains experts ont suggéré que certains payeurs seraient susceptibles de renoncer aux accords de coopération en matière de transparence et de se réengager dans des négociations confidentielles. De même, les entreprises pourraient être moins disposées à accepter des prix plus bas dans les pays à revenu faible et moyen (PRFM) et adapteraient leurs stratégies de prix et de lancement en conséquence. Dans l'ensemble, il y aurait des gagnants et des perdants, et l'impact sur la tarification différenciée et l'équité d'accès ne serait pas clair. Une plus grande transparence des prix pourrait évoluer sous la forme d'un régime hybride, avec un accord sur un cadre formel de tarification par paliers dans lequel les pays pourraient, par exemple, s'engager à divulguer les prix nets dans des fourchettes préétablies, plutôt que de convenir d'un régime de transparence totale en soi.

Cinq actions ont été identifiées comme nécessaires pour faire avancer l'agenda sur la transparence des prix :

- Investir dans la production de preuves de l'impact des initiatives transnationales <u>existantes</u> qui partagent les informations sur les prix afin d'informer les actions futures sur la transparence des prix. Le présent rapport décrit les principales caractéristiques des initiatives transnationales existantes de partage des données sur les prix et met en évidence l'insuffisance des preuves à ce jour démontrant l'efficacité des efforts visant à accroître la transparence des prix des médicaments ;
- Une plus grande clarté sur les problèmes qu'une plus grande transparence des prix est <u>censée résoudre</u>, et la prise en compte de la question de savoir si d'autres options politiques pourraient être plus efficaces/moins risquées. Les motifs d'une plus grande transparence des prix varient d'un pays à l'autre et d'une partie des parties prenantes à l'autre, certaines d'entre elles considérant que la transparence est essentielle pour relever un certain nombre de défis politiques critiques, malgré le manque de preuves empiriques de son efficacité. L'OCDE réalise actuellement une enquête par pays pour comprendre la volonté, les attentes et les motivations des gouvernements et des payeurs en matière de partage des informations sur les prix des médicaments.
- La modélisation des retombées d'une plus grande transparence des prix afin d'anticiper le comportement des parties prenantes et les effets sur les prix et les marchés. La modélisation faciliterait une meilleure compréhension des interactions complexes entre les multiples parties prenantes et pays du marché pharmaceutique mondial, et permettrait de prendre en compte un certain nombre de paramètres, notamment les interconnexions, les incertitudes, l'opacité des informations et les mécanismes statiques et dynamiques. La modélisation doit prendre en compte différents scénarios, car les implications de la transparence des prix devraient différer sensiblement d'un marché à l'autre, par exemple en comparant les conséquences entre les pays à haut revenu (PFR), entre les PFR et les PRFM, au sein de l'Union européenne (UE) ou entre l'UE et les États-Unis ; elle doit également prendre en considération les diverses réactions stratégiques des entreprises en cas de transparence des prix, compte tenu du nombre de concurrents et du type de droits d'exclusivité commerciale accordés ;
- Un accord sur les éléments de transparence qui devraient être prioritaires, les appels à une plus grande transparence portant notamment sur la transparence des prix, les informations sur les brevets, le financement public de la R&D et les données sur les essais cliniques. Les informations disponibles dans le domaine public sur les revenus de l'industrie, les coûts de R&D, les dépenses de marketing sont souvent peu fiables ou incomplètes, les données et les méthodes n'étant souvent pas divulguées et les sources sujettes à controverse. Les données sur les brevets sont accessibles au public mais leur interprétation peut nécessiter une expertise spécialisée, tandis que les données sur le financement public sont orientées vers les entreprises cotées en bourse et ne sont pas structurées de manière à faciliter l'analyse des politiques. Une plus grande clarté sur les objectifs ainsi que sur les données et les cadres analytiques à utiliser est nécessaire pour évoluer vers certaines (ou toutes) formes de transparence ;
- Comprendre quelles informations sur les prix les pays pourraient partager et comment, et les conditions dans lesquelles ils accepteraient de le faire. L'OCDE a entrepris une enquête par pays afin de déterminer les informations (c'est-à-dire quels prix, et pour quels médicaments) qui pourraient être partagées, et par quels mécanismes, en tenant compte des cadres juridiques et des obstacles techniques existants. Une analyse des résultats de cette enquête sera présentée dans un rapport ultérieur. Diverses modalités de partage des données pourraient être envisagées, par exemple, des groupes de pays pourraient convenir de partager des informations confidentielles sur les prix sur une base réciproque entre les autorités compétentes dans un réseau fermé, mais sans divulgation publique.

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This document presents supplementary material available online: https://www.oecd.org/health/Supplementary-Analysis-Price-Transparency-Pharma-Markets-2022.pdf.

#### List of acronyms / abbreviations

AIFA	Agenzia Italiana del Farmaco
BAG	Bundesamt für Gesundheit
BeNeLuxA	Belgium, the Netherlands, Luxembourg, Austria and Ireland Initiative
CMS	Centers for Medicare and Medicaid Services
DAA	Direct Acting Antivirals
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EURIPID	European Integrated Price Information Database
FaAP	Fair and Affordable Pricing Initiative
HIC	High Income Countries
HTA	Health Technology Assessment
IHSI	International Horizon Scanning Initiative
LMIC	Low and/or Middle Income Countries
MEDEV	Medicine Evaluation Committee
MI4A	Market Information for Access to Vaccines Initiative
NCAPR	National Competent Authorities on Pricing and Reimbursement
NHS	National Health System
NICE	National Institute for Health and Care Excellence
OECD	Organisation for Economic Co-operation and Development
РАНО	Pan American Health Organization
рСРА	Pan-Canadian Pharmaceutical Alliance
PPI	Pharma Price Information
PPP	Purchasing Power Parity
PPRI	Pharma Price Information service
R&D	Research and Development
SISMED	Sistema de Información de Precios de Medicamentos
UNICEF	United Nations International Children's Emergency Fund
UNFPA	United National Populations Fund
VII	UNICEF's vaccine independence initiative
WHA	World Health Assembly
WHO	World Health Organization

## 1. Introduction

## **1.1. Calls for greater price transparency of medicines warrant further policy debate**

1. Transparency has become a prominent topic in pharmaceutical policy in recent years. In pharmaceutical markets, price opacity is commonplace, as actual transaction prices paid by purchasers are increasingly disconnected from public or "list" prices, in part the result of the proliferation of confidential agreements between manufacturers and health care payers (Wenzl and Chapman, 2019[1]; OECD, 2018[2]). Some of these agreements are intended to mitigate risks to payers arising from uncertainty around clinical and/or cost-effectiveness of novel products with high price tags, while others are designed to limit expenditure risk and overall budget impact. The result, more often than not, is that actual transaction prices are not open to scrutiny, including by payers from other countries. Payers may negotiate with industry undisclosed up-front discounts, price-volume arrangements or expenditure caps with ex-post rebates, all of which can reduce net prices to well below the list prices proposed by manufacturers. Non-disclosure of this information is the norm and part of confidential agreements between manufacturers and payers, which can assist payers in achieving favourable net prices, and companies in price discriminating between countries. However, the practice also reduces the utility of international benchmarking [See Box 1.1 for a taxonomy of definitions of different price types often used in the price transparency debate].

2. Confidentiality is deemed essential for price discrimination across countries by industry, as it ostensibly supports more affordable access in lower-priced markets, while protecting prices (and profits) in countries with greater ability to pay. However, there is some evidence to suggest that prices are not invariably lower in LMICs (Vogler, Vitry and Babar, 2016<sub>[3]</sub>; lyengar et al., 2016<sub>[4]</sub>; Lopert, 2017<sub>[5]</sub>). As a result, price opacity is undermining the confidence of both payers and patients, and further challenging policy makers attempting to balance rewarding innovation, delivering affordable access, and maintaining the sustainability of health systems. Confidential prices prevent the general public from scrutinising public expenditure, and undermines the accountability of reimbursement and coverage decisions. At the international level, price opacity blurs international price benchmarking, which is used by many OECD countries to regulate the prices of medicines, and makes price comparisons between countries misleading (OECD, 2018<sub>[2]</sub>).

3. Growing public pressure for co-ordinated international action culminated in a resolution calling for greater transparency at the 2019 World Health Assembly (WHA), with countries agreeing to publicly share *"the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives"*<sup>1</sup>. However, precisely what can and should be made more transparent, and how greater transparency would affect the functioning of markets is poorly understood. Empirical evidence of the intended and unintended consequences of price transparency between countries is understandably lacking (WHO, 2020<sub>[6]</sub>; Ahmad, Makmor-Bakry and Hatah, 2020<sub>[7]</sub>).

<sup>&</sup>lt;sup>1</sup> 72<sup>nd</sup> World Health Assembly (2019), Improving the transparency of markets for medicines, vaccines, and other health products, World Health Organization, Geneva. At https://apps.who.int/gb/ebwha/pdf\_files/WHA72/A72\_ACONF2Rev1-en.pdf (accessed 7 April 2020).

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4. To help inform this policy debate, the OECD Health Committee proposed an exploration of the feasibility and potential impact of sharing information on net medicine prices across countries, as part of a broader agenda of work on increasing transparency in pharmaceutical markets. The work has been undertaken in three stages: 1) a review and critical appraisal of the relevant literature and evidence; 2) consultations with experts to explore how price transparency could impact the dynamics of pharmaceutical markets; and 3) a country survey to determine the types of information to which countries desire access and would be willing to share, and the conditions under which they would agree to do so, as well as the existence of any legal or other barriers that might preclude this. This paper presents the insights from the first two stages.

