

## USING COMPETITION LAW TO PROMOTE ACCESS TO MEDICINES AND RELATED HEALTH TECHNOLOGIES IN LOW- AND MIDDLE-INCOME COUNTRIES

### Key messages

- Competition law can be used to promote increased access to medicines and other health technologies as an additional tool to complement other areas of law.
- Countries have successfully used competition law to improve the price, availability and transfer of health technologies. However, it is one of the least discussed flexibilities within the *Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)*.
- Greater use of competition law is recommended by the United Nations Secretary General's High-Level Panel on Access to Medicines, as well as by the Global Commission on HIV and the Law.
- The effective use of competition law can contribute to various Sustainable Development Goals (SDGs).

### Introduction<sup>1</sup>

Access to health technologies – such as medicines, vaccines, diagnostic tests and medical devices – is a fundamental human right. It plays a critical role in sustaining and scaling-up prevention, treatment and care services, particularly in relation to the intensifying double burden of communicable and non-communicable diseases that many low- and middle-income countries (LMICs) now face. Access to health technologies has significant implications for the right to health, eradicating poverty and reducing inequalities and exclusion, which are

central to the 2030 Agenda for Sustainable Development and the Sustainable Development Goals (SDGs). Countries should use all available means to promote access to health technologies, including the use of competition law.

The growing commitment to achieving universal health coverage (UHC) [1] – now an integral target of the SDGs and a proven measure for health improvement, poverty reduction and economic growth – will lead to increased demands for not only existing health technologies, but also for newer, more effective, less toxic and safer ones. But new health technologies may be excessively priced and consequently unaffordable in LMIC settings. In turn, restricted access could ultimately harm the effectiveness, financial sustainability, equity and, as a consequence, the credibility of UHC as a whole.



Photo: Natasha Scripture/UNDP

<sup>1</sup> Unless otherwise referenced, the texts for this Issue Brief are mostly based on UNDP publication *Using competition law to promote access to health technologies: A guidebook for low- and middle-income countries*, available for

download at <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html>

Countries also face increasing public health, financial and social burdens as a result of non-communicable diseases (NCDs) such as cancer, diabetes and heart diseases. Treating NCDs often requires long-term use of costly health technologies, including medicines and medical devices. The growing impact of NCDs is further compounded by persistent health and socioeconomic burdens resulting from neglected tropical diseases (NTDs) and infectious diseases such as tuberculosis (TB), malaria and HIV as well as the emergence of drug resistance to the most more affordable, first-line medicines used to treat HIV [2, 3].

At the same time, middle-income countries are experiencing shrinking financial and policy space to secure access to health technologies. For example, they are increasingly expected to rely on domestic resources to finance national development efforts [4], including health. Global health financing mechanisms that have successfully promoted access to health technologies for many years such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the Vaccine Alliance GAVI are gradually becoming less accessible to many middle-income countries.

Furthermore, LMICs face growing political hurdles to use certain legal measures – such as compulsory licensing – to enable greater access to health technologies. Proliferation of bilateral and regional free trade agreements negotiated outside of the World Trade Organisation (WTO) framework may further narrow countries' policy space through the adoption of various restrictive provisions that go beyond WTO requirements [5].

In this context, LMIC governments may need to look for additional policy space to tackle evolving needs in each of these areas and to safeguard access to essential health technologies. The utilization of competition law can provide an alternative opportunity that draws on both industrial policy management and consumer protection approaches.

In principle, competition law is designed to protect consumer welfare and promote industrial and economic development through restricting or regulating unfair business practices, abuse of market dominance and excessive concentration of economic power.

While competition law does not in itself provide the financial resources necessary to procure and supply health technologies, by promoting greater competition and reduction of corrupt practices it may constrain prices and ensure efficient use of public resources. Competition law can also help stimulate the quicker introduction of new and improved health technologies. These positive effects of competition law will in turn advance the human rights, health, and development objectives enshrined in the SDGs.

