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# 11

## Exploring possible policy options and lines of action

A number of factors can cause high medicine prices or low availability. This chapter illustrates a menu of possible policy options that may be relevant in different circumstances of high prices or low availability.

A meeting of the advisory committee should be held following the survey to present the survey results, discuss their interpretation and develop policy recommendations. It is crucial to determine the factors that are the principal causes of low availability or high prices and/or of price variations in your setting.

Whenever a new policy is introduced, it is important to monitor the impact of the policy change to detect unintended consequences.

The underlying purpose of the price and availability survey is to bring about changes that will result in lower prices and improved availability to patients and, hence, increased access to needed medication. Chapters 7, 8 and 9 have shown how to generate and present summary results from the survey for each individual medicine and each sector, as well as how to analyse treatment affordability and price components. This chapter shows some of the linkages between the price and availability information you can now present, and a range of possible policy actions that will improve regular access to essential medicines at prices affordable to all.

More detailed guidance on the various policy options to address high medicine prices, low availability and poor affordability is currently being developed. Check the HAI web site<sup>1</sup> or contact HAI<sup>2</sup> or WHO<sup>3</sup> for updates.

The potential for change varies dramatically between countries and can also vary over time. The ability to build a case and a constituency of support on a particular issue also depends very much on local circumstances. In many instances it may be necessary to collect additional information before identifying and promoting a particular change.

Because the local context is of overriding importance in determining the most appropriate lines of action to follow in a price survey, this manual can only give general guidance. The previous chapters give clear directions on how to proceed with the design, execution and analysis of the price survey, but this chapter simply identifies possibilities, leaving it to the survey manager/commissioning organization and the advisory committee to research and judge which, in the context of local institutions and politics, are the most appropriate actions to follow.

<sup>1</sup> <http://www.haiweb.org/medicineprices>

<sup>2</sup> [info@haiweb.org](mailto:info@haiweb.org)

<sup>3</sup> [medicineprices@who.int](mailto:medicineprices@who.int)

**BOX 11.1****Other information sources about the pharmaceutical situation in your country**

There are a number of different sources of information that can be reviewed for information about the pharmaceutical and medicine prices situation in your country. These include:

- *National Health Accounts*.<sup>1</sup> The key indicators available from these are the percentage of GDP spent on health, percentage of Total Health Expenditure (THE) spent on pharmaceuticals and percentage of GDP spent on pharmaceuticals.
- *World Health Survey*.<sup>2</sup> This provides data from an extensive household survey. Table 8.2 of the standard report provides information on household health expenditure, including medicines spending as a percentage of total household health spending by different groups.
- *Commercial Surveys Organizations*. Examples of these are IMS Health and Research International, which undertake pharmaceutical market surveys and may, if approached, make available summary reports or relevant information without charging. Enquiring from private sector colleagues may be worthwhile.

Survey findings, for example, may suggest that the prices of individual medicines are 5, 10 or even 40 times higher than the MSH reference prices. Even with the analysis of price composition, however, it may be unclear how much of this price difference is due to high manufacturers' prices and how much to inefficient procurement practices or other price elements in the national system, such as mark-ups and taxes. Each of these possible causes will need to be addressed by a different line of action and will incur support and opposition from different stakeholder groups. A more systematic examination of the different possible contributory factors will always be necessary to ensure that the principal cause is correctly identified.

In some cases, more in-depth research will be required to identify the determinants of high medicine prices, low availability and poor affordability and/or develop appropriate policy responses. For example, in developing a policy to promote increased use of generic medicines, it may be necessary to conduct qualitative research on attitudes and beliefs surrounding generic medicines to determine whether resistance to their use is caused by perceived poor quality, brand loyalty or other factors. Similarly, a country may want to evaluate the effectiveness of its generic substitution policy by conducting a simulated client or a so-called 'mystery shopper' study (more information on conducting these studies is available on the CD-ROM). Survey findings that include poor availability of a particular medicine of national importance may indicate the need to conduct a medicine prices and availability survey for the therapeutic group (see Chapter 3, page 40) to which this medicine belongs so as to better assess availability.