## Box 1.1. A taxonomy of types of prices and pricing information that inform the price transparency debate

- List ex-factory price (manufacturer price, ex-manufacturer price, manufacturer's selling price, manufacturer's list price): The manufacturer's posted price of a pharmaceutical or other product. This generally excludes any confidential discounts or rebates to payers.
- Net prices: price actually received by the supply chain actors (i.e. manufacturer, wholesale, pharmacy retail), after subtracting rebates and discounts.
- Wholesale price (pharmacy purchase price): The price charged by wholesalers to the retailers (usually community pharmacies). It is based on the ex-factory price together with remuneration for the pharmaceutical wholesaler (e.g. in the form of a wholesale mark-up or margin).
- Pharmacy retail price (retail price, consumer price): The price charged by community pharmacies to the general
  public, usually based on the wholesale price with the addition of pharmacy remuneration in the form of a pharmacy markup or margin, and in many cases, a dispensing fee or other additional fees. Consumer prices can include or exclude
  value-added tax (net and gross retail prices, respectively).
- Internal) Therapeutic reference pricing: The practice of using the price(s) of similar medicines (ATC 4 level) or with therapeutically equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country. Under this approach, the amount paid by the insurer is limited to the cheapest (or rarely, the average) price mentioned as the reference price of any medicine within a defined therapeutic cluster in which the medicines are deemed to be therapeutic alternatives for a specific indication. A cluster may contain both on and off-patent medicines. Patients pay the difference between the reference price and the actual pharmacy retail price of the medicine, in addition to any copayments (such as prescription fees, fixed co-payments, or coinsurance i.e. percentage co-payments).
- Reimbursement amount or price (published reimbursement list price): The maximum amount of reimbursement paid by a third-party payer (e.g. a health system or insurer) excluding any adjustment for patient co-payment or coinsurance.
- Maximum regulated price: The maximum price (if any) set by pricing authorities or by regulation or legislation.
- Discounted price: Price resulting from upfront or volume-dependent discounts or ex-post rebates. Discounting can
  occur along the supply chain (e.g. applied to ex-factory, wholesale, retail prices, and patients). Discounts are often
  confidential, so that the net price paid remains undisclosed. Discounts can take the form of a mix of flat discounts
  across groups of medicines, discounts by indication, or be based on volumes or expenditure caps, and may even be
  discounts in kind; thus computation of the final transaction price of a product can be highly complex.

Source: Authors based on the Pharmaceutical Pricing and Reimbursement Network (PPRI) Glossary<sup>2</sup>

5. The paper is organised as follows: Section 2. reviews existing national legislations and practices for sharing information on medicine prices, and critically appraises the limited evidence of the likely impact of sharing medicine prices on the functioning of pharmaceutical markets. Section 3. presents the main reflections derived from consultations with international experts on how price transparency could impact the dynamics of pharmaceutical markets. Section 4. outlines the principal findings from this analysis and identifies the key elements needed to move the policy agenda on price transparency forward.

<sup>&</sup>lt;sup>2</sup> <u>https://ppri.goeg.at/ppri-glossary/R</u>

# 2. Efforts to increase transparency in pharmaceutical markets are "hastening slowly"

6. Despite a number of national and international initiatives, there is little evidence to date demonstrating the effectiveness of efforts to increase medicine price transparency. This section examines the current practices of several OECD countries with regard to the disclosure of medicine price information, and explores the landscape of relevant legal provisions. The latter have been recently adopted by some countries in order to promote or mandate increased transparency of information on negotiated prices, industry revenues, or the extent of public funding of pharmaceutical research and development (R&D). Several countries have established public databases with information on pharmaceutical pricing, or have implemented mechanisms for data sharing between competent authorities in order to facilitate joint price negotiations. However, despite more than 30 cross-country initiatives that, to a greater or lesser degree, share medicine price information, confidentiality of net medicine prices remains the norm.

## 2.1. Various recent national legal provisions seek to deliver more transparent pharmaceutical information

7. A few OECD countries have recently adopted legal provisions intended to increase the transparency of different types of pharmaceutical information, however, as yet, there is no evidence demonstrating their effectiveness. Detailed information about the objectives and scope of these legal provisions can be found in <u>Annex A</u> of the Supplementary Material. For example:

- In the European Union, under the Council Directive 89/105/EEC<sup>3</sup>, the Member States should comply with (procedural) requirements to ensure transparency of national decisions on medicine pricing and reimbursement, despite the decisions themselves being a national competence. Transparency of 'net prices' per se is not within the scope of this Directive, in order to avoid potential obstacles to intra-EU trade. However, the need for transparency of prices of medicines has been raised several times in the European Parliament and at Ministerial level.
- In France, the Social Security Budget Bill 2020<sup>4</sup> requires pharmaceutical companies to disclose to the Pricing Committee, *le Comité Économique des Produits de Santé*, the

<sup>&</sup>lt;sup>3</sup> <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31989L0105</u>

<sup>&</sup>lt;sup>4</sup> LOI n° 2020-1576 du 14 décembre 2020 de financement de la sécurité sociale pour 2021 (1) - Légifrance (legifrance.gouv.fr); Article L162-17-4-3 : https://www.legifrance.gouv.fr/codes/article\_lc/LEGIARTI000042673403

**amount of public funding of R&D** when applying for marketing approval of a new product in France, with the aim to disclose this information in the public domain.

- In Italy, legislation was adopted in 2019<sup>5</sup> requiring pharmaceutical companies seeking reimbursement from the national health system (NHS) to disclose information to the Italian Medicines Agency *AIFA* (Agenzia Italiana del Farmaco) regarding the added therapeutic value of the medicine and other information regarding whether the product is subject to confidential agreements, discounted prices negotiated by *AIFA*, sales data, revenue and marketing expenses, and public funding and subsidies received for R&D.
- Spain has also adopted national legislation requiring transparency in government decisionmaking and enshrining citizens' rights to request access to this information<sup>6</sup>. In 2017, the Ministry of Health began publicly disclosing information on pharmaceutical expenditure, both via community pharmacies and hospitals as well as ex-factory discounts available in community pharmacies<sup>7</sup>.
- In the United States, various federal and state laws require public disclosure of pricing information and price reporting by companies or payers. For example, the 2021 Consolidated Appropriations Act<sup>8</sup> requires manufacturers to report (quarterly) average sales price information to Centers for Medicare & Medicaid Services (CMS) for medications covered under Medicare Part B. Also, the 2019 Executive Order *"Improving Price and Quality Transparency in American Health Care to Put Patients First"*<sup>9</sup> requests public disclosure of hospital billing quality information, including information on whether hospitals provide patients with itemised receipts of hospital services and how often hospitals pursue legal action against patients for outstanding bills<sup>10</sup>. Moreover, the 2018 *Know the Lowest Price Act<sup>11</sup>* and *Patients' Right to Know Drug Prices Act<sup>12</sup>* prohibit gag clauses in Medicare Advantage and Part D plans, that would otherwise prevent pharmacies from disclosing information to patients regarding copayments that exceed the price of the medicine.

8. Some non-OECD countries (Armenia, Belarus, Moldova, Russian Federation and Tajikistan) have also adopted legislation requiring national competent authorities to disclose pharmaceutical prices publicly.

<sup>&</sup>lt;sup>5</sup> https://www.gazzettaufficiale.it/eli/gu/2020/07/24/185/sg/pdf

<sup>&</sup>lt;sup>6</sup> Ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno (hacienda.gob.es)

<sup>&</sup>lt;sup>7</sup> https://www.sanidad.gob.es/profesionales/farmacia/ConsumoRecetasATC/ATC\_2021.htm

https://www.sanidad.gob.es/profesionales/medicamentos.do

https://www.boe.es/buscar/pdf/2010/BOE-A-2010-8228-consolidado.pdf

<sup>&</sup>lt;sup>8</sup> Text - H.R.133 - 116th Congress (2019-2020): Consolidated Appropriations Act, 2021 | Congress.gov | Library of Congress

<sup>&</sup>lt;sup>9</sup> President Trump Signs Executive Order to Expand Hospital Price Transparency | AAMC

<sup>&</sup>lt;sup>10</sup> Hospital Price Transparency | CMS

<sup>&</sup>lt;sup>11</sup> <u>Text - S.2553 - 115th Congress (2017-2018)</u>: Know the Lowest Price Act of 2018 | Congress.gov | Library of <u>Congress</u>

<sup>&</sup>lt;sup>12</sup> <u>Text - S.2554 - 115th Congress (2017-2018): Patient Right to Know Drug Prices Act | Congress.gov | Library of Congress</u>

## Several countries have established databases for sharing medicine prices publicly, but do not necessarily disclose information on rebates or discounts

9. In addition to recent legal measures, some OECD countries have established public databases with information on medicine prices. For example:

- In Australia, the Pharmaceutical Benefits Scheme<sup>13</sup> website provides reimbursement prices of all medicines listed in the national reimbursement formulary, however the prices displayed do not always reflect the actual net prices, as many medicines are subject to confidential discounts and other risk-sharing arrangements;
- In Chile and Colombia, the ChileCompra<sup>14</sup> and the Sistema de Información de Precios de Medicamentos (SISMED) respectively, publicly disclose pricing data online for inpatient and outpatient medicines procured by their respective public sectors;
- In **Iceland**, the Medicine Pricing and Reimbursement Committee<sup>15</sup> publicly discloses representative discounted prices (without value-added tax) from their medicine price lists, which are indicative of the net prices, as well as data on maximum wholesale and retail prices, and reimbursement amounts;
- In Mexico, the Social Security Institute publishes information on prices of publicly procured medicines<sup>16</sup>;
- In **Switzerland**, the Bundesamt für Gesundheit BAG<sup>17</sup> publicly discloses information on **list exfactory prices and negotiated rebates** for a list of medicines reimbursed by compulsory health insurance.

