



## **Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production**







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# Acronyms

API	active pharmaceutical ingredient
ARV	anti-retroviral
BMZ	Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung
DBE	Development Bank of Ethiopia
DRA	Drug Regulatory Authority
DSB	Dispute Settlement Body
EAC	East African Community
EAC-RPMPoA	Regional Pharmaceutical Manufacturing Plan of Action
ECOWAS	Economic Community of West African States
EML	Essential Medicines List
ERP	External reference pricing
EU	European Union
EFTA	European Free Trade Association
FDI	Foreign Direct Investment
FEAPM	Federation of East African Pharmaceutical Manufacturers
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit (German International Cooperation)
GMP	Good manufacturing practice
GNP	Gross national product
HIV	Human immunodeficiency virus
MRH-EAC	Medicines Registration Harmonization Programme of the East African Community
MSF	Médecins sans Frontières (Doctors Without Borders)
NAFTA	North American Free Trade Agreement
PTIA	Preferential Trade and Investment Agreement
R&D	Research and Development
SADC	Southern African Development Community
SDG	Sustainable Development Goals
TBT	Technical Barriers to Trade
TPP	Trans-Pacific Partnership
TRIMS	Trade-Related Investment Measures
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
WAHO	West African Health Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



# Introduction

Under the 2008 World Health Assembly's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the United Nations Conference on Trade and Development (UNCTAD) was invited as a stakeholder to take action on the issue of transfer of technology in the pharmaceutical area and the local production of health products in developing countries.<sup>1</sup> In response, UNCTAD in cooperation with German International Cooperation (GIZ) is implementing, inter alia, a project on "Access to High Quality and Affordable Medicines in Africa and South-East

Asia", which focuses on the need to provide coherence among domestic policies aimed at promoting local production of pharmaceutical products and access to medicines. The present document is one of the outputs of this project. It draws on a 2011 series of case studies on "Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries", which under a joint project with the World Health Organization (WHO) analyzed selected firms and regulatory frameworks in various countries in Africa, Asia and Latin America.<sup>2</sup>

<sup>1</sup> WHO, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Resolution WHA61.21. Available at <http://apps.who.int/medicinedocs/documents/s21429en/s21429en.pdf>. World Health Assembly, 2008, Geneva (accessed on 13 February 2017).

<sup>2</sup> The case studies were undertaken in Argentina, Bangladesh, Colombia, Ethiopia, Indonesia, Jordan, Thailand, and Uganda. See UNCTAD, "Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries. A series of case studies by the UNCTAD Secretariat", Geneva, 2011 (hereinafter UNCTAD case study series). Available at [http://unctad.org/en/PublicationsLibrary/diaepcb2011d7\\_en.pdf](http://unctad.org/en/PublicationsLibrary/diaepcb2011d7_en.pdf) (visited 26 November 2015). This link comprises all case studies cited throughout this Tool Box.



## Objective of this Tool Box

The present document seeks to provide interested governments with an overview of policy tools that may be considered to create a framework conducive for promoting local pharmaceutical production and access to medicines. As the promotion of local pharmaceutical production depends on the coordination of various areas of policy, such as drug regulation, research and development (R&D), investment, trade and intellectual property, the Tool Box emphasizes the importance of ensuring coherence among policies that at first sight appear unrelated to each other. It seeks to assist policy makers in understanding the cross cutting nature of promoting local production. The Tool Box provides a brief presentation of the most relevant policy tools in this regard.

The Tool Box does not attempt to resolve the question of desirability of local production as compared to the importation of medicines (for a brief background, see the following

section). It is addressed to those governments that have made the policy decision to promote local manufacturing and that wish to prepare a framework for sustainable production and, to the greatest possible extent, increased access to medicines.

The Tool Box is meant to contribute to the Sustainable Development Goals (SDG), in particular SDG 3 (Ensure healthy lives and promote well-being for all at all ages by developing and providing essential medicines in accordance with the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health), SDG 9 (Build resilient infrastructure, promote sustainable industrialization and foster innovation by supporting domestic technology development, research and innovation in developing countries), and SDG 17 (Revitalize the global partnership for sustainable development, *inter alia* by enhancing policy coherence for sustainable development).

## Background: Local production and access to medicines

A number of developing countries and least-developed countries (LDCs), especially in Africa and South-East Asia, have in recent years emphasized the need to promote the domestic production of pharmaceuticals to improve access by their populations to essential medicines. It is important to note in this context that improved access is not only measured in terms of price. On the latter, recent evidence shows that local production may or may not offer lower prices than generic imports.<sup>3</sup> Access can also be improved by adapting existing drugs to specific local needs, such as for the development of heat resistant formulation of medicines, or neglected diseases such as malaria, or by making available to foreign investors the existing local distribution network. Local production may make important contributions in this regard.<sup>4</sup>

A further important consideration may be health security, which has motivated some governments to promote local production of essential medicines and to reduce dependence on imports. For instance, **Thailand** in 2007 initiated a project for the local production of influenza vaccines. This was motivated by the concern that in the case of a pandemic, reliable access to a sufficient number of vaccine doses could not be ensured through importation.<sup>5</sup> Similar concerns were raised by the WHO, which warned against a serious shortfall of vaccine doses in the case of a

worldwide pandemic, and serious implications for import-dependent developing countries.<sup>6</sup>

Health security considerations do not only arise in the context of vaccines. In the area of chemical drugs for life-threatening diseases such as HIV/AIDS or cancer, many developing countries have been relying on the importation of generic drugs, mainly from India. One important reason for the availability of affordable Indian generics was the use by India of a World Trade Organization (WTO) waiver on pharmaceutical patents. This waiver expired in 2005. India and all other developing countries now have to make patent protection generally available for more recent pharmaceutical products, which will gradually reduce the number of drugs available in generic version.

Thus, support for local production of pharmaceuticals may be warranted to improve access to medicines. It may also be pursued as an independent industrial policy objective. This Tool Box is based on the premise that policies to support local production and policies to improve access to medicines should be coherent under all circumstances. Policymakers should, however, be alert to the dangers of cross-subsidizing purely industrial policy objectives from public health budgets or from spending on medicines by the population. A local production policy should address this issue (see next section)

<sup>3</sup> See Ewen et al., "Prices and availability of locally produced and imported medicines in Ethiopia and Tanzania", *Journal of Pharmaceutical Policy and Practice* (2017) 10:7 (hereinafter Ewen et al.). Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5242052/> (visited on 7 February 2017).

<sup>4</sup> See WHO, "Local Production for Access to Medical Products: Developing a Framework to Improve Public Health" (2011), p. 35 (hereinafter WHO, Framework). Available at [http://www.who.int/phi/publications/Local\\_Production\\_Policy\\_Framework.pdf](http://www.who.int/phi/publications/Local_Production_Policy_Framework.pdf) (visited on 7 February 2017).

<sup>5</sup> See UNCTAD case study series, Case Study 7, Thailand, p. 252.

<sup>6</sup> See WHO, Global pandemic influenza action plan to increase vaccine supply: progress report 2006-2008, pp. 23, 54/55 (hereinafter WHO, Global pandemic influenza action plan 2006-2008). Available at [http://apps.who.int/iris/bitstream/10665/70018/1/WHO\\_IVB\\_09.05\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/70018/1/WHO_IVB_09.05_eng.pdf) (visited on 7 February 2017).

## Main elements of local pharmaceutical production policies

UNCTAD's work demonstrates that in order for local production to be economically sustainable and at the same time contribute to increased access to medicines, it is crucial to enable domestic producers to meet standards related to the quality, safety and efficacy of medicines and WHO good manufacturing practices (GMP).<sup>7</sup> UNCTAD's work also shows that foreign investment plays an important role in this respect.<sup>8</sup> Governments should seek to make available a legal and policy framework that encourages local producers to strive to meet product and GMP standards and to produce affordable medicines that respond to the country's essential public health needs. Use of policy tools, such as certain support measures, should be tailored to a country's particular situation and should strike an appropriate balance between the need to afford protection to industries at early stages of development and the need for international cooperation to encourage support from foreign investors.

It is important to acknowledge that these support measures will generate costs for the government, such as, for instance, tariff reductions on pharmaceutical ingredients needed for local production, certain subsidies or the application of mark ups in favor of local producers in public drugs procurement. It is up to each government to decide to what extent the overall rationale for local production, such as health security in essential medicines, should supersede more immediate policy goals. Industrial development policy makers may prefer a focus on the development of drugs with the

greatest immediate market potential, irrespective of public health needs. From that perspective, the development of pain killers and life style drugs (obesity, etc.) may appear more attractive than the development of treatments against local types of malaria. Public health policy makers may have a preference for the importation of affordable generics to address immediate access concerns. The objective of a local production policy is to contrast these immediate policy goals with the long-term goal pursued by local production, such as health security, and to arrive at a balanced overall approach, to which all government entities are committed.

The promotion of local production should not exclude the pursuit of more market-driven drug development or the reliance on affordable generics from abroad. Importantly, as long as imported pharmaceutical products offer more affordable prices than local producers, governments need to strike a balance between the long-term goal of health security and the immediate goal of access. Patients should under no circumstance bear higher costs for the sake of industrial development. Governments need to find solutions to prevent higher prices being passed on to patients.<sup>9</sup> Where preferential treatment of local producers generates extra costs for the national health budget, for instance in case of mark ups in government procurement, a local production policy should commit the treasury to raise the health budget by the same amount to avoid a situation where the health budget has to finance measures that by their nature belong to industrial policy.

<sup>7</sup> See UNCTAD case study series.

<sup>8</sup> Ibid. Even in countries that successfully emphasize the home-grown nature of pharmaceutical production capacities, such as Bangladesh and Thailand, local firms have to some extent relied on foreign expertise at some point in their development. See Case Study 2, Bangladesh, and Case Study 7, Thailand.

<sup>9</sup> See also Ewen et al., p. 8.



Local production policies as described in the preceding paragraph should be based on six elements, which this Tool Box will discuss, i.e. (1) government and stakeholder coordination for (2) safe and efficacious medicines that (3) incorporate local innovation corresponding to local needs and that are (4) available and supplied on a sustainable basis, (5) affordable and (6) strategically selected for local production. Elements (2) to (6) are obviously driven by health concerns. UNCTAD and WHO have argued that these elements may also contribute to the development of a sustainable domestic industry and should therefore also matter to industrial policy makers.<sup>10</sup> For instance, local producers will only be able to participate in (domestic and international) drug tenders and supply (domestic and foreign) markets by meeting safety and efficacy standards. Local products that address specific local needs may serve important niche markets. The strategic application of government support measures to those medicines that are essential to the national public health system helps local drug makers become more competitive in an area where there is demand from the government. Having the possibility to make their products available on a sustainable basis is a key investment consideration for any producer. Finally, affordability is a basic requirement to create demand

and to compete. Summing up, elements (2) to (6) may be qualified as goals that are shared between health and industrial policies. The Tool Box therefore discusses how various policies related to health, industrial development, trade, investment, innovation and intellectual property (IP) may be used to contribute to each of the above-mentioned six elements. **Figure 1** on the next page illustrates the shared goals of industrial and health policies, and indicates the government support measures for these goals that will be briefly discussed in the following sections.

By emphasizing the importance of linking goals related to health and those related to local production, the Tool Box seeks to contribute to the strengthening of health systems for the support of universal health coverage, which was affirmed as an important goal in the May 2016 G7 *Ise-Shima Leaders' declaration*.<sup>11</sup> The Tool Box thus follows the approach taken in the Roadmap "Healthy Systems - Healthy Lives" developed by the WHO member states and other key health stakeholders at the 2016 World Health Assembly<sup>12</sup> and builds on some of the recommendations of the September 2016 Report by the United Nations Secretary General's High Level Panel on Access to Medicines.<sup>13</sup>

<sup>10</sup> WHO, Framework, pp. 38ff.