This chapter should be read in conjunction with Chapter 13, which discusses the process of bringing about policy change.

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## **11.1 DATA FROM THE SURVEY AND ITS INTERPRETATION**

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As described in Chapter 8, your survey results allow four different types of price and availability comparisons.

<sup>1</sup> <http://www.who.int/nha/en/>

<sup>2</sup> <http://www.who.int/healthinfo/survey/en/>

**Type 1: Individual medicine price comparisons**

- For every medicine and in each sector, comparison with international reference price benchmarks and, as they become available, against the relevant prices in other country surveys and regional synthesis reports
- For any originator brand medicine, comparison with the lowest-priced generic equivalents, and comparison of the availability of both
- For every medicine, comparison of public and private sector prices and, where appropriate, prices at NGO, church mission or 'other' health facilities
- Comparison of the public sector procurement price with the international reference price and with the retail price for any medicine in each sector.

**Type 2: Availability comparisons**

- Availability of originator brand medicines and lowest-priced generic equivalents in up to four sectors, separately and compared.

**Type 3: Affordability comparisons**

Treatment costs in relation to local wages compared by:

- Condition (14 recommended)
- Treatment affordability by sector: public, private and, where appropriate, 'other' sectors
- Treatment affordability by medicine type: originator brand and lowest-priced generic equivalent
- When available, treatment cost for a given condition compared with the cost of the same treatment in other countries or regions.

**Type 4: Price component comparisons**

- Price components of locally manufactured medicines compared with imported medicines
- Manufacturer's price or tender price compared with retail price
- Comparison of relative size of mark-ups (wholesale and retail), taxes, duties, tariffs, etc. in the final price for originator and generic products
- Comparison of price composition of essential (EML) medicines with non-essential medicines, if applicable
- Comparison of price composition by sector or by region.

In looking for lines of action and policy, it is important to focus on comparisons that show major differences between the following: local and international prices; sectors; originator brand medicines and generics; or between wage levels and treatment costs and in the major components of mark-ups. Differences suggest the possibility that prices can be brought down: the bigger the difference, the greater the scope for change.

Some of the various manifestations of price differences or problems detected will, of course, originate in the same cause. The affordability of treatment may be a problem and prices for an originator brand product may be high in relation to international reference prices, for example, simply because the local manufacturer or agent sets a high price. If procurement is also inefficient, distribution arrangements are expensive due to high mark-ups by wholesalers and retailers, and no generics are available, the price problem could be attacked using several approaches.

Among such approaches would be: better procurement, price negotiation, prescription and dispensing incentive reform – and thus practice reform – promotion of generics or consideration of a compulsory licence or use of any other legal safeguards in national legislation that may make cheaper generic versions of medicines under patent in the country more available.

Where the analysis of price composition suggests that local factors, such as tariffs, taxes and distribution mark-ups contribute significantly to final price, a general review of distribution costs may be necessary. Among other things, this review might consider whether essential medicines are exempt from import duties and other taxes; how distribution costs – particularly mark-ups – compare in the different domestic systems (public, NGO and private); and how medicines distribution costs compare with those of other commodities, such as perishable foods and beverages. In addition, investigation into the economic viability of the supply chain may be necessary to evaluate the feasibility of possible interventions.

Where local add-ons and distribution costs appear to be less important contributors to final price, but prices are high relative to international benchmarks, there may be a need to examine the efficiency of national and subnational procurement processes in getting the best possible manufacturer or seller prices. A supportive national policy on generic medicines – particularly in the selection, procurement, promotion, prescribing and dispensing processes outlined in Table 11.1 – is needed to underpin price regulation. Pooling procurement between hospitals or health authorities, ensuring competitive tendering and use of information about prices in other markets may all help. Where originator brand prices appear to be high relative to prices in other countries, you may wish to consider negotiating for differential prices with the manufacturer or exploring the possibility of parallel importation from a lower-price country, and/or increasing competition, if possible. Compulsory licensing, for local production or importation, may therefore be considered for key limited-source medicines. Fairer financing schemes for medicines can improve access through employment or community-based insurance and social security schemes and other forms of prepayment, and through exemptions in fee systems to minimize the price barrier for poor people.