10. While these are certainly encouraging examples of greater price transparency, for the most part these initiatives do not generally include the disclosure of confidential information on rebates or discounts, thus maintaining overall transaction price opacity. For most of these initiatives, evidence of the impact of the public disclosure of such (yet opaque) medicine prices on the dynamics of the pharmaceutical market is lacking. Substantial modelling would facilitate greater understanding of the complexity of the interactions between multiple stakeholders and countries in global pharmaceutical markets, including the potential impact on external reference pricing of greater price transparency.

## Some countries have used data sharing among competent authorities to strengthen negotiations and inform pricing policies

11. Several OECD countries have established collaborative arrangements between competent authorities for the sharing of confidential information to facilitate joint price negotiations or procurement. For example:

• In **Canada**, the Pan-Canadian Pharmaceutical Alliance (pCPA),<sup>18</sup> a provincial government collective, is mandated to conduct expert-informed negotiations with pharmaceutical manufacturers;

<sup>&</sup>lt;sup>13</sup> https://www.pbs.gov.au/info/about-the-pbs

<sup>14</sup> https://www.chilecompra.cl/

<sup>&</sup>lt;sup>15</sup> https://verd.lyfjastofnun.is/index.php?pageid=83

<sup>&</sup>lt;sup>16</sup> https://compranet.hacienda.gob.mx/web/login.html

<sup>&</sup>lt;sup>17</sup> http://www.spezialitaetenliste.ch

<sup>&</sup>lt;sup>18</sup> https://www.pcpacanada.ca/about

- In **Denmark**, the publicly-owned company Amgros<sup>19</sup> conducts negotiations and runs tenders for medicines for Danish hospital pharmacies;
- In the **European Union**, under the current Pharmaceutical Strategy for Europe<sup>20</sup>, the European Commission is advancing cooperation among national pricing and reimbursement authorities and healthcare payers (i.e. the National Competent Authorities on Pricing and Reimbursement (NCAPR) group) to foster transparency of price information and help strengthen pricing and reimbursement decisions of Member States;
- In the **Netherlands**, the Dutch Hospital Benchmark is a voluntarily mechanism for sharing anonymised data on net prices and volumes for products subject to confidential terms among a network of hospitals. Also, an All-payer Claims Database manages reimbursement data to inform the decisions of Dutch health insurers.

12. Some evidence suggests that some of these initiatives expanding data sharing among competent authorities have strengthened negotiating positions and led to reduced expenditure. For example, in Denmark, the publicly-owned company Amgros that centralises procurement and pricing negotiations is thought to have delivered cost savings of €314 million in 2015 as a result of joint tendering for procurement of medicines for Danish hospital pharmacies (Bartels, 2016<sub>[8]</sub>). In Canada, the provincial government collective pCPA is mandated to conduct joint price negotiations with manufacturers and has thought to have achieved substantive price reductions (Rawson, 2020<sub>[9]</sub>). Through information sharing and joint negotiations among Canadian jurisdictions, pCPA ensures consistent coverage and lower drug costs among participating jurisdictions.

## **2.2. Despite multiple cross-country initiatives, few disclose actual transaction prices**

13. A desk review of current practices identified 30 cross-country initiatives that, to a greater or lesser degree, share information about prices negotiated between national authorities, payers and manufacturers. Those include the initiatives described below. Detailed information about the objectives and scope of these initiatives can be found in <u>Annex B</u> of the Supplementary Material. This section outlines the main characteristics of these initiatives noting that **few disclose actual transaction prices**.

#### The goals of most existing initiatives are broader than price transparency

14. Most initiatives aim for greater price transparency as a means of strengthening collective pricing negotiations, joint procurement, health technology assessment (HTA), and the security of medicine supply. Together with information on prices, most initiatives also aim to share other types of data, such as information about access and horizon scanning, joint negotiations and public procurement, as well as HTA and pricing and reimbursement decisions. For example:

 Information regarding access and horizon scanning to support policy. The International Horizon Scanning Initiative (IHSI) promotes the sharing of information on horizon scanning to support decision-making on new technologies with possible high budget impact, while supporting HTA and regulatory preparation across Belgium, Denmark, the Netherlands, Norway, Ireland, Portugal, Switzerland and Sweden. The Nordic Pharmaceutical Group provides joint horizon scanning among Denmark, Iceland, Norway, and Sweden. The BeNeLuxA Initiative (comprising Belgium,

<sup>&</sup>lt;sup>19</sup> https://amgros.dk/

<sup>&</sup>lt;sup>20</sup> https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/making-medicines-more-affordable\_en

the Netherlands, Luxembourg, Austria and Ireland) and the Valletta Declaration (among Cyprus<sup>21</sup>, Greece, Italy, Malta, Portugal and Spain, Ireland, Romania, Croatia, Slovenia) aim to ensure sustainable and timely access to, and appropriate use of, high quality and affordable medicines in the participating countries.

- Data supporting joint negotiations and public procurement. The Baltic Partnership Agreement between Estonia, Latvia, and Lithuania aims for the centralised joint purchasing of pharmaceuticals and medical devices, to moderate expenditure and ensure affordable access to medicines in the participating countries. The Romanian and Bulgarian Initiative is intended to facilitate the joint negotiation of medicine prices to achieve lower prices and cross-border exchange of information on medicines in short supply. The Nordic Pharmaceuticals Forum supports joint procurement for hospital medicines and helps ensure security of supply. The Pan American Health Organization (PAHO) Strategic and Revolving Funds are two mechanisms for pooled procurement of essential medicines and vaccines across 42 countries in Latin America. The Pharmaceutical Pricing and Reimbursement Network (PPRI)<sup>22</sup> is affiliated with the Austrian National Public Health Institute (Gesundheit Österreich GmbH) and is a collaboration among 50 countries as well as European and international institutions. The members collaborate on sharing medicine price information, and support the generation and sharing of research, policy advice, capacity-building and knowledge transfer among national competent authorities.
- Information for HTA, pricing and reimbursement decisions. The Fair and Affordable Pricing Initiative (FaAP in short), is a joint HTA network that focuses on orphan and high-priced medicines across Hungary, Lithuania, Poland, Slovakia, and Czech Republic. FINOSE is a Nordic collaboration to undertake joint HTA assessments between Finland, Norway and Sweden. The Medicine Evaluation Committee (MEDEV) is a cooperation collaboration between 22 national authorities from 18 Member States and Switzerland responsible for the assessment, pricing and reimbursement of medicines in the EU. The Observatory of Medicines with High Financial Impact involves eight Latin American countries (Chile, Colombia, Costa Rica, Ecuador, El Salvador, Mexico, Peru, Dominic Republic and Brazil) aiming to promote efficient management of high financial impact medicines to improve access and efficiency in the use of public health resources, by providing information on prices, coverage, competition, rational use and HTA.

## Most initiatives are either regional or global and share price information on vaccines and certain high cost medicines

15. Most listed initiatives are either regional cross-country voluntary agreements involving EU member states (15 initiatives<sup>23</sup>) or initiatives led by international organisations such as the World Health Organization (WHO), the PAHO, the United Nations International Children's Emergency Fund (UNICEF),

<sup>&</sup>lt;sup>21</sup> The information in this document with reference to "Cyprus" relates to the southern part of the Island. There is no single authority representing both Turkish and Greek Cypriot people on the Island. Türkiye recognizes the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of United Nations, Türkiye shall preserve its position concerning the "Cyprus issue".

<sup>&</sup>lt;sup>22</sup> <u>https://ppri.goeg.at/medicine\_price\_data</u>

<sup>&</sup>lt;sup>23</sup> These are: the Baltic Procurement Initiative, the BeNeLuxA Initiative, the Central Eastern European and South-Eastern European Countries Initiative, the Declaration of Sofia, the European Integrated Price Information Database (Euripid), the Fair and Affordable Pricing (FAAP), FINOSE, the International Horizon Scanning Initiative (IHSI), the Medicine Evaluation Committee (MEDEV), the Nordic Pharmaceuticals Forum, the bilateral agreement on joint tendering and price negotiations between Norway and Denmark, the Romanian and Bulgarian Initiative, Real World Evidence for Decisions (RWE4Decisions), the Southern European Initiative, and the Valletta Declaration.

the United National Populations Fund (UNFPA), the Global Fund, and the Eurostat-OECD (10 initiatives<sup>24</sup>). Four initiatives<sup>25</sup> involve Latin American countries and one<sup>26</sup>, the Gulf States. Some initiatives are built on consolidated agreements between countries in which responsibilities are defined via specific terms of reference (e.g. the PAHO Strategic Fund), while other initiatives are built on declarations of interest (e.g. the Valletta Declaration). These initiatives share information on:

- Publicly reimbursed drugs (e.g. the European Integrated Price Information Database (EURIPID) maintains a clearing-house mechanism for sharing information on official list prices of publicly reimbursed (mainly outpatient) medicines and pricing regulations in a standardized format across EU member countries (except Germany, Luxembourg, Malta and Romania), Switzerland, Norway, Iceland, and Israel; and the Medicine Evaluation Committee (MEDEV) is an informal cooperation between 22 competent authorities from 18 EU member states and Switzerland to share information about pricing and reimbursement decisions of publicly reimbursed medicines);
- Vaccines (e.g. the Baltic Procurement Initiative shares information to support the joint
  procurement of vaccines for rotavirus and Streptococcus pneumonia; the COVID-19 market
  dashboard publishes COVID-19 vaccine price per dose as reported by the media; various global
  initiatives including the WHO Market Information for Access to Vaccines (MI4A) project, the
  UNICEF supply Division Pricing data, and the UNICEF's VII report public procured prices for
  various vaccines, including cholera, dengue, diphtheria, ebola, hepatitis (A and B), human
  papillomavirus, influenza, measles, rubella, meningococcal, polio, rabies, rotavirus, tetanus,
  typhoid, varicella, and yellow fever);
- Innovative high-cost medicines (e.g. the Valletta Declaration; Observatory of Medicines with High Financial Impact (*Observatorio de Medicamentos de Alto Impacto Financiero*); the BeNeLuxA Initiative; the Nordic Pharmaceuticals Forum; and Fair and Affordable Pricing). Examples of innovative medicines considered by these initiatives include various orphan drugs, selected oncology medicines, and direct acting antivirals (DAAs) for hepatitis C;
- **Treatments for infectious diseases**, such as HIV, tuberculosis and malaria (e.g. the Global Fund's online procurement platform; and Stop TB Partnership's Global Drug Facility);
- **Commodities for reproductive health** (e.g. UNFPA Procurement Service Branch shares publicly procured prices for contraceptives, medical devices, pharmaceuticals, and kits related to reproductive health as well as census supplies and humanitarian supplies for those countries in humanitarian crisis situations);
- Essential medicines and products (e.g. Eurostat-OECD Purchasing Power Parities (PPP) Programme collects volumes and pharmaceutical spending of around 150 essential commonly used pharmaceutical products for EU member states, OECD member countries and associate non-OECD member countries and publishes aggregate figures in the public domain; and the PAHO Strategic Fund publicly reports publicly procured prices for vaccines, syringes, and other related supplies for 42 countries in Latin America); and,

<sup>&</sup>lt;sup>24</sup> These are: COVAX, the COVID-19 Vaccine Market Dashboard, the Eurostat-OECD Purchasing Power Parities (PPP) Programme, the Global Fund's online procurement platform, the Pharmaceutical Pricing and Reimbursement Information (PPRI) network, Stop TB Partnership's Global Drug Facility, UNICEF Supply Division Pricing data, UNICEF's vaccine independence initiative (VII), United Nations Fund for Population Activities (UNFPA) Procurement Services Branch, and the WHO Market Information for Access to Vaccines (MI4A) initiative.

<sup>&</sup>lt;sup>25</sup> These four initiatives are the following: Observatory of Medicines with High Financial Impact (*Observatorio de Medicamentos de Alto Impacto Financiero*), PAHO Revolving Fund, PAHO Strategic Fund, and Pharmaceutical Procurement Service of the Organisation of Eastern Caribbean States (OECS).

<sup>&</sup>lt;sup>26</sup> The Cooperation Council for the Arab States of the Gulf, abbreviated as "GCC" for "Gulf Cooperation Council".

• Yet-to-be-authorised pharmaceuticals (e.g. the IHSI; and the Nordic Pharmaceutical Group).

#### Most existing initiatives do not disclose data publicly or share actual transaction prices

16. To what degree existing initiatives contribute to greater price transparency depends on how public and how detailed the price data is in usefully capturing actual transaction prices. Most cross-country initiatives include mechanisms to collate pricing and other information, but do not clearly disclose actual transaction prices net of discounts and rebates, nor are all the collected data necessarily made publicly available (e.g. the WHO MI4A project; the Observatory of Medicines with High Financial Impact; and the UNICEF Supply Division Pricing data). For example, the WHO MI4A initiative does not disclose which countries submitted data. EURIPID and the PPRI network only share information among participating member countries, and the information from the Global Fund's online procurement platform is shared only among the payers. A systematic review of the literature underscores the persistent lack of transparency of actual transaction prices arising from the increased use of confidential pricing arrangements in most HICs (Mardetko, Kos and Vogler, 2018<sub>[10]</sub>).

17. Despite this, there are several initiatives that disclose information publicly e.g. the UNICEF COVID-19 market dashboard, the PAHO Revolving Fund and Strategic Fund, UNICEF VII, WHO MI4A, UNFA Procurement Services branch, Eurostat-OECD PPP Programme. However, none of these shares information on *net prices*. Instead, most initiatives share information on the following types of prices:

- Official list prices of publicly reimbursed drugs (e.g. Euripid, and MEDEV), high-cost medicines observed in a group of countries (e.g. Observatory of Medicines with High Financial Impact), list prices of COVID-19 vaccines reported by the media (e.g. COVID-19 market dashboard) or suppliers base price (e.g. UNICEF Supply Division);
- Internationally comparable prices (e.g. Eurostat-OECD Purchasing Power Parities (PPP) Programme that establishes PPPs in order to compare price and volume levels for a basket of health products, including medicines, for EU member states and OECD member countries);
- Wholesale and pharmacy purchasing prices, or pharmacy retail prices and official reimbursement prices (e.g. EURIPID, Pharma Price Information<sup>27</sup> (PPI));
- **Procurement prices**, which do not necessarily reflect actual transaction prices, as they generally do not take into account confidential discounts or the effects of risk sharing arrangements (e.g. the Global Fund's Pooled Procurement Mechanism<sup>28</sup>; COVAX<sup>29</sup>; the

<sup>&</sup>lt;sup>27</sup> The PPI is a service of the Austrian National Public Health Institute providing pricing data on request for EU member states as well as Norway, Switzerland and the UK.

<sup>&</sup>lt;sup>28</sup> The Global Fund's online Pooled Procurement Mechanism, wambo.org, offers procurement prices for health products and selected non-health products used primarily for HIV, tuberculosis and malaria health programs and COVID-19.

<sup>&</sup>lt;sup>29</sup> COVAX is co-led by Gavi, the Vaccine Alliance, WHO and the Coalition for Epidemic Preparedness Innovations foundation (CEPI). COVAX makes investments across the portfolio of promising vaccine candidates and negotiates contracts using the pooled purchasing power of participating countries. In addition, UNICEF has partnered with Gavi in the COVAX Facility to manage the procurement of COVID-19 vaccine doses, as well as their transport, distribution and storage. COVAX provides procurement pricing information: <a href="https://www.who.int/docs/default-source/coronaviruse/covax-facility-explainer.pdf">https://www.who.int/docs/default-source/covax-facility-explainer.pdf</a>

UNICEF COVID-19 Vaccine Market Dashboard<sup>30</sup>; UNICEF's vaccine independence initiative (VII)<sup>31</sup>; and the WHOMI4A initiative<sup>32</sup>).

## 2.3. Existing evidence of the impact of greater transparency of transaction prices on the functioning of markets is scant

18. While there is some discussion in the literature of the likely impact of sharing medicine pricing information, empirical evidence of how greater price transparency affects the functioning of pharmaceutical markets is understandably lacking. We undertook an umbrella review of peer-reviewed studies and grey literature in which we identified 22 studies investigating the effects of policies intended to increase sharing of medicine prices in 15 OECD countries (Australia, Austria, Canada, France, Germany, Italy, Latvia, Lithuania, Netherlands, New Zealand, Spain, Sweden, Switzerland, UK, USA) and 9 non-OECD countries (Brazil, China, Croatia, Ghana, India, Jordan, Malaysia, Russia and South Africa). Some of these studies relate to the policies listed in the previous section and examined the impact of initiatives sharing various types of medicine prices, including ex-factory list prices, reimbursed and retail prices, and ex-factory net prices. Box 2.1 provides further details of this review and <u>Annex C</u> of the Supplementary Material lists the studies reviewed, and details information about the outcomes, data, methods and limitations of the initiatives being analysed.

19. The reviewed studies, which included two systematic reviews (WHO, 2020<sub>[6]</sub>; Ahmad, Makmor-Bakry and Hatah, 2020<sub>[7]</sub>) and a recent policy brief (European Observatory on Health Systems and Policies, 2022<sub>[11]</sub>), examined the impact of government initiatives mandating greater price transparency on prices *within countries*, but did not consider any potential spillover effects *across countries*. Also, these studies did not examine the impact on market dynamics of cross-country initiatives for sharing medicine prices.

20. In addition, evidence within individual countries is mixed. **Some studies suggested that there were no clear effects of increased sharing of pricing information**. One study from the Netherlands showed no impact on price levels resulting from hospitals sharing negotiated net prices, though purchasing volumes increased (Den Ambtman et al., 2020<sub>[12]</sub>). A recent study from the United States suggested that the sharing of prescription expenditure data among payers did not affect state Medicaid spending (Noh, Janousek and Park, 2021<sub>[13]</sub>). Five studies from Brazil, India and South Africa showed no consistent price reductions arising from public price disclosure (Bangalee V and Suleman F., 2016<sub>[14]</sub>; Bangalee and Suleman, 2015<sub>[15]</sub>; Mattila, Babar and Suleman, 2021<sub>[16]</sub>; Kohler et al., 2015<sub>[17]</sub>; Gotham, Barber and Hill, 2018<sub>[18]</sub>) Price regulation and disclosure in South Africa has not been seen to have led to withdrawals of medicines from the market as it could have been anticipated (Naidoo and Suleman, 2021<sub>[19]</sub>).

