Mark-up regulation across the pharmaceutical supply and distribution chain

WHO Guideline on Country Pharmaceutical Pricing Policies
A plain language summary

Main points
- In mark-up regulation, governments specify how much suppliers can add to the cost of medicines along the supply chain.
- Setting lower mark-ups for higher-priced medicines can encourage more use of lower-priced medicines such as generics.

Pros
- Mark-up regulation ensures that prices along the supply chain are predictable, consistent and transparent.
- Predictable prices improve expenditure management.
- Carefully designed mark-up regulation can improve spending efficiency because it can maximize the supply of low-priced products to achieve the same health outcomes with the same amount of money.

Cons
- Products may become unavailable if mark-up levels do not meet suppliers’ cost and profit expectations.
- Monitoring prices and enforcing mark-up regulations require high-level skills and resources.
- Failure to enforce the policy can mean failure to make products more affordable.

WHO GUIDELINE
Conditional* recommendations for the policy

1. WHO suggests the use of mark-up regulation across the supply and distribution chain for medicines under the following conditions:
   - Mark-up regulation should be used in conjunction with other pricing policies;
   - Mark-up structure should be regressive, where the mark-up rate decreases as the price increases (rather than a fixed percentage mark-up for all prices).

2. WHO suggests that countries consider using remuneration and mark-up regulation as incentives for supplying specific medicines (e.g. generic medicines, low-volume medicines, reimbursable medicines) or to protect medicine access for specific patients or population groups (e.g. vulnerable groups, or populations living in remote areas).

3. WHO suggests that countries ensure transparency of prices and methods when setting mark-ups along the supply and distribution chain, including disclosure of any rebates and discounts.

4. WHO suggests regular review of mark-up regulation to protect patients from out-of-pocket expenditures.

* Consult stakeholders to understand the conditions within country context before full adoption.
Mark-up regulation across the pharmaceutical supply and distribution chain; WHO guideline on country pharmaceutical pricing policies. A plain language summary

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