

COMPETITION POLICY

As part of the joint World Health Organization (WHO)/ Health Action International (HAI) Project on Medicine Prices and Availability, a series of in-depth reviews have been published on pharmaceutical policies and interventions that may improve medicine availability and affordability. This policy brief summarises the key points from the review on competition policy and access to medicines, which included a systematic literature review and a case study of South Africa's use of competition law in medicines markets.

Page references to the review paper are given in parentheses.

- Competition law
 - Generic competition
 - Competitive tendering
 - Public information

- API manufacturers
- Manufacturers of originators & generics

- Retail pharmacies

- Wholesalers

WHAT IS THE BASIS FOR THIS POLICY BRIEF?

WHO/HAI Review Series on Pharmaceutical Pricing Policies and Interventions. Working paper 4: *Competition policy* by Loraine Hawkins.

www.haiweb.org/medicineprices/policy/index.html

SUMMARY CONCLUSIONS

Is applying competition law feasible for all LMICs?

No. Competition law is most relevant to middle-income countries with adequate legal systems and state institutions. Low-income country examples of applying competition law to the pharmaceutical sector could not be found.

Can competition law be applied to all medicines and all of the pharmaceutical sector?

Yes. Competition law has been applied to every stage of the pharmaceutical supply chain, from product development and manufacturing to dispensing. Competition law does not override the exclusive rights granted to on-patent medicines, but the law is applicable to originator firms if they abuse a dominant position or engage in anti-competitive behaviour to deter generic entry after patent expiry.

What are the key pre-requisites for implementing competition law successfully?

- a legal system with adequate competence and independence;
- adequate human and financial resources in the competition authority.

Are there any complementary policies needed to support effective price competition?

- credible medicines quality regulation;
- generics policies, including openness to trade in quality assured generics;
- liberal regulation of wholesaling and retail pharmacy to encourage efficient consolidation and reduce distribution costs and improve quality assurance;
- provider payment policies that make health facilities cost-conscious and create incentives for prescribers and dispensers to recommend lowest-priced medicines;

- public support for consumer information and advocacy;
- monitoring systems to identify where competition and regulation are not working.

How can competition be promoted in low- and middle-income countries (LMICs) with weak institutions?

In LMICs that cannot implement competition law or medicines quality regulation effectively, market studies to assess competition and regulation can identify a broader range of possible policy interventions that may be more feasible than competition law. Some countries have been able to promote price competition and reduce prices by:

- using the public sector and contracts with NGO or private pharmacies to compete in under-served areas;
- creating supportive conditions for private sector generic pharmacy chains to develop, marketing low-cost generics and providing health advice to low-income clients.

Competition can reduce medicine prices and increase availability if the right conditions are in place. Competition is not effective unless there is credible medicine quality regulation and other supportive policies. Competition law usually has the objective of maintaining and enhancing competition in order to improve consumer welfare. It can help secure competition at all stages of the medicines supply chain. Review of regulations and practices that limit competition may reduce medicines prices. Competition in medicine markets works best when the buyers are price-conscious, expert institutions, such as hospitals, social health insurance agencies, specialist procurement agencies or pharmaceutical benefit management organisations. Institutional buyers can use generic competition to achieve lower prices for off-patent medicines. They can also reduce prices for on-patent products that have close therapeutic substitutes through competition for formulary listing. When individual consumers buy medicines and pay out-of-pocket, competition is imperfect for all but the most familiar over-the-counter medicines. (pp. 5-10)

What is competition law?

Competition laws usually create powers for a competition authority and the courts to:

1. control mergers and take-overs in order to prevent firms becoming too dominant in a market;
2. prevent anti-competitive agreements among firms, such as price-fixing or sharing out the market among a cartel;
3. prevent dominant firms from abusing their position in the market to the detriment of consumers; and
4. perform market studies to identify where and why competition may be ineffective.

Remedies provided to the authorities to enforce competition law usually include powers to impose fines, to monitor and control prices, to require firms to divest part of a business as a condition of merger, and to require undertakings from companies to cease anti-competitive conduct (1, 3 chapter 3). (pp. 11-12)

How has competition law been used in medicines markets?

