WHO/HAI Project on

Medicine Prices and Availability

Review Series on

Pharmaceutical Pricing Policies and Interventions

Working Paper 4: Competition Policy

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Abbreviations

ATC	Anatomical Therapeutic Classification
API	Active pharmaceutical ingredient
ARV	Antiretroviral medicine
BI	Boehringer Ingelheim
EC	European Commission
EU	European Union
DOH	Department of Health
FDA	US Food and Drug Administration
FTC	US Federal Trade Commission
GSK	GlaxoSmithKline
HAI	Health Action International
HMO	Health maintenance organization
INN	International non-proprietary name
JVC	Joint venture company
LMIC	Low- and middle-income country
MSH	Management Sciences for Health
NGO	Non-governmental Organization
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-counter
PHARMAC	New Zealand Pharmaceutical Management Agency
SEP	Single exit price
SME	Small and medium-sized enterprises
UK	United Kingdom
UNCTAD	United Nations Conference on Trade and Development
USA	United States of America
WHO	World Health Organization
WTO	World Trade Organization

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Foreword

WHO/HAI Project on Medicine Prices and Availability

Since 2001, the World Health Organization (WHO) and Health Action International (HAI) have been working in partnership to collect reliable evidence on medicine prices, availability, affordability and price components in low- and middle-income countries. To date over 80 medicine price and availability surveys have been completed or are underway using the WHO/HAI methodology, with results publicly available on the HAI website (www.haiweb.org/medicineprices). While this work continues to expand, the WHO/HAI project has evolved from supporting research to using the results to effect positive changes in related policies and interventions.

The results of the surveys confirm that substantial opportunities exist to increase availability, lower prices, and improve the affordability of medicines in all regions of the world and at all levels of economic development. However, it can be challenging to identify and prepare suitable lines of response.

At the request of national policy-makers, WHO/HAI and a group of international experts have developed guidance on various policies and interventions to increase medicine availability and make medicines more affordable, with a focus on low- and middle-income countries. This guidance takes the form of a series of in-depth reviews on pharmaceutical pricing policies (generics policies, external reference pricing, mark-up regulation, pharmacoeconomics and cost-plus pricing) and other related issues including the role of health insurance in the cost-effective use of medicines, encouraging competition, and sales taxes on medicines. The reviews are not meant to recommend one policy intervention over another, but rather provide guidance to policy-makers on the design and implementation of various policy approaches. For each review, a policy brief will be published that highlights key points from the review.

The results of the policy reviews show that relatively little has been published about the use of pharmaceutical pricing policies and interventions in low- and middle-income countries. Therefore, the review papers are published as working drafts, to be developed as more becomes known on the use of these interventions in low-and middle-income countries. We welcome information and comments that will strengthen these reviews (please forward them to Margaret Ewen, Health Action International email marg@haiweb.org).

WHO and HAI would like to thank the authors of the papers, the reviewers, and all the national contributors who provided information on the use of the interventions in their country. We are also grateful to the members of the Pricing Policy Working Group who have shaped this work.

We hope these papers will be a useful resource, and encourage national policy-makers to tackle the challenge of developing and implementing policies and strategies that ensure universal access to affordable medicines.

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Executive summary

Competition can reduce prices for medicines and increase availability if the right conditions are in place. There is good evidence that:

- Generic medicine entry and generic competition increase the availability of lower-priced generic products.
- Competition is most effective when price-conscious, expert institutions are the purchasers[a] rather than individual consumers. Institutional purchasers can speed up generic entry and may even drive convergence of originator brand and generic prices.
- Institutional purchasers of essential medicines may be able to achieve lower prices for off-patent, multi-source essential medicines by using competition, rather than by using price regulation or other forms of price restraint.
- Institutional purchasers can reduce prices for on-patent products that have close therapeutic substitutes or "me-too" versions by inducing competition for formulary listing. Some studies suggest this competitive leverage may have more impact on prices than buyer power from bulk or pooled purchasing.
- When individual consumers purchase medicines out-of-pocket, pervasive asymmetry of information limits the potential for effective medicine price competition for all but the most familiar over-the-counter medicines.

A completely unregulated pharmaceuticals market will not produce effective, efficient competition. Some core forms of regulation need to be in place and adequately enforced to foster healthy competition. These include general laws (criminal law, contract law, and competition law) as well as pharmaceutical sector regulation to ensure the safety and quality of products in the supply chain. These are necessary to mitigate the effects of limited information and knowledge of consumers, retailers and doctors about the price, quality and appropriate use of medicines.

Countries with well-developed and enforced competition laws have been able to use these laws to address anticompetitive practices that can occur at every stage of the pharmaceutical supply chain. Competition law has been used to apply penalties to companies found to have engaged in monopolization and other forms of anticompetitive conduct that led to wrongfully high prices or restricted availability of essential medicines, and required them to change their behaviour.

Alongside competition law there is a range of complementary policies that health and pharmaceutical sector ministries and authorities need to adopt in order to ensure that competition is effective:

a 'Institutional purchasers' are organizations that use expert capacity to procure medicines or negotiate prices for medicines supplied to their customers/members – such as Ministries of Health, Central Medical Stores, hospitals, social health insurance agencies, and private managed care organizations (e.g. Health Maintenance Organizations, Pharmaceutical Benefit Management companies).

- Transparency over pricing and transparency in regulation;
- Credible regulation of the efficacy, safety and quality of medicines, including low-cost, timely, transparent product registration;
- Simplifying and reducing unnecessary costs of regulation through regional cooperation and regulatory harmonization;
- Openness to trade in quality-assured generic medicines and zero tariffs;
- Avoidance of policies that impose unnecessary costs on suppliers of medicines e.g. mandating international companies to manufacture medicines locally can increase costs of supply, particularly in smaller countries with lower technical capacity;
- Competitive public procurement;
- Competition in distribution and dispensing;
- Incentives in the supply chain designed to promote competition: these can be created by provider payment policies that make healthcare providers price-conscious and align their incentives with the goal of rational use of least cost, quality-assured essential medicines;
- Systems for tracking and monitoring prescribing and dispensing of medicines finances by government or insurance systems, to underpin effective market regulation and provider payment;
- Enforced, ethical codes of conduct for industry, doctors and pharmacists.

These policies are in place in most OECD countries, but are absent or not functioning effectively in many low- and middle-income countries (LMIC).

Stronger price regulation may slow generic entry, though some forms of price regulation incorporate competitive mechanisms. Some forms of regulation reduce competition and raise prices in undesirable ways that do not produce net social benefit. For example, there is some evidence that removal of some forms of retail pharmacy regulation (e.g. location or ownership restrictions, bans on chains, bans on vertical integration, barriers to entry into the pharmacy profession), can reduce medicines prices without adversely impacting patients. However, deregulation leads to consolidation, which calls for pro-active application of competition policy to balance the benefits of economies of scale against the risks of loss of competition. In countries where the State is weak, lacking in transparency and vulnerable to corruption, there is documentation of pharmaceutical industry incumbents exercising undue influence on State authorities to adopt anticompetitive regulation or anticompetitive implementation of regulation (*1*).

It is regarded as good practice for competition authorities and pharmaceutical price regulatory authorities to have some formalized arrangements for coordination or joint competency. Competition authorities can provide health authorities with expert advice on the potential risks involved in pharmaceutical regulation and its implementation including unintended anti-competitive effects. Health and pharmaceutical authorities have an important role to play in providing health-sector expertise as an input to the decisions of the competition authorities.

Even with pro-competition policies in place, the market for sale of medicines to uninsured consumers who pay for medicines out-of-pocket functions imperfectly. This is the largest part

of the pharmaceutical market in most LMIC where it is common to find a wide range of retail pharmacy prices for the same product. Originator brands and heavily marketed branded generics are often sold at a high multiple of the price of low priced generics, with many people paying more than they need to. Consumers do not treat branded medicines and generics as perfect substitutes. This is due to poor information; risk aversion about the quality of low priced generics; mistrust of regulatory enforcement; responsiveness to advertising; lack of availability of low cost generics in private retail outlets; and reliance on the advice of imperfect agents (pharmacists, doctors) influenced by company detailing or profit margins on higher priced medicine sales. The price premium of originator brands and heavily marketed branded generics is likely to be much greater where the national medicines regulatory agency is not effective or credible in assuring the quality of medicines in the supply chain, even if quality-assured generics are available in the market at prices comparable with international benchmarks.

Complementary policies to support consumer participation, education and advocacy may be able to counteract some of these impediments to competition, and increase the potential for competition to deliver lower medicine prices:

- Public support for consumer advocacy organizations;
- Provisions in competition laws and regulations for competition authorities to give greater consideration to consumer interests (as distinct from adopting a narrow focus on market structure and the conduct of companies) where consumers are not well informed or well placed to search for better price/quality purchases;
- Public support for generic medicine advertising/promotion/education for consumers, doctors and pharmacists alike;
- Consumer/patient protection legislation, including functioning systems for post-marketing surveillance and pharmacovigilance;
- Regulation of medicine promotion;
- Moving beyond self-regulation of industry and self-regulation of professional ethics to give greater weight to consumer/patient interests and consumer representation.

But undoubtedly, it is the introduction of third party payment systems (whether through social insurance or public delivery systems) that have the greatest impact on effective competition in the market giving consumers the back-up of a professional, cost-conscious purchaser.

Increasing numbers of LMIC have adopted competition laws or modernized their competition laws in the last 25 years, but implementation has been slow in many of them. It is difficult for LMIC to implement good competition law regimes effectively until certain pre-conditions are in place:

- the judicial system is functioning with adequate independence and competence;
- third party enforcement of contract, law and regulation is able to be exercised without undue political or industry interference; and
- there are adequate human and budget resources for the competition and regulatory authorities (*2*).

There are few documented cases of developing country use of competition laws in the pharmaceutical sector. South Africa's law has been applied to strategically important cases involving multinational firms, local generic medicine manufacturers, wholesaling/distribution, private sector retail pharmacy, and public procurement. Other middle income countries, and low income countries with sufficient general institutional capacity in their legal and regulatory systems, should in principle be able to emulate South Africa's experience. However there is some theory and evidence that in countries with weak legal systems and state institutions, where powerful concentrated business interests are combined with lack of political will to confront those interests, competition law may only deter those without connections and enrich unscrupulous bureaucrats (*3*).

Countries with weak legal systems and state institutions are also rarely able to implement effective safety and quality regulation of pharmaceuticals, and so are doubly disadvantaged in their potential to create effective competitive markets for essential medicines.

Even in the absence of effective competition law, there can be value in using market studies of the sort that competition authorities conduct to assess the state of competition: studies of market structure, restrictive practices, barriers to entry and abuse of dominant positions, for example. This information can be used as a basis for formulating policy recommendations covering a broader range of possible interventions or actions than the remedies available in competition law, and as a catalyst for change and consumer-interest advocacy.

1. Introduction

This paper reviews the evidence on the impact of competition in pharmaceutical markets (including manufacturing, distribution, retail, and dispensing) on the prices and availability of essential medicines, particularly for those in LMIC. The paper seeks to provide a brief introduction to policies that can be used to address monopolization in the pharmaceutical sector, anti-competitive behaviour by industry participants, and anti-competitive features of regulation. The paper has a particular focus on use of competition law (also called 'antitrust law') to influence pharmaceutical prices, but it also reviews evidence on how a range of other government policies affect competition and the impact of competition on prices of medicines.

Other government policies that affect competition in pharmaceutical markets include:

- Public procurement policies
- Intellectual property rights (IPR) protection policies
- Trade policies & industry development/assistance policies
- Pharmaceuticals product/industry/professional regulation
- Medicines & pharmacy reimbursement policies.

2. Methodology

A search for relevant literature was carried out using Google Scholar and SSRN abstracts. In addition, purposive search was carried out of the websites of International Bar Association's Global Competition Forum (which is a resource providing links to international, national, academic and professional sites related to competition and consumer protection law), OECD, World Bank, UNCTAD, WTO and national competition authorities.

Searching the terms pharmaceuticals OR medicines AND competition OR competition policy AND prices yielded a very large number of to issues involving manufacturer-level competition by generic entry after patent expiry references - but overwhelmingly related to developed country contexts. A series of more specific searches to target specific topics in the TORS was carried out by addition (using AND) of the following terms:

- developing countries OR low income countries
- distribution OR wholesaling;
- retail pharmacy OR dispensing OR dispensing doctors
- regulation OR deregulation OR liberalization
- advertizing OR marketing OR promotion
- industry policy OR industry assistance

Additional searches using Google tried to identify grey literature related to specific countries known to have experience with relevant policies.

2.1 Case studies

From the search results, and from informal consultation with colleagues working in competition policy in developing countries, South Africa was identified as the best developing country case for illustrating the application of competition law to the pharmaceutical sector, and for illustrating good practice in coordination between the competition authority and the pharmaceutical price regulation authority. The competition law cases in South Africa are well documented and the documentation is easily accessible, and there is some academic literature and discussion from OECD global competition forums.

Recognizing the relevance of evidence about competition and its impact in countries with less capacity to implement competition law or market regulation, other country cases were also considered. But there are very few other developing country cases where there has been analysis of market competition and implementation of related pro-competition recommendations in the pharmaceutical sector. Some pharmaceutical market competition analysis is available for Bangladesh and Indonesia.

