

# Background note on Transparency Norms

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## 1988

### **1988. December 21. EU Directive on transparency on pricing of medicinal products**

Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems. Available at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31989L0105>

Whereas the objective of this Directive is to obtain an overall view of national pricing arrangements, including the manner in which they operate in individual cases and all the criteria on which they are based, and to provide public access to them for all those involved in the market in medicinal products in the Member States; whereas this information should be public; . . .

Whereas, as a first step towards the removal of these disparities, it is urgently necessary to lay down a series of requirements intended to ensure that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto; whereas, however, these requirements do not effect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products; whereas these requirements also do not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive;

Whereas the further harmonization of such measures must take place progressively,

Article 2.3.

At least once a year, the competent authorities shall publish in an appropriate publication, and communicate to the Commission, a list of the medicinal products the price of which has been fixed during the relevant period, together with the prices which may be charged for such products.

Article 10.1 A Committee called the 'Consultative Committee for the implementation of Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems' shall be set up and attached to the Commission.

## 1993

### **1993. February. The U.S. Office of Technology Assessment report on Pharmaceutical R&D costs.**

Pharmaceutical R&D: Costs, Risks, and Rewards, February 1993, OTA-H-522, NTIS order #PB93-163376, GPO stock #052-003-01315-1

This report ended up relying upon drug company consultant data, and provided the rationale for doing so here.,

There is only one way to get information on both the amount and timing of cash outlays required to produce a successful NCE: take a large and representative sample of R&D projects and, for each project, record incurred costs month-by-month until the project is either abandoned or approved for marketing. Then, outlays over time can be converted to their present value in a particular reference year at the appropriate cost of capital. . . .

The main problem with this approach is that accurate data on the costs and time required to reach specific milestones in the R&D process, and rates of success or abandonment along the way, are proprietary. Researchers must depend on the ability and willingness of companies to supply detailed data on R&D project costs and histories. Hansen and DiMasi relied on surveys of 14 and 12 U.S.-based pharmaceutical firms, respectively, that were willing to provide estimates of R&D outlays and timing for the samples of newly synthesized NCEs. The researchers could not audit these estimates for accuracy or consistency across companies.

Early in this assessment, OTA determined that it would be infeasible to mount an independent project-level study of R&D costs. Although Congress has the power to subpoena company data, pharmaceutical companies have actively resisted providing it to congressional agencies. In the past, the U.S. General Accounting Office (GAO) tried to obtain data on pharmaceutical R&D (and other) costs but was ultimately foiled after many years of effort that involved decisions in the U.S. Supreme Court. (See appendix D for a legal analysis of congressional access to financial data.) Although business confidentiality arguments are not sufficient to block a congressional subpoena (423), such arguments can result in protracted negotiations over whether or not the information will be kept confidential and the scope of the documents that must be turned over. The pursuit of data from a number of companies would be very costly and take many years.

## **2001.**

### **2001. April 10. WHO Secretariat Report on the Revised Drug Strategy.**

[A54/17](#), Provisional agenda item 13.8, 10 April 2001, Revised drug strategy, Report by the Secretariat. Some excerpts follow:

Efforts to make prices affordable have included promotion of generic drugs, advocacy for the equity pricing concept, wider dissemination of information about drug prices, and designing methods for surveying drug prices.

13. A project was initiated with several nongovernmental organizations and a private foundation to standardize methods for drug price surveys, with the aim of increasing the quantity, quality, comparability and transparency of information. Prices for selected essential drugs will be collected for different subsectors of the health system in several countries. Once tested, the methods will be made widely available to enable data collection to be extended to other countries. A first meeting of the project's technical advisers was held in the Netherlands in January 2001.

35. The Director-General's round-table talks have continued with the research-based pharmaceutical, generic drug and self-medication industries, and with public-interest nongovernmental organizations. The round tables have led to new projects and approaches for tackling health problems by increasing access to antimalarial agents, improving drug quality, developing methods for drug price surveys and documenting and critically evaluating drug promotion.

## **2006**

### **2006. April 25. WHO CIPIH Report.**

WHO published the [report of the Commission on Public Health, Innovation and Intellectual Property \(CIPIH\)](#). This landmark 2006 report had the following recommendation on transparency of pricing.

4.6 All companies should adopt transparent and consistent pricing policies, and should work towards reducing prices on a more consistent basis for low and lower middle income developing countries.

## **2007**

### **2007. February 9. U.S. General Accounting Office (GAO) report on oversight of drug pricing in federal programs.**

GAO report number GAO-07-481T, entitled 'Prescription Drugs: Oversight of Drug Pricing in Federal Programs,' which was released on February 9, 2007.

In summary, oversight inadequacies by federal agencies and a lack of transparency in drug pricing practices that affect federal programs have important implications for federal spending on prescription drugs. Regarding the Medicaid drug rebate program, we and others have reported inadequacies in the Centers for Medicare & Medicaid Services' (CMS) oversight of the price information reported by manufacturers to determine the rebates owed to states, including a lack of clarity in CMS's guidance to manufacturers for calculating that price information. Recent litigation involving allegations that drug manufacturers reported inaccurate prices to CMS resulted in

several manufacturers agreeing to pay about \$88 million, \$257 million, and \$345 million to states, thus highlighting the potential for abuse under the program. CMS recently issued a proposed rule intended to provide more clarity to manufacturers in determining the prices they report to CMS.

## **2008**

### **2008. May 15-16. MeTA launch.**

The Medicines Transparency Alliance (MeTA) launch at Lancaster House in London.

“The problems of price, quality and availability can be tackled by improving transparency and access to information. MeTA will provide citizens, health care workers and others with information to challenge corruption, excessive pricing and waste.”

U.K. Secretary of State for International Development, Douglas Alexander. [[DIFID Press Release](#)]

### **2008. HAI, WHO report on measuring drug prices.**

HAI and WHO publish Measuring medicine prices, availability, affordability and price components, 2nd Edition. [WHO/PSM/PAR/2008.3](#)

“Lower medicine prices require much greater transparency in transactions at all levels; more openness and better public information will help to create a constituency for change.” [page 192]

## **2009**

### **2009. Launch of The "Price Information Exchange for Essential Medicines" (PIEMEDS) system**

From the PIEMEDS web page.

The "Price Information Exchange for Essential Medicines" (PIEMEDS) system contains procurement prices in the public sector for medicines that participating countries have shared voluntarily. The project intends to facilitate regular monitoring of the medicine price information. Data from national focal points are collected and processed by the World Health Organization.

As recommended in the WHO Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010), this information system was developed to address these relevant facts:

- price is a significant barrier to access medicines
- there are major differences in medicines prices across countries in the region;
- exchanging price information among countries may help in-country negotiations with suppliers and influence policy and managerial decisions to take measures towards reducing prices, if they appear to be too high when compared to other countries in the Region

## 2010

### 2010. August 2. PhRMA statement on transparency

The Pharmaceutical Research and Manufacturers of America (PhRMA) statement regarding efforts to enhance transparency. ([link](#))

“PhRMA and its member companies have a longstanding commitment to the ethical conduct of clinical trials and to increasing transparency by reporting more information about clinical trials.

“We are always looking for ways to enhance our voluntary industry codes and, to this end, supported a joint position statement in June with the International Federation of Pharmaceutical Manufacturers & Associations to enhance publication of clinical research. The joint statement calls for publication of summaries of all Phase III clinical trials and all clinical trials of significant medical importance in peer-reviewed journals.

“PhRMA’s commitment to enhanced transparency of clinical research is in addition to our member companies’ unanimous support of PhRMA’s recently revised Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, which call for registration and online publication of summaries of all clinical trials in patients for approved medicines. What’s more, PhRMA’s Clinical Trial Principles also call for our member companies to disclose summaries of all clinical trials in patients for investigational medicines whose development programs have been discontinued.



