

5. Promoting price transparency

Questions		1. What is the effect of promoting price transparency on the price, volume, availability and affordability of pharmaceutical products? 2. What contextual factors and implementation strategies may influence the effects of promoting price transparency ?		
Population	Medicines and vaccines for human use	Definition: Price transparency refers to the sharing, disclosure and dissemination of information related to prices of pharmaceutical products to relevant parties and the general public to ensure accountability. Full price transparency includes the publication of prices at all price types (e.g. ex-factory prices, pharmacy retail prices), the disclosure of the net transaction prices between the suppliers (e.g. manufacturers, service providers) and the payers/purchasers (governments, consumers). Transparency of pricing policies involves sharing and publication of the pricing methodology, including description of rationale and magnitude of reimbursement rates, and price components where relevant (e.g. production costs, R&D costs, added therapeutic value). It also involves sharing and publication of the contents of pricing arrangements such as risk-sharing schemes, managed-entry agreements, patent status and licensing arrangements.		
Intervention	Promoting price transparency			
Comparison	Other pricing policies or absence of a pricing policy			
Main outcomes	Price, volume, availability, affordability			
Settings	Country jurisdictions; Public, private and mixed public-private	GDG member(s) with conflicts of interest that led to recusal from the formulation of this recommendation: None		
Assessment				
	Criteria	Judgement	Summary of evidence or opinion	Considerations
Policy importance	Is the policy a priority?	<input type="checkbox"/> No <input type="checkbox"/> Probably no <input type="checkbox"/> Probably yes <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Varies <input type="checkbox"/> Don't know	<p>In 2019, the Seventy-Second World Health Assembly adopted resolution WHA72.08 on <i>Improving the transparency of markets for medicines, vaccines, and other health products</i> (71). This resolution urges Member States, inter alia, to take appropriate measures to publicly share information on the net prices of health products. Some countries have already implemented voluntary or mandatory reporting of prices to improve price transparency, while others have initiated new policies. For example, lawmakers in France have recently proposed the disclosure of the amount of public research and development investment from which private pharmaceutical companies have received for the development of the drugs. It was proposed that this amount could be accounted for by the pricing committee when setting the sale price of the medicines (72). The EU Transparency directive is another transparent pricing policy which requires the publication of the list prices of all reimbursable medicines in Europe (73).</p> <p>It is well recognised that price and pricing transparency are essential for the design and implementation of pricing policies.</p>	There is a proliferation of confidential agreements on rebates and discounts to facilitate faster access to high-cost medicines with uncertain clinical benefits (74). These agreements have masked market transparency, including the level of price competition (2).
	Desirable effects	How substantial are the desirable anticipated effects?	<input type="checkbox"/> Trivial <input type="checkbox"/> Small <input type="checkbox"/> Moderate <input type="checkbox"/> Large <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Don't know	<p>Number of studies included in the systematic review: Two studies from three publications were included. Two publications from South Africa (75,76), which examined a transparency measure for the private sector known as <i>Single Exit Price (SEP)</i> - mandatory disclosure for each medicine of the weighted average of all sales prices after taking into account all discounts and off-invoice rebates. The disclosed prices are subsequently made available on the South African Medicine Price Registry website. The SEP clarifies to logistics service providers or medicine dispensers at which price a manufacturer may sell a pharmaceutical product (75,76). The third study was from the UK (77) which examined a 'cost-feedback' policy aiming to inform the prescribing clinicians about the price of drugs through on-screen display of price (or 'cost') in prescribing software upon selection of a drug.</p> <p>Price: The studies on the impact of SEP in South Africa observed statistically significant reductions in price (1999-2014) for 66 of 73 generic medicines (75) and 35 out of 50 originator medicines (76) examined. The observed price reductions were highly variable, ranging between 1.77% to 55.86% for originator medicines, and -0.70% to 91.5% for generic medicines.</p> <p>Expenditure: The UK study on displaying price in prescribing software demonstrated that a 14% reduction in weekly expenditure on antibiotics observed immediately after the intervention was not sustained as there was a gradual increase in expenditure over the following 12 months. No statistically significant difference was observed for inhaled corticosteroids after the 'cost-feedback' intervention, except when implementing a change local prescribing policy (i.e. prescribing policy was more influential than displaying price) (77).</p> <p>Volume, Availability, Affordability: No information</p>
Undesirable effects	How substantial are the undesirable anticipated effects?	<input type="checkbox"/> Trivial <input type="checkbox"/> Small <input type="checkbox"/> Moderate <input type="checkbox"/> Large <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Don't know	<p>Shortages: Some commentators have presented <u>theoretical</u> arguments noting that price transparency might "increase prices paid by the poor, deter business entry in poor markets, reduce competition, lower investment, and mislead if inaccurately measured by a third party" (79).. For similar reasons, other commentators have expressed opposition to price transparency for on-patent medicines, arguing that "the effect will be to slow the diffusion of innovative products to low-income countries" because "differential pricing is important and can best be achieved in the current environment via confidential discounts" (78) The counterarguments asserted that such theoretical assertions were based contestable assumptions, such as that profit-maximizing firms are likely to set lower prices in lower-income countries, and that firms would be more willing to launch products in countries with lower capacity to pay if prices were not disclosure (2)</p> <p>Quality issues: No information</p> <p>Safety issues: No information</p> <p>Anticompetitive, unethical or illegal conduct: Some commentators noted theoretically that price transparency might "facilitate collusion among sellers" and make "cartels easier to enforce" (79). In contrast, others have noted that price transparency could "help curb price gouging, price manipulation, and overpayments. Importantly, data can illuminate patterns and any outliers, which may suggest that there are over-payments, collusion, or kickbacks happening in the procurement process." (80)</p>	<p><u>Undesirable effects of NOT achieving price transparency</u></p> <ul style="list-style-type: none"> • Conflict with the principles 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 (2) . • Impair public confidence; Growing differences in list price and net transaction price may invite distrust (2). • Impair the effectiveness of existing pricing approaches, such as external reference pricing (2).

