Promoting the use of quality-assured generic and biosimilar medicines

WHO Guideline on Country Pharmaceutical Pricing Policies
A plain language summary

Main points
- Promoting the use of quality-assured generic and biosimilar medicines creates access to lower-priced equivalents or near equivalents of brand-name products.
- Multiple policies are required to achieve low prices and uptake of generic and biosimilar medicines.

Pros
- Promoting the use of generic and biosimilar medicines encourages market competition.
- Generic and biosimilar medicines promote health equity because they are more affordable and can reach more people.
- Countries have extensive experience and policies in place promoting the use of generic medicines.

Cons
- Limited regulatory capacity to ensure quality and substitution of generics and biosimilars undermines trust in these products and limits market competition.

WHO GUIDELINE
Strong recommendations* for the policy

* A strong recommendation of this guideline indicates that the desirable effects of adherence to this recommendation outweigh any potential undesirable effects. This means that in most situations, the recommendation can be adopted as policy.

HIGHLIGHTS
For policymakers responsible for promoting affordable access to health products

1. WHO recommends that countries enable early market entry of generic and biosimilar medicines through legislative and administrative measures, with a view to encouraging early submission of regulatory applications, allowing for prompt and effective review, and ensuring these products are safe, efficacious and quality assured.

2. WHO recommends that countries use multiple pricing policies to achieve low prices for generic and biosimilar medicines that are informed by the cost of production. These policies may include: internal reference pricing, mark-up regulation, tendering, and lower patient co-payments.

3. To maximize uptake of generic and biosimilar medicines, WHO recommends that countries implement, and enforce as appropriate, a suite of policies, including:
   - legislation to allow generic substitution by dispensers and, where applicable, biosimilar substitution;
   - legislative structure and incentives for prescribers to prescribe by International Nonproprietary Name;
   - dispensing fees that encourage the use of low-price generic and biosimilar medicines;
   - a regressive mark-up structure where lower rates of mark-ups are applied for higher-priced products, and appropriate financial and non-financial incentives are applied for dispensers; and
   - education programmes for consumers and professionals regarding the quality, safety, efficacy and price of generic and biosimilar medicines.

1. For the purpose of this guideline, costs of production include manufacturing costs, costs associated with R&D, regulatory processes and compliance, overheads and other operating expenses of the business.
What is the policy?
This policy refers to strategies, directed at patients, prescribers and pharmacists, to encourage the use of quality-assured generic and biosimilar medicines. Generic products have the same active chemical ingredients as brand-name products that are no longer patent protected. Biosimilar products contain biological substances made by living organisms rather than manufactured chemicals. They produce the same therapeutic effects as the original product because they are highly similar, although not chemically identical, to the original product.

Why is the policy implemented?
Quality-assured generic and biosimilar medicines are priced lower than their original, branded equivalents. The use of these alternative products enhances price competition.

How is the policy implemented?
Governments have implemented a range of measures to promote the use of generic and biosimilar medicines. Supply-side measures include removing barriers set by regulation; using voluntary licence agreements or applying World Trade Organization Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities for patented medicines; and implementing specific pricing and purchasing policies for generic medicines, such as internal reference pricing. Demand-side measures include lower patient co-payments for generic medicines; compulsory dispensing of generic or biosimilar medicines; and education campaigns to raise awareness about the efficacy and safety of generic medicines.

How commonly is the policy used?
Promoting the use of quality-assured generic medicines has been an important public health policy globally since the 1990s. Policies for promoting the use of biosimilar medicines are less common and exist mainly in higher-income countries in Europe.

Implementation
- Do we have legislation to allow, or to require, dispensers to substitute generic or biosimilar products for patients?
- Do we have national guidelines on the substitution of generic and biosimilar medicines?
- How will clinicians and pharmacy personnel be educated about appropriate substitution of generic and biosimilar medicines?
- How will we monitor and deal with occurrences of substandard products, or situations where suppliers attempt to unfairly prevent the use of generic and biosimilar medicines in the market?
- Do we have policies in place to enhance price competition, such as supporting local production, using voluntary licence agreements, or applying WTO TRIPS flexibilities for patented medicines?
- Can we strengthen our regulatory capacity by using information from the WHO prequalification programme or other well-established regulatory authorities?

Methodology
- Have we clearly defined the evidence needed to determine which generic and biosimilar products may be substituted for particular branded products?
- Do we have clear technical specifications for quality assurance?
- Can we use internal reference pricing to harmonize the prices of generic and biosimilar medicines?
- When generic and biosimilar medicines enter the market, are prices appropriate relative to production costs?

For more information
See the WHO Guideline on Country Pharmaceutical Pricing Policies for more information, including an overview of the evidence about promoting the use of quality-assured generic and biosimilar medicines and nine other pharmaceutical pricing policies.
https://www.who.int/publications/i/item/9789240011878