## 2011

### **2011. May. HAI/WHO report on external reference pricing.**

WHO/HAI Project on Medicine Prices and Availability Review Series on Pharmaceutical Pricing Policies and Interventions Working Paper 1: External Reference Pricing May 2011. <http://haiweb.org/wp-content/uploads/2015/08/ERP-final-May2011a1.pdf>

Confidential agreements between manufacturers and purchasers often provide buyers with discounts or other benefits. If the results obtained from such negotiating processes are not transparent, it becomes harder to predict their impact in reference countries. [page 4]

Companies can reduce price transparency in many different ways. They can list high prices in reference countries while granting confidential rebates or discounts to them ; i.e. offering a discount or rebate under the condition that it will not be publicised. Companies might also provide a larger number of units than those indicated in the contract in exchange for maintaining the list price. These strategies provide manufacturers with a degree of flexibility in satisfying requests for lower prices from country regulators and payers without compromising prices in other countries that take the former as a reference. [page 22]

The loss of price transparency is probably one of the most undesirable effects of ERP. Prices represent the market's key mechanism for the efficient allocation of resources. Without known prices, markets simply cannot adjust to an efficient equilibrium. Collective decision making cannot be efficient either, since the underlying comparisons of costs and benefits will be biased or completely unfeasible. [page 23]

## 2012.

### **2012. MSH/GTF.CCC, report on cancer medicine prices**

Management Sciences for Health, "Cancer Medicine Prices in Low- and Middle- Income Countries,": Global Task Force on Expanded Access to Cancer Care and Control in Developing Countries (GTF.CCC) .

“Procurement officers often do not have easy access to available pricing information to make the best purchase decisions for public health programs. Transparent, web-based exchange of information on prices and sources of cancer medicines and vaccines should be expanded. Such information can achieve dramatic price reductions –especially on off-patent products– when used in competitively pooled procurement by reliable global, regional, or national procurement and supply organizations. For example, price information transparency for antiretrovirals through initiatives by Médecins Sans Frontières and WHO's Global Price Reporting

Mechanism contribute to informed purchasing decisions for HIV/AIDS programs. Likewise, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) requires that principal recipients submit prices paid for a range of procured medicines for AIDS, tuberculosis, and malaria that are then publicly posted through its Price and Quality Reporting System with country and region specific analyses.”

## 2015

### **2015, February 23. California AB 463, the Pharmaceutical Cost Transparency Act of 2015.**

Member of the California state legislature introduces AB 463, the Pharmaceutical Cost Transparency Act of 2015, setting into motion a series of state legislative efforts to require transparency of drug prices, marketing and R&D costs, and other elements of the pharmaceutical value chain. (To track such efforts, see: <https://nashp.org/rx-legislative-tracker-2019/>)

### **2015. resolution [2071](#) (2015) of the Council of Europe: Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?**

. . . we have seen an upsurge in the price of medicines, allegedly justified by the cost of research and development, which nonetheless remains opaque and broadly disputed.

6. In the light of these considerations, the Assembly calls on the Council of Europe member States:

6.2. with regard to research and development for new therapeutic molecules, to:

6.2.1. oblige pharmaceutical companies to ensure absolute transparency regarding the real costs of research and development, particularly in relation to the public research portion;

## 2016

### **2016. February 18. Joint NGO, member of EU parliament submission to UN SG HLP on A2M.**

18 groups and 3 members of the European Parliament make a [submission](#) to the UN Secretary-General’s High-Level Panel on Access to Medicines on Increasing the transparency of markets for drugs, vaccines, diagnostics and other medical technologies.

Key components of the business model of the pharmaceutical industry, including research, development and commercialisation, remain shrouded in secrecy,

particularly as regards access to information by patients and the general public. This undermines trust in and accountability of the pharmaceutical industry, and leaves patients vulnerable to human rights violations, including the right to the highest attainable level of health and ultimately the fundamental right to life, and makes it unnecessarily more difficult for society to make the appropriate policies regarding the financing and priority setting of R&D, and product purchases. Given the complexity, size and volume of transactions in the pharmaceutical sector, the lack of transparency creates a range of opportunities to exercise power and influence that can have negative health outcomes and can result in corruption. . .

This proposal first identifies areas where it is important to expand transparency – and second, proposes measures that UN agencies, governments and partnerships can adopt to progressively increase transparency in markets for drugs, vaccines and diagnostics.

### **2016. May 3. Report on Access to Health Services in the European Union**

Expert Panel on effective ways of investing in Health (EXPH), Report on Access to Health Services in the European Union, 3 May 2016. doi:10.2875/10002

On the other hand, debates around access to new medicines have intensified. Key issues here also concern coverage (who has access, within and across countries?) and prices (are health systems able to pay for new medicines?), and extend to thinking about how best to provide incentives for innovation (do payment mechanisms encourage the development of medicines that address unmet therapeutic needs?) and how to balance incentives against the budget impact of paying for new products. These issues have led many to call for a re-think of funding for R&D and payment for innovation – a complex challenge that deserves a careful reassessment of existing mechanisms and a thorough exploration of all alternative mechanisms, including mandatory licensing on public health grounds when no price and quantity agreement is reached with innovators and publicprivate policy initiatives such as de-linking prices and R&D costs where appropriate. Such an assessment is, however, beyond the scope of this opinion and its implications go beyond issues of access. (page 73)

#### **National Policy Responses.**

Creating greater transparency around the costs of pharmaceutical products and the price of medicines would provide better grounds for assessing affordability, equitable access, fairness in pricing and incentives to develop new medicines. (page 118)

**2016. July 5. Assistant Director-General Dr. Marie Paule Kieny comment on fair pricing.**

WHO published a written comment by Assistant Director-General Dr. Marie Paule Kieny, titled, [A comprehensive and fair solution to the price of medicines](#) where she provided a preview of WHO's future engagement on fair pricing, including transparency.

To that end, WHO is planning to convene governments, patient groups and industry stakeholders to develop a fair pricing model that can affordably deliver the medicines needed by patients while keeping companies interested in developing new and better treatments and producing generic treatments. That model will need to hinge on greater transparency in industry's research and development and marketing approaches; it will also need to understand what the inputs are into price setting, as well as the barriers companies face in bringing new products to market.

**2016. August 2. President Barack Obama calls for transparency of manufacturers' actual production and development costs.**

Barack Obama. August 2, 2016. United States Health Care Reform: Progress to Date and Next Steps, JAMA. 2016;316(5):525-532. [doi:10.1001/jama.2016.9797](https://doi.org/10.1001/jama.2016.9797)

Congress should act on proposals like those included in my fiscal year 2017 budget to increase transparency around manufacturers' actual production and development costs, to increase the rebates manufacturers are required to pay for drugs prescribed to certain Medicare and Medicaid beneficiaries, and to give the federal government the authority to negotiate prices for certain high-priced drugs.

**2016. September 14. Report of UN Secretary General High Level Panel on Access to Medicines.**

The Report of the UN Secretary General High Level Panel on Access to Medicines was published [here](#) on September 14, 2014. Transparency was discussed in the report, touching on several issues, from prices and R&D costs to clinical trial outcomes. Here are a few sections of the report.

**4.2 Transparency**

**4.2.1 R&D costs and pricing of health technologies**

To realize a fair return for public investment actors and public funders should require clear information on what it costs to innovate and bring a particular health technology to market. Although publicly-traded companies are legally required to disclose a range of financial information in their annual report, privately held ones are not, and even when disclosed, the data can be incomplete and difficult to parse and may not be sufficiently disaggregated, for example between R&D costs and marketing costs. For instance, R&D costs are not broken down by product, nor are precise sources of

income listed in many cases, so a research grant from a government agency may not appear in a grantee's books depending upon accounting practice and the levels of funding involved.<sup>208</sup> Ultimately cost estimates vary widely depending on the source. .