Evidence certainty	What is the overall certainty of the evidence of effects?	<input type="checkbox"/> Very low <input type="checkbox"/> Low <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> High <input type="checkbox"/> Very high <input type="checkbox"/> Don't know	The certainty of the evidence presented in the studies was rated as "moderate". There are gaps in the evidence on other primary and secondary outcomes of the systematic review.	
Balance of effect	Does the balance between desirable and undesirable effects favour the policy or the comparison?	<input type="checkbox"/> Favour comparator <input type="checkbox"/> Probably favours comparator <input checked="" type="checkbox"/> Probably favours the policy <input type="checkbox"/> Favour the policy <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Don't know	The evidence presented in the systematic review suggests that mandatory disclosure of the weighted average of all sales prices after taking into account all discounts and off-invoice rebates, as per the SEP program in South Africa, might deliver lower prices for the health care system. Disclosure of price information to prescribers, as per the UK study, is not likely to produce sustained effects.	WHO Secretariat report on <i>Pricing of cancer medicines and its impacts</i> concludes that "Theoretical arguments on whether greater price transparency would lead to higher or lower medicine prices are inconclusive. There is a lack of evidence of the effectiveness of confidential agreements in lowering prices and improving access. On the other hand, there is limited context-specific evidence that improving price transparency has led to better price and expenditure outcomes. Nonetheless, improving price transparency should be encouraged on the grounds of good governance" (2).
Generalizability	Has this policy been tested or found to be effective only in specific contexts?	<input type="checkbox"/> No <input type="checkbox"/> Probably no <input type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Don't know	The generalizability of the findings is unclear. The SEP program might be generalizable in other lower income countries, provided the program suitability for the national legal requirements and contexts.	
Equity	What would be the impact on health equity?	<input type="checkbox"/> Large positive <input type="checkbox"/> Moderate positive <input type="checkbox"/> Neutral <input type="checkbox"/> Moderate negative <input type="checkbox"/> Large negative <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Don't know	As noted under "Undesirable effects", some commentators have expressed opposition to price transparency for <u>on-patent medicines</u> , arguing that "the effect will be to slow the diffusion of innovative products to low-income countries" because "differential pricing is important and can best be achieved in the current environment via confidential discounts" (78) If proven to be true, this would have negative equity impacts on patient access to innovative medicines in lower income countries. However, such risk remains theoretical and seems comparatively minimal considering the significant disparity of access to on-patent medicines even in the presence of non-transparent prices. Indeed, other commentator has argued that increased transparency would enable more evidence based policy making, therefore could be equity enhancing by improving access (76).	
Acceptability	Is the policy acceptable to government authorities, patients and community?	<input type="checkbox"/> No <input type="checkbox"/> Probably no <input checked="" type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Don't know	Government authorities: Acceptable to most countries considering the adoption of WHA resolution 72.08 on <i>Improving the transparency of markets for medicines, vaccines, and other health products</i> (71). Patients and community: Likely to be acceptable as indicated by wide patient and community supports expressed by patient or non-profitable organizations.	<u>Other stakeholders</u> Insurers: Varies Manufacturers or suppliers: Not acceptable (81) Service providers: Varies (e.g. (82))
Resources required	How large are the resource requirements for implementing the policy?	<input type="checkbox"/> Large <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Neutral <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Don't know	Human resource: Depending on the level of transparency and scope of data Financial resource requirement: Depending on the level of transparency and scope of data Governance requirements: Depending on the level of transparency and scope of data IT infrastructure: Database management with data standards as a prerequisite	
Feasibility	How feasible is the policy to implement in low- and middle-income countries?	<input type="checkbox"/> No <input type="checkbox"/> Probably no <input checked="" type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Varies <input type="checkbox"/> Don't know	The feasibility of implementation in low- and middle-income countries would be dependent on the level and design of transparent reporting. These include: <ul style="list-style-type: none"> • Voluntary or mandatory • Number of points along the supply and distribution chain for which price data need to be collected or reported • Local, regional, national or international (e.g. WHO PIEMEDS) management of database and analytics The legal systems in many countries (and trade agreements) may not allow price transparency from private entities to be obtained	
Sustainability	How would the policy affect the long-term financial sustainability of healthcare system?	<input type="checkbox"/> Reduce <input type="checkbox"/> Probably reduce <input type="checkbox"/> Likely to be neutral <input type="checkbox"/> Probably increase <input type="checkbox"/> Increase <input type="checkbox"/> Varies <input checked="" type="checkbox"/> Don't know	Sustainability would depend on the design and maturity of data infrastructure over time.	