<sup>11</sup> See G7, Ise-Shima Leaders' Declaration, The White House, Office of the Press Secretary, May 27, 2016, available at <https://obamawhitehouse.archives.gov/the-press-office/2016/05/27/g7-ise-shima-leaders-declaration>, (accessed on 7 June 2016).

<sup>12</sup> BMZ, Roadmap "Healthy Systems –Healthy Lives", 2015, (visited on 27 July 2016).

<sup>13</sup> See The United Nations Secretary-General's High-Level Panel on Access to Medicines, Report, 2016, available at <http://www.unsgaccessmeds.org/final-report/> (visited on 28 October 2016)

Figure 1: Local production and access to medical products: A framework for improving public health.



Based on WHO, "Local Production for Access to Medical Products: Developing a Framework to Improve Public Health" (2011)

## Box 1:

# Multi-stakeholder cooperation for policy coherence

UNCTAD's capacity building projects on policy coherence in local pharmaceutical production and access to medicines follow a 4-step approach.

1. Based on UNCTAD's field experience, the promotion of policy coherence should start with fact-finding exercises to:
  - a. Map existing domestic policies that are likely to have an impact on local production and access to medicines (policy matrix);
  - b. Assess the access to medicine situation of the country;
  - c. Map key stakeholders across the sector, including manufacturers, research organizations, donor agencies, and civil society;
  - d. Map policy makers and regulatory and enforcement related agencies; and finally;
  - e. Assess perceptions on policy coherence through face to face interviews, surveys and other means.The questions for assessment of perceptions would vary depending on the stakeholders, i.e. manufacturers, research organizations, civil society, hospitals, procurement agencies, and policy makers.

## How to use this Tool Box

In order to ensure impact, UNCTAD intends to widely use this Tool Box in its technical cooperation activities and make it available to interested governments. Governments are encouraged to refer to this Tool Box when coordinating policies to promote local production and access, for instance in the context of institutionalized coordination mechanisms such as the sectoral committees of the **East African Community (EAC) Secretariat** that are involved in the establishment of the 2017-2021 Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPoA). This being said, the Tool Box contains general observations that are supposed to provide broad guidelines, and readers should be cautious

not to take the policies discussed hereunder as a one-size-fits all prescription to address a country's specific situation. In particular, the concrete examples of domestic policies given throughout the text only serve the purpose of illustration. A country's specific needs can only be examined through a thorough in-country review. In this regard, UNCTAD and its partners provide advisory services and capacity building on policy coherence for greater access to medicines through local production, which may be requested through official requests for technical cooperation. The Tool Box may serve as an instrument to inform the process of multi-stakeholder cooperation for policy coherence as described in Box 1 above.



2. Following the fact finding exercises, it is important to come up with a shortlist of issues for multi-stakeholder consultation, preferably, in a dialogue style, where key actors and policy makers come together to discuss face-to-face the way forward.
3. It is important to designate at least two focal points for the entire process, preferably from the Ministry of Health and Ministry of Trade and Industry. However, it should be noted that the Ministry of Finance has important discretion on tariff and tax policies, through its revenue authority, and on financing the implementation of any policy measure, through its budget preparation power. National planning commissions also play an important role, since any major economic and social initiative may have to be incorporated into the periodical economic plan of the country.
4. The feedback collected from fact finding exercises and multi-stakeholder dialogues may be incorporated into a national planning process, preferably, under a pharmaceutical sector development plan, and endorsed by the cabinet or equivalent authority. In order to advance policy coherence, the plan should:
  - a. Contain action areas on all issues identified through the fact finding exercise and the multi-stakeholder dialogue;
  - b. Allocate institutional responsibility for implementation and coordination;
  - c. Provide for milestones to assess progress;
  - d. Contain a regular review mechanism.



# 1. The art of coordination

This section describes the overall need for policy coordination that is relevant to all subsequent goals of local production as these are shared between industrial and health policies. Those goals relate to the quality, safety, and efficacy of medicines that to the extent possible promote local innovation, are available, affordable, and are strategically selected for local production. Pharmaceutical producers like private sector companies or in some countries state-owned enterprises play the key role in the achievement of these goals. Governments can make an important contribution by coordinating domestic policies to take account of the cross cutting nature of pharmaceutical production and to avoid contradictory effects of different policies. The following paragraphs provide some examples of such coordination.

■ **National development plans:** Referring to local production and access to medicines in a national development plan or similar policy document may ensure that all government agencies accord priority treatment to

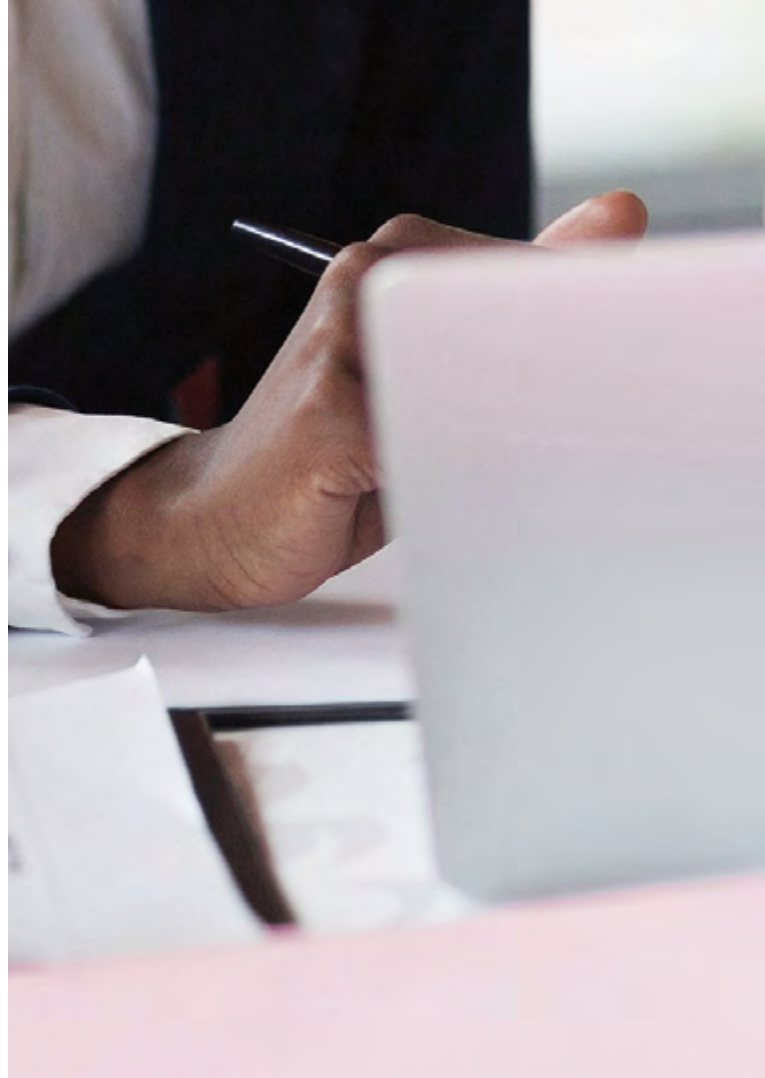
the local pharmaceutical sector. For example, the **EAC** adopted the Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPoA) (2012-2016), which provides inter alia for initiatives to promote regional pooled procurement of inputs and preference schemes for local production, quality improvement of medicines, and the strengthening of pharmaceutical regulation.<sup>14</sup> The EAC-RPMPoA thus complements the regional harmonization of drug regulatory requirements under the EAC Medicines Regulatory Harmonization Programme.<sup>15</sup> In **Kenya**, the Second Medium Term Plan (2013-2017) under Vision 2030 (i.e. the national development plan) prioritizes investment in medical research and local pharmaceutical production and proposes to develop policies to encourage the local production of pharmaceuticals.<sup>16</sup> Kenya's Pharmaceutical Sector Development Strategy underscores the need for all the problems confronting local production of pharmaceuticals to be addressed holistically within a harmonized national and regional policy framework.<sup>17</sup>

<sup>14</sup> See, East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012 - 2016), EAC, 2012, Arusha, Tanzania.

<sup>15</sup> The East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme, 2012, Arusha.

<sup>16</sup> Government of the Republic of Kenya, Second Medium Term Plan 2013-2017 Transforming Kenya: Pathway to Devolution, Socio-economic Development, Equity and National Unity, 2013, Nairobi, Kenya, (pages 4;81).

<sup>17</sup> UNIDO, „Kenya Pharmaceutical Sector Development Strategy“, Vienna, 2012.



■ **Comprehensive industrial policy:** Direct and indirect support measures for the industry should be defined in accordance with the public health objectives of affordability, availability, and safety, efficacy and quality. This requires close coordination between ministries of industry, trade, health, and finance.

■ **Institutionalized government coordination mechanism:** Coordination among ministries should not only be carried out on an ad-hoc basis, as this would likely miss important opportunities. The ministries of health and industry should establish a coordination mechanism, for instance by nominating a special secretariat, made up of ministerial staff to oversee local production and access policies. In **Ethiopia**, the Food, Beverage and Pharmaceuticals Industry Development Institute (FBPIDI) has been created to oversee the implementation of the National Strategy and Plan of Action for Pharmaceutical Manufacturing in Ethiopia (2015-2025). According to the Ethiopian Government, FBPIDI "needs to provide investment and financial advisory services to local and foreign investors, initiate relevant human resource development programmes,

establish market intelligence, promote the Ethiopian pharmaceutical industry, facilitate technology transfer and product and technology acquisition, promote research and development, and facilitate implementation of GMP roadmap and advancement of companies on the value chain."<sup>18</sup> **Box 2** on the next Page provides an overview of institutional coordination in **Thailand** to negotiate the prices of pharmaceutical products.

■ **Mapping of existing relevant policies:** The amount of stakeholders, interests and laws and policies affecting local production and access to medicines may be considerable. Government agencies may easily lose track of the status quo, which in turn may affect their policy making. The governmental body in charge of coordination should provide a list of relevant policies and how they affect the local industry and access to medicines.

■ **Private sector involvement:** In designing industrial support measures for the industry, it is essential that the government be in close consultation with local producers to collect their feedback prior to enacting legislation.

<sup>18</sup> See National Strategy and Plan of Action for Pharmaceutical Manufacturing in Ethiopia (2015-2025), p. 23. Available at [http://www.who.int/phi/publications/Ethiopia\\_strategy\\_local\\_production.pdf](http://www.who.int/phi/publications/Ethiopia_strategy_local_production.pdf) (visited on 27 October 2016). The Strategy emphasizes the need for the Government to promote the funding and staffing of FBPIDI, which is still in its inception phase.

## Box 2:

# Institutional coordination in Thailand to negotiate drug prices

Thailand in 2005 established the *Ad Hoc Working Group for Price Negotiation of Patented Essential Drugs*.<sup>22</sup> In an effort to reflect the cross cutting nature of the drug price negotiation process, the Working Group is chaired by the Thai Food and Drug Administration (TFDA) and comprises *inter alia* staff from the Ministries of Public Health, Internal Trade, and the Patent Office. With inputs from the Subcommittee on medicine selection and the Patent Office, the Working Group specifies medicines that are essential, patent-protected and face access constraints related to high prices. Supported by a Committee on price negotiation, the Working Group then negotiates the price of patented medicines with the patent holder. The country's universal public health care scheme requires essential medicines to be affordable to the government. The Working Group may refer to the possibility of granting a government use license to a domestic producer or an importer as a negotiating tool.

Other stakeholders, such as civil society, should also be consulted. For instance, **Kenya's** Statutory Instruments Act obliges government regulators to consult affected stakeholders prior to the passing of a statutory instrument.<sup>19</sup> In **South Africa**, policy and legislation must be discussed at the *National Economic Development and Labour Council*, where business and labour associations and civil society are represented.<sup>20</sup>

■ **Policy assessment and collection of evidence:** Policies require regular monitoring to ensure their positive impact, and to avoid unforeseen and undesirable outcomes. This can be

done through the collection of concrete data on the impact of a measure like a tariff or a tax on local production and medicines affordability. In the ideal scenario, an economic and social impact assessment should be undertaken prior to the adoption of a measure, for instance by looking at comparable cases abroad. **South Africa**, for instance, requires a Socio-Economic Impact Assessment.<sup>21</sup>

<sup>19</sup> Kenya, The Statutory Instruments Act, 2013, available at <http://www.kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/StatutoryInstrumentsActNo23of2013.PDF> (Section 5) (visited 29 January 2016).