Some upper-income country cases may also be relevant where countries have recently made the development transition from middle-income to upper-middle or upper-income country status,

and which have used pro-competition policies in the pharmaceutical sector during this transition.

In this category, the following country experiences are potentially relevant:

- South Korea is of particular interest to other Asian countries because of concentrated market power, history of industry policy, and the way in which the country tackled the 'imperfect agency' of dispensing doctors.

- Ireland's competition authority reviewed the reasons for high retail pharmacy margins compared to other EU countries, and recommended some deregulation of measures that are found in many developing countries in Eastern Europe, the Middle East and North Africa, and selected other countries.

- Some of the new EU accession states e.g. Poland and Hungary have increased the openness of their pharmaceutical sectors at all levels following EU accession and have come within the scope of EU competition law. These countries have in parallel increased the capacity and credibility of pharmaceutical safety and quality regulation through harmonization with the EU under the shared regulatory institution – the European Medicines Agency.

3. Competition in the pharmaceutical sector and the role of competition law

3.1 Evidence of the effects of competition on medicine prices

3.1.1 Generic entry and competition

There is extensive good quality evidence from OECD countries, and some evidence from LMIC, that competition can reduce prices for essential medicines. One source of evidence is the large body of studies evaluating the effect of laws that countries have adopted to encourage generic medicine entry and generic competition after patent expiry. There are many studies of the effects of generic competition on prices and market shares of generics in the USA following adoption of the Hatch-Waxman Act in 1984 and also studies in Canada, some EU countries, and Australia (*4*), (*5*), (*6*), (*7*), (*8*). The Hatch-Waxman Act in the USA facilitated generic entry in return for an extended period of patent protection. Since this law was adopted, some originator brands lost half their market share in a year after generic medicine entry (*6*). Various US studies estimating the discount in price offered by the first generic entrant find discounts in the range of 15%-40% during the period when there is only one generic competitor, and that prices of generics drop lower as more generic companies enter the market and compete. One study found the average generic wholesale price to be 60% of originator brand price for medicines with only one generic entrant, dropping to an average of 29% with 10 generic entrants and 17% with 20 generic entrants (*8*). The EU adopted regulation to promote the uptake of generic medicines in 2004, which included some similar features to those in the USA. A European Commission (EC) inquiry into a sample of 219 medicines found that generic prices were on average 25% lower than the originator brand price before loss of exclusivity, falling to 40% lower on average two years later. Generic market share was about 30% after a year, and 45% on average after two years. But in some EU countries, prices fell by up to 80%-90% (*9*, *10*, *11*).

3.1.2 Price competition under internal reference price schemes, with well-informed, well-motivated prescribers

A second source of evidence comes from internal reference price schemes for reimbursing prescription medicines. These schemes use patient out-of-pocket payments as a driver of medicines price competition. Where prescribers are informed about what patients will pay under reference price schemes, and motivated to minimize out-of-pocket costs to patients, this form of competition has reduced prices. For example, when Germany introduced internal reference pricing in 1989 – changing from a system in which patients paid a flat prescription fee to one in which social insurers paid the same maximum reimbursement for all generic equivalent medicines and patients paid the difference between reimbursement and producer's price – producers reduced prices by 10%-25%. The decline in prices was most pronounced for brand-name products and for branded products that faced a larger number of generic competitors (*12*, *13*).

3.1.3 Competitive tendering

Another type of evidence comes from studies of the results of competitive tendering for off-patent, multi-source medicines. Management Sciences for Health's (MSH) *International Drug Price Indicator Guide*[a] is based on an index of prices obtained in international tenders for multi-source medicines. Standardized price comparisons across many countries find that countries that practice competitive public procurement to supply the public health sector are able to purchase at prices that are at, or below, the MSH price indicator guide level (*14*). Some countries have also been able to use competitive public procurement to reduce the prices of prescription medicines distributed through the private sector (but financed publicly). For example, New Zealand's public health authorities use international competitive tendering for prescription medicines that are distributed through private sector pharmaceutical supply chains, and achieved price reductions of 15%-20% beyond the already low prices achieved through internal reference pricing. The resulting prices paid are below MSH's international medicine price indicator guide levels, and significantly lower than prices in Australia which regulates generic prices on the basis of a discount down from the originator medicine price (*15*, *16*, *17*).

3.1.4 Competition among 'me-too' medicines

Even for on-patent medicines, competitive pressure from a close therapeutic substitutes, or 'me-too' medicine, can place downward pressure on prices in institutional markets. Hospitals, social health insurance agencies, Ministries of Health, Health Management Organizations (HMOs), and Pharmacy Benefit Management organisations can obtain lower prices by instituting competition for formulary listing among suppliers of 'me-too' medicines within narrow therapeutic classes of medicines (e.g. beta blockers, statins, selective serotonin reuptake inhibitors (SSRIs)). This has been demonstrated in a range of high-income countries (e.g. in the hospital and HMO market in the USA, and in the internal reference price systems of countries such as Norway, Australia, New Zealand), and in some LMIC country social health insurance systems (e.g. Indonesia's social health insurance system for civil servants: ASKES). There is some evidence that the competitive threat of switching or de-listing has more impact on the prices paid than the potential for negotiation of bulk discounts through buyer size alone (*18*). Additionally, competition among licensed generic manufacturers of an on-patent medicine can reduce prices[b].

3.1.5 Wholesaler and retailer competition

Competition among wholesalers/distributers and retail pharmacies can reduce the final patient prices of both on-patent and multi-source off-patent medicines. Much evidence for this is documented in the analyses and case reports of competition and anti-trust authorities e.g. the Federal Trade Commission in the USA (*19*) and the Competition Commission in South Africa with details of settlement agreements of pharmaceutical industry cases and annual reports (*20*). Although low income country evidence is sparse, a study of the effects of competition among retail pharmacies in rural Kyrgyzstan found that the presence of a new village pharmacy in villages that previously had no pharmacy led to competitive pressure on the pharmacies in the district centre at a distance of up to 15 kilometres away, with price reductions observed in 63% of medicines sampled (*21*).

[a] http://erc.msh.org
[b] For an example involving ARVs, see Competition Commission, South Africa and Treatment Action Coalition, 2003 (*73*)

3.2 Common problems with the functioning of markets for medicines

In a well-functioning market for a commodity, competition should in theory restrain prices to a level which covers development, production and distribution costs and a normal return on investment. Competition should also result in convergence in the prices paid for the same product. However, in many countries, patients and other consumers – particularly those who pay out-of-pocket for essential medicines - pay relatively high prices for off-patent medicines that are available from multiple manufacturers. Medicine price surveys across many LMIC (using the WHO/HAI methodology) have identified a very wide range of prices for medicines that should be fully therapeutically substitutable: prices for originator brands and generics in many countries were a high multiple of MSH's international medicine price indicator guide prices, and high mark-ups were applied to the manufacturer or importer price. There is variation between countries and within countries in medicine prices that does not appear to be able to be explained by readily identifiable factors such as transport costs or tariffs and taxes (*14*, *22*). Where this pattern of prices is found, one of the potential explanations is lack of competition or anti-competitive conduct by firms involved at one or more levels in the medicines manufacturing and distribution chain[a].

3.2.1 Healthy competition requires effective regulation in medicines markets

It must be strongly emphasized that certain core laws and regulations are essential in order for medicines markets to operate safely, effectively and efficiently, because of pervasive asymmetry of information. Firstly, medicines markets, along with markets for other commodities, rely on at least a minimum level of enforcement of general fundamental laws, including criminal law, contract law, trade regulations and border control laws. Competition law – or some form of regulatory power that deals with monopoly and abuse of dominant position – ideally should form part of this core set of laws for regulating markets, although some countries have constitutional provisions that make regulation of monopoly difficult (*23*). Secondly, regulations on medicine safety and quality, as well as manufacturing and distribution, need to be effective and credible. Countries where these foundational laws and regulations are lacking or unenforced are exposed to risks of supply of counterfeit and substandard products, and to formation of cartels that are able to monopolize supply or distribution, resulting in excessive prices. In the worst cases, reputable suppliers of medicines withdraw from operation in the country, and medicines manufactured in the country are not accepted in other countries. This was the case, for example, in Nigeria during the late 1980s to 1990s. During this period, quality tests of samples of medicines on the market found over 50% (in some cases as high as 80%) of medicines were substandard and in some cases entirely lacked active pharmaceutical ingredients. It took concerted and courageous action by the National Agency for Food and Drug Administration and Control, and civil society advocacy for enforcement of the law, to rebuild sufficient regulatory credibility to restore supply of quality medicines (*1*).

[a] Lack of competition and profiteering are not the only explanation of high mark-ups and wide variation in prices for the same medicine. In many LMIC, the distribution and retail system is highly fragmented and inefficient compared to the increasingly streamlined distribution chains found in larger industrialized countries (62). Some research suggests that the costs of providing retail pharmacy services to dispersed, poor rural populations in developing countries may be high as a multiple of manufacturers' prices. Further research is needed to understand more fully the reasons for these high costs, and identify policy interventions that could address these problems. Additionally, countries with a highly unequal income distribution – as is the case in many LMIC – experience higher levels of product differentiation, and entry by firms that compete on quality in marketing to different segments of the population with different abilities to pay (*74*).

Countries that have carried out misguided or poorly designed de-regulation of medicines safety and quality controls have undermined the potential for price competition from generics. For example, in the 1990s, Peru (in the name of market liberalization), adopted a law that gave automatic market authorization to medicines seven days after application for registration, making it impossible for the national medicine regulatory authority to carry out adequate quality assessments. This led to a high presence of counterfeit and sub-standard medicines which in turn led doctors, pharmacists and patients to prefer originator brands and expensive branded generics. For many patients, higher prices came to be seen as a signal of good quality. As a result of the lack of credible control of quality of medicines in the market, the scope for price competition among generics was undermined (*24*). Peru has recently amended this legislation so as to strengthen medicines registration, not only in order to assure quality of products entering the market, but also to provide a foundation for more effective generics policies to reduce consumer prices through competition.

3.2.2 Monopoly

Both theory and evidence (mainly from other sectors) finds that monopoly suppliers typically charge higher prices and sell lower quantities than those that would be found in a competitive market (*25*). Monopoly suppliers can maximize their profits by charging prices that are as high as consumers are willing to pay. Typically this means charging prices that are higher than the cost of production at the margin, leading to above-normal profits for the producer and prices beyond which some consumers can pay. However, monopoly industries may waste their excessive earnings through inefficiency, due to the absence of competitive pressure to perform well. This, too, harms consumers.

Where a monopolist is able to segment the market and use price discrimination, it can increase its profits and sell more products by charging higher prices to customers who are willing to pay more, and discounting to other customers. It is common to find that manufacturers and wholesalers of medicines practice price discrimination – offering selective discounts and incentives to some retail pharmacies, dispensing doctors and other health care providers. Although this increases access/use of their products, this is achieved at the expense of consumers. Price discrimination by companies is based on market conditions, and may not be equitable. For example, patients covered by managed care insurance schemes are more likely to benefit from discounting than uninsured patients.

3.2.3 Oligopoly

Where a small number of companies have a dominant share of the market (oligopoly), there are higher risks of anti-competitive behaviour – although as long as the barriers to entry to the industry are low, the threat of competition can act as a deterrent against abuse of a dominant position in the market. Where there is oligopoly, collusion and various forms of restrictive agreements that reduce competition are easier to carry out and sustain. Where there is a dominant company facing a competitive fringe of small producers, competition-reducing strategies can be employed to enable the company to sustain increased prices. For example, the dominant company may act as a price leader, with other companies pricing just below the dominant company. The dominant company may be able to deploy strategies that increase rivals' costs of expansion or deter entry into the market. Anti-competitive behaviour may be explicit - such as when companies enter into collusive agreements to raise prices or to avoid competition by sharing out the market between them. But anti-competitive behaviour can also be tacit

or unconscious – for example, when smaller firms adopt a strategy of pricing just a little below the dominant company in the market, without explicit collusion (*25*).

3.2.4 Restrictive practices in vertical relationships

When considering vertical relationships between manufacturers and suppliers of active pharmaceutical ingredients (APIs), and between manufacturers and distributors or wholesalers, there are indications in some markets that originator companies influence the suppliers of APIs in order to restrict access by potential competitors to the ingredients needed to produce generic competitors. There are also instances of agreements between originator companies or branded generic companies and their distributors/wholesalers that restrict or reduce competition at the wholesale and retail level. The trend for large manufacturers to use direct-to-pharmacy distribution may reduce wholesaler competition and make it more difficult for smaller companies to enter the market (*11*, *26*, *27*).

3.2.5 Imperfect competition among retail pharmacies

Retail markets – including retail pharmacy - are often characterized by imperfect competition. It is common to see a range of prices for the same or functionally similar products: competition does not drive prices down to a single price rapidly or completely, even though there are multiple suppliers (*25*, *28*). One of the reasons for this is that it is costly for individual consumers to shop around –to compare prices and quality and switch products or suppliers. Like any other retailer, pharmacies and dispensing doctors can exploit locational advantages enabling them to charge higher margins.