It is important to provide empirical data to policy-makers on the need for policy change and to develop a close understanding of why the differences exist before selecting the line of action and making suggestions on the direction of government policy. Broadly speaking, it may be helpful to think in terms of policies concerned with getting better prices from manufacturers or intermediaries, on the one hand, and those designed to keep prices as close to the manufacturers' prices, through cost containment measures, on the other.

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## **11.2 POLICY OPTIONS TO ADDRESS LOW AVAILABILITY**

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There are likely to be different causes of low availability in the public and private sectors. In the public sector, for example, governments may be under-budgeting and not providing enough funds to meet the national needs. Another possibility is that it might be spending the available money on high-cost originator products when quality-assured generics are available or using the funds for hospital and not primary care medicines. In the private sector, a common cause of low availability of a specific product may be price regulations that discourage a manufacturer/supplier from producing, registering or supplying that product. Alternatively, there may be limited demand and for that reason retailers do not stock the product. Just as for high prices, understanding the reasons for low availability must be clear.

A range of policy options is open to governments to improve availability. Options include having government institutions prioritize the drugs budget, with particular emphasis on essential medicines and keeping this list current. Governments need to purchase low-priced quality generics, not more expensive originator brand products, so they can treat more people with the same resource allocation. If the private sector predominates and availability is poor then there may be a case for providing essential chronic disease medicines through the private sector at public sector procurement prices as the Eastern Caribbean countries and Jamaica have done for a limited medicines list for the elderly.

### 11.3 POLICY OPTIONS VARY FOR ORIGINATOR BRAND AND GENERIC MEDICINES

When considering policy options it is vital to distinguish between originator products that are patent protected – or protected by any other exclusive rights and only produced by the originator company (*single-source*) – and *multisource* products, for which generic equivalent products are also marketed. In the case of *single-source* products, for which no generic versions are available in a country, a monopoly situation exists. Therefore, the government may have to take action to increase access to essential medicines. This may include using therapeutic substitution, direct price negotiations, or use of the flexibilities compatible with the TRIPS Agreement of the World Trade Organization, as reaffirmed in the 2001 Doha Declaration on the TRIPS Agreement and Public Health for the purpose of “promoting access to medicines for all”. One of these flexibilities is Member States’ ability to issue compulsory licences for public health reasons in relation to any pharmaceutical product under patent in the country. For example, the government can permit the local production or importation of generic versions of patented medicines for purposes of public health (1).

Such approaches are inappropriate for *multisource generic products*. Regulating such medicine prices may lead to shortages when the price is set too low, or excessive prices when the price is not adjusted to consider changes in the market. Generic medicines are produced globally and the international market is very competitive such that generic medicine prices in New Zealand and the United Kingdom are very close to the MSH prices.<sup>1,2</sup> Setting a maximum retail price (MRP) for these products will often mean that the MRP comes to mean minimum retail price and all products cluster around this price. If reference pricing is used to set prices for generics, e.g. by stating that generic prices should be no more than 80% of the originator brand price, this creates incentives for agents to import a small quantity of high-priced originator products to set a high price and then sell large volumes of generic products at 80% of this high price. If generic medicines are to be subject to price controls (which we do not recommend) then the price should be set as a fixed margin above procurement prices rather than pricing down from originator prices. Generic medicine prices will be most efficiently reduced while ensuring availability by promoting a transparent market in which prices of quality assured generic medicines are freely published and generic substitution is required or encouraged so that consumers can make choices to purchase the best value generic product (2). Note that where countries limit the number of generic equivalent products available on the market, this may have the effect of limiting competition and lead to higher prices.