21. By contrast, several studies reported discernible, but conflicting, effects of greater price transparency on price levels. For example, one recent study found that the sharing of negotiated cancer drug prices was associated with lower prices over time in Germany and Switzerland (Vokinger et al., 2022<sub>[20]</sub>). Of two studies that examined the procurement of tuberculosis drugs, one from the Philippines (Sarol, 2014<sub>[21]</sub>) and another involving 15 countries (Arinaminpathy et al., 2015<sub>[22]</sub>), both reported lower

<sup>&</sup>lt;sup>30</sup> The UNICEF COVID-19 Vaccine Market Dashboard reports vaccine prices and other information regarding agreements through bilateral and multilateral supply agreements: <u>https://www.unicef.org/supply/covid-19-vaccine-market-dashboard</u>

<sup>&</sup>lt;sup>31</sup> UNICEF's VII supports lower-middle income countries working to become self-reliant in vaccine procurement. UNICEF's VII is a pooled procurement mechanism for vaccines benefiting from economies of scale; payment after delivery instead of in advance; and payment in local currency (as permitted by the UNICEF Treasurer).

<sup>&</sup>lt;sup>32</sup> The WHO MI4A collect and report data on vaccine purchases through the WHO/UNICEF Joint Reporting Form for more than 150 countries.

prices as a result of greater sharing of price information, while another two studies showed evidence of the opposite effect – namely, partial convergence and higher prices – in the United States and Malaysia (Grennan and Swanson, 2020<sub>[23]</sub>; Ahmad, Hatah and Makmor-Bakry, 2019<sub>[24]</sub>). Grennan and Swanson (2020<sub>[23]</sub>) found that US hospitals with access to information on prices paid by other hospitals saw subsequent savings on brands for which they had previously paid relatively high prices. Ahmad et al (2019<sub>[24]</sub>) found that the public disclosure of wholesale and retail prices in the Malaysian market led to significant price convergence with international reference price levels.

#### Box 2.1.Umbrella review of empirical studies and grey literature on price transparency

An umbrella review of systematic reviews, academic studies and grey literature published between January 2015 and May 2022 was conducted focussing on the impact of policies and legal provisions (some of these described in the previous section) pertaining to increased disclosure or sharing of pharmaceutical pricing information (whether information on regulated prices, net prices or secretly negotiated rebates or discounts). Searches were conducted on PubMed, Science Direct, Ovid Medline, and Cochrane and complemented with snowballing, yielding 103 studies. Most of the identified studies were editorials or commentaries, and only 22 studies were empirical investigations. Included studies mainly examined ex-factory wholesale prices (13), with two studies looking at reimbursed and retail prices, and four studies examining ex-factory net prices. The studies covered a range of medicine types, including on-patent medicines, oncology drugs, orphan drugs, diagnostics and drugs to treat tuberculosis. A list of the studies reviewed can be seen in <u>Annex C</u> of the Supplementary Material.

22. The evidence is, however, very limited with respect to considering the spillover effects of greater price transparency *across countries*. Three studies modelled the likely consequences of partial or full transparency of prices and other information.

- The first study used published list prices to simulate the effects of full and partial transparency on on-patent markets across European countries between 1996 and 2008, and suggested not only that full transparency was not viable across the board, but that partial transparency was only viable if certain HICs, including the United Kingdom and Germany, were to commit to sharing net medicine prices; however, these countries would have to accept paying relatively higher prices than those they currently paid under confidentiality (Van Dyck, Riccaboni and Swoboda, 2020<sub>[25]</sub>). The study also showed potential delays to access in LMICs under partial transparency.
- The second study simulated the dynamics of a bargaining game of repeated negotiations between payers and companies from the Netherlands, Germany, Poland, and Spain over the price of an "innovative and highly effective anti-cancer medicine" under two regimes of transparency: (1) *partial* transparency i.e. of price information and (2) *full* transparency i.e. information on prices *and* R&D costs. The study found differing effects under both regimes; while there were no clear effects on prices under partial transparency there were reductions in R&D investment; under full transparency there was convergence toward reduced prices (Franzen et al., 2022<sub>[26]</sub>).
- The third study used a game theory model to simulate the effects and reactions of companies and countries when moving from opacity to transparency (Cabau and Gordon, 2021<sub>[27]</sub>). The model assumed countries negotiated sequentially with the industry; as a result, countries negotiating first would eventually pay higher prices under transparency, while those negotiating later would be able to tailor their willingness to pay in negotiations according to the information disclosed. Companies would be better off under transparency, with both higher negotiated prices and shorter price negotiations.

23. Some authors argue that greater transparency could generate opportunities for anti-competitive behaviour by companies, under certain conditions, thereby harming individuals, health systems and markets (Shaw and Mestre-Ferrandiz, 2020[28]). However, there is no evidence to support this. Evidence from other industries (i.e. retail gasoline, concrete, supermarkets) suggests that price transparency regulations may lead to either increased or reduced prices, and may foster or reduce competition. For example, an online price portal for retail gasoline prices in Germany has been shown to provoke intense competition and downward price pressure (Horvath, 2019[29]). Similarly, in Israel, price transparency policies regulating supermarket chains led to price reductions (Ater and Rigbi, 2018[30]). By contrast, in Denmark the publication of prices of concrete allowed firms to reduce the intensity of oligopolistic price competition, leading to price convergence and increased prices, contrary to the aim of the policy (Albæk, Møllgaard and Overgaard, 1997[31]). In Chile, price disclosure regulation for retail gasoline led to softening competition with increased prices, relatively higher in low-income areas than in high-income areas, thereby exacerbating economic inequality (Luco, 2019[32]). In Italy, a law that required the installation of large electronic pricing signs along roads near petrol stations led to price reductions, albeit with limited effect on price dispersion (Rossi and Chintagunta, 2016[33]).

24. The literature also lacks any examination of the effects of greater price transparency on companies' differential (tiered) pricing strategies and consequential incentives for arbitrage. Evidence is also lacking on quantifying the impact of greater price transparency on mechanisms such as international reference pricing (WHO, 2020<sub>[6]</sub>). For example, a study of enhanced international co-ordination in pharmaceutical pricing in EU countries suggested that disclosing the existence (but not the magnitude) of a discount for a given product would enable the use of its list price for international benchmarking, subject to appropriate caveats (Vogler et al., 2015<sub>[34]</sub>).

## 3. Experts expressed strong and often contrasting views

25. This section presents a distillation of the views expressed in a series of consultations with experts on how price transparency could impact the dynamics of pharmaceutical markets. The consultations comprised a series of semi-structured interviews and a roundtable held in late 2021, with participation from a group of 19 distinguished experts that included academics, payers, and industry representatives. The list of experts appears in <u>Annex D</u> of the Supplementary Material. Detailed information about the questions posed during the semi-structured interviews can be found in <u>Annex E</u>, while the agenda of the roundtable discussion can be found in <u>Annex F</u>. The discussions were wide-ranging, covering aspects of pharmaceutical pricing, economics of pharmaceutical markets, pricing negotiations, competition issues, and legal aspects of transparency. Experts were asked to address three key questions:

- What do you see as the **motives** and **objectives** of various stakeholders in seeking increased price transparency?
- What are the likely reactions of payers, "pricing authorities", and companies?
- What are the likely effects of greater price transparency on the functioning of markets?

26. In addressing these questions, experts expressed strong and often contrasting views on the value of greater price transparency, albeit generally unsupported by tangible evidence. The prospect of greater price transparency provoked both considerable optimism and scepticism regarding the likely effects on the functioning of markets, with both perspectives unsupported by evidence. Two principal ideas emerged:

- Given the various (and contrasting) motives and objectives of countries and stakeholders, establishing some form of global co-ordinated action on sharing data on net prices would neither be desirable nor sustainable; and
- There would be a cascade of interconnected incentives and dynamic effects that would need to be considered in anticipating the strategic reactions of payers, pricing authorities and companies to greater price transparency.

## 3.1. Co-ordinated international action on sharing data on net prices is not necessarily desirable or sustainable

## The feasibility and desirability of sharing prices across countries depend on the objectives of greater price transparency

27. Experts noted motives for greater price transparency reflected two main perspectives: on the one hand, transparency is indicated as a tool to support policy objectives (i.e. "a means to an end" in achieving lower prices and/or expanded access); on the other hand, transparency is viewed as having intrinsic value, essential for accountability and good governance. When questioned about the interests of stakeholders in

seeking increased price transparency, experts noted a plethora of objectives mentioned in the literature, raised in policy forums, and argued by politicians and civil society. These included:

- Countering information asymmetry among payers and manufacturers in order to strengthen the bargaining power of governments and payers in price negotiations with the industry;
- Controlling pharmaceutical spending through reduced prices while reducing excessive prices and expanding patient access;
- Assessing budget impact and eligibility of medicines for coverage and reimbursement decisions and informing cost-effectiveness analyses and equity considerations in reimbursement decisions;
- Empowering patients and civil society while enhancing public accountability of governments regarding the outcomes of price negotiations;
- Enhancing price regulation and improving the relevance and utility of external reference pricing; and
- Defining affordable and acceptable prices with global equity considerations, while contributing to the broader agenda of increasing transparency in pharmaceutical markets to understand industry performance, costs, and therapeutic value.

