Internal reference pricing

WHO Guideline on Country Pharmaceutical Pricing Policies
A plain language summary

Main points

- Internal reference pricing compares the prices of pharmaceutical products that are therapeutically similar and can be substituted for one another, within a country.
- Internal reference pricing works best if countries have policies supporting the appropriate use of generic and biosimilar medicines.

Pros

- Internal reference pricing enables consistent pricing across medicines with the same or similar therapeutic effects.
- Internal reference pricing encourages competition among products that are therapeutically similar.

Cons

- Internal reference pricing requires technical expertise to determine whether products are therapeutically similar.
- Internal reference pricing requires resources to maintain a price database and to track price variations due to increased competition.

WHO GUIDELINE

Conditional* recommendations for the policy

* Consult stakeholders to understand the conditions within country context before full adoption

HIGHLIGHTS

For policymakers responsible for promoting affordable access to health products

1. WHO suggests the use of internal reference pricing for generic and biosimilar medicines according to the principles of generic reference pricing, under the following conditions:

- Internal reference pricing is used in conjunction with policies to promote the use of quality-assured generic or biosimilar medicines.
- Reference prices are obtained and validated from verifiable data sources.
- Consistent and transparent criteria for pricing of generic and biosimilar medicines are explicitly evaluated and stated based on an established methodology.

2. WHO suggests the use of internal reference pricing for medicines according to the principles of therapeutic reference pricing, under the following conditions:

- Internal reference pricing is used in conjunction with other pricing policies.
- Reference prices are obtained and validated from verifiable data sources.
- Consistent and transparent criteria, including therapeutic or dose equivalence, are explicitly evaluated and stated based on an established methodology.

1. Equivalence for the purpose of pricing set through the Anatomical Therapeutic Chemical Classification System 5th Level, with consideration to factors such as dose and pack size.

2. Equivalence for the purpose of pricing set through the Anatomical Therapeutic Chemical Classification System 4th Level based on clinical trial evidence of non-inferiority.
What is the policy?

Internal reference pricing compares and links the prices of pharmaceutical products that are therapeutically similar and can be substituted for one another. There are three types of substitutable products: generics, biosimilar products, and closely substitutable products which contain different active ingredients that produce similar health effects. Determining whether different products are therapeutically similar, and can be substituted for one another, is guided by the Anatomical Therapeutic Chemical (ATC) Classification System. The ATC groups pharmaceutical products according to which part of the body they affect and how they work. Products are considered substitutable if their active ingredients have the same chemical or health effect. Substitution is also guided by the disease or condition the product is intended to treat.

Why is the policy implemented?

Internal reference pricing tries to ensure that prices of comparable and interchangeable products are set at the same or a similar level. It may also encourage price competition among comparable products.

How is the policy implemented?

Groups of products are compared to determine whether they are comparable and interchangeable. This is done by considering factors such as active ingredients; evidence of effectiveness from clinical trials; dose, frequency and method of administering the product; and package size. After establishing their similarities, prices of these products are compared at a common point along the distribution chain (e.g. ex-factory). A benchmark price is then set according to evidence of equivalence. (e.g. X milligrams of medicine A achieves the same health effects as Y milligrams of medicine B).

Implementation

- Can our national regulations and authorities assure the quality of generic and biosimilar medicines?
- How will we promote the prescription and use of generic and biosimilar medicines?
- How will we organize education campaigns to build trust in generic and biosimilar medicines among the public, prescribers and dispensers?
- What incentives exist in the supply chain to support the prescribing and dispensing of generic and biosimilar medicines? How might we adjust incentives to make the best use of internal reference pricing?
- How can we develop flexible policies able to meet growing demand for biosimilar medicines in the future?

Methodology

- What scientific methods can we use to determine therapeutic equivalence?
- How will we deal with exceptional cases, such as when a product costs more or less than the established internal reference price, or when a patient needs a product that costs more than the established internal reference price?
- How does the internal reference price compare to overall production cost?

How commonly is the policy used?

Many countries use internal reference pricing to compare and set prices of generic, biosimilar or closely substitutable medicines. It is also used to set the levels of payment for these products in health-care systems where governments cover the costs of medicines, or control how much private insurers can charge for them.

For more information

See the WHO Guideline on Country Pharmaceutical Pricing Policies for more information, including an overview of the evidence about internal reference pricing and nine other pharmaceutical pricing policies. https://www.who.int/publications/i/item/9789240011878