Some public databases of medicine, vaccine, diagnostic and medical device prices exist. The WHO Global Price Reporting Mechanism (GPRM), for instance, records international transactions (volumes, prices, terms and other information) of HIV, tuberculosis and malaria medicines and diagnostics purchased by national programmes in low- and middle- income countries, as do other international organizations and governments.<sup>208</sup> The Vaccine Product, Price and Procurement web platform (V3P), another WHO initiative, provides information on vaccine product, price and procurement data.<sup>209</sup> Non-governmental organizations, such as Médecins Sans Frontières and Health Action International, have kept databases and produced publications to track the prices of key health technologies.<sup>210</sup> These mechanisms have strengths, but also limitations—such as the surveying of only some countries and some diseases. Furthermore, many complexities get in the way of confirming prices. Discounts, mark-ups, taxes and regional differences mean that prices vary within countries and final prices may not match list and factory prices.<sup>211</sup> Even in relatively transparent systems, published lists do not always disclose pricing arrangements between suppliers and public procurers.<sup>212</sup> Timely, comprehensive and user-friendly databases on costs and prices are needed.

#### **4.2.2 Clinical trials**

Healthcare providers need complete, up-to-date clinical trial data to give patients the safest, best treatments. A 2013 United Kingdom parliamentary committee pointed out the serious problem of lack of information sharing from clinical trials: “Important information about clinical trials is routinely and legally withheld from doctors and researchers by manufacturers. This longstanding regulatory and cultural failure impacts on all of medicine and undermines the ability of clinicians, researchers and patients to make informed decisions about which treatment is best.”<sup>213</sup> . . .

Transparency of clinical trials is not always a given. The initiators of trials commonly require non-disclosure agreements, in which the institutions that conduct the trials consent to keep the protocols, patient data and research results secret.<sup>218</sup> Some conductors of clinical trials have introduced bias into study designs and suppressed negative results,<sup>219</sup> although this does not appear to be common practice. To address the need for global transparency, several years ago WHO established the International Clinical Trials Registry Platform (ICTRP) that can serve as a single database where voluntarily-provided trial data can be made available. However, the ICTRP does not yet include any trial results, although work is underway to do so.<sup>220</sup> In 2014, the European Medicines Agency adopted a new policy to make clinical studies available.<sup>221</sup>

### 4.2.3 Patent information

Transparent patent information can be an important determinant of health outcomes. When the status and details of intellectual property protections are easily accessible, competitors can confidently release cheaper health technologies similar to out-of-patent products. 222 Also, governments, generic companies, researchers and civil society can more easily review and oppose questionable patent applications and grants and monitor whether officials are applying patentability criteria as required by national laws.

Currently, patent information is often confusing, incomplete and fragmented. A single product may be protected by hundreds of patents 223 and compounds may appear under a brand name or an international non-proprietary name (INN). Patents pile up over time, with no indication as to which ones the holder plans to enforce 224 and extend. These factors, as well as excessive patenting, can impede scientific progress and legitimate competition. 225

Multilateral organizations, such as WHO, WIPO and WTO, provide support to countries and procurement agents to navigate the mazes of patent information needed to make procurement decisions. 226 A number of countries and organizations publish patent databases and conduct surveys and analysis (referred to as “patent landscapes”) covering certain fields of health technologies and groups of essential medicines, such as ARVs. 227 These efforts begin the process of creating a comprehensive source of global patent information—but like the data itself, they are still incomplete and scattered.

Additional recommendations of the UNHLP on transparency included:

- (a) Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to:
  - (i) The costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and
  - (ii) Any public funding received in the development of the health technology, including tax credits, subsidies and grants.

### **2016. September 28. PAHO Framework for Access and Rationale use of High-Cost Medicines and other Technologies**

Agenda Item 4.6 Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies. [CD55/10, Rev. 1](#). This framework was approved by 55th Directing Council of PAHO, and includes a set of actions to improve access to and use of high-cost

medicines and technologies. The framework encourage Member States to leverage several policy options in order to improve access to and rational use of quality, safe, and cost-effective medicines and other health technologies. The following is from that document.

11. The high prices of new medicines are often justified due to the costs of research and development borne by the manufacturer. Yet, the precise research and development costs borne by the private sector are hard to establish and subject to controversy (13) since public spending on scientific research can be a major determinant for new discoveries (25). Some recent initiatives address the lack of transparency in research and development costs. In the United States, a number of states are debating the introduction of legislation to improve research and development cost-information (26). In addition, WHO Executive Board report EB138/41 (23) states that “a better understanding of research and development costs would enable a constructive dialogue on how to establish a fair and affordable price for medicines for children.” Proposals to change the prevailing research and development funding model involving de-linkage of research and development costs and prices were documented by the WHO Consultative Expert Working Group report on Research and Development (27).

#### **Policy Option B: Strategies that improve transparency and knowledge for decision making**

27. Policies that promote joint efforts with the pharmaceutical sector to improve transparency and access to timely, comprehensive information on the total cost of production and research and development and on trends, as well as price disclosure and a better understanding of costs and price structure, including distribution, taxes, retail costs, and profit margins, will support product selection, pricing strategies, and regulations. Similarly, countries may establish and promote mechanisms that improve the sharing of information on prices and, when possible, procurement volumes among countries and different actors in each country. National and multicountry price databases are useful for decision making and can be considered mechanisms for cooperation and information exchange. Moreover, supply chain transparency and good procurement practices contribute to the efficiency of the system.

The framework also included this resolution:

#### ***RESOLVES:***

(OP)1. To urge Member States, taking into account their context and national priorities, to:

...

e) work together with the pharmaceutical sector to improve transparency and access to timely and comprehensive information, including in relation to comprehensive research and development costs and trends, as well as pricing policies and price structures, supply chain management, and procurement practices in order to improve

decision-making, avoid waste, and improve affordability of medicines and other health technologies;

**2016. November 7. The Lancet Commission on Essential medicines for universal health coverage.**

Lancet 2017; 389: 403–76, Published Online, November 7, 2016, [http://dx.doi.org/10.1016/S0140-6736\(16\)31599-9](http://dx.doi.org/10.1016/S0140-6736(16)31599-9)

Transparency about prices has been a major feature of these global financing systems, in marked contrast with the situation that pertains to pharmaceutical pricing in other settings. Although little conclusive evidence exists that transparency alone results in price reductions, the possibility has been raised that price transparency could enable collusion or other anticompetitive behaviours between companies<sup>154</sup> or in an attempt to limit price reductions. However, as the case of antiretrovirals has shown, transparency can also be accompanied by drastic price reductions. . .

Transparency is essential to effective data analysis and decision making HTA requires a commitment to transparency between all stakeholders. The data used in assessments should be available for review by both health professionals and consumers. This kind of transparency could have implications for agencies that use commercial in confidence evidence provided by pharmaceutical companies. However, as with medicines regulatory structures, a deliberate policy of maximal transparency helps to engender trust in the procedure and the outcomes of assessments.

The costs of R&D are not transparent High prices for medicines are justified by the pharmaceutical industry as compensation for the costs of R&D and the high failure rate. However, the real costs of R&D are not well known . . .

Governments must lead the process towards a global R&D policy framework and agreements, which include new financing mechanisms to ensure that missing essential medicines are developed and made affordable. Such mechanisms should be based on transparent estimates of the real cost of R&D;

## **2017**

**2017. January 30. Negotiations on WHO Cancer Resolution**

In a drafting group on the WHO cancer resolution, Thailand and Colombia requested WHO to develop a cancer report that included information on the transparency of medicines prices.



Thailand requested that WHO develop a public health and policy-oriented world report on cancer “[on a regular basis including information on utilization, distribution and prices of drug and treatments]” and Colombia added “[that shall include statistics on prices, distribution and uses of cancer medicines, and information on barriers for access to affordable cancer treatments]”.

### **2017. March 2. European Parliament resolution on EU options for improving access to medicines**

The “European Parliament resolution of 2 March 2017 regarding EU options for improving access to medicines,” including specifically points 34-36, and 57-59.