<sup>20</sup> National Economic Development, and Labour Council, 1995. NEDLAC Founding Documents and Protocols, Midrand., Gauteng, South Africa.

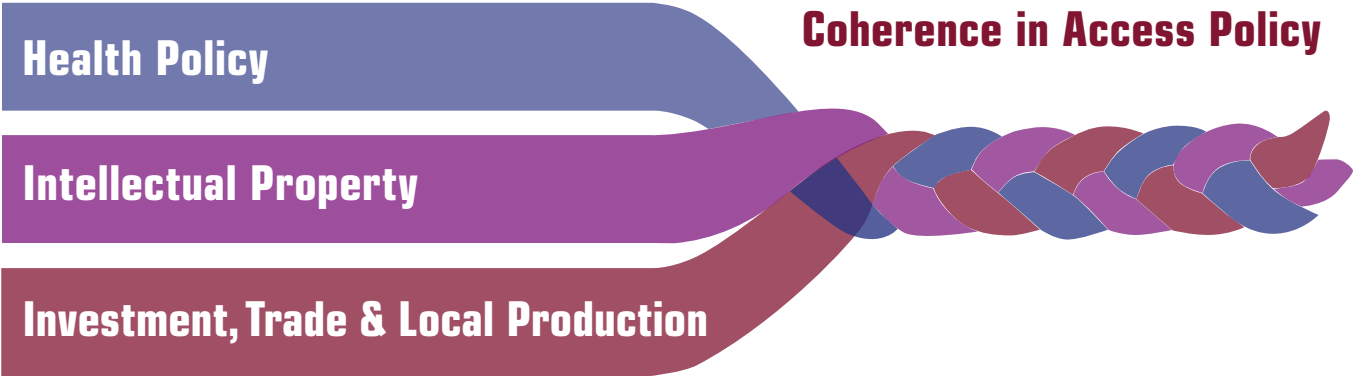
<sup>21</sup> Communication to the authors from the South African Department of Trade and Industry (the dti), 30 November 2016.

<sup>22</sup> Public Health Ministerial Order No. 360/B.E.2548(A.D. 2005)

In case the negotiations fail, the Working Group may recommend to policy makers the granting of a government use license. TFDA will in that case be in charge of registering and approving to the market the generic drug produced under the government use license. The government-owned Government Pharmaceutical Organization (GPO) will subsequently proceed with the production or importation of the medicine as well as its distribution.

The Thai example illustrates how inter-departmental collaboration may contribute to ensuring affordability of essential medicines. The existence of a capable local producer like the GPO arguably adds some credibility to the government's position in the price negotiations with the patent holder.

Source: UNCTAD







## 2. Quality, safety and efficacy

### Outline of issues for quality, safety and efficacy

Policy issues	Instruments	Related issues
Production Perspective	<ul style="list-style-type: none"> <li>• GMP roadmap;</li> <li>• Regulatory incentive.</li> </ul>	<ul style="list-style-type: none"> <li>• Enabling framework (access to capital, reduction of manufacturing cost reduction);</li> <li>• Linking incentives with GMP.</li> </ul>
Regulatory perspective	<ul style="list-style-type: none"> <li>• Regulatory control;</li> <li>• Role of regulatory agencies for local production;</li> <li>• Bio-equivalence requirement;</li> <li>• IP vs drug regulation issues in enforcement;</li> <li>• Efficiency of regulatory agencies;</li> <li>• IP in drug registration and Regional integration.</li> </ul>	
Investor's perspective	Capacity building for local firms under inter-firm agreements.	<ul style="list-style-type: none"> <li>• Local producers' capacity to comply with GMP;</li> <li>• National DRA's capacity to enforce GMP.</li> </ul>

The following section emphasizes the principal policy issues from the perspective of the drug regulator, the producer and foreign investors to ensure the safety, efficacy and quality of medicines.



## 2.1 Production perspective

A firm's capacity to meet WHO standards of good manufacturing practice (GMP) and standards for quality, safety and efficacy is key to both its economic sustainability and the promotion of access to quality medicines. Compliance with GMP and international quality standards will enable a firm to participate in international tenders and thus increase its competitiveness. At the same time, governments need to design appropriate policy incentives to ensure that local producers' investments in quality upgrading do not result in uncompetitive drug prices. The following paragraphs offer some examples of government support in producers' quality upgrading.

**1.** In cooperation with UNIDO, **Kenya's** Ministry for Industrialization and Enterprise Development and the Ministry of Health have issued the Kenya GMP Roadmap to enable the local industry to attain WHO GMP standards in a stepwise manner within five years.<sup>23</sup> The roadmap is the first element of a broader Kenya Pharmaceutical Sector Development Strategy, which in the future is scheduled to expand to other components such as, inter alia, strengthening of the regulatory capacity, access to finance for pharmaceutical investment, devising incentives for the industry to upgrade, and developing human resources. UNIDO and GIZ have supported local companies with gap analyses towards achievement of GMP standards on the basis of which most participating companies have devised Corrective Action and Preventive Action (CAPA)-Plans that will guide their investments and upgrading efforts.

<sup>23</sup> Republic of Kenya and UNIDO, 2014, Kenya GMP Roadmap: A Stepwise Approach for the Pharmaceutical Industry to Attain WHO GMP Standards, Nairobi and Vienna.

**2. Ethiopia's** Food, Medicine and Healthcare Administration Control Authority (FMHACA) expanded its mandate from the regulation and control of medicines to providing assistance to local producers in the building of GMP capacities. In cooperation with stakeholders, FMHACA has established a five-year GMP Roadmap and mapped local firms into three GMP compliance levels, with the aim of building GMP compliance by 2018.<sup>24</sup>

**3.** Upgrading a local firm's capacity to meet GMP and quality standards requires investment and access to capital. Government support measures to reduce manufacturing cost and to provide a conducive framework could be made conditional upon a firm's commitment to invest in upgrading its production capacities in respect of medicines contained on the national essential medicines list (EML). Such conditionality could be designed either

as a reward (i.e. granted after the investment is made) or as an obligation to use support in a certain manner (i.e. prior to the investment). Considering producers' need to access capital to make investments in the first place, the latter approach will in many cases provide the only workable solution, as demonstrated in **Ethiopia** by the use of advance payments to the winners of tenders. Private investment through foreign pharmaceutical companies can play an important role, but the foreign investor will only be attracted if the local partner already has a certain degree of production capacity or provides other advantages. In **Colombia**, for instance, the existence of a well-organized distribution network as well as cultural and linguistic similarities facilitated licensing agreements between local firms and foreign Spanish-speaking investors.<sup>25</sup>

## 2.2 Regulatory perspective

The national drug regulatory authority (DRA) plays an essential role in ensuring local producers' compliance with standards of quality, safety and efficacy. The following paragraphs describe some basic considerations for policy makers.

**1.** The ability of a country's DRA to attest to the quality of medicines and the quality of the overall national medicines regulatory framework makes an important contribution to public confidence in a country's health system and local producers. Part of this is the DRA's capacity to effectively perform post-marketing surveillance, as many unpredictable side effects may only appear after a pharmaceutical product has been used by patients for a longer period of time.

**2.** A well-functioning DRA can also play an important role in building capacities within the local industry to produce in line with quality and safety standards. As most developing countries' local industries are focused on generic drugs, a DRA should be in a position to formulate and enforce clear regulatory standards and processes for the approval of generics, such as the requirements of therapeutic interchangeability (i.e. availability of the same amount of active ingredients and the same dosage form as the originator product) and bioequivalence (i.e. availability of the active ingredient in the patient's blood stream within the same amount of time as the originator product). Part of this enforcement capacity is the ability to monitor the drugs' quality and to identify and sanction producers that do not respect quality standards or GMP.

<sup>24</sup> See Tsige Gebre-Mariam, Kedir Tahir, Solomon Gebre-Amanuel, "Bringing Industrial and Health Policies Closer: Reviving Pharmaceutical Production in Ethiopia", in: *Making Medicines in Africa. The Political Economy of Industrializing for Local Health*, edited by M. Mackintosh, G. Banda, P. Tibandebage, W. Wamae, International Political Economy Series, Palgrave Macmillan, 2016 [hereinafter Ethiopia Study 2016], pp. 80/81.

<sup>25</sup> UNCTAD case study series, p. 126.



**3.** The enforcement of quality standards should not be confused with the enforcement of IP rights (even though they may often overlap). Problems of quality may affect patented drugs as much as generic drugs. The use of wrong information related to drug safety, efficacy and quality should be sanctioned through drug regulation and criminal laws. In many cases, wrong labels will in addition use a trademark without authorization from its holder to free ride on its reputation. This will create additional confusion about the origin of the product, which is both a public health and an IP issue and should additionally be sanctioned under IP-related remedies (injunctions, damages, border measures and, in case of willful trademark counterfeiting on a commercial scale, criminal sanctions). In this context, there should be a clear understanding of the following notions:

**a. Substandard drugs** are products that do not meet certain safety, efficacy and quality standards as established under a country's drug laws. Sanctions should be available under national drug regulatory laws.

**b. Counterfeit drugs** is a term that is used in many domestic drug regulatory laws to address multiple failures to comply with both product quality and intellectual property standards. For example, Ethiopian drug regulatory law defines counterfeiting as "using in any way, the packing material, identification or trademark, trade name or any special mark thereon of an authentic product of a manufacturer and presenting such falsely labeled and packed food or medicine as if it is manufactured by the genuine manufacturer **or** altering content and properties of food or medicine that cause health hazards to human"(emphasis added).<sup>26</sup> Counterfeiting thus covers the intentional unauthorized use of identifiers, but also the making and marketing of substandard drugs. Under the TRIPS Agreement, however, the notion of counterfeiting has been limited to the unauthorized use of a trademark. This has resulted in attempts in some countries to address the problem of substandard drugs through IP legislation and related remedies and to sideline the drug regulator.

As the unauthorized use of a pharmaceutical

trademark may at the same time conceal substandard drug quality, IP and drug regulatory sanctions overlap and require consultation and cooperation between IP enforcement authorities and the DRA.

**c. Generic drugs** are copies of original drugs no longer protected by a patent. Sanctions for alleged patent infringement should be available under national IP/patent law. They should be limited to civil remedies (injunctions, damages) and avoid criminal sanctions (imprisonment, fines), providing safeguards against unfounded claims by certain patent holders of alleged patent infringements by generic producers.<sup>27</sup>

**4.** Efficiency and work speed of the DRA is an important factor for both domestic producers and foreign investors. Below are a few examples of national approaches to speedier drug approval.

**a. Argentina's** DRA, the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (ANMAT), waives the clinical trials requirement for those drugs that were previously approved in Argentina or a country with a high level of health surveillance (mostly EU countries, Israel, Switzerland, and the United States). Not all of those previously approved drugs need to be fully tested for bioequivalence, but only high-risk APIs and APIs used in anti-retroviral medicines. For other previously approved drugs the producer may invoke pharmaceutical similarity. The latter requires the producer to present certain labelling and packaging information, product information (e.g. name, formula, drug form, pharmacological classification) and certain technical information (e.g. methods of control, methods of manufacturing in line with GMP, shelf life, and information regarding bioequivalence or bioavailability as compared to similar products),<sup>28</sup> which is less burdensome and costly than full bioequivalence testing, and does not require an originator product in the market.