3.2.6 Competing through complementary services

Retailers, including pharmacists, dispensing doctors and other medicine sellers, also provide a range of ancillary services or service attributes in addition to the product they sell. Price variations for the same products may in part be accounted for by these differences, which may include quality of premises and display, staff skills, waiting time, opening hours and customer credit services. In low income communities in some LMIC, customer credit and other forms of reciprocal obligations within the community seem to be a significant factor underlying people's decisions to patronise small, informal village or neighbourhood stores - which commonly sell essential and other medicines illegally - although their prices are relatively high and customers are price sensitive. These complexities of retail services complicate price comparison and market analysis (*29*).

3.2.7 Advertising and promotion

As well as product differentiation, brand-building advertising and promotional activities of manufacturers and retail chains reduce the likelihood of consumers switching to a competitor product or pharmacy and make them less price sensitive. In the pharmaceutical sector, direct-to-consumer advertising and detailing by company medical representatives are complementary strategies that enable brand-name suppliers to increase prices (*30*). Promotion and price advertising of generics – usually permitted for over-the-counter (OTC) medicines - has the opposite effect and is pro-competitive. In countries where doctors and patients do not have confidence that quality control regulation is effective, the effect of product differentiation and branding is even more marked because product quality cannot easily be assessed by consumers. Consumers who are risk-averse about quality are reluctant to switch from familiar products or reputable brands. There is evidence that many consumers perceive high prices as a

signal of good quality. One study found that a higher priced placebo had a stronger placebo effect than a lower priced placebo. An EC study found some indications that originator companies' marketing not only promoted their own products, they also sought to call into question the quality of generics (*11*).

3.2.8 Limited information and consumer dependence on professionals

The role of consumers is important in determining the outcome of competition; their information, beliefs, attitudes, and resources such as time and transport, make a major difference (*31*). Consumers rely heavily on professional advice for their choice of medicine, and pharmacists and doctors can direct patients to the most profitable products. These are unlikely to be the cheapest option for the patient unless there is policy intervention to align the financial incentives of prescribers and dispensers with the interests of patients (*32*). If the doctor or pharmacist provides neutral professional advice in the patient's interest, they could mitigate these problems and help patients to access the lowest priced quality-assured medicine.

In developing countries, and also in some upper income countries in Asia, doctor dispensing is prevalent, and not restricted to rural patients. Several studies have shown that doctor dispensing leads to prescribing practices that are influenced by profit margins on dispensing (*1*). While the doctors' profit motive is an engine of generic competition, the patient does not benefit and the doctor's prescribing patterns may deviate from what is therapeutically optimal and most cost-effective. A study in Japan found that dispensing doctors are more influenced by the out-of-pocket cost of the medicine to the patient than by their own profit margin, but their prescribing patterns do still respond to the profit incentive (*33*). In countries such as Japan where there is partial public reimbursement of medicine costs, the authorities may have some ability to monitor these margins and adjust reimbursement prices to align incentives of doctors, but accurate data is difficult to obtain and price discounting is typically very fast-changing. In many developing countries with weak and unenforced professional ethics, the financial incentives provided by medicine manufacturers together with poorly designed provider payment regimes, create a scenario in which the advice of health professionals on medicines is biased by personal profit.

3.2.9 Inequity and competition: are there trade-offs?

Originator companies price their patent-protected products at the level the market will bear in the absence of competition. If companies can segment the market they can increase their profits by pricing differentially in different markets. Because of this, some companies have voluntarily priced originator products at lower levels in some low income countries and regions. However, this kind of differential pricing cannot be sustained over time if there is widespread parallel trade. Some policy advocates argue for restrictions on parallel trade – although this is a restriction on competition – in exchange for agreements with companies on "equity pricing" – negotiated differentials on prices in favour of lower income countries. The distributional and welfare effects of differential pricing are not always positive and so analysis of proposals for equity pricing would need to be carried out on a case-by-case basis.

3.3 Definition and role of competition law

The primary objective of competition law is "to maintain and enhance competition in order ultimately to enhance consumer welfare" (*23*). Competition law gives the State's competition authorities the power to prevent companies from acquiring a dominant share of the market or entering into agreements with other companies that restrict competition. It also gives the competition authorities power to take action against companies that abuse a dominant position in the market – such as charging excessive prices or restricting access by other companies that seek to enter the market and compete (*34*).

Competition is not an end in itself – it is a means to the objective of economic efficiency. It benefits consumers by restraining prices and encouraging companies to innovate to provide better quality for the price paid. However, in some circumstances a monopoly or coordinated network of companies may be the most efficient arrangement such as where there are substantial economies of scale. Competition laws usually allow the competition authorities to assess the trade-off between the costs or harm to consumers of permitting a monopoly, versus potential benefits (e.g. economies of scale, better coordinated services) (*2*).

Competition law applies fully to the pharmaceutical sector. Holding a patent for a medicine does not exempt a company from the application of competition law. The company that holds the patent for an originator brand product has exclusive rights that give the company considerable market power. Patent rights are given with the express purpose of allowing the company to earn above-normal profits on top of manufacturing costs for a period of time to cover the costs of research and development and provide an incentive for innovation. However, a patent does not give the company a right to monopolize the supply chain. In both the USA and the EU, competition law has also been used to investigate anti-competitive action by originator companies to 'evergreen' their patents by using vexatious litigation to extend the effective period of patent protection, for example (*35*).

3.3.1 Components of competition law

Competition and antitrust law usually covers several broad components (*36*):

- Control of mergers and takeovers to determine whether the resulting market structure will result in a dominant company or increase the merged company's market power. Mergers may be horizontal (among companies engaged in the same activity) or vertical (between companies at upstream/downstream levels in the manufacturing and distribution process e.g. between a medicine wholesaler and a retail pharmacy chain).

- Restrictive agreements that reduce competition. These may be horizontal agreements such as price fixing (explicitly banned in many competition laws), quantity fixing, collusion or bid-rigging, sharing out the market and refusal to deal. Some vertical agreements may also be restrictive - though these often require case-by-case consideration - including resale price maintenance (sometimes called 'retail price maintenance') which can be a form of price-fixing, quantity forcing, exclusive dealing, and tying.

- Abuse of dominant market position, which includes exploitative abuses (such as charging excessively high prices to customers and price discrimination among customers) and exclusionary abuses directed at driving out competitors or preventing entry (such as refusing to deal, predatory pricing, and other mechanisms to increase competitors' costs). The latter type of case requires analysis of costs and benefits,

because a dynamic market should see more efficient companies driving out those that are less efficient. Economic criteria have been proposed as a basis for assessing whether abuse has occurred:

- A 'sacrifice test' asks if the company's conduct would be profitable but for its effect in reducing competition.
- An 'as efficient competitor' test asks if the company's conduct is excluding equally efficient or more efficient firms.
- A 'consumer harm test' asks if a company's conduct is excluding rivals whose presence enhances consumer welfare (*37*).

In applying competition law, technical criteria are used to determine what counts as a market dominance. Some country laws or regulations specify a maximum range of market share that would be permitted. Other competition authorities use a measure of market concentration to trigger reviews.

3.3.2 Market definition

Defining the market for a medicine – the range of products and the geographic area in which suppliers could compete - is not always straightforward. Competition authorities usually use standard medicine classification systems as a basis for deciding what products are likely to compete with each other - commonly Level 3 of the Anatomical Therapeutic Classification (ATC) system supported by the World Health Organization (WHO) - although they may use broader or narrower classifications based on evidence about actual or potential competition in the specific case. In addition, the major OECD competition authorities all accept that the market for institutional purchases of medicines (purchases by government authorities, hospitals, managed care plans, etc.) is different from the market for individual consumers paying out-of-pocket for prescription or OTC medicines from retail outlets, and take this into account when determining the potential for competition. Institutional purchasers are better informed, and they buy larger volumes over a longer time frame through national or even international purchasing. Individual consumers buy their medicines much more locally[a] and have much less time and information for comparing prices and assuring themselves of product quality. Hospital patients with acute illnesses may have no opportunity for choice over medicines prescribed and sold to them. Thus individual consumer markets for medicines are typically much smaller and more vulnerable to anticompetitive practices (*38*). In many markets for a particular therapeutic class of medicines, only one or two firms account for most or all of the supply.

3.3.3 Penalties and remedies

Competition law provides for a range of remedies and penalties including blocking mergers, forcing partial divestment as a condition of merger, fines for restrictive practices and abuses, and (in some jurisdictions) jail sentences for certain practices such as price-fixing. Competition authorities can also institute price monitoring and price restraints as one of their remedies and require specific undertakings by the company (e.g. to desist from particular anticompetitive action). In the USA, the competition authorities have recently set precedents for offending companies to pay financial compensation to consumers and state authorities for the harm caused by illegal excessive pricing (*19*).

[a] Though mail-order dispensing and internet ordering of medicines in countries where this is permitted creates new issues of market definition for competition authorities.

3.3.4 The relationship between competition law and regulation

In some countries, competition bodies have a mandate to undertake broad policy reviews of competition and regulation and a number have carried out reviews of pharmaceutical markets, pharmaceutical price regulation regimes, pharmacy regulation, and wholesale/distribution arrangements. UK, Australian and Irish competition bodies and the OECD have carried out research and market studies that compare prices internationally, analyze the extent of competition in pharmaceuticals markets at all levels, identify barriers to entry, identify abuse of dominance, and study the effects of regulation on competition. They make policy recommendations for a range of policies affecting competition – not only the operation of the competition and consumer protection laws.

Many countries have separate economic regulation agencies that regulate prices and other aspects of market behaviour for industries with natural monopoly characteristics or other special features. This is one of the rationales for creating specialist pharmaceutical price regulatory agencies - to ensure that the market power created by patent protection for pharmaceuticals is not abused. Alternatively, specific sectoral ministries carry out this function. There is an obvious interface between the objectives and scope of the competition law and the role of competition authorities on the one hand, and sector-specific price and market regulation on the other. There is a range of legal and institutional practice for how countries coordinate and harmonize competition law and other price and market regulation. It is generally regarded as good practice (by institutions such as the World Bank and the OECD) to have formal provisions for coordination, if not joint jurisdiction, between the competition authority and the agencies responsible for sector-specific price regulation. South Africa is regarded as an example of good practice in this regard, and its coordination arrangements encompass pharmaceuticals.

Consumer protection law is complementary to competition law and contract law. It provides a lower-cost redress mechanism for consumers who experience small losses due to unfair or incomplete contracts or misrepresentation in selling (compared to the very high costs for individuals of seeking application of criminal, contract or competition law). In some countries a single authority administers both competition and consumer protection laws, but they are often administered by separate agencies. Some agencies also have a mandate to conduct consumer education and support consumer advocacy organizations. In practice it is little used for essential medicines because separate health and/or medicines legislation usually gives health sector regulatory agencies responsibility for ensuring consumer protection in relation to medicines and other therapeutic products.

3.3.5 Competition law and health insurers, funders or purchasers

Competition law applies to health insurers and other organizations that purchase health services in ways that may affect their ability to use market power to achieve lower prices for medicines. If health insurers or institutional purchasers come together to establish joint negotiation of their medicines formularies and medicine reimbursement prices, for example, they may be subject to charges of collusion. Some countries adopt specific exceptions to competition law for price regulation or price-setting schemes used by national health systems. The agency responsible for public reimbursement of medicines in New Zealand (PHARMAC) operates under an exemption from New Zealand's Commerce Law. This exemption was challenged by the pharmaceutical industry in the courts, but was upheld (39). South Africa has also encountered this type of challenge (discussed in the case study – *see Section 5*). South Africa's Department of Health is currently proposing to seek a specific exemption from its Competition Act to enable it to lead a collective price negotiation process with healthcare providers (*40*).

3.4 Countries where competition law has been implemented

Canada introduced competition legislation in 1889, and the USA and UK in 1890. Japan, Germany, India and South Africa introduced competition law between 1945 and 1969, although the Indian and South African legislation was viewed as inadequate by the 1990s and has been replaced with legislation based on lessons from international practice. The Treaty of Rome has initiated wider development of competition law in the EU since 1955. In the 1970s and 1980s there was increasing adoption of competition law in both developing and developed countries in all regions, including: Chile, Guatemala, Argentina, Cote d'Ivoire, Kenya, Israel, Pakistan, Sri Lanka, Korea, Australia, New Zealand, France, Spain, Greece, Luxembourg, Switzerland, and Austria. Since 1990 at least another 63 countries have adopted competition laws, among them many LMIC. Conditionality in aid programs has been one of the drivers of this process. Unsurprisingly, the pace and effectiveness of implementation of these laws has been variable and slower and less effective in poorer countries with low resource allocation to their new competition authorities (*2*). As a result, there is very little actual experience in the application of competition law to the pharmaceutical sector in LMIC countries – though there is a substantial case history in the sector in the USA, EU, and some other OECD countries.

South Africa's new 1998 Competition Act is regarded as a good practice example by international institutions active in this field. Under this law, a range of pharmaceutical sector cases have been pursued. In Bangladesh, Indonesia, Brazil and Jordan where new competition laws are in place, some pharmaceutical sector market studies have been carried out. In Indonesia, the consumer representative on the competition authority is from an organization devoted to advocacy for consumers in health policy and advocacy for access to essential medicines.