Competition laws have been used to address anti-competitive practices at every stage of the pharmaceutical supply chain. Competition law has been used to penalise originator companies, producers of active pharmaceutical ingredients, generic medicines manufacturers, distributors, retail pharmacies and pharmacy associations that acted to wrongfully inflate prices or restricted availability of medicines. In the USA, the competition authorities have required companies to pay substantial amounts to consumers and state agencies who were harmed by excessive prices. Competition law has been used to prevent merging originator companies from becoming too dominant in particular therapeutic areas. It has also been used to prohibit them from delaying and deterring generic entry after patents expire. Competition authorities have intervened in mergers between manufacturers and pharmacy benefit management companies to require use of open formularies, selected by independent therapeutics advisory committees. They have required merging

pharmacy chains to divest some branches, to prevent the company becoming too dominant in a locality. They have conducted market studies and reviews of regulation to identify anticompetitive practices that are not in the public interest (2). (pp. 14-17)

How and where has it been implemented?

Most international experience comes from upper-income countries with high capacity competition authorities and well-functioning courts and law-enforcement. The USA and European Union (EU) have a large body of case law and studies. The experience of some countries that have undergone rapid development in recent decades (such as South Korea, Ireland and the recent EU accession states) may offer lessons for middle-income countries on relevant applications of competition law in the pharmaceutical sector. (p. 4) Since the 1970's there has been increased adoption of competition laws in LMICs, often driven by conditionality in aid programmes, but the pace and effectiveness of implementation has been slow in most of these. There is very limited LMIC experience with applying competition law or conducting market studies in the pharmaceutical sector, with a few exceptions, including Argentina, Brazil, Indonesia, Jordan and South Africa (3, chapters 1 and 3). (p.14)

What institutional and technical capacity and information is required to implement the policy effectively?

In order to implement competition law effectively, countries need to have:

1. a judicial system with a reasonable degree of independence and competence;
2. functioning third party enforcement of laws, regulations and contracts, free from undue political or industry intervention; and
3. adequate human and financial resources for the competition authority and medicines regulatory agency. (3, chapter 4) (p. 41)

Complementarity with other policies

A range of other policies are important for promoting competition to reduce prices, while assuring the quality and availability of medicines. Most of these policies can also be effective in countries without functioning competition laws. Key policies that can support effective competition, if they are well designed and implemented, include the following:

- *increasing the credibility, efficiency and transparency of the national medicines regulatory agency*: Without credible regulation, prescribers and patients will prefer higher-priced originator products and premium-branded generics and may perceive lower prices as an indicator of lower quality. (p. 24)
- *generics policies*: Competition can be promoted by flexible provisions in intellectual property and pharmaceutical laws permitted under TRIPS to expedite entry of generics into the market after patent expiry, and by permitting imports of quality-assured generics with zero tariffs. Mandating or promoting generic prescribing or permitting generic substitution by pharmacists can also stimulate generic competition, but is only likely to be effective if medicine quality regulation is credible, and needs to be supported by doctor and pharmacist education and financial incentives. (pp. 20, 25-26)
- *competitive public procurement*: National and regional procurement agencies may be able to achieve lower procurement prices than smaller local health authorities or facilities. (p.19)
- *using the public sector and contracts with NGO or private pharmacies or accredited drug stores to increase competition while assuring quality*: In LMICs such as Kyrgyzstan and Tanzania, this has been effective in areas where the poor are under-served, such as remote rural areas and urban slums. Some countries (e.g. New Zealand, Brazil) have successfully reduced prices by distributing publicly procured generic medicines through private pharmacies (4,5). (p. 23)
- *provider payment and medicine reimbursement policies that create incentives for competition in the supply chain*: Health insurance agencies or public health systems can include medicines costs in the prices they pay for healthcare services (e.g. in global budgets or case-based payments for hospitals), to encourage providers to dispense low-cost generics. They can use competition for formulary listing and for setting reimbursement rates. They can design remuneration systems for private community pharmacists to give them incentives to dispense low-cost generics (6,7). (pp. 21-23)
- *consumer information and protection policies*. This can encompass regulation of advertising and promotion, professional ethical codes to protect consumers from misinformation, education campaigns and advocacy to promote generic medicines as "good value". (p. 24)