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2017-0061+0+DOC+XML+V0//EN>

34. Points out that Directive 89/105/EEC (‘the Transparency Directive’) has not been revised in 20 years and that, in the meantime, important changes have taken place in the medicine system in the EU;
35. Underlines, in this context, the need for independent processes of data collection and analysis and for transparency;
36. Notes that the EURIPID project needs more transparency from Members States to include the real prices paid by them;
57. Calls on the Commission to revise the Transparency Directive with a focus on guaranteeing timely entry into the market for generic and biosimilar medicines, ending patent linkage according to the Commission’s guidelines, accelerating pricing and reimbursement decisions for generics, and precluding the multiple reassessment of the elements supporting marketing authorisation; believes that this will maximise savings for national health budgets, improve affordability, accelerate patient access and prevent administrative burdens for generic and biosimilar companies;
58. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;
59. Calls for a new Transparency Directive to replace Directive 89/105/EEC with the aim of ensuring effective controls and full transparency on the procedures used to determine the prices and the reimbursement of medicinal products in the Member States;

#### **2017. May 4. Negotiations on WHO Cancer Resolution**

The May version of the cancer resolution had the following text:

OP2.5ter) [To prepare a comprehensive technical report towards the end of 2018, on existing research and financing mechanisms, and, [where appropriate,] (DEL) new alternative and/or complementary mechanisms and R&D [pharmaceutical] (Secretariat) options for prevention, diagnosis and treatment of cancer, including mechanisms for enhancing transparency in R&D costs and product prices, [(where appropriate and effective, and consistent with strong intellectual property protections,)] /[(bearing in mind international intellectual property regulations)] [the relationship between cost inputs and product prices,] [R&D incentives, the identification of any financing gaps and review of any innovation mechanisms for cancer that would enhance the affordability and accessibility of medicines and health products for cancer;] [where appropriate,] [including the progressive delinkage between R&D costs and product prices]

#### **2017. May 31. Final text of the WHO cancer resolution**

The final text of the WHO cancer resolution ([WHA70.12](#)) had the following language which requested WHO to:

prepare a comprehensive technical report to the Executive Board at its 144th session that examines pricing approaches, including transparency, and their impact on availability and affordability of medicines for the prevention and treatment of cancer, including any evidence of the benefits or unintended negative consequences, as well as incentives for investment in research and development on cancer and innovation of these measures, as well as the relationship between inputs throughout the value chain and price setting, financing gaps for research and development on cancer, and options that might enhance the affordability and accessibility of these medicines”.

#### **2017. May. Fair Pricing Forum, Netherlands.**

Transparency of R&D costs and prices were among the core themes addressed: see page 6 of the meeting report:

[https://www.who.int/medicines/access/fair\\_pricing/FairPricingForum2017MeetingReport.pdf?ua=1](https://www.who.int/medicines/access/fair_pricing/FairPricingForum2017MeetingReport.pdf?ua=1)

#### **Transparency of R&D costs and pricing**

Particular attention was drawn to the need for greater transparency on R&D costs. However, it was acknowledged that this should take into account the complexity of the different elements that require costing, including failed drug development attempts, and decisions not to proceed with drug development on commercial grounds. With regard to achieving greater transparency on prices, a first step could

be that governments agree to acknowledge or 'flag' where the published price is not the actual price paid while noting that the commercial nature of these agreements may mean that it is not possible to identify the price paid for individual products. However, it was emphasised that achieving greater transparency has the potential to result in additional benefits, for example, targeted rewards for needed innovation. It was suggested that the obstacles to achieving greater transparency are considerable and that governments have an important role to play in driving reform.

**2017. November 22 - 24. Fair Pricing Forum Informal Advisory Group Meeting WHO Headquarters, Geneva.**

<http://apps.who.int/medicinedocs/documents/s23205en/s23205en.pdf>

. . . there is a notable lack of robust data and transparency on R&D costs. As the European Commission concluded in 2008, "[t]he costs of bring a new medicine to market is subject to wide debate and a variety of estimation." [page 7]

The bottom line, however, is that more clarity is needed on the costs of R&D. The Advisory Group discussed the possibility of insisting on greater transparency from the pharmaceutical industry. [page 8]

**2017. October. EU unsuccessful attempts to insert language on transparency in Sao Paulo Declaration on Hepatitis.**

EU efforts to include language on transparency in the Sao Paulo Declaration on Hepatitis were blocked by Australia and the United States of America.

**2017. November. US Senate Finance Committee proposals to make U.S. Orphan Drug Tax Credit public.**

U.S. Senate Finance Committee proposes to make the U.S. Orphan Drug Tax Credit transparent as to the amount, taxpayer and therapy. (Discussion [here](#)).

**2017. November. WHO recommendations of the Overall Programme Review (OPR) of the global strategy and plan of action on public health, innovation and intellectual property.**

<http://www.who.int/medicines/areas/policy/GSPA-PHI3011rev.pdf?ua=1>

The recommendations of the overall programme review included:

Member States to support the WHO Secretariat in promoting transparency in, and understanding of, the costs of research and development. (Indicator: Reports on the costs of research and development for health products prepared in 2019 and 2021.)

The WHO Secretariat to provide guidance to Member States on promoting and monitoring transparency in medicine prices and on implementation of pricing and reimbursement policies. (Indicator: Guidance developed and disseminated in countries by 2020.)

In relation to the recommendation on the transparency of R&D costs, an internal WHO Secretariat memo, identified element 6.3(e) of the GSPA as the basis for the transparency recommendation on R&D costs.

This is most closely related to sub-element 6.3 (e) “consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products, and further support WHO’s ongoing work on pharmaceutical pricing”. It also contributes to sub-element 5.3 “explore and, where appropriate, promote a range of incentive schemes including addressing, where appropriate, the delinking of the costs of research and development and the price of health products...”

In relation to the recommendation on the transparency of medicines prices, an internal WHO Secretariat memo identified element 6.3(b) of the GSPA as the basis for the transparency recommendation on medicines prices.

Supports implementation of sub-element 6.3 (b) – “frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements” and 6.3 (e) “consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products, and further support WHO’s ongoing work on pharmaceutical pricing”

### **2017. November 30. Publication of U.S. National Academies Report on Drug Pricing.**

National Academies of Sciences, Engineering, and Medicine. Making Medicines Affordable: A National Imperative. 2018. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24946>. Released November 30, 2017.

#### **Recommendation C**

#### **Assure Greater Transparency Of Financial Flows and Profit Margins in the Biopharmaceutical Supply Chain.**

Specific implementation actions are:

\* Require biopharmaceutical companies and insurance plans to disclose net prices received and paid, including all discounts and rebates, at a National Drug Code level

on a quarterly basis. Obtain, curate, and publicly report this collected information. Conduct analyses of these data and inform relevant congressional committees, and examine these data to identify and act upon any anti-competitive practices in the market.

\* Require biopharmaceutical companies to submit an annual public report stating list prices; rebates and discounts to payers, including changes thereto; and the average net price of each drug sold in the United States. All net drug price increases that exceed the growth in the consumer price index for the previous year should be reported to the relevant congressional committees.

\* Expand the disclosure requirements on all sources of income by organizations in the biopharmaceutical sector that are exempt from income tax under the Internal Revenue Code.

## 2018

### 2018 January 12. The WHO Secretariat document (EB/142/13) on access to medicine.

The WHO Secretariat document (EB/142/13) for the 142nd session of the Executive Board, [Addressing the global shortage of, and access to, medicines and vaccines](#), contained the following priority options to be considered by Member States:

8. The scaling up of the following actions is considered as having a **potentially high impact on access to safe, effective and quality medicines, but involves greater complexity and requires additional resources.**

- Support the development and implementation of systems at the national level for **collecting and monitoring key data on medicines and vaccines**, such as availability, **price, expenditure**, usage, quality and safety, and ensuring use of these data for better evidence-based policy-making.
- **Develop policies that promote transparency throughout the value chain, including the public disclosure of clinical trial data, research and development costs, production costs, procurement prices and procedures, and supply chain mark-ups.**

In January 2018, the transparency recommendations of the OPR of the GSPA were the subject of intense [debate](#). The recommendation on price transparency was accepted as a recommendation that mandated the Director-General to implement; this was decided in May 2018 ([Decision 71\(9\)](#)).