This makes it more difficult for certain originator firms to abuse the bioequivalence requirement, for instance by withdrawing an original product from the market to prevent the generic competitor from establishing full bioequivalence.<sup>29</sup>

<sup>26</sup> Article 25 of the Ethiopian Food, Medicine and Health Care Administration and Control Proclamation No. 661/2009.

<sup>27</sup> For example, between 2000 and 2007, generic producers in the EU prevailed in 62 per cent of the final judgments rendered by European courts in patent litigation cases between originator and generic companies. The vast majority of these cases were initiated by originator companies. See Competition Directorate General of the European Commission, "Pharmaceutical Sector Inquiry", Final Report, 8 July 2009, p. 12 (para. 3.2.2.).

<sup>28</sup> UNCTAD case study series, Case Study 1, Argentina, pp. 35-37, and footnote 28.

<sup>29</sup> These were the facts in the case AstraZeneca v European Commission, T-321/05.



**b. Colombia's** DRA, the Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA), facilitates the marketing approval of originator drugs by referring to approvals granted abroad: where two of those exist, the originator only needs to submit a summary of the clinical information, rather than the entirety of clinical trials. Generic applicants are not required to demonstrate absolute bioavailability and bioequivalence through in vivo testing except in cases of high risk drugs.<sup>30</sup>

**c. Thailand's** Food and Drug Administration (TFDA) as of 2016 is testing a pilot project for a step-by-step registration of products under development. It is hoped that such stepwise approach would benefit the industry through continuous feedback from TFDA on the drug development process and would enable the industry to reorient drug development at early stage, if necessary.<sup>31</sup>

**d.** Regional approaches: In regional trade agreements or other regional arrangements, it is useful for the local industry and foreign investors to be subject to only one GMP and product quality inspection, in exchange for a single fee. The **EAC** has established harmonized drug regulatory requirements to accommodate local producers in its Medicines Registration Harmonization Programme (MRH), but there is no regional approval authority. In addition, MRH seems to generally require

the demonstration of full bioequivalence, which has been criticized by EAC-based producers as too burdensome and costly.<sup>32</sup> The EAC is undertaking pilot projects to test the feasibility of joint inspections by teams of the Partner States' national DRAs to enable companies to obtain one joint regulatory approval from all Partner States' DRAs. Going beyond this, the Federation of East African Pharmaceutical Manufacturers (FEAPM) has proposed the mutual recognition of national approvals, which would make joint inspections unnecessary.<sup>33</sup> This however presupposes comparable capacities among all involved DRAs.

**e.** The interface between IP laws and drug regulation may have an impact on the speed of generic approvals. Even where the drug regulatory laws promote the fast registration of products, IP obligations under some preferential trade and investment agreements (PTIAs)<sup>34</sup> may provide certain obstacles for the registration of generic drugs. As outlined in Section 5 below, the DRA may be prevented from approving generic drugs on the basis of exclusive rights in pharmaceutical test data, exclusive marketing rights or a patent linkage requirement. The TRIPS Agreement by contrast does not oblige WTO Members to provide for exclusive data rights or patent linkage.

<sup>30</sup> UNCTAD case study series, Colombia case study, pp. 113, 128.

<sup>31</sup> Communication from TFDA to the authors, June 2016.

<sup>32</sup> September 2015 UNCTAD-GIZ-EAC Secretariat Regional Workshop on Policy Coherence for Local Production of Pharmaceutical Products and Other Means to Improve Access to Medicine and Medical Products in the East African Community and Beyond, 21-23 September 2015, Kampala, Uganda (hereinafter UNCTAD-GIZ-EAC Regional Workshop). Available at [http://unctad.org/meetings/en/Sessional Documents/tot\\_ip\\_0027\\_en.pdf](http://unctad.org/meetings/en/Sessional Documents/tot_ip_0027_en.pdf) (visited on 25 October 2016).

<sup>33</sup> Information from stakeholders at the UNCTAD-GIZ-EAC Regional Workshop.

<sup>34</sup> This term is derived from the area of trade in goods. It is understood that the TRIPS Agreement does not allow PTIA parties to limit preferential conditions to themselves. As opposed to the GATT, Article 4 TRIPS applies the most-favored nation principle to post-TRIPS regional or bilateral trade agreements.



## 2.3 Investor's perspective

Foreign investors attach considerable importance to the drug regulatory environment in a potential target country. Cooperation with local producers to a great extent depends on the latter's capacity to comply with drug quality standards and GMP, and the drug regulator's capacity to enforce these standards.<sup>35</sup> This will avoid a scenario where producers of quality products have to

compete with non-complying manufacturers. Capacity building by international development partners may play an important role. In addition, foreign investors may be interested in providing technical assistance to local firms, provided the latter can offer interesting opportunities in exchange, for instance their local drug distribution networks.

<sup>35</sup> UNCTAD interview with representatives from the International Generic and Biosimilar Medicines Association (IGBA), Geneva, 9 December 2016.



### 3. Local innovation: Innovation for local needs and related R&D

<b>Outline of issues for local innovation</b>		
Policy issues	Instruments	Related issues
Innovation and related R&D for local needs	<ul style="list-style-type: none"> <li>• R&amp;D priorities and financial incentives;</li> <li>• Public R&amp;D funding;</li> <li>• R&amp;D coordination;</li> <li>• Skills &amp; knowledge development;</li> <li>• Linkages between academia and industry.</li> </ul>	National science and innovation policies.
Appropriate IP systems for local needs	<ul style="list-style-type: none"> <li>• Utility models;</li> <li>• Compensatory liability regimes;</li> <li>• Trade secrets;</li> <li>• Licensing agreements with foreign IP holders;</li> <li>• Patent application and disclosure of innovation;</li> <li>• Commercialization of R&amp;D.</li> </ul>	<ul style="list-style-type: none"> <li>• Low use of patents by developing country firms;</li> <li>• Herbal medicines;</li> <li>Incremental innovation.</li> </ul>





In addition to meeting standards of quality, safety and efficacy, domestic medicines production should also address specific local needs (public health perspective) and promote domestic innovation capacity (industrial policy perspective). For example, certain drugs may not be available in heat stable form or as pediatric formulations. A national public health framework should therefore seek to promote local innovation. Providing appropriate incentives to the private sector and coordinating its activities with public research and development (R&D) efforts is key in this regard.

This is not meant to suggest that local production is not worthwhile supporting if producers do not engage in any innovation. In many developing countries, especially LDCs, the private sector is not engaged in innovative activity, for reasons related to lack of capacity or lack of investment incentives. But a certain level of R&D activity is required to help producers address their gaps in quality production and to remain competitive in the medium to long term.

## 3.1 Research and development and skills development

An appropriate legal and policy framework should comprise at least the following elements to address this issue.

**1. National R&D policy:** Defining domestic R&D priorities and related policy and financial incentives can be tailored to promote private sector engagement for local health needs.

**Kenya's** Institute for Public Policy Research and Analysis (KIPPRA) for instance has underlined the importance for the country to adopt a national R&D policy to address these issues.<sup>36</sup> A national policy also demonstrates political commitment by the government.

**2. Incentives:** Tools to incentivize R&D in drug development and drug quality upgrading could range from tax breaks, R&D subsidies, facilitated access to capital, active matchmaking with foreign investors, and appropriate use of IP. The latter can be used (1) as a tool to encourage investment in incremental innovation and (2) as a source of technology transfer.

**3. Public R&D funding:** In their struggle to increase competitiveness, many local producers in developing countries are hesitant to invest in R&D. There is thus a need for public R&D to address health priorities. In **Brazil**, the Sao Paulo Research Foundation, which undertakes research to promote health-related knowledge, is funded by receiving 1 per cent of the total Sao Paulo state tax revenue, which in turn it reinvests in research funding and dissemination of technology.<sup>37</sup> In **Ethiopia**, the 2012 national science and technology policy sets a target of at least 1.5 per cent of the gross national product (GNP)

per year to be allocated to R&D activities in all industrial sectors, albeit not specifically pharmaceuticals. In addition, the policy indicates the channeling of 1 per cent of annual profits of all productive and service sectors into a central R&D fund. However, there is no evidence that shows if Ethiopia has achieved its goal currently, considering the challenges for LDCs to channel resources into R&D.<sup>38</sup>

**4. R&D coordination:** health-related R&D is both a health and an industry issue. In order to avoid inefficient duplication of work and ensure that R&D efforts are directed towards essential medicines, a national R&D policy should coordinate health-related R&D activities undertaken by various public bodies. For instance, UNCTAD has found that in **Ghana**, health-related R&D is scattered across different ministries and could benefit from improved coordination and linkages.<sup>39</sup> The Ministry of Environment, Science, Technology and Innovation oversees health research carried out by the Science and Technology Policy Research Institute, while the Ministry of Education supervises health-related R&D conducted by the Noguchi Memorial Institute for Medical Research. There seems to be no overall strategy on health-specific R&D. In **Brazil**, by contrast, the establishment of the National Sanitary Surveillance System, which covers industrial, trade, science, technology, and health policies, has enabled government authorities to coordinate activities to better achieve national health objectives. Complementing national efforts, regional R&D coordination could play an important role in addressing common epidemiological needs.

<sup>36</sup> Stakeholder interviews, UNCTAD fact finding mission to Kenya, October 2013.

<sup>37</sup> See for the São Paulo Research Foundation, FAPESP, at <http://www.fapesp.br/en/about> (visited on 17 January 2017).

<sup>38</sup> See Ethiopia Study 2016, p. 80.

<sup>39</sup> Stakeholder interviews, UNCTAD fact finding mission to Ghana, February 2014.

**5. Linkages between academia and industry:** A problem in many developing countries is the missing link between university R&D institutes and the industry's needs. In **Kenya**, the Kenya Medical Research Institute has the capacity to carry out innovative research for the development of new products, such as malaria vaccines. The local industry however is not ready to take advantage of this capacity, as it focuses on the production of well-known, existing products, rather than engaging in riskier experimentation. The reason for this is the higher competitiveness of foreign importers, leaving local producers with limited motivation or capacity to allocate resources to invest in costly R&D.<sup>40</sup> In **Thailand**, the *Talent Mobility Program* is in place to promote R&D and to increase the exchange of research personnel between the public and the private sector. The lack of R&D undertaken by the private pharmaceutical sector is a particular problem in **Vietnam**. The Vietnamese Ministry of Health through an action plan envisages providing orientation for the private sector in applied research on the development of pharmaceutical raw materials as well as new technologies in the drug manufacturing process, in excipients, secondary packaging and the production of medicinal herbs. The Ministry also intends to steer research priorities to the production of those drugs contained in the EML.<sup>41</sup>

**6. IP for publicly funded research:** In the context of linkages between academia, research centers and universities with industry, countries may adopt laws to address issues of patenting and licensing of IP rights arising from publicly funded research projects under specialized laws. For example, all results of publicly funded research projects and the IP rights acquired by universities used to belong to the Government of the **United States**. In 1980, the Bayh-Dole Act (Patent and Trademark Law Amendments Act) provided that titles to inventions sponsored by the federal government belong to the universities. The Act obliges universities to establish

a technology transfer mechanism.<sup>42</sup> Such laws allow governments to provide incentives for research and encourage linkages with the private sector, but also provide preference to local exploitation, such as local manufacturing, under certain conditions. In **South Africa**, the Intellectual Property Rights from Publicly Funded Research and Development Act 51 of 2008 is similar in scope and objective to the Bayh-Dole Act. Some other major economies, such as **Canada**, do not have a centralized law governing IP right titles and transfer of technology requirements for publicly funded research projects. The **European** and developing country Bayh-Dole type frameworks are also very recent phenomena.<sup>43</sup> Bayh-Dole type IP and technology transfer laws have been designed for an environment where public funding and a mature technology market are available for universities to undertake research, acquire exclusive rights on novel products and processes and transfer the technology for development and application by the industry.