28. This wide list of objectives was argued by some experts as undermining the policy debate on price transparency, because several of them are not achievable through increased price transparency, but would instead require policy reforms related to intellectual property protection and pricing and reimbursement mechanisms. For example, despite legal provisions in the United States requiring Medicare Part B<sup>33</sup> to publicly report information on quarterly net average selling prices, evidence suggests this has not reduced spending nor controlled price increases (Lieberman, 2022[35]). Moreover, evidence of wide variations in retail prices across the United States suggests that public disclosure of price information has not led to price reductions or lower out-of-pocket spending (Rodwin, 2018[36]). In addition, various objectives may actually conflict or would require implicit trade-offs, and this is reflected in some countries' experiences. In Norway, for example, despite concerns over lack of public accountability of reimbursement decisions, and claims that secrecy undermines economic and equity considerations in public resource allocation, legal provisions aimed at greater price transparency were repealed in 2016 in order to maintain confidential agreements that would achieve greater cost savings and support broader access to expensive medicines. Prices and rebates for hospital medicines went from being publicly available to being kept confidential as a result of changes in the procurement practices of state-owned hospitals. The Norwegian government also imposed confidentiality of prices for selected outpatient medicines purchased via competitive tendering, and removed a ban on claw-backs (i.e. rebates paid if certain sales levels are achieved) and retroactive rebates, thus obscuring actual transaction prices (Stortinget, 2016[37]; Østby and Solli, 2019[38]). These moves towards greater confidentiality have generated heated public debate among politicians and civil society<sup>34</sup>.

#### Motives and objectives differ between countries and across stakeholders

29. When questioned about the attitudes of countries towards greater price transparency, experts considered that these varied across countries according to differences in national wealth; the size of the

<sup>&</sup>lt;sup>33</sup> US Medicare Part B provides payments to physicians and hospital clinics for outpatient services and covers medicines administered in physician offices and hospital outpatient departments, most notably cancer, ophthalmic, and rheumatology therapies.

<sup>&</sup>lt;sup>34</sup> <u>https://www.stortinget.no/no/Saker-og-publikasjoner/Publikasjoner/Innstillinger/Stortinget/2018-2019/inns-201819-207s/</u>

pharmaceutical market; the existence of a domestic pharmaceutical industry; and the negotiating power of national competent authorities. As evidence of these differences, experts cited dissociation from the 2019 WHA resolution by Germany, the United Kingdom and Hungary. LMICs expect greater price transparency will create leverage to negotiate prices lower than those paid by HICs, and facilitate expanded access to medicines for their populations, while HICs expect to safeguard equitable access and minimise price differentials between countries with similar ability to pay. There is some evidence that prices are not invariably lower in LMICs (Iyengar et al., 2016[4]); large differences in prices for COVID-19 vaccines were cited as an example, with some sub-Saharan countries paying higher prices than the EU.<sup>35</sup>

30. When considering how greater transparency might affect the functioning of markets, it is necessary to take into account the complexities of multiple stakeholders and countries, and the interplay between sub-national, national, and international market dynamics of the pharmaceutical industry. Experts agreed that among stakeholders - namely the industry, payers and pricing authorities, policy makers, and civil society - motives for greater price transparency were not necessarily aligned. While the industry seeks to maintain confidentiality in order to maximise revenue, payers and pricing authorities see price transparency as a "means to an end" to obtain better prices or broader access, and do not necessarily endorse the public disclosure of net prices. This is consistent with insights from current practice in sharing prices across countries, with no initiative currently sharing net price data (as discussed in Section 2.2)<sup>36</sup>. Experts viewed policy makers as having a variety of objectives, including greater accountability in the allocation of public resources; enhanced sustainability of budgetary decisions regarding pharmaceutical spending; and more equitable access to medicines. Lastly, civil society increasingly voices concerns over a lack of trust in the industry and that insufficient public accountability undermines sustainable and equitable access to medicines, particularly in LMICs. For these reasons politicians had been pressured to bring price transparency to the forefront of public debate, including at the WHA. A recent policy brief (European Observatory on Health Systems and Policies, 2022[11]) also highlighted the differing needs of countries and the many complexities and interdependencies among countries and stakeholders that must be taken into account when considering the potential impact of greater price transparency.

## Co-ordinated international action on sharing net pricing data would require extraordinary political commitment to overcome dominant national self-interest

31. Despite several cross-country initiatives aimed at greater net price transparency, net prices remain opaque (as discussed in Section 2.2). Experience from EURIPID shows there are significant barriers to intensifying international co-operation toward greater price transparency, including non-disclosure provisions in agreements between companies and public payers (Russo et al., 2021<sub>[39]</sub>). Experts overwhelmingly recognised that extraordinary international action would be required for countries to establish a mechanism to share net price information, a point also raised by the European Observatory (European Observatory on Health Systems and Policies, 2022<sub>[11]</sub>). Political commitment from a large number of countries would have to be assured in order to establish a new level playing field between companies and payers in price negotiations, while maintaining the confidentiality of legitimate business issues. The G7 initiative on global transparency of taxes was cited as an example.<sup>37</sup> Experts cited the need for co-operation among regions representing at least 60-70% of the global market (e.g. between the EU, the European Economic Area (EEA), Japan or the United States). Additionally, some experts argued that co-ordinated action would also require countries to agree with the industry *ex-ante* on a certain level of differential pricing between HICs and LMICs, and clearly define concepts and thresholds of affordability,

<sup>&</sup>lt;sup>35</sup> <u>https://www.unicef.org/supply/covid-19-vaccine-market-dashboard</u>

<sup>&</sup>lt;sup>36</sup> With the existing information made publicly available we cannot infer whether rebates or discounts are accounted for in the price data disclosed.

<sup>&</sup>lt;sup>37</sup> https://www.ft.com/content/a308bbff-5926-47a1-9202-6263e667511e

and policies regulating parallel trade. However, the case of anti-retrovirals was argued by experts to demonstrate that differential pricing with price transparency is attainable if is negotiated and accepted, even in the absence of coordinated action. Experts also noted the ongoing debate led by WHO on the feasibility to establish a formal tiered pricing framework building on the principles of solidarity, transparency and sustainability at global level (Docteur, 2022<sub>[40]</sub>). One possible way forward might be the establishment of a hybrid regime under which countries would commit to disclosing net prices within pre-specified ranges, rather than aiming for a regime of complete transparency per se.

32. Experts also put forward contrasting views on the sustainability of internationally co-ordinated action on sharing net medicine prices. While some identified legal provisions pertaining to price transparency recently adopted by an increasing number of countries (e.g. Spain<sup>38</sup>, France<sup>39</sup>) as evidence of political support for action on the WHA resolution, others argued that any concerted action was infeasible because of the existence of a "prisoners' dilemma" (OECD, 2018<sub>[2]</sub>) – i.e. countries have a dominant incentive to pursue domestic interests ahead of choosing to co-operate internationally. This is particularly true for countries who risk becoming worse off under price transparency – experts flagged concerns about parallel export from countries such as New Zealand, where medicine prices are lower, and risk facing increased prices under transparency. Experts noted that the negotiation of prices for COVID-19 vaccines had proven to be an example of dominant national interest undermining international cooperation.

## **3.2.** Anticipating the cascade of reactions by payers, pricing authorities, and companies

### Payers may deviate from co-operating-in-transparency agreements and re-engage in confidential negotiations

33. Payers and national pricing authorities seeking to secure the lowest prices have an incentive to free ride on information disclosed by others and hide information on negotiated rebates and discounts domestically. Evidence from international reference pricing, for example, has described the ambiguity pavers face when disclosing pricing information that will inform prices paid by other countries (Kanavos et al., 2020[41]; Rand, 2021[42]; Rodwin, 2020[43]; Gill et al., 2019[44]). When reflecting on the strategic responses under greater price transparency, experts anticipated payers and "pricing authorities" have large incentives to deviate from a co-operating-in-transparency strategy and continue to engage in confidential agreements with the industry. Payers could hesitate to disclose information if they deduce there is uncertainty about how companies would adjust pricing strategies across countries, especially for patented and single-source medicines. To a certain extent, confidentiality drives a 'win-win' situation in which payers and companies can maintain nondisclosure of discounts and rebates within a heterogeneous and fragmented landscape of payers. In fact, when surveyed, health care payers and authorities recognise that, although they may benefit from confidential agreements when they negotiate for an individual product, they may not collectively benefit from increasing confidentiality and asymmetry of information between companies and payers (Morgan, Vogler and Wagner, 2017[45]).

34. Conversely, some countries, especially small pharmaceutical markets and national competent authorities lacking negotiation capacity with the pharmaceutical industry, have stronger incentive to cooperate and share information. For example, small groups of countries, such as the Nordics or

<sup>&</sup>lt;sup>38</sup> Ley 19/2013, de transparencia, acceso a la información pública y buen gobierno (art 14) at <u>https://www.boe.es/buscar/act.php?id=BOE-A-2013-12887</u>

<sup>&</sup>lt;sup>39</sup> LOI n° 2020-1576 du 14 décembre 2020 de financement de la sécurité sociale pour 2021/ Social Security Budget Bill at LOI n° 2020-1576 du 14 décembre 2020 de financement de la sécurité sociale pour 2021 (1) - Légifrance (legifrance.gouv.fr)

BeNeLuXa, are self-motivated to cooperate with other countries and established some level of international collaboration to help achieve their national health system goals through information sharing.