The recommendation on the transparency of R&D costs however, was subject to further negotiation; the World Health Assembly in May 2018 provided the following instructions (Decision 71(9)) in urging Member States to: “further discuss the recommendations of the

review panel not emanating from the global strategy and plan of action on public health, innovation and intellectual property”.

## **2018. January 17. EU Report on Innovative Payment Models for High-Cost Innovative Medicines.**

Innovative Payment Models For High-cost Innovative Medicines. Report of the Expert Panel on effective ways of investing in Health (EXPH). 2018. doi:10.2875/835008 Opinion on Innovative payment models for high-cost innovative medicines. The EXPH adopted this opinion by written procedure on 17.1.2018 after public hearing on 25.10.2017

### **4.1.2. Price transparency**

There are several claims that price setting should be more transparent and should not be left to industry alone. A clear view on the issue of price transparency was already present in the EXPH (2016b) “Opinion on access to health services in the European Union”: ”Creating greater transparency around the costs of pharmaceutical products and the price of medicines would provide better grounds for assessing affordability, equitable access, fairness in pricing and incentives to develop new medicines. (p.79)

A crucial transparency element in price transparency is information about R&D and operation costs (including manufacturing, marketing and distribution costs), without implying, as discussed in this Opinion, a cost-plus pricing rule, as this rule does not provide adequate incentives to R&D. The disclosure of information on costs to health care payers is different from posting list prices and adopting price-referencing schemes. Such disclosure of information by pharmaceutical companies can be done in a way that preserves commercial confidentiality regarding rivals.

### **On Managed Entry Agreements (MEAs).**

The strong points of MEAs are different for distinct stakeholders (health care payer, patients, companies), as each focus on a different main objective (for example, respectively, budget control, access, obtaining reimbursement with a non-disclosed price). On the weaknesses side, the main one identified in Ferrario and Kanavos (2013) and in KCE (2017) is the absence of support to the expected gains. Another major weakness is the costs associated, which seem to have been larger than anticipated by health care payers (monitoring requirements do require specialized resources from both sides, health care payers and companies). The non-disclosure conditions on the exact terms and results of MEAs, part of the agreements set, lead to lack of transparency and difficulties in assessing whether or not objectives are achieved. Page 25-26

The report cautions policy makers from basing prices on costs incurred on specific products, in order to avoid incentives to spend excessively on R&D efforts, but it does express the view that having data on R&D costs is helpful, particularly in evaluating the impact of pricing and more generally incentive schemes, and providing curbs on “very high” prices. The

report also expresses caution in implementing price transparency, if it discourages discounting.

### **5.1. Greater price and cost transparency**

Current price-setting models are inserted into an institutional framework that is benevolent with market power exercise, exacerbated by financial protection systems (health insurance) that reduce the price-sensitivity of demand.

Fully transparent cost-based prices are not an alternative to replace the current system, as they would promote high cost R&D efforts, irrespective of results, as a way to obtain better prices. This being said, the lack of systematic and reliable knowledge on costs incurred by companies is a feature that facilitates very high prices asked by pharmaceutical companies that commercialize the new products (which may not be the innovator firm). The reporting of cost information to regulatory bodies, even if kept as commercial secrets, will act as an implicit deterrent on very high margins.

On the other hand, competition, when feasible, takes place sometimes by way of "commercial confidential" price discounts. Such price competition element should not be discarded, and advises against full posting of all prices (as it would discourage its practice in the first place). Of course, in a world where full information on efficient costs of doing R&D and producing new products is available and where all decisions by all relevant economic agents can be costless included in complete contracts, prices set according to costs and known to everyone would be optimal. However, economic activities are performed in imperfect settings, in which full price transparency and cost-based prices can easily be sub-optimal.

### **2018. February 14-15. Informal expert consultation to develop a price information sharing platform in the South-East Asia Region**

[http://www.searo.who.int/entity/medicines/summary\\_report\\_price\\_info\\_sharing.pdf](http://www.searo.who.int/entity/medicines/summary_report_price_info_sharing.pdf)

Countries in the WHO South-East Asia Region (SEAR) identified specific actions for regional collaboration on strategic procurement and pricing, as ways to leverage regional capacities and strengths of regional markets. Some excerpts from the report of the meeting follow:

Specifically, information sharing on medicines' prices and quality was identified as one concrete action to move towards strategic procurement and was endorsed by Member States during the 70th Regional Committee (Sept 2017). Various global and regional platforms exist, including the Price Information Exchange for Medicines (PIEMEDS). . . .

Procurement experts from five South-East Asia countries shared their perspectives and experiences, and discussed how to better use procurement price information to support price negotiations and make their countries' make public procurement

systems more efficient and flexible. There was a consensus to use and further develop the existing Price Information Exchange for Medicines (PIEMEDS), hosted by the Asia eHealth Information Network (AeHIN) and invite voluntary participation from the 11 Member States via their national or state-level public procurement agencies.

1. All eleven SEAR countries to be officially invited by WHO SEARO to participate in voluntary price data sharing via PIEMEDS by 15 March 2018.
2. Countries to confirm willingness to share medicines price information by 15 April 2018, and identify focal point(s) for further communication regarding regular upload and sharing of procurement prices.
3. Countries to share web-links of already existing public information about procurement prices, quality and supplier information. Web-links to be collected and displayed via WHO SEARO Medicines webpage portal by 30 April 2018.

### **2018. Report of WHO European Observatory on Health Systems and Policies on redesigning drug pricing, reimbursement and procurement.**

2018. POLICY BRIEF 30. Sabine Vogler, Valérie Paris, Dimitra Panteli. Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? European Observatory on Health Systems and Policies. WHO Regional Office for Europe. ([Link](#)).

This report highlighted “information asymmetry” as a factor that harms public authorities in negotiations over prices.

#### **Identified barriers and limitations for the existing pharmaceutical pricing, reimbursement and procurement framework**

##### **Intransparency**

A major limitation is the lack of knowledge among policymakers and procurers about the extent of the discounts that marketing authorization holders grant to other countries. They are expected to trust the promise that they get ‘a good deal’ without having any possibility for verification. As shown above, the unavailability of ‘real price’ information in other countries has negative consequences for policies such as external price referencing. Furthermore, this information asymmetry impacts the bargaining power of public payers and procurers in price negotiations.

Another important lack of information concerns the actual costs incurred by companies for developing and producing medicines, which also limits public authorities in their price negotiations as they once again have no possibility of verifying the figures for R&D and production costs purported by marketing authorization holders. While prices are not set based directly on R&D costs, investments in R&D are always brought forward by industry as an argument for higher prices. Intransparency does not only affect pricing.



Asymmetry of information, also regarding the status and results of clinical trials, may affect the elaboration of clinical guidelines, and the choices of individual prescribers and consumers, as well as the results of HTAs.

### **Imbalances in negotiation power**

Information asymmetry related to 'real' prices, discounts and procurement conditions, to costs for research, development and production as well as medicines in the pipeline, reflects one aspect of the imbalances in market power: national procurers and payers (and in some cases, actors at regional or provider level, e.g. hospitals) meet globally acting pharmaceutical companies that have the overview of their product portfolio worldwide.

Page 20

### **2018. The OECD Report on Drug Pricing.**

OECD (2018), Pharmaceutical Innovation and Access to Medicines, OECD Health Policy Studies, OECD Publishing, Paris, <https://doi.org/10.1787/9789264307391-en>.