**7. Skills & knowledge development:** Under an overall national local production policy, the Ministry of Education should encourage universities to design curricula that take account of the needs of the local industry, rather than limit education to the profile of retail pharmacists as is currently the case in various countries such as **Ghana**<sup>44</sup> and **Kenya**<sup>45</sup>. This should happen in close cooperation with the industry. Curricula at schools of pharmacy should include mandatory internships with the local industry. Chulalongkorn University in **Thailand**, on the other hand, offers a very progressive industrial pharmacy program (the "*PharmD-program*") in which students specialize from year 2 in industrial pharmacy and receive comprehensive practical training in the university's own small-scale production lab. The *PharmD-program* is being disseminated by *Chulalongkorn University* through a certified practical course, inter alia to pharmaceutical students from Ghana.

<sup>40</sup> Stakeholder interviews, UNCTAD fact finding mission to Kenya, October 2013.

<sup>41</sup> Information on Thailand and Vietnam taken from participants' presentations at UNCTAD Workshop on Policy Coherence for Local Pharmaceutical Production and Access to Medicines: The Experiences of Thailand and Vietnam, Hua Hin, Thailand, 6-9 September 2015. Workshop report available at <http://unctad.org/en/pages/MeetingDetails.aspx?meetingid=1012> (visited 15 January 2016).

<sup>42</sup> United States Code, Title 35, Chapter 18 (Patent and Trademark Law Amendments Act), 1980.

<sup>43</sup> For the EU, see European Commission, 2004, 2004 EUR 20915 EN, 8-9.

<sup>44</sup> Stakeholder interviews, UNCTAD fact finding mission to Ghana, February 2014.

<sup>45</sup> Stakeholder interviews, UNCTAD fact finding mission to Kenya, October 2013.

## 3.2 IP for incremental innovation

Discussions on IP incentives in developing countries often neglect the fact that most innovation in those countries happens at the sub-patentable level. Alternative tools should be identified to promote innovation and technology transfer. The following considerations appear of particular relevance in this context.

**1.** Patent statistics by the World Intellectual Property Organization (WIPO) reveal that in developing countries, including those at more advanced stages of technological development, the bulk of patent grants benefits foreign, rather than domestic applicants.<sup>46</sup> Incremental improvements of existing products, which are often within the range of developing country stakeholders, typically fail the inventive step test. Even under the broadest possible type of experimental use exception, the marketing of a product containing incremental improvements over a patented product requires the patent holder's authorization.<sup>47</sup> Economies that depend on step-by-step improvements and lack capacity to "invent around" an existing patent require access to existing technologies. **Compensatory liability regimes** have been suggested to enable access to product improvements while rewarding the incremental inventor.<sup>48</sup> In brief, three separate rights have been proposed in this context, i.e.

- a) The right for the incremental innovator to prevent others for a certain period of time from wholesale imitations of its improved product;
- b) The right for the incremental innovator to claim reasonable compensation from any third party that uses the protected innovation for further value-

adding improvements. This right would be time-limited (e.g. 20 years) and could be preceded by a much shorter period of exclusivity (e.g. two years) for the right owner to establish its brand in the market;

- c) The inventor of the original product could claim from the incremental follow-on innovator to obtain access to the improved technology, in exchange for a reasonable compensation and for a certain period of time.

Patent law in **Switzerland** follows a non-exclusive approach to enable the use of biotechnological inventions as research tools and thus potentially the development and marketing of new products.<sup>49</sup> This could provide an interesting option for developing countries.

**2.** Utility models could provide another tool to promote incremental innovation. As the TRIPS Agreement provides no minimum requirements of protection, WTO Members are free to design utility models as they deem appropriate, especially as far as the term of protection and the eligibility requirements are concerned. Countries such as **Germany** and **Japan** used utility models extensively in the past, before their inventors reached the capacity to benefit from the patent system.<sup>50</sup> At the same time, utility model rights due to their exclusive nature potentially raise problems similar to patents, i.e. a blocking effect for follow-on innovation in countries that lack capacity to "invent around" the exclusive right. Short terms of protection or the use of non-exclusive IP rights as discussed above could provide a remedy.

<sup>46</sup> For example, Thailand in 2013 granted 1081 patents to non-residents, but only 68 to resident applicants. In Vietnam, 1123 patents were granted to non-residents in 2013, as compared to 59 patent grants to residents. Indonesia in 2013 received 6787 patent applications from non-residents, but only 663 from residents. In Sub-Saharan least-developed countries (LDCs), figures are much lower but show a comparable ratio. For instance, Ethiopia in 2007 (last available data) granted 13 patents to non-residents and 0 to residents. See [http://www.wipo.int/ipstats/en/statistics/country\\_profile/](http://www.wipo.int/ipstats/en/statistics/country_profile/) (visited 11 January 2016).

<sup>47</sup> For details, see UNCTAD Reference Guide, pp. 61, 105: While the experimental use exception enables the **development** of improved products based on the patented product, the **commercialization** of such products requires the authorization from the patent holder to the extent that the new product cannot be made without using the patented product.

<sup>48</sup> Ibid, pp. 56 ff, especially 61, 62.

<sup>49</sup> See Article 40b of the Swiss Patent Law, available at <https://www.admin.ch/opc/en/classified-compilation/19540108/index.html> (visited 12 January 2016).

<sup>50</sup> Suthersanen, Uma, 2006, Utility Models and Innovation in Developing Countries, ICTSD and UNCTAD, Geneva.



**3.** Incremental innovation may contain commercially valuable information. Such information may be protected as a trade secret, provided the information holder has taken reasonable steps to keep it secret. Trade secrets protect information from being disclosed to the public or used by unauthorized parties in a manner contrary to honest commercial practices (Article 39.2 of the TRIPS Agreement).<sup>51</sup> Production processes are typically protected as trade secrets. As opposed to patents, there is no limited term of protection. By contrast, trade secrets law does not prohibit reverse engineering of products to discover the production process through honest commercial means. In the area of small chemicals, reverse engineering is fairly straightforward. This could make trade secrecy less interesting as a tool to promote investment in incremental innovation, unless the production process is so complex that reverse engineering of the product is unlikely to result in its discovery.

**4.** Licensing agreements with foreign IP holders can provide a source of technology transfer. In **Argentina**, the local firm ELEA received know-how for the production of various drugs for allergy and skin treatment from Warner Lambert/Pfizer, which held the domestic patents. The patent holder considered it more economical to withdraw from Argentina and to entrust ELEA with the manufacture of its entire product line. In return, ELEA committed to GMP compliance and quality controls. Warner Lambert ensured ELEA's compliance through inspection.<sup>52</sup> It has been noted that the negotiation of licensing agreements can be challenging for generic producers, and that, in addition, these agreements often focus on business interests rather than public health needs.<sup>53</sup> An exception in this regard is the *Medicines Patent Pool (MPP)*, a non-profit foundation that facilitates the licensing of patented technologies to generic producers for the production of affordable medicines in the areas of HIV, viral hepatitis C

and tuberculosis treatments in low- and middle-income countries.<sup>54</sup> The MPP licensing facility may be used by local producers that meet WHO GMP and quality, safety and efficacy requirements.

**5.** Patent applications often do not contain sufficiently detailed information for a person skilled in the art to understand the underlying technology. Developing countries are free under Article 29 of the TRIPS Agreement to require patent applicants to disclose the best mode of carrying out an invention, based on the skills of local, rather than international experts.

**6.** Commercialization of R&D: Private sector R&D may be incentivized through good prospects for commercialization of R&D results. IP systems in many developing countries are, however, not appropriately tailored to the local needs and capacities. In Ghana, for instance, neither public research institutions nor the private sector are engaged in patenting, due to (1) the prohibitive cost of filing applications; (2) the slow processing of applications; (3) the general lack of awareness of the benefits of the patent system; and, importantly, (4) the incremental nature of research (e.g. herbal medicines) that in many cases will not meet the patentability requirement of inventive step.<sup>55</sup> This latter problem may be addressed by designing specific IP rights for sub-patentable innovations, such as compensatory liability regimes or utility models, as outlined above.

<sup>51</sup> For more information, see Frederick M. Abbott, Thomas Cottier, Francis Gurry, "International Intellectual Property in an Integrated World Economy", Aspen Publishers, Wolters Kluwer, 2007, Chapter 5, pp. 591 ff.

<sup>52</sup> See UNCTAD case study series, pp. 23/24.

<sup>53</sup> See WHO, "The role of intellectual property in local production in developing countries. Opportunities and challenges", 2016, p. 17. Available at [http://www.who.int/phi/publications/int\\_prop\\_role\\_local\\_prod\\_opportunities-challenges.pdf?ua=1](http://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf?ua=1) (visited on 17 January 2017). The WHO in this context refers to the division of markets among the contractual parties.

<sup>54</sup> See <http://www.medicinespatentpool.org/about/> (visited on 17 January 2017). The MPP enters into licensing agreements with the patent holder and makes the licensed technology available to interested generic producers under a sub-license. See <http://www.medicinespatentpool.org/current-sub-licensees/> (visited on 17 January 2017).

<sup>55</sup> Stakeholder interviews, UNCTAD fact finding mission to Ghana, February 2014.



## 4. Availability and sustainable supply

### Outline of issues for availability and sustainable supply: conducive enabling framework

Policy issues	Instruments	Related issues
Measures to improve sustainability of local manufacturing	<ul style="list-style-type: none"> <li>• Price preference in government procurement;</li> <li>• Pooled Procurement.</li> </ul>	<ul style="list-style-type: none"> <li>• Impact on availability and price of medicines;</li> <li>• Linkage with GMP and quality;</li> <li>• GATT exemption;</li> <li>• Donor agencies.</li> </ul>
Treatment of imports	<ul style="list-style-type: none"> <li>• Tariff regimes and import restrictions;</li> <li>• Tax regime;</li> <li>• Subsidies;</li> <li>• Competition safeguards and periodic policy reviews.</li> </ul>	<ul style="list-style-type: none"> <li>• Bound MFN tariffs vs preferential tariffs;</li> <li>• Infant industry protection;</li> <li>• WTO SCM limitations on subsidies;</li> <li>• Oligopolies.</li> </ul>
Improved access to capital for producers	<ul style="list-style-type: none"> <li>• Increase understanding between commercial banks and local producers;</li> <li>• Recourse to public development bank loans;</li> <li>• Credit through pre-funding tenders;</li> <li>• Credit through foreign investors.</li> </ul>	



Policy issues	Instruments	Related issues
Investment policies	<ul style="list-style-type: none"> <li>• Sector-specific data and the promotion of investment;</li> <li>• Financial and fiscal incentives, Subsidies;</li> <li>• Performance requirements;</li> </ul> UNCTAD Investment Policy Framework for Sustainable Development.	<ul style="list-style-type: none"> <li>• Transparency of rules;</li> <li>• SCM limitations;</li> <li>• Balance between foreign and domestic investment.</li> </ul>
Economies of scale	Regional harmonization of laws & policies.	<ul style="list-style-type: none"> <li>• Regional trade;</li> <li>• IP policy and technology transfer.</li> </ul>
Trade facilitation	<ul style="list-style-type: none"> <li>• Consultation with private sector;</li> <li>• Coordinated enforcement procedures;</li> <li>• Customs clearance specific to pharmaceuticals.</li> </ul>	IP enforcement: border measures, goods in transit.

Domestic policy frameworks that seek to promote local production need to provide measures that create a conducive enabling framework for local production.

While the policy objective of medicines affordability (see below, Section 5) is mainly concerned with price as an immediate need, the goal of medicines availability seeks to ensure sustainability of supply, taking medium to long-term considerations into account. From a public health perspective, this means that at least essential medicines as defined on the national EML should be available without interruption and across the geographical spectrum. Local production can contribute to the avoidance of stock outs and long lead times in delivery from producers abroad, as recommended by the WHO in the area of vaccines.<sup>56</sup> Governments should consult closely with the domestic industry to realistically assess which medicines have to be imported and where there are shortcomings in the procurement of APIs and other inputs. Many developed countries for instance follow a mixed approach in the area of seasonal influenza vaccines, importing some while producing others domestically.