Given such potential, the Global Commission on HIV and the Law, an independent panel of prominent leaders tasked to examine the relationship among human rights, law and public health in the context of HIV, recommended that “Countries must proactively use other areas of law and policy, such as competition law, price control policy and procurement law which can help increase access to pharmaceutical products.” [6]

### *Advantages of using competition law*

There are a number of important reasons why LMICs may choose to make greater use of competition law and policy to promote access to health technologies.

First, multilateral trade rules allow substantial flexibility in the development and application of competition law and policy. Competition regimes provide considerable flexibility and less political hurdles to overcome as compared with intellectual property rights regimes.

For example, the WTO *Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS)* permits national authorities to address anti-competitive conduct involving intellectual property in ways that are best suited to national interests. The TRIPS Agreement requires that governments make available certain forms of intellectual property rights protection, and sets out some general conditions for that availability. However, it does not significantly restrain national authorities from choosing appropriate approaches to address abuses of intellectual property rights through competition law. In fact, competition law is one of the least discussed flexibilities within the TRIPS Agreement.

Second, as a consequence of accommodating the variety of potential competition approaches, remedies available to address anti-competitive conduct may permit a broader range of remedial action than some other public health-related flexibilities, which may be associated solely with patents.

Third, competition law typically empowers a broad range of affected parties to request or initiate enforcement action without high burdens and risks. For example, enforcement of competition law can be initiated by government authorities, or by affected persons or groups, without the need to demonstrate intellectual property infringement or without being the subject of an infringement claim by an intellectual property right holder. Additionally, damages or penalties can be assessed on the basis of effects on the market, and need not be limited to individual claimants.

Intellectual property law, by way of comparison, may limit remedial or enforcement action to narrowly-defined parties and interests. These limitations may exclude various parties that might otherwise seek to defend the public interest.

### Box 1: What is a dominant firm/ dominant position?

It refers to having sufficient power in its relevant market to raise prices above competitive market prices and maintain those prices for a substantial period of time.

Fourth, competition law may offer scope for embracing excessive pricing or excessive price doctrine [7]. This is particularly relevant in the case of new health technologies, which may be excessively priced. For example, the *South Africa Competition Act* prohibits a dominant firm (see Box 1) to “charge an excessive price to the detriment of consumers,” where ‘excessive price’ is defined as “a price for a good or service which bears no reasonable relation to the economic value of that good or service”, and higher than the economic value (i.e. unreasonably expensive) [8]. Although less explicit, the *Thailand Competition Act* also prohibits a firm with a dominant market position from “unreasonably fixing or maintaining purchasing or selling prices of goods or fees for services.” [9]

Finally, engaging competition authorities can also open a new opportunity for facilitating a multisectoral approach to health and greater policy coherence for human development across different sectors. Since health constitutes an integral part of public welfare that competition law and competition authorities in many countries are mandated to promote, addressing access to health technologies may well enhance the outcomes and credibility of competition authorities.

It is possible that competition law and measures against anti-competitive conduct may not always provide a pathway for promoting access to health technologies. However, as a relatively underdeveloped, yet promising option, competition law and policy should be given greater prominence for its potential to complement efforts in other areas such as intellectual property rights regimes. The 2016 report of the UN Secretary-General’s High-Level Panel on Access to Medicines affirms this argument: “Should governments pay closer attention to competition law, it could serve as an important policy tool for increasing access to health technologies.” [10]

### Anti-competitive conduct

Most competition laws examine anti-competitive conduct in relation to agreements between companies, as well as monopolization or abuse of dominant position. Anti-competitive activity is further viewed as either ‘horizontal’ or ‘vertical’. Horizontal anti-competitive activity refers to conduct among independent companies that are suppliers of goods or services that are in competition, or potentially in competition, with each other. Vertical anti-competitive activity refers to the supply chain controlled by a producer, beginning with inputs to production, intermediate distribution and, ultimately, the retail

sale of goods or services.

Some agreements between companies are so inherently anti-competitive that proof of the existence of the agreement is sufficient to establish a violation. Such agreements are referred to as either *per se* anti-competitive or hard-core competition law violations.

Examples of horizontal anti-competitive conduct that are *per se* illegal in most jurisdictions include price-fixing among competitors, output restraints and allocation of geographic territories (i.e. an agreement to divide markets among competitors) (see also Box 2).