35. Experts argued payers would eventually focus on reforming pricing and reimbursement policies instead of sharing or disclosing price information. Because of the growing complexity of pricing arrangements signed under confidentiality, negotiations actually result in increasingly opaque prices involving a mix of rebates across groups of medicines, discounts by indication, or based on volumes or expenditure caps, all of which mean it is complex to compute the final transaction price of a product. Experts considered that countries would therefore tend to increase the use of performance-based agreements. The incentives to reform pricing and reimbursement policies would vary between countries and might depend on how patient co-payments or deductibles were determined. In some countries copayments paid by patients are determined relative to official list prices, providing incentives for payers to keep rebates and discounts confidential in order to shift costs to patients, particularly for high-priced medicines. These views align with evidence from the peer-reviewed literature. For example, the public drug plan in Quebec in Canada reimburses 35% of the official list medicine price, with catastrophic coverage only applicable if spending is above 4% of an individual's annual income (Phillips, 2016<sub>[46]</sub>; Tadrous et al., 2018[47]; Tadrous et al., 2018[48]). In the United States, increasing evidence suggests private insurance companies prefer the more expensive medicines with higher rebates when managing drug formularies (Consumer Reports, 2020[49]).

## Companies would adjust their pricing and launch strategies to continue differential pricing

36. Pharmaceutical companies are profit-seeking and aim to expand the return-on-equity targeted by their shareholders, and which may include setting different prices across markets in order to maximise revenue from countries with differing willingness or ability-to-pay, or capacity to negotiate. The existing literature does not offer any insights into the effects of confidential rebates on the use of external reference pricing, or their implications for companies' differential pricing practices (Danzon, 2018<sub>[50]</sub>; Towse et al., 2015<sub>[51]</sub>). When reflecting on the strategic responses of pharmaceutical companies under greater price transparency, experts anticipated efforts to maintain confidentiality, with pricing strategies adjusted to continue to discriminate across markets in order to realise pre-transparency levels of return-on-equity. Some experts thought that companies would eventually develop novel pricing arrangements allowing for some degree of price confidentiality, for example, a two-part tariff such as the Netflix model, where the first part – a proportion of the price – would be transparent across countries, and a second part - a lump sum – would be negotiated on a country-by-country basis. Opposing views were that it would be the magnitude of the differences in drug prices between the United States and the global market that would drive the industry's reactions, rather than price transparency *per se*.

37. Experts also argued that companies would adopt other non-pricing strategies to enforce differentiation across markets – namely using launch sequencing to maximise revenue by launching first in markets (countries) with greatest willingness to pay. Under greater price transparency, companies would decide where and when to launch medicines tactically, comparing the revenue forgone where launching would target a relatively lower-priced market sooner rather than later. Companies predict financial consequences of a couple of scenarios – *delay launch* versus *launch immediately* – and, as current evidence shows, companies generally launch first in high-priced markets — i.e. the United States, given its absolute market size (Danzon, Wang and Wang, 2005<sub>[52]</sub>; Kyle, 2007<sub>[53]</sub>; Maini and Pammolli, 2020<sub>[54]</sub>). Companies might also adjust contract terms – for example, fixing the negotiated price for a certain number of years, with no possibility of price reduction over that period. Pressure exercised by governments could eventually erode discounts and rebates for other countries; companies would play the game of delay until existing agreements expired, and new agreements would have to be negotiated.

#### Both industry and governments may cite threats to patient access

38. Experts differed on whether companies would (or would threaten to) exit the market or deny access to certain medicines in response to the adoption of price transparency policies. Some experts argued these threats were real and cited as an example Zynteglo®, a gene therapy for patients with transfusion dependent thalassemia, which was withdrawn from Europe.<sup>40</sup> The risk of withdrawal of some medicines from the Turkish market was also mentioned as a consequence of China referencing medicine prices in Türkiye, where prices are low due to the devaluation of the Turkish Lira, and trade regulations ban parallel export (Mondaq, 2022<sub>[55]</sub>). However, other experts referred to these threats as a tactic used by industry for leverage in negotiations; in fact, the adoption of price transparency policies in some countries, such as South Africa, has not been seen to have led to withdrawals of medicines from the market (Naidoo and Suleman, 2021<sub>[19]</sub>). Some policymakers are concerned that moves towards greater price transparency could negatively impact accessibility, since companies could threaten withdrawal from markets or set prices at unaffordable levels (European Observatory on Health Systems and Policies, 2022<sub>[11]</sub>).

39. Experts also noted that existing national legal frameworks can provide governments with tools to counter threats to deny or delay market entry of medicines in response to price transparency policies. Experts cited studies showing that, in the majority of cases, threats of compulsory licensing were either withdrawn or not granted, after prompting large price discounts or donations in lieu (Cohen, 2006<sub>[56]</sub>; Qunaj, Kaltenboeck and Bach, 2022<sub>[57]</sub>; Tejavanija, 2011<sub>[58]</sub>).

#### 3.3. Limited evidence prompts scepticism about greater price transparency

#### Transparency may strengthen payers' bargaining power but may also enable anticompetitive behaviour among companies

40. When questioned about the likely impact of greater price transparency on the functioning of markets, most experts cited effects on the bargaining power of payers. Some experts suggested that payers could use price information to increase their bargaining power by adjusting their willingness to pay, particularly those in higher-priced markets and countries with lesser capacity to negotiate. Price disclosure could also incentivise payers and governments to collaborate internationally in joint procurement initiatives. Examples such as international collaboration on vaccine procurement in Latin America and the Caribbean (McQuestion et al., 2017<sub>[59]</sub>) and single-procurement price published by PAHO were offered as examples (PAHO, 2022<sub>[60]</sub>). However, other experts suggested that price transparency would instead reduce the relative bargaining power of some payers, particularly in on-patent markets, where companies exercise monopolistic power. This could be particularly detrimental for those countries currently enjoying relatively lower prices.

41. Experts also discussed the potential effect of greater price transparency on the anti-competitive behaviour of companies, with some experts taking the view that price disclosure might facilitate some degree of collusion among companies, albeit acknowledging that the evidence was understandably scant. Some authors argue that greater transparency could generate opportunities for anti-competitive behaviour by companies under certain conditions, thereby harming individuals, health systems, and markets (Shaw and Mestre-Ferrandiz, 2020<sub>[28]</sub>). However, a review of the literature and investigations of cases of potential collusion in the pharmaceutical industry show that there is little evidence to suggest that price transparency leads to price collusion. While evidence from other industries is often cited, it is not necessarily transferable to pharmaceutical markets. For example, two studies from Denmark and Italy caution that transparency may expose companies to antitrust liabilities, as the exchange of commercially sensitive information

<sup>&</sup>lt;sup>40</sup> Although Zynteglo® was cited as an example, public sources have pointed to issues of excessive pricing as the more likely reason for withdrawal: <u>https://www.labiotech.eu/trends-news/bluebird-bio-gene-therapy-zynteglo/</u>

between competitors may facilitate co-ordination and convergence of prices for concrete and retail gas, respectively (Albæk, Møllgaard and Overgaard, 1997<sub>[31]</sub>; Rossi and Chintagunta, 2016<sub>[33]</sub>).

#### Does greater transparency lead to lower prices?

42. Experts were divided on the likely consequences of greater price transparency on price levels and patient access. On prices, some experts argued that transparency could drive convergence towards higher price levels, while others disagreed, citing a lack of evidence. Some literature on international reference pricing suggests mixed evidence about price convergence, depending on the sample of medicines and countries (Houy and Jelovac, 2015[61]). (Bangalee V and Suleman F., 2016[14]; Grennan and Swanson, 2020[23]; Ahmad, Hatah and Makmor-Bakry, 2019[24]; Bangalee and Suleman, 2015[15]; Naidoo and Suleman, 2021[19]). On patient access, experts noted that transparency could, in theory, favour competition, as companies could better predict the financial consequences of market entry decisions; however, this would not necessarily lead to broader or faster access. Experts also noted, however, that evidence from Europe shows that external reference pricing under price opacity can undermine the availability of medicines and lead to launch delays (Kanavos et al., 2020[41]; Maini and Pammolli, 2020[54]). There was also anecdotal evidence from England suggesting that some decisions by companies not to launch medicines (e.g. Vertex' new cystic fibrosis drug and several oncology drugs) in the UK were driven by concerns over an excessive level of public transparency of decision-making by NICE, which enabled other payers to back-calculate confidential prices.

43. It is not possible to empirically quantify the impact of greater price transparency on the global functioning of markets, partly because current price levels are opaque. Evidence to date has been drawn from modelling the impact of simulated scenarios of partial and full transparency, drawing on list prices and making assumptions about discounts and rebates that cannot be verified (Van Dyck, Riccaboni and Swoboda, 2020<sub>[25]</sub>; Franzen et al., 2022<sub>[26]</sub>; Cabau and Gordon, 2021<sub>[27]</sub>). Additionally, there are considerable cascading effects of price disclosure that are difficult to anticipate, and that may not be fully captured in either theoretical models or empirical evidence. This is not surprising given the complexities and interconnections between multiple stakeholders and countries in the functioning of the pharmaceutical market globally, and the many factors that influence, and are influenced by, the decisions and reactions of companies, including pricing, launch sequencing, the actions of competitors, the attitudes of payers operating under budgetary constraints, and the variety of reimbursement mechanisms and procurement policies of different countries.