Sustainability of supplies through domestic producers pre-supposes a competitive industry. Governments should examine appropriate industrial and trade policy interventions. In general terms, local infant industries require some level of protection from foreign competition while more developed industries should not be insulated from foreign competition, as competitive pressure may promote price reductions and innovation. This is a guideline that should inform the design of industrial and trade policies in the area of pharmaceuticals. Developing country governments differ in the extent to which they have recourse to industrial policy support for local manufacturers. **Ghana** is an example of a country that has emphasized the need for industrial policies to promote the local pharmaceutical sector.<sup>57</sup> **Kenya**, on the other hand, has been more hesitant in this regard,

providing less direct assistance to its local pharmaceutical sector.<sup>58</sup> Considering the existence of powerful generic competitors from countries such as **China** and **India**, any policies fostering local production of generics should address the possible consequences for public health when favoring infant local producers over existing foreign manufacturers. Public health and industrial development policy makers are encouraged to seek for coordinated responses, as outlined in the introductory part of this Tool Box (Main elements of local pharmaceutical production policies).

A government may consider a number of industrial and trade policy measures that create conducive legal and economic framework conditions.<sup>59</sup> Before addressing these policy measures, however, it is important to emphasize that beyond economic considerations, there are other factors that complicate medicines availability and the sustainability of supplies. Stock-outs are a frequent problem in many developing countries. They result from supply chain mismanagement, especially the incapacity to properly forecast demand for certain medicines. There needs to be reliable data for the Ministry of Health to evaluate which medicines are needed in which quantity. The procurement entity, such as a central medical store, should coordinate distribution of the medicines with the local public and private sector actors. The Ministry of Health should steer procurement of needed medicines through an updated EML.<sup>60</sup> Sustainable supply of medicines may also be threatened by poor infrastructure.

As far as the use of industrial and trade policy is concerned, the measures discussed in Sections 4.1 - 4.8, below, may play an important role to ensure a conducive enabling framework for local production.

<sup>56</sup> See WHO, Framework, p. 49, and WHO, Global pandemic influenza action plan 2006-2008.

<sup>57</sup> See UNCTAD-GIZ-EAC Regional Workshop, pp. 8/9.

<sup>58</sup> Stakeholder interviews, including local producers, UNCTAD fact finding mission to Kenya, October 2013.

<sup>59</sup> See Figure 1. See further WHO, 2011, Local Production for Access to Medical Products: Developing a Framework to Improve Public Health, Geneva, at [http://www.who.int/phi/publications/Local\\_Production\\_Policy\\_Framework.pdf](http://www.who.int/phi/publications/Local_Production_Policy_Framework.pdf) (visited 29 January 2016).

<sup>60</sup> For more details, see "Smart logistics for medication. Improving access to medicines and diagnostics in Kenya", BMZ and GIZ, May 2016, especially pp. 26 ff.



## 4.1 Measures to improve sustainability of local manufacturing

Government procurement may offer important tools to make local producers more competitive, in particular through preferential mark ups and pooled procurement.

**Price preferences in public procurement:** Procurement of medicines by the government plays an important role in the supply of medicines for a country's public health system. In mature economies, transparent and non-discriminatory procurement practices foster competition, build business confidence, help deter corruption, and promote the attainment of value for money and thus access and affordability. In a specific infant industry context, procurement rules may also be used as a support tool for local producers, i.e. by providing a margin of preference in favor of domestic manufacturers over the lowest bid from an international supplier, or by even restricting procurement to local producers alone. **Ethiopia** for instance favors bids from domestic producers even if these are up to 25 per cent higher than competing bids.<sup>61</sup> **Ghana** and **Kenya** by contrast limit the price margin preference for local producers to 15 per cent.<sup>62</sup> In Kenya, however, the local industry has observed that even importers benefit from a 10 per cent mark up in tenders provided they are 51 per cent Kenyan-owned, thereby practically erasing the advantage available to local producers.<sup>63</sup> In Ghana, a lot of procurement is done at the sub-national level, where procurement entities do not implement the 15 per cent preference margin.<sup>64</sup>

Preferential prices for local producers or restrictions of tenders to local producers may to some extent limit the availability of medicines in the national public health system, as the same amount of government resources could be used to purchase greater quantities of more affordable foreign drugs. Striking the appropriate balance

between immediate access needs and longer-term health security and industrial development objectives appears particularly important in this context and requires close coordination among government departments. Price preferences should be lowered gradually as local producers become more competitive.

Local producers in the **EAC** have suggested a 20 per cent flat net advantage in public procurement for local producers as compared to importers.<sup>65</sup> In order to encourage investments in quality upgrading, Kenyan producers propose that such price advantage could be staggered according to the extent to which the producer complies with international requirements on production site GMP and product safety, efficacy and quality.<sup>66</sup>

From a legal point of view, price preferences for local producers constitute a discrimination of foreign suppliers. This being said, the General Agreement on Tariffs and Trade (GATT) (Article III.8(a)) exempts government procurement from the obligation to avoid discriminatory treatment of foreigners as compared to locals (national treatment). This has, however, no effect on tenders by international procurement agencies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and UNICEF, which follow their own rules on the selection of bids and may even require governments that use their funds to apply non-discriminatory selection criteria. Developing countries may lose the flexibility available under the GATT by adhering to the WTO Plurilateral Agreement on Government Procurement (GPA) or by agreeing to non-discriminatory procurement under preferential trade and investment free agreements (PTIAs). For example, the **EU-Vietnam Free Trade Agreement (FTA)**

<sup>61</sup> Ethiopia Study 2016, p. 154.

<sup>62</sup> On Ghana: UNCTAD-GIZ-EAC Regional Workshop pp. 9 ff. On Kenya: Stakeholder interviews, including local producers, UNCTAD fact finding mission to Kenya, October 2013.

<sup>63</sup> Stakeholder interviews with local producers, UNCTAD fact finding mission to Kenya, October 2013.

<sup>64</sup> Stakeholder interviews, UNCTAD fact finding mission to Ghana, February 2014.

<sup>65</sup> Federation of East African Pharmaceutical Manufacturers (FEAPM), "FEAPM Position Paper No. 1. The EA Pharma Policy Incentive Package", 2015 (on file with the authors).

<sup>66</sup> Stakeholder interviews with local producers, UNCTAD fact finding mission to Kenya, October 2013.

provides an obligation to design Vietnamese procurement rules in line with the GPA, and especially to open bidding procedures to EU companies for public contracts with 34 public Vietnamese hospitals.<sup>67</sup> It is important to note that even under GPA-like obligations, a country may seek to limit its commitments to (1) cover only selected goods and services; (2) a certain minimum financial value threshold that triggers the application of GPA-like rules; and (3) lists of procurement agencies that will be subject to GPA-like disciplines.

**Pooled Procurement:** The regional pooling of resources for medicines procurement creates economies of scale for suppliers, enabling them to offer lower prices. Countries that share similar health problems should therefore consider the establishment of a regional drugs procurement policy and even a regional procurement entity. For instance, the **West African Health Organization (WAHO)** procures on a regional scale from producers based in member states of the Economic Community of West African States (ECOWAS). Member States of the **Southern African Development Community (SADC)** have identified pooled procurement as a means to rationalize expenses and obtain lower prices for greater volumes of medicines.<sup>68</sup>

For the regional market incentive to become operational, it is important that the participating governments show the political will to harmonize national rules and practices in the areas of price control policies, drug regulation, and, ideally, joint R&D in diseases affecting the region.

UNCTAD has in the context of pooled procurement suggested the creation of Regional Pharmaceutical Supply Centers (RPSCs), which could offer to holders of foreign patents the entire regional market in exchange for their

commitment to sell at affordable prices and to provide assistance to local producers in terms of technology transfer, quality upgrading and the supply of APIs for innovative medicines.<sup>69</sup> In case the patent holder is not ready to accept the offer, the RPSC could procure the medicine from a generic producer abroad, who could use the WTO "Paragraph 6 System" to export medicines made under a compulsory license to countries with insufficient local manufacturing capacities.<sup>70</sup> This generic supplier could be subject to the same commitment to assist local producers. Re-exportation of medicines produced under the Paragraph 6 System among Parties to a regional trade agreement consisting mostly of LDCs would be possible without any further notifications, thus supporting local production within the region. Compulsory licensees that produce within an LDC-dominated regional trade agreement for exporting to other parties of the regional agreement would not even be bound by any requirement to limit production to a pre-estimated amount, as is normally the case under the Paragraph 6 System.<sup>71</sup>

Even without such a regional procurement entity, national government entities may practice regional procurement from suppliers based within a given region. Nothing prevents a government from opening its bids for suppliers from other countries. This is facilitated by the harmonization of procurement laws within a given region, such as the **EAC**.<sup>72</sup> In the short term, such intra-regional procurement would mostly benefit those producers that can produce reliable quality at most affordable prices. On a longer term, however, even less capable producers could benefit to the extent their host countries can offer other benefits to foreign investors such as transparent business registration procedures, reliable infrastructure and affordable real estate to expand and upgrade existing production facilities.

<sup>67</sup> See European Commission, 2015, Press Release, EU and Vietnam reach agreement on free trade deal, available at <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1358> (visited 26 November 2015).

<sup>68</sup> SADC, 2011, Strategy for Pooled Procurement of Essential Medicines and Health Commodities, 2013-2017, available at [https://www.sadc.int/files/7614/1898/8449/SADC\\_\\_\\_Strategy\\_for\\_Pooled\\_Procurement\\_of\\_Essential\\_Medicines\\_and\\_Health\\_Commodities.pdf](https://www.sadc.int/files/7614/1898/8449/SADC___Strategy_for_Pooled_Procurement_of_Essential_Medicines_and_Health_Commodities.pdf) (visited on 17 January 2017).

At least some SADC Member States procure the same pharmaceutical products, sometimes even from the same producers.

<sup>69</sup> See UNCTAD Reference Guide, pp. 143/144.

<sup>70</sup> Decision of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO General Council, WT/L/540 of 2 September 2003 [hereinafter Paragraph 6 Decision]. This Decision has been translated into the Decision of 6 December 2005, Amendment of the TRIPS Agreement, General Council, WT/L/641 of 8 December 2005 [hereinafter TRIPS Amendment Decision], which entered into force on 23 January 2017. For a detailed analysis of the Paragraph 6 System see WTO, WIPO, WHO, "Promoting Access to Medical Technologies and Innovation. Intersections between public health, intellectual property and trade", 2012, pp. 177 ff (hereinafter WTO, WIPO, WHO). Available at [https://www.wto.org/english/res\\_e/booksp\\_e/pantihowipowtoweb13\\_e.pdf](https://www.wto.org/english/res_e/booksp_e/pantihowipowtoweb13_e.pdf) (visited 27 November 2015).

<sup>71</sup> UNCTAD Reference Guide, pp. 131 ff and Box 7.

<sup>72</sup> This has been recommended for the EAC by stakeholders, see UNCTAD-GIZ-EAC Regional Workshop, p. 13 (current challenges for local producers in the EAC).

## 4.2 Capacity building for local producers

Procurement instruments alone are unlikely to enable local producers to become more competitive. They need to be accompanied by capacity building efforts for local producers to upgrade to higher quality of production and to reach GMP standards. GMP compliance is also a prerequisite for local producers to access procurement

by international donor agencies such as UNICEF and Médecins sans Frontières (MSF). Investments into upgrading of quality assurance systems and production sites in turn require access to affordable capital. This issue is discussed separately under Sub-section 4.4 on producers' access to capital, next pages.

## 4.3 Treatment of imports vis-a-vis domestic products

Local producers' competitiveness may be raised by various industrial policy support measures, especially tariffs, taxes, and certain subsidies.

**1. *Tariff regime and import restrictions:*** Many local manufacturers in developing countries depend on the importation of ingredients needed for production, such as excipients, binders and, most importantly, active pharmaceutical ingredients (APIs). The higher the tariff on these ingredients, the higher the cost of local production, which in turn has an impact on local competitiveness vis-à-vis foreign importers of finished pharmaceuticals.