### Box 2: Examples of anti-competitive conduct

- Price-fixing
- Output restraints
- Allocation of geographic territories
- Bid-rigging, corrupt payments
- Buyouts of generic patent challenge, or pay for delay
- Abusive or excessive pricing

Examples of vertical restraints that are *per se* illegal in many, but not all, jurisdictions include ‘resale price maintenance,’ or the fixing of the minimum price at which retailers may sell, and ‘exclusive grant-back’ requirements in which a patent licensee is required to grant back to the patent licensor an exclusive right to make use of any improvement in the licensed invention.

Other types of conduct may initially appear to be anti-competitive, but have an underlying pro-competitive justification. In such cases, competition authorities assess the balance under the ‘rule of reason.’ For a competition law violation to be found, the anti-competitive aspect of the arrangement should outweigh potential pro-competitive benefits. In the case of ‘resale price maintenance’ in some jurisdictions, for example, the court or administrative authority explores whether the benefit to the producer and its distribution network is sufficiently great (e.g. by allowing it to continue producing) to offset the harm to consumers (i.e. through payment of higher prices).

There are significant risks of anti-competitive conduct in the pharmaceuticals market that are fairly widespread and deserve close attention from competition authorities. In fact, competition authorities in many countries have taken a proactive stance to investigate and remedy anti-competitive conduct related to the pharmaceutical sector, potentially affecting the price and availability of medicines, public welfare, and domestic industry development. The following cases

demonstrate the critical role of competition authorities in promoting access to health technologies and protecting public welfare through fair competition, elimination of corrupt practices, and effective law enforcement.

Anti-competitive conduct by patent-owning companies includes the charging of excessive prices, as illustrated in Cases 1 and 2.

### *CASE 1: Abuse of a dominant position to (1) charge excessive prices and (2) refuse licensing on reasonable and non-discriminatory terms (South Africa)*

Two originator pharmaceutical companies were accused of **abusing their dominant positions by charging excessive prices for HIV medicines** and not allowing competitors to import/manufacture generic versions on reasonable and non-discriminatory terms (e.g. a patent license is reasonably priced and granted fairly among competitors).

South Africa's Competition Authority found the two originator pharmaceutical companies **guilty of excessive pricing**,<sup>2</sup> denying a competitor access to an essential facility (i.e. refusal to license in this case);<sup>3</sup> and exclusionary behaviour.<sup>4</sup> The findings led to voluntary settlements and voluntary licensing to generic companies and subsequent **large price reductions** [11].

### *CASE 2: Abuse of a dominant position to charge excessive and unfair prices (United Kingdom)*

The UK Competition and Markets Authority (CMA) in December 2016 imposed its highest fine ever (GBP 90 million, equivalent to approximately US\$ 110 million in total) on two pharmaceutical companies (a brand pharmaceutical manufacturer and a distributor) for breaching competition law by charging excessive and unfair prices for a medicine.

After the distribution rights were sold to this single distributor, **the price of the medicine was raised by up to "2,600% overnight"**. As a result, **the cost to the National Health Service (NHS) increased by 25 times**. A senior CMA official stated: "Businesses are generally free to set prices as they see fit but those holding a dominant position should not abuse this situation and set prices that are excessive and unfair." [12] The pharmaceutical companies were also ordered to reduce their prices within 4 months.

<sup>2</sup> Defined as a price that "bears no reasonable relation to the economic value of the product" and "is higher than the economic value". Article 1.1 (ix) of *South Africa Competition Act*.

<sup>3</sup> Defined as "an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide

Anti-competitive conduct may also include the abuse of the patent system where an originator pharmaceutical company, for the purpose of preventing entry of generic products, applies for and secures a patent with the knowledge that it has made an invalid claim. Case 3 also illustrates the misuse of regulatory procedures.