<sup>1</sup> New Zealand: <http://www.pasa.nhs.uk/PASAWeb/Productsandservices/Pharmaceuticals/Electronicmarket informationtooleMIT.htm>

<sup>2</sup> United Kingdom: <http://www.pharmac.govt.nz/interactive/>

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#### **11.4 POLICY OPTIONS VARY IF MEDICINES ARE PURCHASED BY THE STATE OR HEALTH INSURANCE SCHEMES COMPARED WITH OUT-OF-POCKET PURCHASES**

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There are major differences in policy options related to who is paying for the medicines. If the government is purchasing the medicines to be given or sold to its citizens through cost recovery schemes, policies to improve access and reduce prices could include establishing a national Essential Medicines List, pooled procurement of government institutions, tendering and for patent-protected medicines employ the TRIPS flexibilities under the government use provision. (For example, the United States Federal Government has defined these powers in national law).<sup>1</sup> Governments are also in strong positions to use their powers to encourage differential pricing policies and to exempt themselves from tariffs and taxes that are often paid on government purchases.

Health insurance organizations are also in a strong position to negotiate prices of products that they reimburse. For originator products for which there are therapeutic substitutes, the organization may require dramatic price reductions before an originator product could be allowed on the organization's formulary. Where no therapeutic equivalent exists, aggressive use of pharmacoeconomic techniques may be used to drive down prices. If the company is unwilling to reduce its prices, the insurance organization has the option of refusing to reimburse or setting the patient copayment at a high level. Conversely, when the insurer wants to encourage use of a specific product, it can reduce copayments. By monitoring consumption closely insurers can intervene to promote cost-effective therapeutics. For multisource generic products, the insurer can choose to reimburse at the lowest or median market price.

For consumers who pay out of pocket (OOP), the power relationship is very different. Governments have a duty to inform and protect these consumers but the government's power is very different when it is not paying for the medicines. The government can inform these patients by providing objective comparative medicines information, by patient education campaigns and by providing comparative price information in a transparent fashion. To protect the patients who purchase their own medicines, governments can regulate to ensure that generic medicines on the market are of good quality; require or at least promote generic substitution; control mark-ups; and remove taxes and duties charged on prescription medicines. In addition, governments can work with professional associations of doctors and pharmacists to ensure that professional standards are followed and that conflicts of interest, such as occurs with dispensing doctors, are banned. Hopefully, in time, more of those consumers who presently pay for medicines themselves will be covered by health insurance or social security schemes.

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#### **11.5 CONTROLLING MARK-UPS IS ALWAYS DIFFICULT**

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As has been seen in some medicine price and price component surveys, additional charges that occur between the manufacturer and the patient may more than double the price paid by the patient. For some of these, e.g. taxes and tariffs, it is easy to argue that such charges are contrary to the public good in that it is obviously regressive and inequitable to target the sick to pay these taxes. However, for other components, such as storage and transport costs, wholesaler and pharmacy charges, individuals and organizations deserve to be paid for the value of

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<sup>1</sup> See also US Code: Title 28, part IV, CHAPTER 91, 1498. Patent and copyright cases

**BOX 11.2****Medicine price and availability surveys lead to positive policy changes**

Medicine price and availability surveys have already led to positive policy changes in selected countries in the Eastern Mediterranean Region. For example, following a medicine prices and availability survey in Lebanon in February 2004, the Ministry of Health implemented a new pricing structure for all imported medicines:

FOB \$	Shipping insurance	Customs clearance	Importer mark-up	Pharmacy mark-up	Cumulative mark-up
0-US\$ 10	6.0%	10%	10%	30%	<b>66%</b>
US\$ 10- US\$ 50	4.5%	8.5%	10%	30%	<b>62%</b>
US\$ 50-US\$ 100	3.5%	7.5%	9%	27%	<b>54%</b>
> US\$ 100	2.5%	6.5%	8%	24%	<b>46%</b>

This new pricing structure has reduced medicine prices by an estimated 3–15%.

the services that they provide. Moreover, the economic viability of the supply chain must be ensured to maintain or improve medicine availability.

However, unlike groceries, medicines are not common goods and are subject to professional and regulatory controls. Wherever possible, fixed fees are preferable to proportional fees. For example, if a pharmacist is paid a 25% mark-up for dispensing a product, he/she has a strong financial incentive to recommend the highest-priced originator product. However, if a fixed fee is charged, the incentive is reversed and the cheapest generic product will be the most profitable to sell.