### **E. Strengthen the information base to better inform policy debates.**

#### **Increasing price transparency in pharmaceutical markets.**

Levels of price opacity in pharmaceutical markets are high and increasing, both within and between countries, in part due to the proliferation of confidential agreements between the industry and private and public payers. The disconnect between list prices and transaction prices has a number of drawbacks: high list prices serve as an anchor in all price negotiations; they blur international benchmarking, which is used by many countries; analyses of price trends become uninformative, and manufacturers may be criticised for high list prices that do not apply in reality. [from executive summary]

### **2018. August 30. WHO Bulletin article on transparency.**

Anne Paschke et al. Transparency and accountability in pharmaceutical systems, Bulletin of the World Health Organization; Type: Policy & practice. Article ID: BLT.17.206516

“A high level of transparency and accountability is critical for minimizing opportunities for fraud and leakage. In the past decade, the Good Governance for Medicines programme and the Medicines Transparency Alliance focused on improving accountability in the pharmaceutical system and on reducing its vulnerability to corruption by increasing transparency and encouraging participation by a range of stakeholders.”

**2018. December. WHO [Draft RoadMap for access to medicines, vaccines and other health products, 2019-2023.](#)**

This roadmap will be the subject of inter-sessional negotiations in the run up to the 72nd World Health Assembly in May 2019. The roadmap underscored how it aligned with WHO's Thirteenth General Programme of Work, including the following output:

“improved and more equitable access to health products through global market-shaping and supporting countries to monitor and ensure efficient and transparent procurement and supply systems”

As a principle, the WHO roadmap highlighted how transparency is central to ensuring accountability and confidence in public institutions.

“There is a pressing need to improve access to timely, robust and relevant information concerning health products. Unbiased information that is free of any conflict of interest is vital for the sound selection, incorporation, prescription and use of health products. **Transparency of this information is central to accountability, strengthens confidence in public institutions and improves the efficiency of the system. Activities in the road map address the transparency of clinical trials enabling support for clinical trial registries and address price transparency** through the Market Information for Access to Vaccines (MI4A platform), for example.”

In relation to coordinated actions on health research and development, the WHO Secretariat clearly marked the transparency of R&D costs as a deliverable.

Promotion of transparency in research and development costs; development of incentive mechanisms that separate/delink the cost of investment in research and development from the price and volume of sales; and establishment of additional incentives for research and development of new products where there are market failures.

In relation to actions to foster innovation and access to health products by appropriate intellectual property rules and management, the WHO secretariat identified the transparency of patent landscapes as deliverable.

Promotion of public health-oriented licensing agreements and transparency regarding the patent status of existing and new health technologies.

In relation to actions to encourage more transparent and better policies and actions to ensure fairer pricing and reduction of out-of-pocket payments, the WHO secretariat identified global and regional collaboration as an action to increase price transparency.

Global and regional collaboration to increase price transparency, support decision-making on pricing and reimbursement, facilitate dialogue between public payers, government decision-makers and industry, and improve capacity for price negotiation.

## **2018. December 18. WHO Report: Pricing of cancer medicines and its impacts.**

WHO published its [Technical report on pricing of cancer medicines and its impacts](#) and many of its findings revolved around transparency. See this KEI blog for context and to highlight some of the [Key findings](#). The WHO Cancer Report called for international action to improve transparency in pricing, as well as in reporting the costs of R&D and production, including public sources of funding.

The following are passages from the WHO Cancer medicines report on price transparency:

### **4.5.1 Rebates and discounts have impaired price transparency**

As discussed in Section 0, over the past decade, many payers globally have entered into MEAs with pharmaceutical companies to enable patient access to medicines under certain conditions, of which, discounts and rebates are the most common provisions in these agreements (Fig. 3.10, p.42). Newer cancer medicines are most commonly subject to these agreements because of their high prices and uncertain clinical benefits (192,193). In other jurisdictions (e.g. the USA), rebates or discounts may be offered directly to consumers through coupons and vouchers, or to intermediaries such as wholesalers, pharmacy benefit managers and clinical service institutions (48,353).

The use of discounts and rebates may signal competition in the market and is often considered a legitimate competitive practice if applied within the boundaries of laws. However, the terms and conditions of these agreements are often confidential. The confidential terms include non-disclosure of the discounts and rebates, rendering the net transaction prices of medicines between the sellers (e.g. manufacturers, service providers) and the payers (governments, consumers) opaque. This lack of price transparency and its possible impacts on access to affordable medicines has been a recurrent point of discussion in the debate on medicine prices, discussed below.

...

### **4.5.4 Possible impacts of lacking price transparency**

At a conceptual level, a lack of price transparency is not consistent with the notion of good governance and contravenes the principles of economic theory in enhancing market efficiency.

The principles of good governance demand that the process leading to change and the outcomes derived therefrom should be accountable, transparent, abide the rule of

law, responsive to the needs of the community in a timely and appropriate manner, fair and inclusive, effective and efficient, as well as participatory and consensus-oriented (358). By not disclosing the terms and conditions of MEAs, tax-payers, or at least well informed stakeholders, would not be in a position to participate in decision-making and judge if the responsible authorities have acted in the best interest of tax-payers or not. This could potentially compromise clear lines of accountability – a commonly espoused objective of national medicines policies (Section 3.1, p.16). A lack of price and process transparency may even lead to corruption, especially in health care systems with weak overall governance (359).

...

From the perspective of conventional economic theory, confidential pricing arrangements mask market pricing structures and create informational asymmetry – a known condition for causing market failure. Economic theory suggests that one of the conditions to achieve an efficient market is to ensure that both parties of a transaction have all relevant information to make the best decision from their respective positions. If all other conditions for a competitive market were to be met and all other things equal, pricing transparency would enhance efficiency by promoting price competition. However, in the medicine markets, the imbalance of power in transactions is common, where multinational pharmaceutical companies have more information on prices, and even information on the benefits and harms of medicines during price negotiation, than the party negotiating on behalf of national, regional, or individual health care authorities. In wanting to achieve access to new medicines for their patients and in the absence of full information, purchasing parties reportedly felt “pressurised” into accepting the offers and conditions proposed by pharmaceutical companies, despite having insufficient information to be confident if a favourable deal or offer had been achieved or not (360). This suggests that confidential agreements might result in inefficient outcomes from an economic perspective.

...

#### KEY POINTS

- **Increased use of confidential rebates and discounts have impaired price transparency:** The use of discounts and rebates may signal competition in the market and is often considered a legitimate competitive practice if applied within the boundaries of laws. However, the proliferation of confidential agreements on rebates and discounts to facilitate faster access to high-cost medicines, including cancer medicines with uncertain clinical benefits, have masked market transparency, including the level of price competition.
- **Growing differences in list price and net transaction price may invite distrust and may impair the effectiveness of external reference pricing:** The industry may be perceived as pushing medicine prices higher by factoring in a higher level of

discounts, with a view of masking the true increases in medicine price, particularly at the level of individual medicines. Pharmaceutical companies may also be motivated to keep list prices high to impair the effectiveness of external reference pricing.

▪ **A lack of price transparency is not consistent with the notion of good governance:** Confidential agreements may compromise clear lines of accountability – a commonly espoused objective of national medicines policies. A lack of price and process transparency may even lead to corruption, especially in health care systems with weak overall governance.

▪ **Theoretical arguments regarding the effect of price transparency are equivocal:** Conventional economic theory indicates that price transparency would enhance efficiency. In contrast, it has been argued that increasing price transparency might cause price convergence towards the mean, potentially making lower-income countries worse off. However, both arguments are based on debatable assumptions, given the complexity of the health care market.

▪ **By default, there is a dearth of evidence on the effectiveness of these confidential agreements:** While perceived as beneficial by most authorities from public or social health insurance systems, it is unknown if these agreements have in fact lowered the prices of medicines and improved patient access to medicines than would be otherwise achieved in the absence of confidential provisions.

▪ **On the other hand, there is limited context-specific empirical evidence to indicate that improving price transparency leads to better price and expenditure outcomes:** Further research is needed to monitor the impact of improving price transparency.

