USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

JOINT LEARNING NETWORK For Universal Health Coverage

Learning Exchange on Pricing Strategies for Medical Products

Reference Document

There are many different medicines pricing strategies. The Learning Exchange focused only on external reference pricing, internal reference pricing, regulating mark-ups and promoting generic medicines. This document highlights some of the key points discussed in the Learning Exchange and is not intended as a comprehensive reference on pricing strategies.

I. Common Pricing Strategies

External reference pricing (ERP). Comparison of the price of a medicine to one or several other countries to derive a benchmark or reference price for the purpose of setting or negotiating the price or reimbursement rate of the product in a country. Also known as international reference pricing, international price comparison, external price referencing, or cross-reference pricing. Compared to some other pricing strategies ERP is less costly to implement and will help prevent extremely high prices. However, it is critical to have skilled personnel, adequate resources and well-defined cost components to ensure valid comparisons. It is important to evaluate the effects of implementing ERP including unintended consequences such as delay in product launch and product withdrawal from the market. ERP is appropriate for both single-source and multisource products.

Some key issues to consider with external reference pricing (ERP):

- ERP should be only one part of a broader pricing strategy
- It is critical to have well defined cost components to ensure valid comparisons
- Depending on the choice of the country and the basket of medicines the comparison may be distorted
- Define what medicines will be subject to ERP
- Develop clear guidelines and procedures
- Requires price transparency

Internal reference pricing. Comparison of prices within a given country. Typically, prices are set by comparing products with their therapeutic equivalents and/or a medicine with no added benefit over existing therapies is priced equivalently. Prices of generic medicines are usually set as a percentage price reduction from the originator brand. This strategy works well for generics in a competitive market and can protect from 'ever-greening'. However, it requires strong and effective payment systems.

Regulation of mark-ups. Regulation of additional charges and costs that are applied to price of a product in order to cover overhead costs, distribution charges, and profit. Policies might involve regulation of distributor/wholesale mark-ups, retail mark-ups and fees, and pharmaceutical remuneration.

Promotion of the use of generics. Generic medicines are produced and distributed without patent protection. Promotion of use of quality assured generic medicines includes:

- Mandating and/or providing flexibility for generic substitution within health system

- Strategies to foster competition and encourage generic introduction in market (e.g. early entry of and/or fast track approval of generics, Internal reference pricing, procurement legal frameworks and contracting mechanisms).
- Using TRIPS flexibilities and LDC status to increase access to generics

Additional readings on pricing strategies

Babar, Z. U. D. (2015). *Pharmaceutical prices in the 21st century*. Springer International Publishing AG.

Jommi, C., Armeni, P., Costa, F., Bertolani, A., & Otto, M. (2020). Implementation of value-based pricing for medicines. *Clinical Therapeutics*, *42*(1), 15-24.

Holtorf, A. P., Gialama, F., Wijaya, K. E., & Kaló, Z. (2019). External Reference Pricing for Pharmaceuticals—A Survey and Literature Review to Describe Best Practices for Countries with Expanding Healthcare Coverage. *Value in Health Regional Issues*, *19*, 122-131.

Knowledge Portal on Innovation and Access to Medicines. (2018). Research Synthesis: Price controls / Regulation.

Moon, S., Mariat, S., Kamae, I., & Pedersen, H. B. (2020). Defining the concept of fair pricing for medicines. *BMJ*, *368*.

Verghese, N. R., Barrenetxea, J., Bhargava, Y., Agrawal, S., & Finkelstein, E. A. (2019). Government pharmaceutical pricing strategies in the Asia-Pacific region: an overview. *Journal of Market Access & Health Policy*, *7*(1), 1601060.

WHO. (2020). *WHO guideline on country pharmaceutical pricing policies*. World Health Organization. Available at https://www.who.int/publications/i/item/9789240011878.