### *CASE 3: Abuses of a dominant position to prevent or delay market entry of generic competitors through misuse of the patent system and regulatory procedures (European Union)*

The European Commission concluded that an originator pharmaceutical company abused its **dominant position in two ways for the purpose of preventing or delaying generic entry into markets** [13]:

First is the **misuse of the patent system**, where the company provided misleading information to patent offices of several countries in order to obtain an extra period of patent protection. Second is the **misuse of national regulatory procedures**, where the company de-registered the capsule form of a drug in several countries while launching a tablet form of the same drug. This was done for the purpose of preventing generic competitors from registering their generic equivalents of the capsule form of the drug, which rely on clinical data of the original manufacturer with whom the original marketing authorization still exists.

Perhaps the most widely discussed form of anti-competitive conduct by patent owners involves 'buying out' patent challenges by generic pharmaceutical producers that might otherwise result in the early market entry of generic products. Such buy-outs upset the balance that legislators strive to achieve between granting patents and authorizing their challenge to foster competition for public welfare. Similarly, patent-owning companies might pay generic competitors to delay their market entry.

Other anti-competitive conduct in the pharmaceutical sector may include bid manipulation in public procurement of health technologies, whereby a group of potential competitors may agree not to submit bids below a set price and to allocate the 'lowest set price' bid to a particular company (see Case 4). Such activity may also involve corruption or inappropriate payments to government officials who might otherwise report the anti-competitive practice. The costs of such corrupt practices to

goods or services to their customers.' Article 1.1 (viii) of *South Africa Competition Act*.

<sup>4</sup> Defined as conduct "that impedes or prevents a firm entering into, or expanding within, a market, if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain." Articles 8 (c) and 1.1 (x) of *South Africa Competition Act*.

society and the poor could be enormous, particularly in LMICs where medicines typically account for a substantial proportion of out-of-pocket health expenditures (up to 100% in some countries) [14], which impoverish millions of people every year [15].

#### **CASE 4. Illegal kickbacks to doctors, leading to medicine price increase (Republic of Korea)**

The Republic of Korea Fair Trade Commission found that 6 pharmaceutical companies had provided illegal kickbacks/rebates to doctors, nurses, clinics and hospital staff to promote their products. These kickbacks, allegedly amounting up to US\$ 45 million, included free travel and lecture fees linked to the amount of their drugs sold by the doctor, and various gifts such as wines and carpets.

The Fair Trade Commission stated that **these kickbacks harmed consumers by: (1) increasing the medicine price; (2) wastefully diverting resources away from the development of the pharmaceutical industry and innovative drugs [16].**

Another example may involve requiring a distributor or retailer of health technologies to purchase a complete line of products as a condition of purchasing a particular product or products (i.e. a 'tying' arrangement) as well as unfair conduct to drive out competitors (Case 5).

Mergers and acquisitions may also adversely affect product markets by, for example, allowing combined companies to raise prices for medicines previously in competition with each other. Anti-competitive conduct also affects markets for innovation, such as when a patent is illegitimately used to prevent the development of new products not within the scope of the patent, or when patent-owning companies combine to control markets.

#### **CASE 5. Abuse of a dominant position for driving out competitors (China)**

The National Development and Reform Commission of China fined two pharmaceutical distribution companies for violating the *Anti-Monopoly Law* and ordered them to terminate exclusive sales agreements (e.g. restricting the sale of goods or services to the contracted parties). Two pharmaceutical companies made exclusive sales agreements with the only two manufacturers of key ingredients for a popular medicine.

Subsequently, the two pharmaceutical distributors raised the price of the key ingredients by up to 6 times, **leading to an increase in the price of the medicine by up to 5 times.** Furthermore, other pharmaceutical companies affected had to

suspend production due to high ingredients costs, **leading to supply shortage of the medicine in the market [17].**

In addition to the highlighted cases, competition law has also been invoked in Indonesia [18] and Thailand [19] to address alleged anti-competitive conduct related to medicines. While the allegations were dismissed in both cases, they have added important precedents of employing competition law for promoting access to health technologies in developing country contexts.

#### **Remedial measures for anti-competitive conduct**

Remedial actions to address anti-competitive conduct may be initiated by public authorities or private parties. There are various administrative and judicial remedies, including: settlement; injunctions (e.g. an order to refrain from anti-competitive conduct); technology remedies (e.g. compulsory licences); damages (e.g. compensatory payment); and merger and acquisition controls (e.g. blocking orders and divestment orders). Anti-competitive conduct may also be subject to criminal penalties including substantial fines, and imprisonment for individuals.