- *removal of regulatory barriers to efficient distribution and retail pharmacy*: overly restrictive regulations of over-the-counter sales of medicines, of retail pharmacy ownership and location, of the pharmacy profession and of wholesale distribution can restrict competition and prevent efficient consolidation of medicines distribution. Countries that allow efficient combination of integration and competition appear to be best placed to achieve lower mark-ups on sales of medicines. Pharmacy chains with their own distribution system can help to build consumer confidence in the quality of generic medicines sold (8). (pp. 26-30)

PRIVATE SECTOR COMPETITION FROM GENERIC PHARMACY CHAINS

Emergence of new private pharmacy chains marketing low-cost generics to lower income customers has occurred in Mexico (*Farmacia Similares*) and the Philippines (*The Generics Drugstore*). These chains brought price competition into areas that had previously been served by a mix of high-priced market-dominant chains and inefficient independent drug stores and spread into rural market towns, improving rural access. Private sector competition was fostered by:

- liberal pharmacy regulation permitting chains, corporate, distributor-retail integration;
- a franchise model that enabled rapid growth, mobilised capital from small investors;
- public promotion of generics by advocacy for generics medicine legislation.

What effect does the policy have on prices and availability?

There is extensive good quality evidence from upper income countries and some evidence from LMICs that competition can reduce prices for essential medicines in retail pharmacies. Much of this comes from studies of the price reductions and market share changes after generic competitors enter the market. Some comes from studies of internal reference price schemes. Studies of competitive tendering and of competition for formulary listing demonstrate price reductions achieved by institutional purchasers. (pp. 5-6) Economic evaluations of the impact of competition law do not provide findings specifically about the pharmaceuticals sector. However, analyses, case reports and settlement agreements of competition authorities such as the Federal Trade Commission in the USA and the Competition Commission in South Africa document evidence of price and other effects of anti-competitive behaviour and competition law rulings. (3, 8) Although low-income country evidence is sparse, a study of the effects of retail pharmacy competition in rural Kyrgyzstan found that a new pharmacy could bring about price reductions in districts up to 15 kilometres away (4).

What are the challenges and risks associated with the policy in LMICs?

Unclear law, technically weak decision-making and variable enforcement are challenges in a number of LMICs that can lead to inconsistent and unpredictable application of the law, with unintended negative effects, including the risk of deterring entry of new, more efficient businesses or deterring efficient consolidation of fragmented sectors like the pharmaceutical sector. In countries with weak capacity in

competition authorities and the courts, the processes involved in competition law deliberations and enforcement can be too slow and costly. At worst, in countries with weak legal systems, where powerful, concentrated business interests are combined with a lack of political will to confront those interests, competition law may be evaded by those with connections and enrich corrupt officials and politicians (3, chapters 6, 7 and 9). (pp. 15-16)

COUNTRY CASE STUDY: SOUTH AFRICA (pp. 31-39)

South Africa adopted a new Competition Act in 1998 after an inclusive policy process. The Competition Commission has since considered a range of cases covering:

- abuse of dominant market position by multinational manufacturers;
- exclusive distribution agreements used by multinationals;
- mergers of retail pharmacy chains;
- collusion in public procurement by local firms.

Substantial fines, orders to divest, and undertakings to change conduct have been imposed under the new law.

What specific challenges were encountered and what lessons can be learned?

As a new agency with limited resources, the Competition Commission increased its impact by choosing strategically important cases to set precedents, and used public education and guidance to encourage the whole sector to comply with the principles established by landmark cases. Its willingness to tackle a high profile case concerning in-patent antiretroviral medicines of high public health importance was important for credibility. The Commission and consumer groups mobilised international technical and donor resources to build specialist capacity and support legal action.

How has the policy been monitored and evaluated?

South Africa established a committee to monitor prices and recommend actions needed from the Competition Commission, the health and medicines authorities or other agencies. This reflects a judgement that competition law – though beneficial – is not enough on its own to protect consumers from paying higher prices for medicines than they need to (9, 10).

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OTHER USEFUL RESOURCES

A list of useful links and resources, other reviews and policy briefs in this series, and a glossary of terms used in the policy briefs can be found at: www.haiweb.org/medicineprices/policy/index.html