II. Pricing Data Resources

Select government pricing information

- Australia
- Colombia
- India
- The Philippines
- South Africa
- Other government sources available via the Knowledge Portal on Innovation and Access to Medicines National price data sources

Regional data sources

- DIME Provides information on the price of 38 selected medicines in 8 Latin American and 8 reference countries (Australia, Brazil, Canada, England, France, India, Norway and Sweden).
- PIEMEDS Price Information Exchange for MEDicineS is a web-based platform and portal for registered users to voluntarily share and view public procurement prices for medicines. The platform collects, compares and presents information. (Background)
- EURIPID Collaboration. A voluntary and strictly non-profit cooperation between mostly European countries on building up and maintaining a database with information on national prices and pricing regulations of medicinal products in a standardized format.
- World Health Organization (WHO) Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (European)

International

- UNICEF supply catalog. Includes indicative pricing information about vaccines, safe injection and nutrition products, mosquito nets and cold chain equipment. Provided for general information and should not be used for benchmarking.
    - All Products
    - General UNICEF pricing data
        - PCV vaccine
        - HPV vaccine
        - HIV prices
    - Frequently asked questions
- Knowledge Portal on Innovation and Access to Medicines Global and regional price data sources
- MSH International Medical Products Price Guide
- HAI Medicine Prices, Availability, Affordability & Price Components Database

Proprietary

- IHS Markit
- IQVIA

III. Key Factors Influencing Price Negotiations

Price negotiation. A step in the procurement process that aims to reach an agreement with potential suppliers on price, volume, quality, delivery and other conditions.

- Requires information on clinical value, cost-effectiveness, quality specifications, market authorization, patent status and volume needed
- Requires appropriate legislative framework and governance and administrative structures, supported by technical capacity
- Information gaps/asymmetry with respect to price is often a problem
    - Prices reported are not actual prices paid by providers (list prices)
    - Prices vary throughout the supply chain
    - Variations in what costs are included in the price
    - Negotiated prices are confidential and not reported

(See presentation)

Additional readings on medical product price negotiations

Raventós, P., & Zolezzi, S. (2015). Electronic tendering of pharmaceuticals and medical devices in Chile. *Journal of Business Research*, *68*(12), 2569-2578.

Rintoul, A., Colbert, A., Garner, S., Kotwani, A., Vogler, S., Bouvy, J., & Hill, A. (2020). Medicines with one seller and many buyers: strategies to increase the power of the payer. *BMJ 369*.

Wouters, O. J., Sandberg, D. M., Pillay, A., & Kanavos, P. G. (2019). The impact of pharmaceutical tendering on prices and market concentration in South Africa over a 14-year period. *Social Science & Medicine*, *220*, 362-370.

IV. Monitoring and Evaluating the Effects of Pricing Strategies

It is very important to measure unintended effects of the pricing strategies. For instance, one common unintended consequence of pricing policy is the exit of products from the market because the manufacturer decides that it is insufficiently profitable for the price the manufacturer can charge. Measuring the number of products on the markets and the number of products exiting the market is relevant. This can be done using market intelligence information in combination with market authorization information.

Another important consideration is how to capture the 'counterfactual'. In other words, what would have happened in the absence of the strategy or policy implementation. The use of a counterfactual is relevant to establish causal inference between the policy implementation and the effect that is of interest (e.g. price decrease). Many policy evaluations are not designed to establish causal inference.

Since randomization into control and intervention group is often not feasible, many policy evaluations use a quasi-experimental design such as time series. Results of a time series can easily be visualized and understood by decision-makers. An example of an evaluation of policy strategies using time series is the evaluation of the single price exit strategy in South Africa.

Some key issues to consider:

- Think about evaluation of the pricing policy before policy implementation
- Identify the key outcome variables to be measured according to the policy being implemented
- Price is not the only outcome variable that matters
- Identify potential unintended consequences and how they might be measured
- Choose the right study design
- Identify and mitigate bias and potential conflict of interest
- Collaborate with academic partners or other experts on the evaluation (see presentation)

Additional reading on monitoring and evaluating pricing strategies

Moodley, R., & Suleman, F. (2019). The impact of the single exit price policy on a basket of generic medicines in South Africa, using a time series analysis from 1999 to 2014. *PloS one*, 14(7), e0219690.