It is not uncommon for a government to enter into some form of settlement agreement with an accused company, whereby the company agrees to cease its anti-competitive activities and may also make a payment either as damages or as a penalty. Such settlements may be approved and/or supervised by courts.

A judge (or relevant administrative authority) may also direct a violator to undertake affirmative acts intended to remedy the damage it has caused. One such type of order is to provide a license to a third party or parties to use certain technologies. There are also other types of judicial orders or directives that may be issued as remedy. For example, if a pharmaceutical company had been found to be anti-competitively charging excessive prices for its health technologies, the company may be ordered to supply products at a defined lower price (i.e. 'price controls'), as the aforementioned UK example (Case 2) illustrates. This order may be given as an alternative to, or in conjunction with, a compulsory license.

Specific types of remedies may be used to address anti-competitive conduct that is undertaken to block the introduction of generic products. This may include requiring pharmaceutical patent owners to compensate public procurement authorities, generic producers and others for damages caused by the unfair use of patents. Strong consideration should be given to prohibiting patent owners from 'buying out' generic producers' challenges to patent validity or assertions of non-infringement.

## Defining the market – a critical element for assessing the presence of anti-competitive conduct

One important aspect of competition law as it applies to health technologies relates to how a market is defined. This is a critical element in determining whether a given conduct is anti-competitive. The pharmaceuticals market is distinctive in this regard: While there are a substantial number of competing originator companies, some of the products developed and sold by these companies are unique, or comparatively unique. If, for example, an originator company develops a new pharmaceutical product that successfully treats a previously untreatable disease, it may control or dominate the market for that product by virtue of its uniqueness. In addition, that new product will typically be patented, thereby preventing other companies from producing and marketing a substantially identical product.

When considering a potential claim relating to market dominance, it is necessary for competition authorities to determine the relevant market for a patented pharmaceutical product. It is suggested that competition authorities begin by assuming that the patented medicine is unique, focusing on the narrowest therapeutic class (which at the international level is described as Anatomical Therapeutic Chemical (ATC)<sup>5</sup> level 5), and inherently dominant in its relevant market.

The burden then shifts to the originator company to prove that there are acceptable substitutes for the product and that there is competition in the relevant market such that consumers are not unduly burdened with excessive prices as a result of the originator's dominant position.

Dominant position and assessment of the relevant market are also important in the context of evaluating mergers and acquisitions. When two or more pharmaceutical companies combine, they are combining their portfolio of health technologies. Prior to the merger or acquisition, there may have been competition between drugs in the respective portfolios, which would have placed downward pressure on prices. Once the merger or acquisition takes place, the incentive for price competition is removed; the combined company would benefit

the burden of proof to the combining companies to demonstrate that drugs in the portfolio are not in competition, for example, by demonstrating their uniqueness from a market standpoint.

## Challenges

The use of competition law and policy is not without its challenges. Many LMICs have come to the adoption and implementation of competition law fairly recently). They face substantial challenges in effectively using competition law to promote affordable access to health technologies.

There are a variety of components involved in the development of effective competition law frameworks, including the introduction of legislation that is suitable to local conditions; the establishment and operation of competition law authorities; capacity for the investigation and prosecution of cases; mechanisms for the effective engagement of the private sector; and the involvement of civil society in these activities.

Competition law enforcement typically involves investigation of private business practices, which often requires authorities to be equipped to issue and execute demands for documents, testimony etc. A case must be built based on the evidence that has been assembled by the investigation. For a competition law authority to undertake its mission effectively, adequate budget and staffing are therefore critical, as well as the political will for establishing an enabling legal and policy environment. However, competition authorities in LMICs often face budgetary constraints that directly affect their ability to hire and retain qualified personnel and to pursue anti-competitive conduct in the health technologies sector.

There is no simple or common solution to making budgetary resources more readily available to such authorities. But the competition authority may stress that creating a vibrant, competitive economy will cut costs of procurement in some sectors and increase business activity and, therefore, tax revenues. Competition authorities may, to a certain extent, finance their own activities through fees on activities such as

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