The following are recommendations from the WHO Cancer medicines report on R&D transparency:

### **5.3.3 Reporting the costs of research, development and production, including any public sources of funding**

**Rationale:** The costs of R&D have been used to justify the prices of cancer medicines: return on investment needs to be sufficient to cover the costs of past R&D and to incentivize the discovery of future medicines. However, there is considerable paucity of data on the costs of R&D and production because of the proprietary nature of the information (Section 3.2). Furthermore, the public sector has provided significant contributions towards drug discovery through direct funding or R&D incentives (Section 4.4.2). In any case, the costs of R&D and production may bear little or no relationship to how pharmaceutical companies set prices of cancer medicines (Section 3.2.1.5). Reporting the costs of R&D and production, including any public sources of funding, would inform the debate on medicine pricing as well as

how to manage the relationship between the government, industry and university when pursuing joint research ventures.

**Considerations:** Any policy to mandate reporting should consider the global nature of R&D and production. Attribution of public funding for basic science research and research not specific to an anatomical site would be challenging and would require careful planning.

## 2019

**2019. February 1. Italy submits transparency resolution to the World Health Organization.**

**2019. February 5. United States, State of the Union Address, by President Trump.**

The next major priority for me, and for all of us, should be to lower the cost of healthcare and prescription drugs -- and to protect patients with pre-existing conditions. Already, as a result of my Administration's efforts, in 2018 drug prices experienced their single largest decline in 46 years. But we must do more. It is unacceptable that Americans pay vastly more than people in other countries for the exact same drugs, often made in the exact same place. This is wrong, unfair, and together we can stop it.

I am asking the Congress to pass legislation that finally takes on the problem of global freeloading and delivers fairness and **price transparency** for American patients. We should also require drug companies, insurance companies, and hospitals **to disclose real prices** to foster competition and bring costs down.

**2019. February 6. U.S. Department of Health and Human Services (HHS) proposed rule to make pharmaceutical benefit manager rebates transparent.**

Document Citation: [84 FR 2340](#). Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.

From the notice:

### **3. THE REBATE SYSTEM IS NOT TRANSPARENT**

In some or many instances, plan sponsors under Medicare Part D and Medicaid MCOs have limited information about the percentage of rebates passed on to them

and the percentage retained by their PBMs. The terms of rebate agreements manufacturers negotiate with PBMs may be treated as highly proprietary and, in many instances, may be unavailable to the plans. For example, in a 2011 evaluation, OIG learned that some Part D plan sponsors had limited information about rebate contracts and rebated amounts negotiated by their PBMs.[35] To the extent still true, this lack of transparency could potentially impede the ability of parties to disclose, report, and otherwise account accurately for rebates where required by program rules (and potentially, under the discount safe harbor). This, in turn, creates a potential program integrity vulnerability because compliance with program rules may be more difficult to verify. We are interested in stakeholder feedback on the issue of transparency and compliance with program rules, particularly as it relates to bundled rebates, price protection or rebate guarantees, and other information not readily apparent when rebates are reported.

...

## **II. Summary of the Major Provisions**

This proposed rule would amend the discount safe harbor at 42 CFR 1001.952(h) by adding an explicit exception to the definition of “discount” such that certain price reductions on prescription pharmaceutical products from manufacturers to plan sponsors under Medicare Part D, and Medicaid MCOs would not be protected under the safe harbor. In addition, the proposed rule would add one new safe harbor to protect discounts between those same entities if such discounts are given at the point of sale and meet certain other criteria. Finally, this proposed rule would add a second new safe harbor specifically designed to protect certain fees pharmaceutical manufacturers pay to PBMs for services rendered to the manufacturers that relate to PBMs' arrangements to provide pharmacy benefit management services to health plans.

The proposed rule would not alter obligations under the statutory provisions for Medicaid prescription drug rebates under Section 1927 of the Social Security Act, including without limitation the provisions related to best price, the additional rebate amounts for certain drugs if the rate of increase in AMP and the increase in the consumer price index for all urban consumers (CPI-U), or provisions regarding supplemental rebates negotiated between states and manufacturers. Nor would this proposed rule alter the regulations and guidance to implement Section 1927 provisions, although the Department may issue separate guidance if this proposal is finalized to clarify the treatment of pharmacy chargebacks in calculation of AMP and Best Price. This proposed rule recognizes that rebates paid by manufacturers to Medicaid MCOs should be treated differently than supplemental rebates paid by manufacturers to states because of the differing risk posed under the Federal anti-kickback statute.

## ANNEX 1. Selected United States, state level legislative proposals relating to transparency of R&D

| U.S. State    | Bill                      | Year | Title   |
|---------------|---------------------------|------|---|
| Massachusetts | <a href="#">MA S 652</a>  | 2017 | Pharmaceutical Price Gouging Prevention                 |
| Nevada        | <a href="#">NV A 215</a>  | 2017 | Reporting of Information Relating to Prescription Drugs |
| New York      | <a href="#">NY A 2939</a> | 2017 | Prescription Drug Cost Transparency                     |
| Washington    | <a href="#">WA S 5586</a> | 2017 | Prescription Drug Cost Transparency                     |
| Massachusetts | <a href="#">MA S 627</a>  | 2018 | Prescription Drug Price Transparency                    |
| Massachusetts | <a href="#">MA S 652</a>  | 2018 | Pharmaceutical Price Gouging Prevention                 |
| New York      | <a href="#">NY A 2939</a> | 2018 | Prescription Drug Cost Transparency                     |
| Virginia      | <a href="#">VA H 1436</a> | 2018 | Prescription Drug Price Transparency                    |
| Washington    | <a href="#">WA S 5586</a> | 2018 | Prescription Drug Cost Transparency                     |
| Washington    | <a href="#">WA S 5401</a> | 2018 | Prescription Drug Cost Transparency                     |

## ANNEX 2. Recent U.S. Congress bills on transparency

### Bills that include R&D transparency provisions

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| <a href="#">H.R.1776</a> , 115th Congress<br><br>Introduced in House<br>(03/29/2017) | Improving Access To Affordable Prescription Drugs Act | Rep. Schakowsky, Janice D. [D-IL-9] + 23 cosponsors | Require annual reporting requirements to applicable manufacturers of an approved drug. The information would be submitted to the HHS Secretary and to Congress and would include, with respect to each drug: “(A) the total expenditures of the manufacturer on— (i) domestic and foreign drug research and development, including an itemized description of— (I) basic and preclinical research; (II) clinical research, broken out by clinical trial phase; (III) |
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|  |  |   | development of alternative dosage forms and strengths for the drug molecule or combinations, including the molecule; (IV) other drug development activities, such as nonclinical laboratory studies and record and report maintenance; (V) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act; (VI) carrying out postmarket requirements related to such drug, including under section 505(o)(3) of such Act; (VII) carrying out risk evaluation and mitigation strategies in accordance with section 505–1 of such Act; and (VIII) marketing research;”   |
| <a href="#">H.R.2439</a> , 115th Congress<br><br>Introduced in House<br>(05/16/2017) | Fair Accountability and Innovative Research Drug Pricing Act of 2017 | Rep. Schakowsky, Janice D. [D-IL-9] + 24 cosponsors | Require manufacturers of certain drugs and biological products with a wholesale cost of \$100 or more per month to report to the HHS price increases that result in a 10% or more increase in the cost of a drug over a 12-month period or a 25% or more increase over a 36-month period. The report would include "(E) the current list price of the drug" and "(G) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds; "(H) the total expenditures of the manufacturer on research and development for such drug that is used for— (i) basic and preclinical research; (ii) clinical research; (iii) new drug development; (iv) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act; and (v) carrying out postmarket requirements related to such drug, |