The problem with such an approach is that under some circumstances poor patients purchasing low-cost generic products may be charged a great deal, more than the medicine cost. To address this difficulty, many countries have combined a low fixed dispensing fee with a regressive margin in which the percentage mark-up decreases as the price of the medicine increases. The problem is compounded by the fact that the cost of doing business may vary, depending on where a pharmacy is located. A high-volume pharmacy located in a major city with easy access to wholesalers and low transport costs can afford to charge lower mark-ups and remain viable but a rural pharmacy with low volume demand will struggle to survive with equal mark-ups. It may be necessary to cross-subsidize distribution costs and allow a rural premium to ensure the viability of such pharmacies as is done in Sweden.

## **11.6 DEALING WITH REBATES AND DISCOUNTS IS EVEN MORE DIFFICULT**

Developing policy options to take account of rebates and discounts that manufacturers and wholesalers offer is a challenge in all environments. For example, a manufacturer or wholesaler may offer a US\$ 10 000 rebate to customers (e.g. pharmacists) who buy US\$ 100 000 of its products. Discounts or bundling may be offered with deals such as buy three get one free. Under both of these scenarios the benefits accrue to the wholesalers or the pharmacies and are usually not passed on to the insurers who reimburse at the fixed price or to the patients. These practices contribute to increased margins, which may or may not affect the viability of the medicine supply chain participants. In many countries, obtaining information

on rebates and discounts is difficult; however, in a price components study in New Delhi, India, such information was available (3).

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### **11.7 MONITORING AND EVALUATION**

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Any change in policy should have monitoring of implementation and evaluation of outcomes as integral components. When changes are made to regulations or incentives with the intention of lowering prices or increasing availability, sometimes the desired results are not achieved due to unexpected effects or influences. Reliable data are needed to be able to know whether to modify the interventions or introduce additional measures.

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### **11.8 SUMMARY OF POLICY OPTIONS**

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A wide range of policy measures exists to deal with price and availability problems. Table 11.1 summarizes some of the possible policy actions to influence price, based on the WHO publication *How to develop and implement a national drug policy* (4). A mix of options is likely to be required. Different choices will need to be made for the public and for the private or NGO sectors.

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### **11.9 LIMITATIONS OF PRICE CONTROLS**

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Price floors or ceilings set a minimum or maximum price for a product. Price controls alter free-market outcomes by encouraging over-production by a price floor or over-consumption by a price ceiling or a lack of availability if the ceiling price is set too low. Manufacturers are often prepared to stop producing low-price controlled products and replace them with slightly different products – 325 mg instead of 300 mg – to ensure that they can sell at a profit. When a MRP is defined for a product this often becomes the minimum retail price with all of the prices clustering around this price. When attempts have been made to control mark-ups the market has responded with concealed practices (such as co-marketing fees, where pharmacies are paid to contribute to marketing efforts, as a way of hiding a discount). Under some circumstances, manufacturers may combine into a producer cartel, where they set prices and then compete on rebates and discounts.

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### **11.10 CONCLUSION**

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In conclusion, bear the following messages in mind about linking the survey findings to lines of policy action:

- Ensuring the availability of essential medicines is the government's responsibility. It can be achieved by government purchase and provision through the public sector, and it requires adequate budgetary provision as well as appropriate procurement and distribution strategies. Many of the initial medicine prices surveys have drawn attention to poor availability in the public sector, suggesting a widespread need to focus advocacy on restoring or strengthening this role of the government in ensuring public sector availability. Availability can also be improved by the government working through nongovernment and private sectors, although this requires that the government work in a different way, facilitating and enabling these organizations to achieve their objectives.