3.5 OECD examples of applying competition law to the pharmaceutical sector

There is a large body of competition case law, together with extensive documentation of the investigations and decisions of the competition authorities, related to the pharmaceuticals sector from the USA, EU, and some other OECD countries with high capacity to enforce their laws. These cases are subject to detailed investigations and analysis, which is subject to strong tests of robustness by the legal processes in these countries. This body of documentation provides good quality evidence on the impact and cost to consumers, and public health authorities, of anti-competitive market structures and anti-competitive behaviour. The cases provide good examples of how the penalties and remedies of competition law can be used to eliminate, deter and obtain redress for these illegal activities. Following are examples of how Competition Law has been applied at each stage of the medicines supply chain (*19*, *38*).

3.5.1 Applying competition law to manufacturers of originator brands

Originator companies have been found to engage in an array of anticompetitive strategies to monopolize the market after patent expiry. In the USA, litigation has been brought successfully against originator companies for fraudulent patent applications, frivolous lawsuits to delay generic entry, reverse payments to first generic entrant not to compete, among other charges. For example, the Federal Trade Commission (FTC) issued a consent order against Bristol-Myers Squibb (C-4076, 2003) after it found the company had committed these types of offences over a period of 10 years to maintain its monopoly over three branded medicines (BuSpar, Taxol and Platinol). The FTC estimated that consumers had paid hundreds of millions of US dollars of excessive costs

as a result. The order prohibited these types of conduct and other types of conduct designed to 'evergreen' patents. EU studies find similar tactics have been employed by originator companies in Europe in addition to other strategies, including product differentiation across countries, selective culling of product lines, and quantity restrictions, designed to reduce parallel trade and price arbitrage across the EU (*41*).

The EU authorities have addressed a range of strategies by companies to prevent parallel trade among EU member states – for example, through restrictive agreements or limitation in quantity supplied to wholesalers and distributors in a given country - to assess whether these practices illegally restricted free movement of goods and competition. The EU case law has upheld the principle of free movement of goods, and hence permitted parallel trade among EU member states[a].

The USA and EU competition authorities reviewed several mergers of large multinational pharmaceutical companies that took place in the last decade. Their reviews examined whether the mergers would reduce competition in research and development, including clinical trials in particular therapeutic areas, as well as whether the mergers would lead to excessive concentration of the markets for particular therapeutic groups and products. For example, the review of the 2004 merger between Sanofi-Synthélabo and Aventis was found to reduce competition in three pharmaceuticals in the USA. As a condition of the merger, the FTC required divestment of products that were still at the clinical trials stage of development. It required divestment of manufacturing facilities to a competitor (GlaxoSmithKline), and required the companies to help GlaxoSmithKline to complete clinical trials and gain regulatory approval. The FTC also required divestment of clinical studies, patents and other assets related to cytotoxic colorectal cancer medicines to Pfizer (*19*).

The FTC has also reviewed some vertical relationships between medicine manufacturers and health care management providers that could reduce competition. Merck and Eli Lilly acquired pharmacy benefits management (PBM) companies in the US, which could have led them to favour their own medicines in the PBM's formularies. The FTC issued a consent order requiring the companies to maintain an open formulary, selected by an independent Pharmacy and Therapeutics Committee according to objective criteria (*19*).

The UK authorities identified predatory under-pricing of medicines to hospitals and over-charging for the same product in follow-up prescriptions in outpatient settings in the community in a case that recognized the influence of the prescriptions from hospital doctors in determining follow-on therapy that patients receive in the community for long-term and chronic conditions (*43*).

3.5.2 Applying competition law to generic manufacturers

The FTC has found cases in which generic companies have conspired to monopolize markets for generic medicines. For example, in 2000, it found that four companies (Mylan Laboratories Inc. et al[b]) had arranged exclusive licensing agreements for the supply of raw materials for producing lorazepam and clorazepate, enabling a dramatic increase in the price of generic lorazepam and clorazepate. In a precedent-setting decision, the FTC required the companies to distribute US$ 100 million to consumers and state agencies who were harmed by the excessive prices.

[a] It is beyond the scope of this paper to discuss the evidence regarding parallel trade. See Maskus and Chen (2000) for a review of this evidence (42).
[b] http://1.usa.gov/ib2Je6

The FTC has also reviewed takeovers of one generic manufacturer by another to assess whether the merged company would reduce competition in markets for particular essential medicines and OTCs. For example, when Teva Pharmaceuticals acquired IVAX Corporation in 2006[a], the FTC ordered the companies to divest their assets for 15 generic medicines, including formulations of amoxicillin clavulanate potassium in which they had a very high market share (over 50%, and up to 100% for certain formulations).

The Australian authorities have also reviewed cases of mergers between manufacturers and wholesalers, which raised concerns of the risk of favouring the manufacturer's own products, and the risk of sharing of information up and down the supply chain that could facilitate collusion among firms (*38*).

3.5.3 Applying competition law to retail pharmacies and pharmacists

In countries such as the USA and the UK where the law allows corporate chains of retail pharmacies, the competition authorities review mergers and acquisitions between pharmacy chains to ensure that no single chain dominates a local market. Competition authorities frequently order the merging chains to sell off a number of branches and outlets in particular localities in order to preserve competition. Recognizing that pharmacy chains are able to be more efficient than individual independent pharmacies, the FTC sometimes requires divestment to another chain, rather than to independents, to ensure that the buyer can compete effectively.

Several OECD country competition authorities have taken action against associations of pharmacies or pharmacists for coordinating prices or restricting entry to the profession. For example, in a series of decisions in the 1990s, the FTC found that associations of pharmacies and pharmacists in several states and cities had attempted to fix prices and other terms and conditions of dealing with third-party payers (health insurance plans). In some cases, the associations threatened to boycott government programmes for indigent patients unless they were paid higher fees and restricted the ability of individual pharmacists to deal with third party payers individually. The FTC issued orders prohibiting these restrictive agreements (*19*).

3.5.4 Market studies by competition authorities

Even without effective competition law, there can be value in using market studies of the sort that competition authorities conduct to assess the state of competition, including studies of market structure, restrictive practices, barriers to entry and abuse of dominant positions. These studies are used as a basis for formulating policy recommendations covering a broader range of possible interventions/actions than the remedies of competition law alone – including policy actions and consumer-interest advocacy. International organizations with a competition and trade and industry policy brief – including the EC and OECD – have conducted studies of pharmaceutical market competition across a range of countries. For example, the EC conducted a pharmaceutical sector inquiry under the EC competition rules in 2008, based on information that suggested restriction of competition in both originator and generic markets, leading to a reduction in the number of innovative medicines reaching the market and delays in generic entry. The inquiry found that originator companies used a range of strategies to extend exclusivity and delay generic entry as long as possible such as filing up to 1300 patents for a single medicine (creating 'patent thickets'), and

[a] http://1.usa.gov/i51k5E

engaging generic companies in costly litigation, even though the courts upheld originator patent litigation claims in only 2% of cases. It estimated that faster generic entry could reduce public expenditure on medicines by over 5%. The inquiry also identified defensive patenting strategies used by originator companies to block other originator companies from developing competing products. The inquiry invited comment from stakeholders on the causes of the problems and potential remedies, and assessed these. The findings on possible solutions ranged across patent law and its administration, and analysed bottlenecks in procedures for obtaining marketing authorization and obtaining approvals for pricing and reimbursement status (*11*).

3.5.5 Policy reviews and guidance by competition authorities on pharmaceuticals sector regulation

The expertise of competition authorities have can be usefully tapped by Ministries of Health and pharmaceutical regulatory authorities to assess whether pharmaceuticals regulation can be made more efficient and more compatible with stimulating competition. The South Africa case study provides an example (*see Section 5*). It is recommended good practice for price regulation authorities to have joint competency with the Competition Authority or some other form of coordinated decision-making. The Office of Fair Trading in the UK, for example, has conducted studies of the UK's pharmaceutical price regulation scheme, and trends in wholesale and distribution markets and their implications for the price regulation scheme (*27*, *44*). The EC and OECD have conducted studies of competition and pharmaceuticals sector regulation in their member countries. These studies have been influential on policy in some member states. For example, OECD studies of competition in Ireland identified relatively high costs arising from regulatory barriers to competition among retail pharmacies and barriers to entry to the pharmacy profession (*45).*

4. Health sector policies and practices that affect competition

4.1 Policies that can support effective competition

In addition to competition law, policies that can promote competition to reduce medicine prices and/or improve availability while assuring the quality of lower priced medicines that enter the market, include the following:

1. Adopting 'Bolar-type' provisions in intellectual property and pharmaceuticals laws and regulations. These are provisions that expedite licensing and entry of generics into the market after patent expiry. Conversely, competition can be aided by avoiding adoption of more restrictive 'TRIPS Plus' provisions in bilateral trade agreements.

2. Generic prescribing and/or generic substitution policies.

3. Competitive public procurement.

4. Using competition to set national/social insurance reimbursement prices for medicines.

5. Addressing perverse incentives that arise if prescribers who recommend medicines to patients (hospitals, clinics, dispensing doctors and community health workers) earn income from profit margins on sales of medicines.

6. Using public sector and NGO sector pharmacies and/or social franchising to promote retail competition.

7. Improving the credibility, efficiency, and transparency of the national medicine regulatory authority to achieve lower costs, more rapid regulatory clearances for generic entrants, effective regulatory enforcement, post-market surveillance and pharmacovigilance to countervail the risk of sub-standard products entering the market as it opens up to competition.

8. Using information provision (to the sector and the public) supporting consumer advocacy organizations to promote price competition and improved availability.

All but the first of these policies are substantially within the scope of responsibility of Ministries of Health and related health sector agencies. Even where other government agencies take the lead, it is important for Ministries of Health to have the capacity to engage with these policies.

The evidence base for the impact of these policies on medicines prices and availability varies in extent and quality. LMIC evidence is sparse, with the exception of evidence on competitive public procurement and revolving medicine funds. For the last three policies on the list above, there is a smaller evidence base, consisting of a number of case studies of projects or initiatives with limited scale, and a few higher quality studies of selected individual country experiences.

4.1.1 Generics policies

There is a strong body of evidence on the benefits for medicine prices and availability of adopting a complementary set of generics policies, including statutory provisions and regulations to expedite generic entry, and to permit generic substitution and/or mandate generic prescribing policies. Generics policies are more effective if they are supported through doctor and pharmacist education with appropriate financial incentives (*9*, *46*). However, many LMIC have found it difficult to implement comprehensive generics policies, particularly in hospitals and the private sector. Generic substitution or generic prescribing policies have been defeated in many countries by a combination of pharmaceutical industry and professional opposition: widespread unethical promotional incentives for doctors; inadequate capacity to monitor and enforce the policy; weakness in the national medicine regulatory agency's capacity to assure the quality of generics. There are some exceptions – Sri Lanka, for example, has over time been able to achieve a gradual voluntary increase in generic prescribing through medical education.

Box 1. **Case study: private sector competition by generics pharmacy chains**

In **Mexico** in 1997-1998 and in the **Philippines** in 2007-2008, the governments advocated for the introduction of legislation and policies to promote use of generics and reduce medicines prices. In both countries, the public advocacy for generics policies appears to have helped create conditions for greater private sector investment in sales of generics medicines. In both countries, beginning at the same time, there was rapid growth of new private sector pharmacy chains called *Farmacia Similares* (Mexico) and *The Generics Pharmacy* and *The Generics Drugstore* (Philippines), marketing low-cost generics to lower income customers. In both countries, these chains also partnered with low cost or free medical clinics. These new low-cost chains brought retail price competition into areas that had previously been served by a mix of high-priced oligopolistic chains and inefficient, fragmented independent drug stores. The chains spread into rural market towns, improving access for the rural poor. Some common features in both countries may point to conditions – both positive and negative - that help to foster this kind of private sector initiative:

- The Government and civil society advocates promoted knowledge and understanding of generic medicines as providing more affordable, better value treatment; private entrepreneurs capitalized on this by using the words '*similares*' or 'generics' in their brand name.
- Retail pharmacy regulation is liberal: chains and corporates are permitted.
- There is a very large and growing poor and near poor population who were ill-served by both the private retail pharmacy sector and the public sector prior to emergence of the low-cost pharmacy chains. Entrepreneurs recognized the value of the 'bottom of the pyramid' market.
- In the Philippines, *The Generics Pharmacy* adopted a franchising model that was very attractive to small family investors, including many overseas Filippino workers. This enabled rapid growth in a context where access to capital finance is difficult for many small and medium sized enterprises.
- The new chains did not compete head-on with the established dominant retail pharmacy chains, which continued to target a more affluent market segment.
- In the Philippines, the national drug regulatory authority has initiated a partnership with one of the new chains for post-marketing surveillance and adverse reactions monitoring. This focus on quality and safety is mutually beneficial.