Conclusion

- Strong recommendation against the policy Conditional recommendation against the policy Conditional recommendation for either the policy or comparison Conditional recommendation for the policy Strong recommendation for the policy

Recommendations

5.A. WHO suggests that countries improve the transparency of pricing and prices through the following mechanisms.

- Share the net transaction prices of pharmaceutical products with relevant stakeholders, within and external to the country.
- Disclose prices along the supply and distribution chain.
- Report publicly the R&D contributions from all sources.
- Communicate pricing and reimbursement decisions to the public.

5.B. WHO suggests that countries improve the transparency of pricing and prices through a clear description of pricing approaches and their technical requirements.

Justifications

- The GDG acknowledged the very limited evidence on promoting the transparency of prices and pricing of pharmaceutical products from comparative studies conducted to the standards of the WHO-commissioned systematic review. The GDG considered the overall balance of effects in favour of the policy because disclosure of price and pricing information is essential for safeguarding accountability, informing the design and implementation of effective pricing regulations (particularly on ex-manufacturer price).
- The GDG recognized that improving transparency may require measures to address non-disclosure requirements stemming from the use of confidentiality agreements, including, where needed, legal or policy or regulatory changes. In line with the World Health Assembly resolution WHA72.8 *Improving the transparency of markets for medicines, vaccines, and other health products*, the GDG urged stakeholders to take the necessary steps towards achieving greater transparency of the factors influencing the supply and demand of pharmaceutical products, particularly on medicine prices.
- The GDG considered disclosed prices and pricing information could serve multiple purposes for improving pricing policies, including citizen engagement, external reference pricing, public sector negotiations, monitoring and evaluation of pricing policies and impacts.

Implementation

- Effective operation of policies to promote transparency of prices and pricing at the national level should consider the following factors:
 - a. Development and implementation of national policies relevant to the transparency of markets for health products, including disclosure of prices along the supply and distribution chain, and reimbursement rates/amounts, where relevant.
 - b. Harmonization of decision-making and communication frameworks across government agencies to facilitate reporting.
 - c. Collaboration to improve the reporting of information by suppliers of registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives.
 - d. Use of financial-based managed-entry agreements (e.g. flat discounts, price-volume agreements, capping) and performance-based managed-entry agreements (e.g. risk-sharing agreement, coverage with evidence development) only if such arrangements:
 - o facilitate early access to new medicines at affordable prices;
 - o address uncertainty about performance of the product (e.g. clinical efficacy and cost-effectiveness), maximize the product use in population most likely to benefit, or placing a limit on budget;
 - o are operationally manageable without having to dedicate a disproportionate amount of resources for complex monitoring and contract management; and
 - o are on non-confidential terms.
 - e. Clarification of the extent of disclosure that is required or permitted according to national legal frameworks, including existing confidentiality agreements.
 - f. Enact legislation, regulations or rules to mandate transparent pricing and reporting of prices, where appropriate.
- Operation of policies to promote transparency of prices and pricing at the international level should consider the following factors:
 - a. Availability of international data platforms (e.g. database) and forums for sharing of information on prices and pricing approaches.
 - b. Development of data standards for pricing information to enhance data interoperability across jurisdictions, with consideration of existing frameworks (e.g. International Commercial Terms (Incoterms) and the data interoperability guide by the United Nations Statistical Commission) as well as potential linkage with data on other related metrics (e.g. Product Quality Review).
 - c. Clarification of the extent of disclosure that is required or permitted according to international legal frameworks, including existing confidentiality agreements.

Considerations towards research needs

- Study the intended and unintended impacts of price transparency on affordability and availability of products.
- Review frameworks and information needed to enable comparisons across jurisdictions.
- Assess the technical and governance components required for achieving transparency of prices and pricing within countries, including the feasibility and benefits of common web-based tools for sharing information.