European governments should align medicines pricing practices with global transparency norms and legal principles

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European governments should align medicines pricing practices with global transparency norms and legal principles

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Secret medicines prices are hotly debated as European health systems struggle to finance medicines for patients. Proponents of secrecy generally argue that confidential purchase prices allow suppliers (usually pharmaceutical companies) to grant discounts and rebates that benefit buyers (i.e. governments or publicly-funded bodies) and ultimately, patients. When there are one or few suppliers, or there is a supply shortage, this model relies on governments' willingness to pay and allows companies to determine appropriate discounts and rebates. This model can result in inequitable price setting and the risk of higher medicines prices.[1,2] For example, the leaked purchase prices of the Oxford-AstraZeneca Covid-19 vaccine revealed that South Africa paid more than double than the European Union (EU) for the same product.[3]

Advocates of transparency argue that openness about a medicine's price components (ex. research and development (R&D) costs, production costs, discounts and rebates etc.) is essential to know whether the price is 'fair' to the seller *and* the buyer.[4] This Comment highlights the normative basis for transparency, and recent initiatives in Europe supporting increased transparency of medicines and medical product price components. Aligning governments' transparency practices with their commitments and legal principles is urgent as cross-country collaborations (for medicines information sharing, and joint assessment and price negotiation) take shape in Europe, and as the European Commission expands its role in centralized medicines procurement.[5]

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Transparency of medicines prices is an emerging global norm and related to human rights

Greater transparency of pharmaceutical markets is an emerging global norm. In 2019, 194 Member States of the WHO adopted the 'Transparency Resolution' (WHA resolution 72.8) that urges Member States to take steps to publicly share information on the net prices of health products (official/list prices less rebates and discounts), and calls on Member States to work collaboratively to improve the reporting by suppliers of sales revenue, prices, units sold, marketing costs, investments and subsidies.[6] Although not legally binding, this Resolution illustrates a high level of commitment and support from all Member States to achieve the objectives it sets.

Transparency of medicines prices is also related to the human right to access public documents, enshrined in international law (ex. International Covenant on Civil and Political Rights, among others) that is binding on 173 states, and in national law. Recent cases in Spain (Kymriah) and Colombia (Covid-19 vaccines) illustrate how the right to access public documents has been applied to medicines purchase prices, criteria, and procurement contracts.[7] A decision by the Spanish Council of Transparency and Good Governance (Resolution 079/2019) highlighted the societal and legal importance of knowing how public powers make decisions that affect public health and its financing. The Council underscored that the right to access to public information has 'intrinsic value to the concept of democracy'.

Room for more European governments to implement transparency commitments

A recent WHO report shows that there is still scope for other European governments to undertake legal and policy measures to create a supportive environment for price and cost disclosure.[8] Two European governments (France, Italy) have adopted laws requiring

pharmaceutical manufacturers to disclose the public R&D investments in new medicines seeking reimbursement.[8] Fifteen national governments in the WHO European Region publish the various types of medicines prices in publicly accessible online registries; these prices usually do not reveal the net price, except in Switzerland.[8] Switzerland is one of the last high-income countries to publish the rebates it negotiates on selected medicines, offering an under-explored 'laboratory' to study the dynamics of discounting and disclosure on the pharmaceutical market.[9] This laboratory is threatened by proposed legal reforms that would legitimize confidential rebates as part of federal health insurance.[9]

Trust is critical for price sharing initiatives involving multiple partners

As government action on price transparency remains wanting, some buyers have taken matters into their own hands. The Dutch Hospital Benchmark Initiative is a demand-side clearing house of net purchase prices of medical products created by hospitals, for hospitals.[10] Most of the price information provided to the clearing house is reasonably thought to be protected by confidentiality clauses that prevent buyers from sharing information. Nevertheless, 50% of Dutch hospitals voluntarily shared this price information with the clearing house. Why? One, the perceived power imbalance between 'small' hospital purchasers and large suppliers, and a lack of comparative information available to the former, motivated buyers. Two, the assurance that the buyers providing information would be anonymized, and that access would be restricted to other buyers on a reciprocal basis, was critical for buyers' trust. In some cases, non-disclosure agreements were signed with a few participating hospitals. Overall, the Dutch Hospital Benchmark Initiative illustrates that buyers' motivation and trust in the clearinghouse curators appears to be critical for information sharing. Despite what is commonly thought, confidentiality clauses in purchase contracts may not be a definitive factor for sharing net product prices. It would be in the spirit of the WHA Transparency Resolution for public purchasers not to agree to confidentiality clauses in these procurement contracts.

Declaration of interests

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References

1 Gamba S, Pertile P, Vogler S. The impact of managed entry agreements on pharmaceutical prices. *Health Econ*. 2020;29:47–62.
2 Bonetti A, Giuliani J. Implications of drugs with rebate in Europe. *Lancet Reg Health Eur*. 2021;3:1–2.
3 Sullivan H. South Africa paying more than double EU price for Oxford vaccine. *Guard*. 2021. https://www.theguardian.com/world/2021/jan/22/south-africa-paying-more-than-double-eu-price-for-oxford-astrazeneca-vaccine.
4 Moon S, Mariat S, Kamae I, Pedersen HB. Defining the concept of fair pricing for medicines. *BMJ*. 2020;368:l4726. https://doi.org/10.1136/bmj.l4726.
5 Boulet P, 't Hoen E, Perehudoff K, Mara K, Tan E. *Advanced Purchase Agreements for Covid-19 Vaccines: Analysis and Comments*. Brussels: The Left in the European Parliament; 2021 https://left.eu/content/uploads/2021/07/Advanced-purchase-agreements-1.pdf.
6 World Health Assembly. *Improving the Transparency of Markets for Medicines, Vaccines, and Other Health Products*. Geneva: World Health Assembly; 2019. https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf.
7 Fish Hodgson T, Quintero MR, Quijano-Evans A. *Maximum Disclosure: Secrecy in COVID-19 Vaccine Contracts and Other Shortcomings of Colombia's Vaccine Rollout*. Geneva: International Commission of Jurists; 2021. https://www.icj.org/wp-content/uploads/2021/08/Columbia-Vaccine-Briefing-Paper-ENG-2021.pdf.
8 Perehudoff K, Mara K, 't Hoen E. *What is the Evidence on Legal Measures to Improve the Transparency of Markets for Medicines, Vaccines and Other Health Products (World Health Assembly resolution WHA72.8)?* Copenhagen: WHO Regional Office for Europe; 2021. August (Health Evidence Network (HEN) synthesis report 73), https://apps.who.int/iris/bitstream/handle/10665/342474/9789289055789-eng.pdf.
9 Carl DL, Vokinger KN. Patients' access to drugs with rebates in Switzerland—Empirical analysis and policy implications for drug pricing in Europe. *Lancet Reg Health Eur*. 2021;3:100050.
10 Den Ambtman A, Knoben J, van den Hurk D, Van Houdenhoven M. Analysing actual prices of medical products: a cross-sectional survey of Dutch hospitals. *BMJ Open*. 2020;10(2):e035174. https://doi.org/10.1136/bmjopen-2019-035174.