4.1.2 Public procurement policies

Many LMIC have been able to use competitive public procurement to achieve low prices for multi-source generic medicines (*14*, *22*). But in countries with decentralized health systems, it has proved difficult to achieve competitive, transparent procurement of medicines by all local governments and individual health facilities for reasons that commonly include a combination of weak financial and procurement capacity and poor governance For example, a study of pharmaceutical procurement by national and decentralized health facilities in the Philippines, found higher average procurement prices at local municipality level than at province level, and lowest average prices at national level (*47*).

Public procurement processes that award the whole market for a medicine to a single supplier may result in potential competitors leaving the market and reduce competition in subsequent rounds of tendering. To avoid this problem, South Africa, for example, contracts the two or three lowest-price suppliers and offers to contract other suppliers if they agree to move their prices to this level. Some competition authorities have issued guidance on how to conduct public procurement in a way that strikes a balance between the goal of achieving the lowest prices in a given tender and the goal of maintaining a competitive market structure over the medium to longer term (*48*).

4.1.3 Using competition in setting prescription reimbursement rates for social or private insurance

In many countries, the prescription medicines reimbursement systems of public health systems and social and private insurers are designed to drive price competition for the supply of multi-source medicines in private wholesale and retail pharmaceutical supply chains. Many social insurance systems reimburse a flat price per item on a formulary that uses the International Non-proprietary Name (INN) of the medicine. They allow the pharmacists or dispensing doctors to keep the profits from any discounts they achieve from sourcing lower-priced medicines from competing wholesalers or direct-to-pharmacy distributers (*49*). This provides a profit-based incentive for wholesalers and pharmacists to search for the lowest cost suppliers.

Where prescriptions are written generically (i.e. using the INN name), or if generic substitution is permitted, this reimbursement mechanism is also a driver of generic entry and generic price competition. Although in the short term the benefits of price competition are kept by the pharmacists, over the longer term, periodic price reviews and dispensing fee reviews can claw back the benefits of competition for the payer. The UK's National Health Service regularly surveys the level of discounts pharmacists obtain from competing wholesalers and claws back the average level of discounts with a lag (*15*, *27*).

Some countries set the reimbursement price for multi-source medicines based on an index – for example the average of the three lowest-priced generic equivalents in the market place – and allow pharmacists and dispensing doctors to retain any surplus if they are able to source the medicine at a lower price. The index is updated regularly, enabling the payer to benefit from the price-lowering effect of competition over time. The competition induced by this approach enabled Norway to reduce prices below the levels achieved through price cap regulation (*50*, *51*, *52*).

Even in large, mature markets in countries with generally open trade policies and functioning competition (e.g. the UK), the generics market may be quite concentrated and specific medicines often have only one or two suppliers. In these contexts the risk

of periodic break-down in competition or forms of collusion becomes high. For example, in the UK in 1999, a sharp rise in the price of generics supplied to the National Health Service under competition-oriented pricing arrangements led to recommendations for actions to reduce barriers to entry to the UK generics market (*15*).

In some countries, manufacturers give undocumented, informal bonuses in the form of free medicines to wholesalers, who in turn pass them on to retailers, to crowd out competitors in the supply chain. In some cases it appears that these bonuses are such an important part of pharmacy and wholesaler income that price or margin regulation becomes secondary in its influence on behaviour. Controlling these practices is challenging for countries with weak regulatory capacity and may require collaboration and information sharing with third party payers and tax authorities that are defrauded by such practices.

In smaller markets these problems are greater because some of the costs of entry are 'fixed' – such as the cost of licensing applications - while aggregate returns are lower. In these contexts, use of international competitive tendering (with appropriate quality controls) may be needed to attract sufficient generic entry to minimize prices. In New Zealand, two local generic companies dominated supply until the mid-1990s. The agency responsible for public reimbursement of medicines (PHARMAC) successfully combined public international tendering for over 150 multisource essential medicines with competitive private sector wholesale and retail pharmacy distribution through framework contracts with manufacturers and contracts with pharmacists. This private distribution results in good availability and efficient logistics management. PHARMAC achieved price reductions of 15%-20% beyond the already low prices achieved through internal reference pricing. The resulting prices paid are below MSH's *International Drug Price Indicator Guide* levels (*15 16, 53*).

Originator brand medicines that are still on-patent may face no competition if they are highly innovative "break-through" products. On-patent originator brands that have close therapeutic substitutes or 'me too' product face competition in institutional purchaser markets, so long as the institutional purchasers are price conscious. Institutional purchasers include hospitals, social health insurance or public health system formularies, HMOs, and PBM companies who can negotiate lower prices by inducing competition for formulary listing, and/or using value-based reimbursement prices. This has been demonstrated in a range of developed countries (e.g. in the hospital and HMO market in the USA, in the internal reference price systems of countries such as Norway, Australia, New Zealand), and in some developing countries' social health insurance systems (e.g. Indonesia's social health insurance system for civil servants: ASKES). As mentioned previously, there is some evidence that the competitive threat of switching/de-listing has more impact on the prices paid than the potential for negotiation of bulk discounts through buyer size alone (*18*).

However, in LMIC limited coverage of essential outpatient medicines by social insurance schemes, limited population coverage of social insurance, and administrative and financial problems in many insurance schemes reduce the potential impact of this category of policies on prices and affordability of medicines. Nonetheless, there are examples of success albeit on a limited scale (*24*).

4.1.4 Policies to create appropriate incentives for prescribing and dispensing

OECD countries with universal population coverage of social health insurance or national health systems, and with a well-funded prescription benefits package, are in a

strong position to use public health financing and purchasing systems to design appropriate incentives for prescribers and dispensers of medicines (*13*, *32*, *54*). Flat reimbursement schedules for pharmacists and dispensing doctors, with fixed dispensing fees, creates stronger incentives for dispensing lower cost medicines than paying pharmacists a standard or regressive percentage margin on the acquisition cost of the medicine (*48*).

The dominant mechanism OECD countries use to create appropriate incentives for hospitals or primary care clinics is to put the hospital or clinic under pressure to minimize the total costs of health care including medicines as one input to care. Typically this means providers are financed through a payment for services that includes the cost of medicines – whether through a global budget, case-based payment, or capitation payment system. This payment mechanism creates powerful incentives for the hospital or clinic to use therapeutic and generic competition to reduce medicine prices. Alongside this, however, are strong mechanisms for monitoring provider performance to ensure necessary medicines are always available. More sophisticated payment systems also seek to create incentives for the costs of care to be managed across the whole patient pathway – including both inpatient and outpatient care. This can help to deter hospitals from seeking to shift the costs of inpatient medicines to follow-up prescriptions in the outpatient sector.

By contrast, in many (perhaps most) LMIC, hospitals, clinics and dispensing doctors sell medicines to patients and rely on profit margins from medicines for a significant share of their income. This is true even in public and NGO hospitals and clinics. While this improves medicine availability, it reduces affordability and creates incentives for irrational prescribing. There is evidence that in this environment, providers and dispensing doctors increase the quantities prescribed and shift their prescribing patterns to favour products which attract the highest profit margin (*55*).

Introducing and enforcing regulatory limits on doctor dispensing is widely recommended as a basis for improving doctors' incentives to prescribe in the patient's interest, uninfluenced by profit margin. While there is evidence that dispensing prescription practices are distorted by financial incentives, the evidence from countries that have recently introduced more stringent regulation of doctor dispensing (notably Korea) is limited and is confounded by the effect of other aspects of financing policies. South Africa has strengthened regulation to limit doctor-dispensing, and has sought to introduce an innovative form of price regulation to improve the incentives of prescribers and pharmacists. The regulations ban non-transparent discounts and control wholesale and retail margins for medicines above a minimum price level. The new regulations have been subject to litigation by affected interest groups and subsequent delays in full implementation and so have not yet been evaluated. This will be an important policy experiment for future research.

4.1.5 Using the public sector and contracted or franchised NGOs to increase retail competition

Studies of using public sector pharmacies and accredited drug stores in Tanzania (*56*) and Kyrgyzstan (*21*) have shown they have the potential to increase availability. Positive cost-effectiveness evaluation of the accredited drug stores initiative in Tanzania has led to scaling up and expansion of this approach in Uganda. The Kyrgyzstan study has also demonstrated the potential for this type of initiative to increase medicine price competition, even in rural areas. Governments in countries (e.g. Guatemala, Uganda) that have contracted non-profit organizations to provide health services have allowed the NGOs to provide retail pharmacy outlets selling lower priced medicines (*57*).

4.1.6 Increasing the credibility, efficiency and transparency of the national medicine regulatory agency

Many countries have introduced streamlined procedures, shorter regulatory deadlines for application processing and lower licensing fees for generic medicines to reduce barriers to entry for generics and so foster competition. Smaller countries have introduced abridged applications procedures requirements for medicines already granted licensing authorization in an established market with a credible regulatory agency. This increases efficiency and enhances the credibility of the regulatory agency. Regulatory harmonization as practiced in the European Union has similar benefits, and has been important to increasing confidence in generics and generic competition in the new EU accession states in Central and Eastern Europe. Countries that have attempted to promote generic competition to decrease prices without adequate, credible quality control regulation have failed to increase generic market shares or reduce prices. In some cases they have reinforced the position of imported originator brands from multinational companies as all local generic manufacturers were affected by loss of reputation due to regulatory failings. For example, Pakistan's attempt to ban brand-name selling and force generic competition in the 1970s had this effect leading to policy reversal (*58*).

4.1.7 Consumer information and advocacy initiatives

Price competition is facilitated by information initiatives directed at making consumers more willing and able to switch between generic substitutes. Regulation requiring labels on medicines packs to show the INN is beneficial to competition. Policies to provide patient and prescriber information and education about generics have been shown to make a difference in upper income countries to the willingness of doctors and patients to switch to lower cost generics. Public dissemination of medicines price information has been shown to reduce consumer search costs and lower market prices in a New York government initiative[a]. Citizen monitoring of availability and prices of essential medicines has been attempted in some LMIC, although the evidence of impact mainly relates to availability. But the detailed design of information-related initiatives is important. A US initiative to provide comparative information on medicines prices to consumers over the internet in conjunction with introducing a Medicare discounted medicines card was found to have only a modest impact on prices, and did not have the expected effect of increasing competition. The disappointing results may have been due to specific features of the scheme that limited the potential for competition (*59*).

4.2 Government policies and practices that limit competition

Not all barriers to competition are undesirable. Government regulation to ensure safety, quality and efficacy of medicines obviously increases the costs of supply and creates barriers to entry, but for good reasons that can produce net social benefits. The design detail and implementation of these regulations can make the difference between efficient market regulation and inappropriately costly regulation that stands in the way of competition among quality-assured pharmaceutical products. Ideally, such regulation should undergo assessment of costs, risks (including risks to access as well as safety risks) and benefits, and these may differ across countries. In countries with low literacy and education or countries with very low levels of health human resources, for example, the costs and risks associated with regulation and deregulation may differ compared to the situation prevailing in most upper income countries. At the same time, the feasibility of effective enforcement of regulation differs across countries

[a] See http://rx.nyhealth.gov/

and the assessment of costs and benefits of regulation needs to be based on realistic assumptions about enforcement and compliance.

There is also a risk that pharmaceutical companies, health professional groups and healthcare provider lobbies may influence governments to adopt regulations that reduce competition. Some forms of regulation have been found to protect industry, professional or healthcare provider interests at the expense of patients (*60*). More flagrantly self-interested forms of industry or provider influence on regulation for anti-competitive purposes – often described as 'state capture' – have also been documented. Product registration and provider licensing are sometimes used to deter entry by generic competitors or competition in distribution in a number of countries. Public procurement rules and practices in some countries restrict competition in pharmaceuticals by excluding participation by quality-assured international generic manufacturers (*1, 24, 61*).

There is a range of policies and practice – most within the mandate of Ministries of Health - that may have unintended or undesirable effects on competition and hence on prices and/or availability, unless carefully designed and implemented. These include:

1. Trade barriers, high import tariffs and local industry protection policies.

2. Pharmacy regulations that restrict ownership, location, formation of chains and vertical integration with wholesaling/distribution.

3. Regulations that mandate wholesalers to be 'full-line' – that is, able to supply every registered medicine.

4. Unduly restrictive approaches to classifying medicines as 'over-the-counter (OTC)', versus 'prescription only', and the restriction of some OTC medicines as 'pharmacy only' – that is, only able to be sold in licensed pharmacies.

5. Regulations requiring manufacturers or industry associations to set maximum retail prices and print these on the packaging.

6. Price cap regulation and forms of internal reference pricing, depending on detailed design and implementation.

7. Regulation of retail mark-ups to a fixed percentage without any exceptions or thresholds to allow higher mark-ups on low priced generics, or higher mark-ups in rural pharmacies where product turnover is low.

8. Prescription medicine reimbursement that pays pharmacies a standard percentage mark-up without any exceptions or thresholds for low priced generics.

The effects of most these policies on price competition also depends on the market structure. The risks of adverse effects are typically much greater if the market is quite concentrated with a small number of companies dominating, or if the market is segmented and there is only a small number of companies in the 'top tier' of premium branded generics. Countries with small pharmaceutical markets are therefore often more vulnerable to these adverse effects.