From an industrial development and also a public health perspective, it makes sense to reduce tariffs on ingredients needed for local production. From the perspective of infant industry protection, it may in addition be desirable to make local producers more competitive by raising tariffs on imports of those finished pharmaceuticals that can be made locally, or even ban such imports entirely. This would, however, raise a number of legal and public policy issues that need to be carefully considered.

**a)** In legal terms, a WTO Member that has committed to a maximum tariff ("bound tariff") on an industrial good such as a pharmaceutical product must

## Box 3:

# The use of import tariffs in Argentina and Colombia

Until the 1990s, Argentina applied tariffs on pharmaceutical products to protect domestic producers. Colombia from the 1940s and 1950s restricted the importation of pharmaceutical products, which motivated foreign firms to establish domestic plants. Local Colombian producers only appeared in the 1970s and 1980s. In both countries, these measures were complemented by other policy tools: Argentina until the 1990s excluded patent protection of pharmaceutical products and exercised price controls. Colombia likewise excluded pharmaceutical product patents and had a policy of encouraging the prescription of generic substitutes for original drugs made under patented processes. The 1990s witnessed a policy change in both countries, introducing patent and investment regimes that favored foreign originator companies, as well as phasing out tariff protection for local producers. Neither country nowadays has specific industrial policy tools in place to promote local producers. The share of domestic firms in the Argentinean market fell from 61 per cent in 1994 to 49.1 per cent in 2000. Colombia, on the other hand, experienced the opposite scenario: despite the introduction of foreign investor-friendly IP and investment regimes, multinational companies divested massively and left the country. While multinational firms owned 100 operating plants in 1995, this number came down to only 10 plants in 2010. The stronger presence of Colombian manufacturers however could not make up for the loss of

generally not apply customs duties or comparable charges in excess of the bound tariff (Article II.1(b) GATT). However, some important qualifications apply.

i. The GATT obligation not to raise tariffs does not apply to those WTO Members that have not committed to any maximum tariffs in the area of pharmaceuticals/chemicals. **Ghana** for instance has only bound 1.3 per cent of industrial goods, and 0.2 per cent of chemical goods. By contrast, **Angola** has bound 100 per cent of industrial goods and chemicals. Countries that do have a commitment in this regard but that actually apply a lower tariff are free under Article II GATT to raise the actually applied tariff to the bound rate. Angola has committed to a simple average of 60.1 per cent for industrial goods, but only applies a simple average of 9.5 per cent, which it may thus raise up to 60.1 per cent.<sup>73</sup>

ii. WTO Members that are LDCs are authorized to modify or withdraw maximum tariff bindings under the specific GATT "infant industry" exception under Article XVIII, which authorizes LDCs to grant "tariff protection required for the establishment of a particular industry" (paragraph 2) without necessarily seeking other Members' approval, but in exchange for compensation. However, in certain cases the affected Members are free to modify or withdraw substantially equivalent concessions made to the LDC.<sup>74</sup> This risk of retaliation may be the reason why this provision has never been invoked. Instead, it appears more practical for LDCs and other Members<sup>75</sup> to seek a temporary waiver from their bound tariffs under Article IX.3 of the Marrakesh Agreement Establishing the World Trade Organization.

<sup>73</sup> Figures for Angola from 2014; figures for Ghana from 2013. Available at WTO Trade Profiles: <http://stat.wto.org/TariffProfile/WSDBTariffPFRporter.aspx?Language=E> (visited 2 February 2016).

<sup>74</sup> Article XVIII Section A (para 7 (a), (b)) GATT. Accordingly, the LDC seeking withdrawal or modification of its tariff commitments needs to negotiate with the affected Members. In case of agreement, the LDC may proceed with the withdrawal or modification. In case of disagreement, the LDC in order to proceed would need to demonstrate to other WTO Members its reasonable effort to reach agreement and to offer a reasonable compensation. Where the other WTO Members do not consider such compensation adequate, the affected Member may modify or withdraw concessions made to the LDC.

<sup>75</sup> Non-LDC Members are barred from deviating from tariff commitments in the context of the infant industry exception. See Article XVIII paras. 22, 23 and 20 GATT, which subject any measure for the establishment of a particular industry to the obligation in Article II GATT to respect maximum tariff commitments.



foreign know-how: while in 1994, 90.4 per cent of the demand of the domestic market could be met through domestic production sites, this was true for only 73 per cent in 2007. The main reason for multinational divestment was the globalization process in the pharmaceutical industry, which enabled multinational firms to save costs by concentrating production in a few larger markets. In this sense, Colombia was at a disadvantage as compared to larger markets such as Argentina, and the political instability in Colombia during the 1990s further aggravated the situation. The economic crisis following the devaluation of the Argentinean peso in 2002 resulted in a similar situation for Argentina, with multinationals divesting and domestic companies buying their production plants. By 2009, Argentinean companies had regained 58.8 per cent of the domestic market.

It should be noted that there is no evidence that access to medicines (in terms of availability and affordability) altered significantly at any stage of the developments described above, confirming that local production of pharmaceuticals can be pursued as an independent industrial policy objective.

Source: UNCTAD, case study series, Case Study 1, Argentina, pp. 28/29; Case Study 3, Colombia, p. 105.

**iii.** PTIAs may further restrict developing countries' freedom to impose tariffs on finished pharmaceuticals. For instance, the 2015 FTA between the EU and Vietnam obliges the latter to allow duty-free imports for 50 per cent of EU pharmaceuticals from the entry into force of the FTA, and for the remainder seven years after entry into force.<sup>76</sup>

**b)** The industrial histories of **Argentina** and **Colombia** illustrate the use of tariffs as a means to protect local pharmaceutical infant industries (Box 3, above). Some of these practices pre-dated the GATT and its obligations (see above). Also, experience in these countries shows that tariffs are only one element of industry promotion, which needs to be embedded in a coherent set of policy measures. Finally, both countries' experiences also highlight the importance of overall economic and business considerations,

which may be stronger than any industrial policy incentives.

**c)** Import bans are contrary to Article XI.1 GATT. LDCs and developing countries may invoke Article XVIII Sections C or D to be exempted from this obligation, but need to secure agreement of the other WTO Members to avoid trade retaliation.<sup>77</sup> Alternatively, imports could be banned *de facto* by refusing marketing approval by the drug regulator, based on health standards. While this may not qualify as a trade measure in violation of Article XI.1 GATT, it would nevertheless constitute an infringement of the national treatment principle regarding the internal sale of imported like products under Article III.4 GATT, if made discriminatory. Again, the usefulness of the exemption under Article XVIII would be very limited. Furthermore, Article 2 of the Agreement on Technical Barriers to Trade (TBT) requires national treatment

<sup>76</sup> See European Commission, 2015, Press Release, EU and Vietnam reach agreement on free trade deal, available at <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1358> (visited 26 November 2015).

<sup>77</sup> See GATT Article XVIII.21 for Members at early stages of development and Article XVIII.22 for other developing countries.

and that technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. The TBT imposes similar requirements for the procedures for assessment of conformity to technical standards under Article 5. Hence the use of medicine regulation should be on a non-discriminatory basis.

**d)** From a public health point of view, making imported drugs more expensive means a decrease in the affordability of those products at least in the short term. Such measures should therefore be coordinated with the national health ministry and should be subject to periodical review regarding its impact on (1) the competitiveness of the local industry and (2) access to medicines in the country. Additional tools such as tax incentives for domestic R&D should be considered, as they may in some cases encourage necessary improvements in local quality without preventing access to imported finished products.

**2. Tax regime:** Exempting producers from paying taxes such as VAT on pharmaceutical raw materials (whether domestic or imported) used in the production process helps firms lower their prices and become more competitive. At the same time, taxes and other internal charges could be levied on imported finished products to the extent this appears acceptable from an access to medicines and affordability perspective. Such practice would be in line with the GATT (especially Article III on national treatment on internal taxation and regulation), as pharmaceutical ingredients on the one hand and finished products on the other hand cannot be considered "like" products that require non-discriminatory treatment.<sup>78</sup> Such a VAT exemption for pharmaceutical producers on raw materials would constitute a subsidy to them, however. If such a subsidy were specific, it could be the subject of counteractions by other WTO Members in respect of the finished pharmaceutical products (see sub-section (3) on subsidies, below). The example of the **Kenyan VAT Act of 2013** illustrates the need for tax authorities to coordinate their policies with other ministries in charge of developing the local pharmaceutical sector (Ministry of Industry and Ministry of Health) to avoid unintended negative consequences for local producers. The Kenyan VAT Act originally imposed VAT charges on pharmaceutical ingredients but not on imported finished medicines, thus putting local producers at a disadvantage

as compared to importers.<sup>79</sup> The problem was eventually addressed after a number of consultations with the relevant government agencies.<sup>80</sup>

**3. Subsidies:** In terms of the WTO Agreement on Subsidies and Countervailing Measures (SCM), a subsidy consists of a financial contribution (through grants, loans, or loan guarantees, non-collection of government revenue otherwise due, provision of goods or services, or purchase of goods) by a government or public body, itself or through entrustment or direction of a private body, that confers a benefit (Article 1.1(a)(1) SCM). A benefit exists when the financial contribution is provided on better-than-market terms. Subsidies therefore provide recipients with advantages that they would not be able to find in the market and can thus potentially increase the competitiveness of the local industry. Industrial and public health policy makers should be aware of a number of important restrictions and qualifications in the use of subsidies under the SCM. These are provided in the following paragraphs (a-g).

**a)** Subsidies contingent on export performance or on the use of domestic over imported goods are prohibited (Article 3 SCM) (and deemed to be "specific") and their withdrawal may be requested through the WTO Dispute Settlement Body (DSB). Such subsidies also can be the subject of countervailing measures applied by an importing WTO Member.

**b)** Subsidies specific to certain enterprises, industrial sectors or regions that in addition cause adverse effects to the interests of other WTO Members may give rise to complaints under the DSB, which may result in the obligation to remove the adverse effects or withdraw the subsidy ("actionable subsidies", Articles 5, 2.1, 2.2, 7 SCM). Such subsidies also can be the subject of countervailing measures applied by an importing WTO Member.

**c)** Non-specific subsidies are not covered by the disciplines of the SCM, and thus cannot be subject either to the WTO dispute settlement proceedings contained in the SCM or to countervailing measures applied by an importing WTO Member. Non-specific subsidies thus can be used without potential action pursuant to the SCM Agreement. The SCM specifies that subsidies that are provided in line with objective criteria or conditions for eligibility and amount of subsidization are not specific, so long as the eligibility is automatic and the criteria are strictly adhered to.

<sup>78</sup> Under WTO/GATT terminology, products are "like" if they share the same physical properties, serve the same end uses, are perceived as substitutes by consumers and share the same international tariff classification.

See [https://www.wto.org/english/tratop\\_e/envir\\_e/envt\\_rules\\_gatt\\_e.htm](https://www.wto.org/english/tratop_e/envir_e/envt_rules_gatt_e.htm) (visited on 21 October 2016).

<sup>79</sup> Stakeholder interviews, including local producers, UNCTAD fact finding mission to Kenya, October 2013.

<sup>80</sup> Information from Kenyan stakeholders at the September 2015 UNCTAD-GIZ-EAC Regional Workshop.