**Table 11.1 Regulating price as part of an integrated medicines policy**

Component of medicines policy	Examples of actions to influence price, availability and/or affordability
1. Selection of essential medicines	<ul style="list-style-type: none"> <li>■ Formulation/updating of essential medicines lists and institutional formularies</li> <li>■ Development and use of Standard Treatment Guideline</li> <li>■ Development of quality-assured therapeutic substitution policy</li> <li>■ Requiring the inclusion of medicines on the national EML in health insurance reimbursement lists with minimal co-pay</li> </ul>
2. Procurement/purchasing	<ul style="list-style-type: none"> <li>■ Competitive procurement with price transparency</li> <li>■ Use of pharmacoeconomics or international price comparisons as guidelines for fixing prices of originator products</li> <li>■ Pooled procurement with other national buyers, such as hospitals or health authorities</li> <li>■ Examination of purchasing practices in other sectors to ensure best practice</li> <li>■ For single-source products, pressure for differential prices and exploration of possible parallel importation and the use of TRIPS flexibilities to stimulate generic competition (seek the advice of an intellectual property expert, review the experiences of countries that have implemented TRIPS flexibilities, and/or consult the <i>Guidelines for price discounts of single-source pharmaceuticals (5)</i>).</li> <li>■ Assurance of transparent and quality price monitoring and public information</li> </ul>
3. Distribution system	<ul style="list-style-type: none"> <li>■ Analysis of efficiency, transparency, competitiveness and intervention to correct, e.g. by contracting to private and not-for-profit logistics and security organizations with target-setting and performance-monitoring</li> <li>■ Monitoring and regulation/control of mark-ups with fixed fees and regressive margins</li> </ul>
4. Generic competition	<ul style="list-style-type: none"> <li>■ Assurance of effective quality assurance capability and promotion of generic substitution at all levels</li> <li>■ Promotion of generic acceptance by professionals, patients and the general community</li> <li>■ Prequalification of generic manufacturers and publication of the quality assurance of such manufacturers</li> <li>■ Fast-tracking of regulatory approval of generic medicines</li> </ul>
5. Prescribing and dispensing	<ul style="list-style-type: none"> <li>■ Assurance that consumers, the private sector and NGOs are informed about and involved with generic and therapeutic substitution, where allowed</li> <li>■ Building of incentives to prescribe and dispense generic medicines</li> <li>■ Encouragement of separation of prescribing and dispensing, including banning dispensing doctors</li> <li>■ Assurance of unbiased consumer medicine information</li> <li>■ Assurance that promotion of products by pharmaceutical companies is strictly regulated according to WHO Ethical Criteria and prevention of direct-to-consumer advertising of prescription medicines</li> <li>■ Monitoring of prescribing and dispensing practices, using WHO Drug Use Indicators</li> </ul>
6. Financing	<ul style="list-style-type: none"> <li>■ Encouragement of pooled and prepaid financing of medicines, e.g. through employment-based or social insurance schemes</li> <li>■ Support of community-based insurance initiatives focused on improved access to essential medicines</li> <li>■ Assurance of exemptions or differential fee systems to protect access by indigent and disadvantaged groups</li> <li>■ Monitoring of prices and access; for example, routine monitoring of medicine prices and availability is under way in Kenya and Uganda<sup>a</sup></li> <li>■ Assurance that health insurance schemes use limited formularies, based on cost-effective therapeutic guidelines</li> </ul>

<sup>a</sup> <http://www.haiafrica.org/>

- Any individual price problem may have several contributing causes and may require action on several fronts.
- It is critical to be sure about the most important contributing causes before deciding on a strategy to change policy. It is counterproductive to employ cost-containment strategies when the problem lies with manufacturers' prices and vice-versa. Ascertaining this may require more research and technical support. Look for help from international experience with similar problems, such as mark-up levels and regulation.
- Analyse the relevant stakeholder positions, strengths and weaknesses carefully before deciding on how to formulate a plan for change. Build your coalition of support carefully and selectively. Read Chapter 13 on advocacy carefully.

- Use your judgment about whether, when and how to involve the mass media.
- Consider facilitating cohesive policy-making, e.g. a roundtable with ministry of health officials from your region.
- Monitor and evaluate any policy or other interventions intended to lower prices or increase availability.
- 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. Change is possible!

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