4.2.1 Trade and industry protection policies

Kaplan and Laing (*62*), drawing on limited available evidence, concluded that in most developing countries, local production of generic medicines only involves finishing off imported active ingredients at relatively high cost. They argue that local production in

these conditions is unlikely to improve access to medicines and may have negative effects on access. The authors conclude that in general, only larger countries with a sufficiently large population, economy and domestic market, adequate highly skilled human resources and good general industrial competitiveness are likely to be able to become competitive producers of generics. In some larger countries, development of a local industry increased future competition in a context in which there were high barriers to importation of generics. However, the level, duration and modality of industry assistance make a difference to whether it results in a competitive sector.

Where governments do choose to assist a local pharmaceutical industry, input subsidies can make the local industry more competitive internationally and may result in lower prices to consumers, while tariffs and domestic preference weightings for public procurement are likely to increase prices to domestic consumers and reduce international competitiveness. But where subsidies are high and long-lasting, the local industry is unlikely to become competitive.

Trade and industry policies to protect or subsidize local industry are widespread in LMIC, often supported by arguments about the need to protect local industries until they achieve economies of scale or by a goal of transfer of technology. However, these policies often increase the cost of medicines for patients and public/social health systems in some of the poorest countries of the world.

Removing trade barriers and other forms of domestic industry protection to enable importation of quality-assured generic medicines should reduce prices and improve availability, so long as medicines quality and safety regulation is applied effectively and transparently to imported medicines. For example, the Philippines Government introduced importation of selected off-patent essential generic medicines for distribution to public hospitals (previously only available as originator brands or domestically produced generics) and by doing so was able to achieve price reductions of 22%-382 percent (*63*). The effects of trade barriers and other barriers to competition in the Bangladesh pharmaceutical market have also been studied (*61*). Many developing countries have found it difficult to implement trade liberalization and reduce protection of their domestic pharmaceutical industry because of political-economy constraints.

4.2.2 Restrictive regulation of retail pharmacy and the pharmacy profession

While all countries regulate retail pharmacy to ensure safety and quality, there is a wide variation in aspects of regulation that are arguably not essential for safety and quality, but which add costs and create barriers to entry. Regulations in this category include requirements that only a pharmacist can own a pharmacy, bans on forming pharmacy chains, restrictions on the distance between pharmacies and licensing arrangements that require demonstration of population need or that control pharmacy-to-population ratios. Studies commissioned by the European Commission found evidence that countries within the EU with more restrictive regulation for pharmacies have higher fees and prices (*64*). A review of pharmacy regulation in six countries (USA, Canada, France, Germany, Norway and the Netherlands) found clear evidence that there is greater competition in the more deregulated markets. The review concluded (with some caution because of limitations in the available evidence) that there are benefits from deregulation and competition among pharmacies in terms of lower medicine costs for patients and/or public payers and insurers, and ease of access to pharmacies (*45*).

Countries that permit pharmacy chains are able to achieve greater discounts from suppliers (e.g. USA, Canada, the Netherlands, and Norway). Reviews of regulation in Ireland, Iceland and Norway identified that some former restrictive regulations

operating in these countries led to avoidably higher costs. Iceland, Norway and Estonia deregulated in response to this evidence and experienced subsequent consolidation of pharmacies into chains and some vertical integration. This brought down costs but in these small countries raised issues about the need for pro-active monitoring to ensure that the market does not become too concentrated. Norway set limits on market share to manage this risk (*44*, *65*).

Some LMIC regulate where new pharmacies can be opened in an attempt to redistribute pharmacy graduates to rural and lower-income areas. Mali, for example, does not allow new pharmacy graduates to open a pharmacy in the capital, Bamako, due to perceive saturation of the market. However, there is some evidence that this does not succeed in persuading pharmacists to relocate to rural areas and that this kind of regulation also has undesirable side-effects on price competition. A study of pharmacy legislation and regulation in 12 LMIC with large private health sector expenditure found that seven of these countries had ownership regulation that prevented corporate ownership and five had regulation that restricted ownership to either a single pharmacist or partnership of pharmacists with degree or diploma qualifications. Additionally, sometimes there were restrictions to prevent ownership by non-nationals. In two countries that deregulated pharmacy ownership (South Africa, which allowed corporate ownership under 2004 legislation, and India which adopted more liberal interpretation of legislation gradually from 2000-2004), there was rapid development of pharmacy chains. The early effects of this appear to be lower prices and greater competition, without significant net loss of outlets: chain stores newly opening in shopping centres balancing the closure of independent pharmacies (*26*).

The study identified four factors which restrict consolidation and chain formation among private pharmacies in LMIC:

- Legislation restricting pharmacy ownership
- Pharmacy licensing regulation (which may create barriers to opening of new pharmacies, based on need criteria, for example)
- Availability of national qualified pharmacists (although the requirement to have a pharmacist in the store also applies to chain pharmacies, chains may be less able to get away with breaching this requirement than the many small independent ‘mom and pop’ pharmacies.)
- Access of pharmacists to finance to be able to establish a pharmacy.

It is possible to combine territorial planning of the location and distribution of pharmacies with competition by having insurance agencies (or other public health funding agencies) tender for pharmacies to serve their population. Tendering in this way can also be used to assess whether it is necessary to pay more to ensure access to a pharmacy in a rural area. South Africa combines competitive pressure with certificate-of-need regulation for pharmacies by allowing new pharmacy chains to apply to enter a market if they offer lower priced services, even if there is already a pharmacy present in the locality.

In the Netherlands and in some developing countries (Uganda, Ghana and Indonesia, for example) there is a two-tier regulatory regime for pharmacies and other types of drug stores. Typically, the latter are not allowed to sell prescription-only medicines, are not required to employ a pharmacist, and are not obliged to be able to supply the full range of medicines. In many LMIC, there is an informal tier of drug selling as well and widespread availability of prescription-only medicines without prescription in

pharmacies, drug stores and informal outlets. The two-tier system of regulation has the potential to increase availability and increase price competition. But in LMIC, the illegal sale of prescription-only medicines through these outlets increases risks of inappropriate and harmful use and loss of quality control in the supply chain. The existence of this more lightly regulated or unregulated tier of medicine selling can have the effect of forcing down the margins on popular, high turnover medicines, and reducing the market share of licensed pharmacies. If there is no price regulation, this might be expected to widen the range of prices observed for a given product and its generic substitutes in the market, and may increase market segmentation and the prices of originator and premium brand because the licensed pharmacies may be forced to reduce their mark-ups on the products that face competition and will seek to recover their overheads from products that do not face competition.

4.2.3 Restrictive regulation of wholesaling or distribution and vertical integration

Wholesaling and distribution exhibit economies of scale. In smaller countries in particular, this can result in an oligopoly situation that may require monitoring of wholesale costs and margins, market analysis and the capacity to intervene through competition law if necessary. Some upper income countries mandate that all wholesalers must be 'full-line' i.e. able to supply any licensed product to retail pharmacies, clinics or hospitals. This enables full-line wholesalers to cross-subsidize distribution of faster moving and slower moving products, but reduces competition by 'short-line' wholesalers who may be more agile in taking advantage of price arbitrage opportunities.

Some countries ban vertical integration between wholesaling and retail pharmacy. Where there is no such ban, or where this type of regulation is repealed, vertical integration commonly develops. These arrangements are not necessarily anticompetitive. There appear to be real business synergies: the OECD countries with deregulated wholesale and retail systems (e.g. USA, UK, Norway since recent deregulation), appear to have achieved among the lowest mark-ups in the distribution chain, together with good geographic availability. These countries have good transport infrastructure and also have specific policies or systems for ensuring the availability of prescription medicines in sparsely populated areas – conditions which do not apply in many LMIC.

Wholesale and distribution in many LMIC is often the section of the supply chain where there is limited competition and high market power. In some countries there is oligopoly and/or sharing out of the market. There are often exclusive distribution arrangements for distribution of imported originator brands and other 'premium' branded generics at high prices, which give the supplier substantial market power. There may be barriers to entry into wholesaling in developing countries that need to be tackled, or lack of effective competition law may be at work.
There are, however, some LMIC where distribution is highly fragmented, with many 'short-line' wholesalers or grocers who deal only in a small and shifting range of discounted products, and many intermediaries and brokers. Although only a small share of the national market, these companies may also have exclusive control over a regional or institutional market segment e.g. a wholesaler controlling the business with a community hospital (*66*). While these distributers may compete on price, the set-up makes quality regulation and assurance very difficult, and the inefficiencies resulting from fragmentation contribute to high mark-ups. Sometimes fragmentation is an artefact of regulation e.g. Indonesia's local governments require wholesalers and distribution companies to be registered in the relevant district, inhibiting industry consolidation and adding to costs.

4.2.4 OTC and 'pharmacy only' regulation

Giving medicines over-the-counter (OTC) status can increase price competition for these products via several mechanisms and it increases the number of outlets selling the products making it easier and cheaper for consumers to access them. OTC prices are usually unregulated in OECD countries even where prescription medicine prices are regulated. Additionally, many OECD countries permit price advertising for OTC medicines. An increasing range of essential medicines have been classified as OTC in many upper income countries over the past 25 years, although there is variation across countries in this classification. This trend has partly been driven by a desire to reduce costs of medicines in publicly financed health systems, but it has also been underpinned by analysis of the effects on costs and benefits, benefits and risks. Studies of pharmacy regulation in EU countries identify savings in cost and improvements in availability from expansion of use of OTC classification and expansion of sales outlets (*48*). A European Commission directive provides guidelines to its member states on the criteria to be used in determining whether a medicine justifies 'prescription only' status in order to encourage an appropriate balance between competition and ease of access on the one hand, and risk management on the other. Some countries also have regulations limiting some or all OTCs for sale by pharmacies or under pharmacist supervision, which also limits access and reduces price competition.

There is a need for more research of whether and how this benefit/risk trade off might differ in LMIC contexts where there are lower levels of education and literacy and limited availability of pharmacists and pharmacy assistants, and where the affordability of OTC medicines for the poorest might be expected to affect the impact of regulation.

4.2.5 Unintended effects of some forms of price regulation on competition

Studies of price regulation in European Union countries find that medicines price controls reduce price competition because the regulated price becomes the market price; it acts as a floor, not just a ceiling. The regulated price becomes a mechanism for suppliers to coordinate pricing – a form of tacit collusion – with prices clustering closely around the regulated level and no incentive for suppliers to price below this. It is more profitable for them to compete on other dimensions, such as by promoting their brand or reputation for quality through detailing, to increase market share, or by paying bonuses to distributers to compete for shelf space, crowding out competitors (*67*). In Canada, price regulation that requires generic entrants to price down by a specified percentage below the originator brand was found to result in prices clustering around the regulated limit (*68*). Regulation in India that required maximum retail prices (set by the industry association) to be printed on the pack has also been found to lead to clustering of prices around this level, and reduced competition (*69*).
Price regulation sometimes inadvertently sets the price ceiling below the costs of production for some suppliers, or at levels that are less profitable for retailers and prescribers than alternative products. In these cases, there will be a withdrawal of suppliers from the market or retailers will not stock the low priced products. This will in turn reduce competition. This appears to have occurred under China's 'reduced price' policy which led to successful rounds of price cuts on manufacturers and distributers based prices on 'social average cost' criteria. Alternative forms of regulation are now under discussion (*70*).

Regulation of wholesale and retail margins at a standard percentage rate may have similar effects. In particular, it may discourage distribution and stocking of low cost generics because the margin on these products may be less than the distribution costs

and so undermine price competition. The effects may be more marked in remote locations with higher distribution costs and lower product turnover.

As discussed above, some forms of price regulation are designed to permit or encourage competition (some forms of internal reference pricing), although there is evidence that this type of regulation can attenuate generic price competition over time (*17*).

5. South Africa case study

South Africa adopted a new Competition Act (No.89) in 1998 after an intensive and inclusive policy-making process. The Apartheid era in South Africa had seen the emergence of an industrial structure that was highly concentrated in the hands of a relatively small number of white-owned conglomerates. Although there was a competition law in place during this period, its provisions were not best-practice and enforcement was weak. After the end of the first democratic elections in 1994, reforming and enforcing competition law was seen as important not only for creating impetus for companies to become more efficient and internationally competitive, but also for diluting concentrated economic power and increasing the opportunities for growth of black-owned businesses (*71*).

South Africa's Competition Act includes equity and distributive goals in addition to its primary purpose of increasing economic efficiency. These include promoting competition in order to provide consumers with competitive prices and product choice, measures to ensure small and medium-sized enterprises (SMEs) have equitable opportunities to participate in the economy, and promotion of business ownership by historically disadvantaged people (*72*). The Act explicitly addresses many of the concerns often cited by LMIC governments about whether competition law might inhibit efficient consolidation and growth of small enterprises to achieve economies of scale and international competitiveness. In the interests of good governance, the Act took away ministerial power to override the decisions of the competition authorities, which had existed during the Apartheid era.