## There will be winners and losers, with unclear impact on differential pricing and equity of access

44. Experts argued that the impact of greater price transparency on the functioning of markets would likely lead to unequal effects across countries. Evidence from a game theory model simulating the effects and reactions of companies and countries when moving from opacity to transparency suggests that countries negotiating first would eventually pay higher prices under transparency, while those negotiating later would be able to tailor their willingness to pay in negotiations according to the information disclosed (Cabau and Gordon, 2021<sub>[27]</sub>).Transparency could be expected to benefit those countries with smaller markets, or without sophisticated pricing models in place, as they could *free ride* on the negotiated prices of larger countries. By contrast, transparency would certainly harm larger countries currently enjoying strong leverage in price negotiations and single-payer systems with monopsony power. It was also argued that the impact of greater price transparency would tend to vary among different types of medicines, with some experts reasoning that greater benefit could be expected for less essential medicines, while others thought that transparency could instead undermine access to on-patent medicines, particularly in relatively high-priced markets. This could generate a *race-to-access* for some medicines in countries impatient to get rapid access, with the United Kingdom, Italy and other countries that raced to be first in getting access

to CAR-T cell therapies cited as examples (Patel N et al., 2020<sub>[62]</sub>; Jørgensen, Hanna and Kefalas, 2020<sub>[63]</sub>; Mckinsey, 2022<sub>[64]</sub>).

45. Greater price transparency certainly prompts consideration of distributional and equity effects. Under greater price transparency, payers and governments would become aware of cross-country differences in prices negotiated with the industry, but this would not mean that all countries would pay the same. Some authors suggest that price transparency could increase prices paid by the poor, deter business entry in poor markets, reduce competition, and lower investment (Kyle and Ridley, 2007<sub>[65]</sub>). Others have highlighted the potential risk of price convergence between higher and lower-income countries (or larger and smaller markets) resulting in higher prices and/or reduced patient access in countries with lesser ability to pay (Danzon and Towse, 2003[66]; Mestre-Ferrandiz et al., 2016[67]). Many OECD countries use international benchmarking to regulate pharmaceutical prices and some of them reference a wide range of countries with varying income levels. With transparent prices, companies could be less willing to agree to reduce prices in LMICs, as these could influence prices in HICs. In addition, public opinion in HICs could pressure governments to negotiate reduced prices to match those obtained by LMICs. This risk is not properly considered in the current literature, nor is the willingness of countries to become worse off under greater transparency. Price transparency is often presented as a barrier to tiered pricing (Acosta et al., 2014[68]; Shaw and Mestre-Ferrandiz, 2020[28]) and greater transparency may require agreement on acceptable approaches to differential pricing between high and low income settings. A key question remains of how these approaches should be derived, and how arbitrage can be discouraged in this transparent environment.

## 4. Conclusions

- 46. The principal findings and conclusions of this analysis are:
  - Current efforts towards increasing transparency in pharmaceutical markets are "hastening slowly". Recently, some OECD countries adopted legal provisions aimed at increasing transparency of different types of pharmaceutical information. In fact, several countries have established public databases with information on pharmaceutical pricing, or have implemented mechanisms for data sharing between competent authorities to facilitate joint price negotiations. Yet, despite around 30 cross-country initiatives that involve some form of sharing pricing information, few disclose actual transaction prices. Most initiatives are either regional cross-country voluntary agreements involving EU member states, or led by international organisations such as the WHO, the PAHO, UNICEF, UNFPA, the Global Fund, and the Eurostat- OECD. A few initiatives involve Latin American countries, and one engages the Gulf States. To date, there is little evidence demonstrating the effectiveness of these initiatives in advancing transparency in pharmaceutical information, particularly for those initiatives established recently.
  - There is limited empirical literature examining the impact of greater transparency policies on actual transaction prices within countries, and poor consideration of spillover effects across countries. Evidence from within individual countries is inconclusive, with some studies suggesting no clear effect of greater price transparency on price levels, while others claiming price movements in both directions. Evidence is lacking on the impact of greater price transparency on various dimensions of the functioning of pharmaceutical markets, including pricing and coverage decisions, use of external reference pricing, and differential pricing and parallel trade between countries. In the search for better evidence on the impact of greater price transparency on the functioning of markets, one has a complex task to consider the impact of various multi-dimensional factors that include the characteristics of the products available to target a certain condition, the market supply-side conditions (e.g. monopoly and exclusivity rights), the demand-side conditions (e.g. payer's bargaining power over companies, reimbursement and coverage policies), as well as other policies regulating prices and access to medicines and other system-level characteristics interacting at regional and global level. Such a multitude of factors may translate into a rather non-linear and non-universal relationship between price transparency and price levels, with specific relationships applying in certain situations or between certain countries.
  - Experts disagreed on how greater transparency could impact the functioning of markets. Some were confident that greater price transparency could render significant benefits, namely stronger bargaining power for public payers in price negotiations with the industry, greater public accountability, and legitimacy of coverage. Others saw greater price transparency as introducing some risks to the functioning of markets, for example, price convergence, with the potential for higher prices and/or reduced patient access in countries with lesser ability to pay, unclear effects on differential pricing and parallel trade, and uncertain consequences for long term decisions by companies regarding participation in certain markets and on investment in R&D.

There remains a lack of clarity and certainly a lack of consensus about the objectives of price transparency, or which information should be made more transparent. Transparency is viewed both as "a means to an end" to attain lower prices and/or expand access, and as having intrinsic value for public accountability. Price transparency is often presented with discussions about transparency of other sorts of pharmaceutical information – including industry revenues and costs, clinical trial data, patents and exclusivity rights, and public funding of R&D. Information available in the public domain on industry revenues, R&D costs, and marketing expenditure is often unreliable or incomplete, with data and methods often not disclosed and subject to controversy. Patent data are publicly available but require legal expertise to interpret correctly, while data on public R&D funding are biased towards publicly listed companies and are not structured in a way that facilitates pharmaceutical policy analysis. Careful analysis of the evidence of the risks and benefits of making this information more transparent needs to be undertaken when deciding whether to move towards some (or all) forms of transparency.

#### 4.1. How can the transparency agenda move forward?

- 47. From this analysis, five key actions are identified as needed to take this agenda forward:
  - Investing in evidence generation to assess the impact of existing cross-country initiatives that share price information in order to inform future action on price transparency. This report outlines the main features of the existing cross-country initiatives sharing price data and highlights the insufficient evidence to date demonstrating the effectiveness of efforts to increase medicine price transparency.
  - Clarifying the issues price transparency is intended to address, both on on-patent and off-patent markets, and considering whether other policy options may be more effective/less risk prone. Motives for pursuing greater price transparency vary across countries and among stakeholders, some of whom view transparency as a way to address a range of policy challenges, despite the lack of empirical evidence of effectiveness. The OECD is currently undertaking a survey to understand the expectations and motives of governments and payers in sharing information on medicine prices. Analyses of the survey results will provide some insight into the issues governments expect to be able to address with greater price transparency, and may enable the identification of alternative policy options that may be more acceptable or less prone to the potential risks. For example, regulation mandating simultaneous pan-European market launch as a condition of registration could be used as a means of addressing delayed access due to launch sequencing. Pricing and procurement policies could be optimised to foster price competition in on-patent markets. Pooled procurement or joint negotiation could improve the leverage of payers in price negotiations with industry. This could address concerns that greater transparency is essential to reducing prices.
  - Modelling the spillover effects of greater price transparency. Some significant modelling needs to be undertaken to inform policy on the cascading effects of greater price transparency across countries. Evidence to date has been drawn from theoretical modelling of the impact of simplified simulated scenarios, drawing on list prices and making assumptions about discounts and rebates that cannot be verified. For example, it would be helpful to model the impact of price information sharing on prices using methodologies developed by complex systems analysis (e.g. network analysis) to better understand the complexity of the interaction between the multiple stakeholders and countries in the global pharmaceutical markets. Such models allow the consideration of a number of parameters, including interconnections, uncertainties, information opacities, and static and dynamic mechanisms. These could borrow from different disciplines, such as economic growth and investment decisions on innovation, to gain an understanding of the interdependencies of economic factors across countries. An example of this is the application

of network analysis to systemic risk in financial markets using an approach of Systemic Cascades in Financial Networks<sup>41</sup>. Modelling could accommodate a range of scenarios since the implications of price transparency are expected to differ quite substantially across markets, e.g. comparing consequences among HICs; between HICs and LMICs; across the EU, or between the EU and the US; as well as considering the various strategic reactions of companies under price transparency with varying numbers of competitors and market exclusivity scenarios.

- <u>Gaining international agreement on which aspects of transparency should be prioritised.</u> Besides prices, there are many aspects of the pharmaceutical market that would arguably benefit from greater transparency, including clinical trial data, industry revenues and R&D costs, marketing expenditure, patents, and public R&D funding and subsidies. Greater clarity on the priorities for increasing transparency would enable a more focused forward-moving agenda.
- <u>Ascertaining what price information could be shared and how.</u> The OECD is currently
  undertaking a country survey to determine the information (i.e. which prices, and for which
  medicines) that could feasibly be shared, and by what mechanisms, taking into account existing
  legal frameworks and technical barriers. Various arrangements for sharing data could be
  considered, for example, using the principle of reciprocity for example, a network of countries
  could agree to share, but not publicly disclose, net pricing data.

<sup>&</sup>lt;sup>41</sup> <u>https://www.oecd.org/naec/new-economic-policymaking/Hurd\_NAEC\_Networks\_Panel.pdf</u> (accessed on 7 April 2020).

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