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|  |   |   | including those under section 505(o)(3) of such Act;”  |
| <a href="#">H.R.4116</a> , 115th Congress<br><br>Introduced in House<br>(10/25/2017) | Transparent Drug Pricing Act of 2017                  | Rep. Doggett, Lloyd [D-TX-35]<br>+<br>33 cosponsors | Require annual reporting requirements to manufacturers of an approved drug. The information would be submitted to the HHS Secretary and to Congress and would include: “(1) the total expenditures of the manufacturer on— (A) domestic and foreign drug research and development, including an itemized description of— (i) basic and preclinical research; (ii) clinical research, reported separately for each clinical trial; (iii) development of alternative dosage forms and strengths for the drug molecule or combinations, including the molecule; (iv) other drug development activities, such as nonclinical laboratory studies and record and report maintenance; (v) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act; (vi) carrying out postmarket requirements related to such drug, including under section 505(o)(3) of such Act; (vii) carrying out risk evaluation and mitigation strategies in accordance with section 505–1 of such Act; and (viii) marketing research;” |
| <a href="#">S.771</a> , 115th Congress<br><br>Introduced in Senate<br>(03/29/2017)   | Improving Access To Affordable Prescription Drugs Act | Sen. Franken, Al [D-MN]<br>+<br>15 cosponsors       | Require annual reporting requirements to applicable manufacturers of an approved drug. The information would be submitted to the HHS Secretary and to Congress and would include, with respect to each drug: “(A) the total expenditures of the manufacturer on— (I) basic and preclinical research; (II)  |

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|  |   |   | <p>clinical research, broken out by clinical trial phase; (III) development of alternative dosage forms and strengths for the drug molecule or combinations, including the molecule; (IV) other drug development activities, such as nonclinical laboratory studies and record and report maintenance; (V) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act; (VI) carrying out postmarket requirements related to such drug, including under section 505(o)(3) of such Act; (VII) carrying out risk evaluation and mitigation strategies in accordance with section 505–1 of such Act; and (VIII) marketing research;”</p>   |
| <p><a href="#">S.1131</a>, 115th Congress</p> <p>Introduced in Senate (05/16/2017)</p> | <p>Fair Accountability and Innovative Research Drug Pricing Act of 2017</p> | <p>Sen. Baldwin, Tammy [D-WI] + 1 cosponsor</p> | <p>Require manufacturers of certain drugs and biological products with a wholesale cost of \$100 or more per month to report to the HHS price increases that result in a 10% or more increase in the cost of a drug over a 12-month period or a 25% or more increase over a 36-month period. The report would include "(E) the current list price of the drug" and "(G) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds; "(H) the total expenditures of the manufacturer on research and development for such drug that is used for— (i) basic and preclinical research; (ii) clinical research; (iii) new drug development; (iv) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act; and (v)</p> |

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|  |   |   | carrying out postmarket requirements related to such drug, including those under section 505(o)(3) of such Act;"   |
| <a href="#">S.1348</a> , 115th Congress<br><br>Introduced in Senate (06/13/2017) | Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2017 | Sen. Wyden, Ron [D-OR]<br>+<br>9 cosponsors   | Require manufacturers of drugs with specified percentage increases in their wholesale costs to submit to the CMS written justification for certain increases in drug prices. The report would include "(4) The percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds. (5) The total expenditures of the manufacturer on research and development for such drug."  |
| <a href="#">S.3411</a> , 115th Congress<br><br>Introduced in Senate (09/05/2018) | Affordable Medications Act  | Sen. Smith, Tina [D-MN]<br>+<br>14 cosponsors | Require annual reporting requirements to applicable manufacturers of an approved drug. The information would be submitted to the HHS Secretary and to Congress and would include, with respect to each drug: "(A) the total expenditures of the manufacturer on— (i) domestic and foreign drug research and development, including an itemized description of— (I) basic and preclinical research; (II) clinical research, broken out by clinical trial phase; (III) development of alternative dosage forms and strengths for the drug molecule or combinations, including the molecule; (IV) other drug development activities, such as nonclinical laboratory studies and record and report maintenance; (V) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act; (VI) carrying out postmarket requirements related to such drug, including under section 505(o)(3) of such Act; (VII) |

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|  |  |  | carrying out risk evaluation and mitigation strategies in accordance with section 505–1 of such Act; and (VIII) marketing research;” |
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**Bills that only relate to price (not R&D) transparency provisions**

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| <a href="#">H.R.1316</a> , 115th Congress<br><br>Introduced in House<br>(03/02/2017) | Prescription Drug Price Transparency Act                            | Rep. Collins, Doug [R-GA-9]<br>+<br>56 cosponsors   | Adds certain transparency requirements for pharmacy benefits managers under Medicare, Medicare Advantage, TRICARE, and the Federal Employees Health Benefits Program.  |
| <a href="#">H.R.5739</a> , 115th Congress<br><br>Introduced in House<br>(05/09/2018) | Prescription Drug and Medical Device Price Review Board Act of 2018 | Rep. DeLauro, Rosa L. [D-CT-3]<br>+<br>2 cosponsors | Establish a Prescription Drug and Medical Device Price Review Board. The Board would require each manufacturer of drug or medical device sold in the U.S. periodic reports related to the price charged by the manufacturer or the affiliates for that drugs or medical devices, and the costs of the manufacturer and the affiliate to produce and market the drugs or medical devices. |
| <a href="#">H.R.6144</a> , 115th Congress<br><br>Introduced in House<br>(06/19/2018) | Know the Lowest Price Act of 2018                                   | Rep. Doggett, Lloyd [D-TX-35]<br>+<br>31 cosponsors | Prohibits a health-benefits plan or pharmacy-benefits manager under Medicare or Medicare Advantage from restricting a pharmacy from informing an enrollee of any difference between the price of a drug under the plan and the price of the drug without health-insurance coverage.  |
| <a href="#">H.R.6576</a> , 115th Congress<br><br>Introduced in House<br>(07/26/2018) | Drug-Price Transparency in Communications Act                       | Rep. Schakowsky, Janice D. [D-IL-9]                 | Impose a penalty to drug companies to do not include the wholesale acquisition cost for a 30-day supply of the drug in direct-to-consumer advertising. Also require drug companies to disclose wholesale acquisition cost to practitioners.  |

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| <p><a href="#">S.637</a>, 115th Congress</p> <p>Introduced in Senate (03/15/2017)</p>  | <p>Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017</p> | <p>Sen. Wyden, Ron [D-OR]</p> <p>+ 4 cosponsors</p>         | <p>Require HHS to publish on its website, with respect to each PBM, information regarding: (1) the amount and type of rebates and discounts negotiated by the PBM and the extent to which these rebates and discounts are passed on to the plan sponsor, and (2) the difference between the amount paid by the plan sponsor to the PBM and the amount paid by the PBM to pharmacies.</p>    |
| <p><a href="#">S.2157</a>, 115th Congress</p> <p>Introduced in Senate (11/16/2017)</p> | <p>Drug-Price Transparency in Communications Act</p>                            | <p>Sen. Durbin, Richard J. [D-IL]</p> <p>+ 7 cosponsors</p> | <p>Impose a penalty to drug companies to do not include the wholesale acquisition cost for a 30-day supply of the drug in direct-to-consumer advertising. Also require drug companies to disclose wholesale acquisition cost to practitioners.</p>  |
| <p><a href="#">S.2553</a>, 115th Congress</p> <p>Introduced in Senate (03/14/2018)</p> | <p>Know the Lowest Price Act of 2018</p>  | <p>Sen. Stabenow, Debbie [D-MI]</p> <p>+ 15 cosponsors</p>  | <p>Prohibits a prescription drug plan under Medicare or Medicare Advantage from restricting a pharmacy from informing an enrollee of any difference between the price, copayment, or coinsurance of a drug under the plan and a lower price of the drug without health-insurance coverage. This bill became law.</p>  |
| <p><a href="#">S.2554</a>, 115th Congress</p> <p>Introduced in Senate (03/14/2018)</p> | <p>Patient Right to Know Drug Prices Act</p>                                    | <p>Sen. Collins, Susan M. [R-ME]</p> <p>+ 15 cosponsors</p> | <p>Group health plans or health insurers shall not restrict pharmacies from informing an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage. This bill became law.</p> |

## **Text From Selected Proposals in US Congress that Address Transparency**

This is a separate document, [here](#).