The Competition Commission has ruled on health sector competition issues that have implications for the pharmaceuticals market. In 2004, the Commission ruled that private medical insurance schemes could no longer engage in collective negotiations over reimbursement prices with the associations of hospitals, doctors and other healthcare providers: it took the view that these negotiations amounted to collusion. The Department of Health now proposes to seek a limited exemption from the Competition Act to enable it to lead a steering group to negotiate a health price tariff in a process that seeks to be fair and reasonable to both payers and providers. The Competition Act permits exemptions to be granted for collective action of this sort where there is "a non-commercial socioeconomic objective"[a]. The Department has argued that a socioeconomic rationale arises because "the private market for healthcare suffers from a number of systemic market deficiencies" which, if not addressed ... will undermine access to healthcare in South Africa" (*73*).

In the decade since the Act was adopted, the Competition Commission, together with other involved authorities in South Africa, has successfully applied the Competition Act to a range of different cases in the pharmaceutical sector, covering originator brand and generic manufacturers, wholesale and distribution arrangements, retail pharmacy, and public procurement. These are summarized below.

[a] Competition Act section 3(1)(e). South Africa Competition Commission www.compcom.co.za

5.1 Pharmaceuticals sector cases pursued by the South Africa Competition Commission

5.1.1 Exclusive distribution arrangements opposed by wholesalers

In South Africa, pharmaceutical wholesalers traditionally supplied all prescription medicines, over-the-counter medicines and a range of other consumer products to retail pharmacies. Wholesalers purchased medicines from manufacturers at a discount of 17.5% of the manufacturer's list price, and kept a margin of 5%-7% of the list price as the wholesale margin. However, for hospitals and the State, manufacturers sold and distributed directly to the end user, without any role for wholesalers (*74*, *75*).

In 2001, a number of pharmaceutical wholesalers submitted complaints to the Competition Commission about an exclusive distribution arrangement that had been established in South Africa by a number of major multi-national pharmaceutical manufacturers. These manufacturers established a joint venture company (JVC) *International Healthcare Distributors* (IHD) in which they each held an equal shareholding, to be the exclusive distributor of their medicines in South Africa. The JVC would only sell to wholesalers at the same price that it sold to retail pharmacies and hospitals so there was no possibility for wholesalers to earn a margin on sale of these products. The wholesalers argued that this effectively excluded them from the market. Unlike wholesalers, the JVC did not own the medicines it distributed – these remained in the ownership of the manufacturer until they were sold to the retail pharmacy or other end user.

The Competition Commission's investigation found evidence that the IHD joint venture may have facilitated collusion by the manufacturers that owned it, and the vertical linkage IHD had created between manufacturers and the distributor involved restrictive practices that reduced competition. The Commission negotiated a settlement agreement under which the manufacturers would dispose of their ownership interests in IHD and pay a settlement of 2 million Rand.

However, the complainants appealed the Competition Commission's settlement and the case was referred to the Competition Tribunal. The Tribunal first upheld the wholesalers' complaint. The decision was again appealed. By the time the Tribunal heard the case for a second time, the manufacturers had sold their interests in the JVC, but they continued to contract with the company under its new ownership to be their exclusive distributor. On its second hearing, the Tribunal set aside the wholesalers' complaints.

In presenting its decision, the Tribunal noted that there has been a trend in other sectors (notably grocery) for the wholesaler's intermediary role to be squeezed out as retailing consolidated into larger chains (the supermarkets) with greater purchasing power, that are strongly motivated to pursue lower prices for consumers. The Tribunal noted that there has been steadily increasing pressure to reduce pharmaceutical prices in South Africa as in many countries – pressure from emerging retail pharmacy chains, from managed care in the health insurance sector, and from public funders. These larger purchasers of medicines do not have much need for the services of wholesalers unlike the traditional small independent retail pharmacy which has less capacity to finance and store inventory and more difficulty in forecasting its medicine purchases. In these changing market conditions, it is to be expected that manufacturers whose own pricing is under pressure will look for opportunities to reduce costs and margins in the

downstream distribution chain. The Tribunal noted that this is not necessarily sinister - it can be a driver of increased efficiency in distribution. Rather than reducing competition, this may be a response to the competitive processes and rising purchaser power within the pharmaceuticals market – to the potential benefit of consumers. Additionally, this JVC is not dominant in the market for distributing pharmaceuticals.

5.1.2 Applying the Competition Act's public interest provisions: Ring Pharmacies case

Ring Pharmacies is an association of 33 individually owned pharmacies, some of which serve rural and poorer areas that are unattractive to the large chains of pharmacies which have proliferated in urban areas in South Africa. The association applied for an exemption from the Competition Act so that they could conduct joint marketing activities in order to enable them to achieve economies of scale and compete with the big pharmacy chains. The Competition Commission granted a five-year exemption based on the Act's commitment to ensure equitable opportunities for small and medium size enterprises to develop, and also the benefits to consumers of access and availability of medicines in some communities not targeted by large pharmacy chains (*72*).

5.1.3 Acquisition of several pharmacy chains by a single company

The Competition Commission reviewed the proposed acquisition by a single company (Clicks Organization (Pty) Ltd) of four other companies which together owned and controlled 83 retail pharmacies nationwide, operating under six different brand names. The issue was whether this would lead to a significant lessening of competition in the market. In this case, the Commission concluded there would not be a significant reduction in competition and approved the acquisition and merger of the pharmacy chains.

This type of case is important in countries like South Africa and many upper income countries which have deregulated ownership of retail pharmacy to allow development of retail chains (subject to continuous pharmacist supervision in each outlet). Chains can achieve considerable economies of scale, bringing benefits to consumers, but it is important to use competition law to prevent any single chain from becoming too dominant in any one geographic area, which would run the risk of reduction of competition, leading to excessive prices.

5.1.4 Pharmaceutical cartels: collusion among bidders in State tenders and market-sharing agreements

The Competition Commission investigated a cartel involving four local manufacturers who colluded in bidding in State tenders to supply parenteral fluids and administration sets to Department of Health (DOH) hospitals between 1999 and 2007. The value of the tenders was about 713 million Rand in 2007 alone. The Commission also uncovered collusive tendering and division of the private hospitals market by the companies. The Commission's settlements with the guilty parties included fines on annual turnover ranging from 5%-8% and agreement by companies to implement a compliance programme to prevent future misconduct.

The Commission has extensive powers to investigate cases of price-fixing and cartels including powers to search without warrant, obtain documents and other information, and issue summons. It also has the power to exercise leniency against companies that cooperate with its investigations – an important tool for detecting collusion. In this case, one company cooperated with the authorities and confessed involvement in the

cartel in return for immunity from prosecution. The Competition Act is now being amended to criminalize price-fixing, which will enable jail sentences to be imposed in this type of case in the future (*76*).

The DOH publicly welcomed the Competition Commission's role in uncovering the cartel and commissioned an audit to assess the extent of overcharging and potential for recovering damages. The DOH also stated that there is a risk that there are other cases of collusion among companies bidding to supply the public sector. Based on the Competition Commission's actions in this case, the DOH called for other pharmaceutical suppliers to confess to such practices in the public interest and expressed the hope that this case will deter collusive behavior in the future (*40*).

5.1.5 Abuse of dominant position case: GlaxoSmithKline and Boehringer Ingelheim

In 2002, the AIDS Law Project filed a complaint with the South Africa Competition Commission on behalf of four people living with HIV/AIDS, four healthcare workers, the Treatment Action Campaign and two other organizations. Other parties, including the AIDS Consortium, later joined the case. The complaint was that GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) were charging excessive prices for certain antiretroviral medicines (ARVs) to the serious detriment of people for whom these medicines are essential and life-saving. The complainants argued that the prices were excessive, even after allowing for the costs of research and development, licensing fees, and higher profits to create incentives for innovation. It is important to understand that this case deals with originator brand products produced under compulsory licensing provisions because of their high public health importance. For these reasons, it almost certainly cannot be interpreted as setting a precedent for all on-patent originator brand medicines.

After carrying out its own investigation, the Competition Commission concluded that there was evidence of excessive pricing (prohibited by law) and evidence of other anti-competitive behaviour that it considered to be in breach of the 1998 Competition Act. It found that GSK and BI were using their exclusive patent rights to deny licences to appropriate generic manufacturers in South Africa and were restricting sales in ways that reduced competition and availability, and enabled the companies to maintain their prices at excessive levels:

- Each company licensed only one company (Aspen Pharmaceuticals) in South Africa to manufacture the ARVs in question, thus preventing proper competition among generic manufacturers that would help to ensure efficiency and provide downward pressure on prices.

- Aspen had not registered the relevant ARVs at the time with the South Africa Medicines Control Council so they could not yet be sold in South Africa. Additionally, other generic manufacturers had already registered a combination tablet of three ARVs that would improve treatment adherence. By refusing licences, GSK and BI were using their patent rights to prevent these other companies from distributing ARV combination products – including the GSK and BI ARVs in South Africa – thus depriving patients of products that can increase compliance with treatment regimens.

- Additionally, the terms of the licences did not allow the manufacturer to produce and sell products to the private health sector. A large percentage of

South African patients – including many poor, rural patients - rely on private doctors and private pharmacies for accessing medicines. At the time, it was expected that it would take at least five years before the public and NGO sector could have ensured availability nationwide.

- GSK's licence prevented Aspen from exporting its ARVs even to the public sector in neighbouring countries, and BI's licence limited exports.

Based on this evidence, the Competition Commission referred the case to the Competition Tribunal for adjudication – the next step in the process provided under the Competition Act. Soon after referral, the Competition Commission was able to conclude a settlement agreement with GSK and BI. The Commission believed that the settlement addressed the issues and achieved similar results to those it hoped to achieve through the Tribunal process but in a much shorter time frame and at lower cost to all the parties.

Specifically, under the terms of the settlement:

- GSK agreed to grant licences to four generic manufacturers and BI to three generic manufacturers in South Africa, to produce and/or import, distribute and sell the ARVs that were the subject of the complaint to the Competition Commission;
- Both GSK and BI agreed to reduce their licence fee to 5% from pre-settlement rates of 30% for GSK and 15% for BI;
- The licences allow for sale to the private sector as well as the public sector, and for export to all sub-Saharan African countries;
- The licences cover adult and paediatric formulations;
- The licences also allow for use of these ARVs in the manufacture of fixed dose combination ARVs (provided the manufacturer holds licences for other active pharmaceutical ingredients in the combination). This enabled therapeutically important triple therapy combination products to be produced by some of South Africa's generic manufacturers using the post-settlement licences from GSK and BI, together with licences that Bristol- Myers Squibb had already issued voluntarily.

This landmark settlement in 2003 achieved all of the main measures needed to harness competition to increase the availability and affordability of ARVs in South Africa and the region. At the same time, the Competition Commission sought to respect patent holders' rights (*20, 77*).

5.2 The role for pharmaceutical price monitoring and its relationship to application of competition law in South Africa

The pharmaceuticals sector is one of two sectors (the other is food) in which the South African government has established a separate committee or body to monitor prices and make recommendations on responses that may be needed by the competition authorities, the health and medicines authorities, or other agencies. This reflects a judgement that reliance on pursuing cases under competition law – though demonstrably beneficial - may not be enough on its own to safeguard consumers against anti-competitive behaviour in these sectors (*70*). The decision to create a special price monitoring mechanism recognizes the need to be pro-active in monitoring potential problems in the pharmaceuticals market because these are essential goods which have a major impact on health and poverty. This pro-active monitoring can also assist the competition authorities to identify strategic priorities: which cases it should pursue in order to have the greatest impact. While this is an important issue for all competition authorities it is particularly important for new authorities with limited resources given the high cost and time involved in pursuing competition law cases. The price monitoring committee brings in additional resources and specialized health and pharmaceuticals sector expertise beyond those available to the competition authority. The committee can also help to foster a comprehensive and consistent approach in using a range of different policy and regulatory mechanisms to influence prices and access to pharmaceuticals: this requires coordination between competition authorities and the government's health and pharmaceuticals authorities.

5.3 The role for pharmaceutical price regulation and its relationship to application of competition law in South Africa

The South Africa DOH sought to introduce pharmaceuticals price regulation – what it calls 'single final exit price' regulation – under the Medicines and Related Substances Act in 2004-05. The DOH was concerned about lack of transparency as well as evidence of a high level of discounting and payment of incentives within the pharmaceuticals supply chain. This behaviour was evidence of a form of competition within the supply chain that did not benefit consumers. Retail pharmacies and dispensing doctors were able to capture the benefit of discounts and incentives while patients continued to pay the official manufacturers' listed price. The DOH initially proposed to impose price regulations that would reduce the listed prices of medicines by 50% across the board.

In South Africa – in line with recommended good practice – decisions on price regulation in specific sectors should be coordinated with the Competition Commission, which is able to provide analysis of the state of competition in the market, and alternative ways of stimulating competition. In this case, the Competition Commission advised against the across-the-board price regulation. The Commission advocated that greater use should be made of mechanisms in existing legislation that would have increased price competition including compulsory licensing, parallel importation and generic substitution. However, the DOH was concerned that even if competition was increased at the manufacturer and product level by these types of measures, it would still be difficult to transmit these benefits into greater competition and lower prices at the pharmacy/dispensing level. Patients rely on doctors and pharmacists for advice on what medicine to purchase. There is evidence that the advice of doctors and pharmacists is influenced towards prescribing and dispensing the medicine on which they make the most profit. Unless the incentives in the supply chain could be changed, doctors and pharmacists will

not always substitute the generic which is lowest priced for the patient but rather dispense the most profitable medicine in many cases.
Following exchanges of views with the Competition Commission, the DOH decided to adopt regulations to ban non-transparent discounts and incentives, and to require any future medicine price increases to be subject to DOH approval. The DOH also regulated the wholesale, distribution and retail margins for medicines above a minimum price level. The DOH also decided to enforce more stringent regulation to prevent doctor dispensing except in cases where the doctor was issued with a 'certificate of need' to confirm that they served patients in areas distant from a pharmacy.

In this case, the Competition Commission and the DOH did not completely agree. The Commission made a case in favour of strengthening competition, and pointed out the risks of unintended effects of direct price regulation. The DOH argued for regulation from the point of view of specific health sector concerns about lack of consumer information, and patient reliance on doctor and pharmacist advice. The final decisions taken represented a middle way – the regulations were more tightly focused on addressing the problem of undesirable incentives for prescribing and dispensing than the initial proposal for across-the-board price cuts and price controls. Litigation by affected industry interest groups delayed implementation of the regulations, so at the time of writing, no evaluation evidence was available of the impact of the new regulations. Future evaluation of the effects of these regulations on competition, market behaviour and on prices will be of interest to many other middle income countries.

5.4 Discussion and lessons

5.4.1 General lessons

South Africa's experience highlights the importance of the wider political economy and reform context to the effectiveness of implementation of competition law in LMIC. The conditions during the Apartheid era were not conducive to competition – highly concentrated industry and economic power, distorted regulation and trade – but were similar to conditions in a number of middle income countries. The end of Apartheid and the enfranchisement and empowerment of the majority of the population created conditions in which there was strong political will to tackle these problems. South Africa adopted and implemented the law as part of a comprehensive package of microeconomic reforms that also addressed trade, industry development, labour market policies and equity-oriented policies.

South Africa also put a lot of effort into consultation and communication about the policy to build wider understanding of how competition and the competition law could be used to achieve various policy objectives. The context and the consultative process produced a law that included a broad range of public interest objectives in addition to the core objective of promoting economic efficiency through competition, although these objectives can – and are – pursued by other policy instruments. This was important for addressing a range of concerns commonly voiced in LMIC about competition law – such as concern about the development of poor, informal, small businesses, and concern about the need for local businesses to expand to achieve economies of scale so as to become internationally competitive. But in order to ensure that these broader objectives and trade-offs did not lead to inconsistent or non-transparent decisions, the Competition Act explicitly defines four public interest pillars: the development of small and medium-sized enterprises and black empowerment; employment; impact on a particular industry or region; and the ability of national industries to compete internationally. It places bounds on how public interest issues can be considered and applied in the context of competition law. This recognizes that promotion of public interest objectives may often be better achieved by other policies (*72*).

South Africa also focused on building capacity in its Competition Commission. Using competition law effectively requires a type of interdisciplinary expertise in law and economics which many LMIC lack. Application of the law also requires cooperation between lawyers, economists and sectoral experts. South Africa has made good use of global institutions and networks that provide technical support and learning opportunities for smaller and newer competition authorities such as the OECD.

5.4.2 Specific lessons for competition law and the pharmaceuticals sector

The Competition Commission and Competition Tribunal have tackled a number of strategically important cases at every level in the pharmaceuticals supply chain in its first 10 years of operation. These include patent-protected originator brands produced by multinational companies, licensed local manufacture of patent-protected brands, generic manufacturers, wholesaling and distribution, and competition and consolidation among retail pharmacy chains. Its cases have produced benefits for the public sector (addressing collusion in public tenders) as well as for consumers/patients in the private sector.

It was particularly important for South Africa to demonstrate that competition law can be applied to the market for patent-protected medicines and to do this in an area of high public health importance - ARVs for the treatment of HIV/AIDS. This case highlights that patent rights do not entail a right to monopolize the market for the patent-protected medicines to the detriment of consumer access.

A key lesson from South Africa's experience in the first decade of implementing its new law, is that both consumer groups and the Competition Commission itself need to exercise care when considering which cases they should pursue in order to set important precedents that can be used to guide behaviour in the sector. Legal cases are costly and take time, but their impact can be increased by strategic selection of cases, and by using public education and information to advocate for the wider pharmaceuticals sector to comply with the principles and guidelines established by these landmark cases.

Additionally, South Africa has demonstrated the potential benefit of using international donor and technical resources to support legal action under the Competition Act – using the support of the AIDS Law Project and advocacy and support organizations for people with HIV/AIDS.

South Africa's case also demonstrates that competition and competition law are not enough on their own to address some of the problems that undermine competition in pharmaceutical markets, although it is helpful in tackling anti-competitive behaviour among manufacturers, wholesalers/distributers and pharmacy chains. But competition law on its own is not able to address some of the problems that occur in the interface between patients, doctors and pharmacists. Where many patients are paying out-of-pocket for their medicines, and where there is a high level of doctor dispensing, the private market for medicines is very imperfect. Patients rely on doctors' advice, but there is evidence that doctor and pharmacist advice can be biased by financial incentives created by suppliers of medicines. Tackling these problems requires complementary measures to be adopted by health and pharmaceutical authorities.

South Africa has used a range of remedies under its competition law to deter anti-competitive behaviour, including substantial fines, requiring divestment of parts of a company, and undertakings from the companies to change their business conduct. It is likely to adopt stronger remedies – including criminal sanctions – in the future. Among the remedies provided in the competition law are price monitoring and price restraint. South Africa has decided to establish a specific body to monitor pharmaceutical prices. Price monitoring and analysis is complementary to competition law – it can be used to identify priorities for investigation by the Competition Commission.

South Africa – like most OECD countries – also has specific pharmaceuticals legislation that permits price regulation. In line with recommended good practice, South Africa has institutionalized coordination between the Competition Commission and the DOH's medicines price regulation authority. The two agencies do not always fully agree on the need for price regulation or the form it should take, but the quality of policy analysis and the evidence base for policy decisions for price regulation have undoubtedly been improved by the involvement of both agencies, each with specific strengths in terms of capacity, knowledge and analytical skills. In South Africa, price regulation is not seen as a substitute for competition and competition law – both are viewed as having an important role to play.

6. Conclusions and lessons

Countries with well-developed and enforced competition laws have been able to use these laws to address anti-competitive practices that can occur at every stage of the pharmaceutical supply chain and which result in wrongfully high prices or restricted availability of essential medicines. Estimates of the costs to consumers and public health authorities of anti-competitive practices in these countries are high. Some countries have been able to use competition law to impose financial penalties on offending companies, and to use these funds to compensate consumers and state health programmes that have been harmed by excessive prices. The body of case law and analysis from larger OECD countries provides good evidence for the potential benefits of effective use of competition law for improving access to medicines through competition.

It is difficult for LMICs to implement good competition law regimes effectively until certain pre-conditions are in place:

- the judicial system is functioning with adequate independence and competence;
- third party enforcement of contract, law and regulation is able to be exercised without undue political or industry interference; and
- there is adequate human and budget resource for the competition and regulatory authorities (*2*).

South Africa's competition law has been applied to landmark cases involving multinational companies, local generic manufacturers, wholesaling/distribution, private sector retail pharmacy, and public procurement. Other middle income countries, and low income countries with sufficient general institutional capacity in their legal and regulatory systems could learn from South Africa's experience with building specialist capacity, developing clear and consistent implementation of competition law, and choosing strategically important cases to create precedents and guidance to improve the functioning of effective competition.

There is some theory and evidence that in countries with weak legal systems and state institutions, powerful concentrated business interests, and lack of political will to confront these interests, competition law may only deter those without connections and enrich unscrupulous bureaucrats (*3*). In these countries, other policy levers may be more feasible and effective in promoting generic competition (e.g. increasing openness to imports of quality-assured generics, deregulation to allow consolidation of retail pharmacy so as to increase the power of the consumer-end of the supply chain to obtain discounts from suppliers).

Competition law has been demonstrated to be effective in tackling a range of anti-competitive structures and behaviour among manufacturers, wholesalers/distributors and retail pharmacies. However, it is difficult for competition law to tackle problems that arise from the problems that consumers – and doctors and pharmacists – face in assessing the quality of medicines in the market. It is also difficult for competition law to tackle problems that arise between consumers/patients and doctors or pharmacists if the advice of healthcare providers is influenced by earning profits from sales of medicines or unethical marketing incentives.

Alongside competition law, there is a range of complementary policies that health and pharmaceutical sector ministries and authorities need to adopt in order to tackle these problems and make competition more effective:

- Credible regulation of the safety and quality of medicines, including low-cost, timely, transparent product registration, e.g. abridged documentation requirements for generics, recognition of regulatory decisions by and for countries with 'hard' regulatory agencies;
- Openness to trade in quality-assured generic medicines and low/zero tariffs;
- Avoidance of policies that impose unnecessary costs on suppliers of medicines e.g. mandating that international companies manufacture medicines locally can lead to unnecessary costs except in larger countries with adequate technical capacity;
- Competitive, transparent public procurement;
- Competition in distribution/wholesale, and competition and consolidation in retail pharmacy/ dispensing;
- Provider payment policies that make healthcare providers price-conscious and align incentives in the supply chain with goals of rational use of least-cost, quality assured essential medicines;
- Effective monitoring systems to control against fraud, ensure providers are not able to manipulate systems of price regulation and provider payment to their own advantage, and adjust policies over time in the light of implementation experience.

With the above policies in place, it should be possible to achieve effective competition in the institutional markets for pharmaceuticals. However, the market for sale of medicines to uninsured patients who pay for medicines out-of-pocket (which is the largest part of the pharmaceutical market in most developing countries) is still likely to exhibit a wide range of prices between heavily marketed originator brands and branded generics, and low-priced generics, with many consumers paying more than they need to.

Consumers do not treat branded medicines and generics as perfect substitutes, whether due to poor information, risk aversion about quality, mistrust of regulatory enforcement, responsiveness to advertising, or reliance on the advice pharmacists and doctors who are influenced by profits from medicine sales or pharmaceutical promotion. In addition, market segmentation strategies by brand name suppliers which enable them to charge different prices for the same medicine, are likely to be more widespread in countries with very unequal income distribution (*78*). And the price premium of originator brands and reputable, heavily marketed branded generics is likely to be much greater in countries where the national medicine regulatory agency is not effective or credible in assuring the quality of medicines in the supply chain.

Complementary policies to support consumer participation, education and advocacy may be able to counteract some of these impediments to competition, and increase the potential for competition to deliver lower prices. Such policies include:

- Public support for consumer advocacy organizations;

- Provisions in competition law and regulations for competition authorities to give greater consideration to consumer interests and consumer/demand-side concerns (rather than market structure and conduct of companies), for products or services such as medicines where consumers are not well informed or well placed to search for better price/quality purchases;

- Public support for generic advertising/promotion/education;

- Regulation of advertising, detailing and other forms of pharmaceutical promotion;

- Putting increased information on prices, availability and quality into the public arena to increase transparency, as a catalyst for policy change;

- Moving beyond self-regulation of industry and self-regulation of professional ethics to achieve better enforcement of ethical codes by consumer representation or other mechanisms to give greater weight to the interests of patients and payers.

In addition, many countries have concluded that there is a role for pro-active medicine price monitoring and analysis (which complements competition law), and for price regulation for medicines dispensed through retail pharmacies. Some forms of price regulation do combine elements of competition with regulation, but institutional purchasers of essential medicines, including social or private health insurers, may be able to achieve lower prices for multi-source essential medicines by using competition rather than by using price restraint. Institutional purchasers can reduce prices for on-patent products that have close therapeutic substitutes or are 'me-too' medicines by inducing competition for formulary listing.

It is regarded as good practice for competition authorities and pharmaceutical price regulatory authorities to have some formalized arrangements for coordination or joint competency. Competition authorities can provide health authorities with expert advice on the potential risks of unintended anti-competitive effects found in the detailed design of pharmaceutical regulation and in its implementation. Health and pharmaceutical authorities have an important role to play in providing health-sector expertise as an input to the decisions of the competition authorities.

Some forms of regulation, including some forms of general (multi-sectoral) price and market regulation regimes and pharmaceutical sector regulation, reduce competition and raise prices in undesirable ways that do not produce net social benefit.

There is evidence from both OECD and developing countries that some forms of retail pharmacy regulation (e.g. location or ownership restrictions, bans on formation of chains and vertical integration, barriers to entry into pharmacy profession, restrictions on sales of some OTC medicines to 'pharmacy only'), can increase medicines prices, and removal of these regulations can reduce prices without harm to patients. However, pharmacy deregulation leads to consolidation which calls for pro-active application of competition policy to balance the benefits of economies of scale against the risks of loss of competition. In countries where the State is weak or lacking in transparency and vulnerable to corruption, there is documentation of pharmaceutical industry incumbents exercising undue influence on State authorities to adopt anti-competitive regulation or anti-competitive implementation of regulation (*1*).

Even in the absence of effective competition law, there can be value in using market studies of the sort that competition authorities conduct to assess the state of competition, as a basis for formulating policy recommendations covering a broader range of possible interventions/actions than solely the remedies of competition law.

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