Such criteria or conditions are defined as those that are neutral, do not favor certain enterprises over others, and are economic in nature and horizontal in application, such as number of employees or size of enterprise (Article 2.1(b), footnote 2, SCM). For example, tax credits can avoid a finding of specificity if they are subject to objective eligibility criteria and not only available to one specific enterprise. It should be noted in this regard that specificity can be established on a *de jure* or a *de facto* basis (in the latter case, based on information as to the actual use of the subsidy).<sup>81</sup>

**d)** Many of the tools considered under industrial policy constitute subsidies. Provided they are subject to objective eligibility criteria, tax credits and tariff reductions as discussed above would not necessarily fall within the ambit of prohibited or actionable subsidies under the SCM, i.e., to the extent that they were not specific. Tariff reductions on ingredients, if they applied across the board, i.e., they were not limited to only some industries using those ingredients, would not constitute specific subsidies. On the other hand, if only certain industries (e.g., the pharmaceutical industry) could obtain the ingredients at a lower tariff rate than the normal applied rate, this reduced tariff arguably would constitute a specific subsidy to that industry. To the extent that the traded finished goods generated adverse effects of the types provided for in the SCM (i.e., injury, serious prejudice, nullification or impairment of multilateral benefits), other Members could resort to WTO DSB action (or, in the case of injury, could apply a countervailing measure). In the case of subsidies provided by developing Members, however, serious prejudice claims cannot be brought (SCM Article 27.9).

**e)** Summing up, tariff reductions and tax credits that only apply to the pharmaceutical industry may be qualified as specific under the SCM, but other WTO Members would need to show the generation of certain adverse effects to their interests before they may challenge these policy measures as actionable subsidies before the WTO DSB. In addition, any developing country receives more favorable treatment in the evaluation of the impact of potentially actionable subsidies (Article 27, paragraphs 8 and 9 SCM). Finally, the above restrictions in respect of export subsidies under the SCM do not apply to LDCs and to a number of non-LDCs as per

Annex VII(b) of the SCM,<sup>82</sup> provided that the subsidized product has not yet reached export competitiveness (Article 27, paragraphs 4 and 5 SCM).

**f) Bangladesh** has made extensive use of its LDC status to apply export subsidies to its domestic industry. The main incentives available for pharmaceutical exports include, inter alia, up to 50 per cent income tax exemption for export earnings, duty-free import of capital machinery for export-oriented facilities, a tax holiday and duty drawback scheme, and up to 15 per cent retention of foreign currency for reuse.<sup>83</sup>

**g)** Developing countries should be prepared to defend their local producers' interests by challenging foreign subsidies that undermine the competitiveness of the local industry. Available trade remedies under the SCM are:

- i.** WTO dispute settlement in respect of prohibited subsidies and actionable subsidies (Parts II and III SCM);
- ii.** Countervailing measures on imports relying on prohibited or actionable subsidies that cause injury to the domestic industry (Part V SCM);
- iii.** Anti-dumping action on imports at dumping prices (WTO Agreement on the Implementation of Article VI GATT – "Anti-Dumping Agreement"); and
- iv.** Safeguard measures as an emergency measure to address a surge in imports that causes or threatens to cause serious injury to the domestic industry (WTO Agreement on Safeguards).

**Competition safeguards:** It is important from both a public health and an industrial development perspective to avoid a situation where the domestic industry takes undue advantage of infant industry protection measures. Inefficient oligopolies whose dominant market positions allow them to determine medicines prices and avoid competitive pressure to innovate are not in the interest of patients. Governments are therefore advised to undertake periodical reviews of policy measures to ensure these still correspond to the actual needs and capacities of the domestic pharmaceutical sector. As the domestic industry's technological capacity advances, preferential treatment measures may be gradually phased out, while foreign competition should be gradually phased in. Taking account of the low level of technological capacities of many developing country and especially LDC pharmaceutical sectors, it is understood that such gradual

<sup>81</sup> Previous provisions (Article 8 SCM) on certain subsidies, such as subsidies for research and development, that were specific but nonetheless non-actionable expired in 1999, so this category of non-actionable subsidies no longer exists.

<sup>82</sup> As of the most recent calculation, the following non-LDC Members are included in Annex VII(b) and thus are exempt from the prohibition on export subsidies: Bolivia, Plurinational State of; Cameroon; Congo; Côte d'Ivoire; Ghana; Guyana; Honduras; India; Kenya; Nicaragua; Nigeria; Pakistan; Senegal; and Zimbabwe. The relevant calculations are circulated annually, in the documents series G/SCM/110/...

<sup>83</sup> UNCTAD case study series, pp. 76/77.

## 4.4 Improve producers' access to capital

Producers need access to capital to invest in making production facilities GMP-compliant and improving drug quality standards. The following paragraphs outline some useful measures in this regard.

**1. Increase the mutual understanding between the domestic pharmaceutical sector and domestic financial institutions:** It has been observed that many developing country-based pharmaceutical firms lack capacity in effectively raising and managing finance.<sup>84</sup> At the same time, many financial institutions are unaware of the particular needs of the pharmaceutical industry, which often prevents the design of appropriate and helpful business solutions tailored to local producers.<sup>85</sup> These could include lower interest rates, more favorable repayment conditions and advance payment in government tenders. This lack of awareness can be addressed through targeted training of staff from financial institutions, like in the case of **Zimbabwe**, where the domestic affiliate of an international bank for two years (1998-2000) provided pharmaceutical industry-related training to its staff. In the ideal scenario, such specific training measures should be adopted on a much longer-term basis.<sup>86</sup>

**2. Credit through bank loans:** Access to finance is an essential requirement for any investment to improve long-term competitiveness. UNCTAD interviews in **Ethiopia**, **Ghana** and **Uganda** have revealed that local producers face considerable difficulties in securing affordable credit because local commercial banks seek to make optimum

returns on their investment and charge high interest rates. Public funding options are often not available. The Development Bank of Ethiopia (DBE) seeks to address this problem by offering up to 70 per cent of the capital for new pharmaceutical investments or expansion projects at lower interest rates and under more favorable repayment conditions.<sup>87</sup>

**3. Credit through pre-funding tenders:** Paying an advance to the winner of the tendering process may provide an important source of working capital. In **Ethiopia**, the government entities pay up to 30 per cent of the value of the tender upon signature of the contract, thus complementing any DBE-loans for pharmaceutical investment (see previous item).<sup>88</sup>

**4. Promote foreign investment:** A potentially important way of accessing credit may be through foreign investors, especially foreign direct investment (FDI). UNCTAD case studies in **Argentina**, **Bangladesh** and **Colombia** have found that many successful local manufacturers, after having created basic capacities through reverse engineering and infant industry protection policies, at some point benefitted from foreign investment to upgrade domestic capacities.<sup>89</sup> Such investment may involve capital, know-how and technology transfer. Attracting foreign investors requires the availability of specific incentives, sector-specific information and a conducive legal and policy framework.

<sup>84</sup> Alastair West, Geoffrey Banda, "Finance and Incentives to Support the Development of National Pharmaceutical Industries", in: Making Medicines in Africa. The Political Economy of Industrializing for Local Health, edited by M. Mackintosh, G. Banda, P. Tibandebage, W. Wamae, International Political Economy Series, Palgrave Macmillan, 2016, pp. 278ff.

<sup>85</sup> Ibid, pp. 287, 289.

<sup>86</sup> Ibid, p. 291/292.

<sup>87</sup> UNCTAD case study series, p. 153.

<sup>88</sup> Ethiopia Study 2016, pp. 65ff.

<sup>89</sup> UNCTAD case study series.

## 4.5 Investment

Investment in local production may provide needed capital to upgrade production capacities, promote technology transfer and skills development, as well as open up new markets abroad. Investment policies in this context mainly relate to the provision of appropriate incentives, investment promotion, and the regulation of foreign investment. The following sub-sections will discuss these issues.

**1. Investment incentives:** Incentives could be financial (e.g. grants, loans at concessional interest rates), fiscal (e.g. tax holidays), or other (e.g. subsidized infrastructure). For example, the **Thai** Food and Drug Administration (under the Ministry of Health) and the Ministry of Industry have decided to work together to increase the tax exemption benefit for local pharmaceutical investment.<sup>90</sup> It should be borne in mind that many investment incentives are specific subsidies, and thus subject to the WTO SCM as described above.

**2. Investment promotion:** Investors require sector-specific information on market data (e.g. size of market, of public procurement, drugs pricing, health insurance coverage, etc.); financing possibilities; potential domestic partners for joint ventures; and the availability of qualified domestic personnel and visa regulations for foreign experts. In this context, UNCTAD has developed an electronic tool called *eRegulations* to help governments make rules and procedures fully transparent and to facilitate business, trade and investment.<sup>91</sup> In addition, UNCTAD and the International Chamber of Commerce

provide investors with online up-to-date information on business costs, opportunities and conditions in developing countries.<sup>92</sup>

**3. Regulation of foreign investment:** While investment promotion may be an important means to enable local producers to access credit and to benefit from the influx of new technologies and know how, governments may at the same time wish to make sure that foreign investors act in accordance with domestic interests and actually contribute to the development of domestic capacities and a country's sustainable development objectives.<sup>93</sup> Measures in this regard may be taken to (1) screen foreign investments prior to their entry and/or (2) require certain performances by foreign investors after their establishment. Both types of measures require cautious consideration of pros and cons. The following paragraphs provide some examples for illustration as well as a brief background on pertinent WTO rules.

**a) Argentina, Bangladesh and Colombia** prior to the 1990s restricted access for foreign investors to their domestic pharmaceutical markets, often by measures that de facto affected foreign firms more than domestic producers. In **Argentina**, intellectual property legislation played an important role in that regard, i.e. by exempting pharmaceutical products from patent protection and by enabling the drug regulator to rely on the clinical trial data submitted by originator firms in the context of generic approvals.<sup>94</sup>

<sup>90</sup> Personal communication from Thai FDA, February 2016.

<sup>91</sup> See further UNCTAD's Business Facilitation Programme, available at <http://businessfacilitation.org/eregulations/> (visited 3 December 2015).

<sup>92</sup> See further, iGuides, available at <http://www.theiguides.org/about.html> (visited 3 December 2015).

<sup>93</sup> For details, see UNCTAD, "Investment Policy Framework for Sustainable Development", New York and Geneva, 2015. Available at [http://unctad.org/en/Pages/DIAE/International%20Investment%20Agreements%20\(IIA\)/IIA-IPFSD.aspx](http://unctad.org/en/Pages/DIAE/International%20Investment%20Agreements%20(IIA)/IIA-IPFSD.aspx) (visited 17 January 2017).

<sup>94</sup> See UNCTAD case study series, Case Study 1, Argentina, pp. 30, 37.

**Bangladesh's** 1982 National Drug Policy mandated deregistration of drugs not considered essential by the health authorities. This mainly affected foreign producers. The same policy also restricted local firms from contract manufacturing for multinational firms, thereby making Bangladesh less attractive for foreign investors, which in many cases sold their production sites to local firms and left the country.<sup>95</sup> Finally, **Colombia** in the 1940s and 50s restricted the importation of finished pharmaceuticals and favored local production, thereby motivating foreign investors to establish domestic production sites, which subsequently created technology transfer opportunities for the nascent domestic sector.<sup>96</sup> While the two Latin American countries in the 1990s liberalized their foreign investment regimes (see Box 3), Bangladesh has maintained restrictions until to-date. It thereby enabled its local sector to thrive, including in the area of biosimilars. The country is now at a point of development where a phasing in of foreign investment and competition may be beneficial for the affordability of medicines as well as for their quality.<sup>97</sup> The result of investment liberalization in Argentina was a limited decline of market share for the domestic sector, coupled with an increase in competitiveness. By contrast, the share of the domestic sector in Colombia even increased, due to reasons external to the country's investment regime (see Box 3). These three examples at the same time demonstrate the potential of foreign investment regulation (Argentina and Bangladesh) but also its interdependence with other policy factors (Colombia).

**b.** Performance requirements typically require the foreign investor to act in a way considered beneficial

for the host country. This may involve requirements to transfer technology, undertake R&D locally, or source raw materials in the host country. While countries are generally free to impose such requirements, it should be noted that:

**i.** The WTO Agreement on Trade-Related Investment Measures (TRIMS) considers certain requirements to be inconsistent with the GATT, such as the obligation for an enterprise to purchase local products or to balance the volume of its imports with local purchases (Annex to TRIMS, paragraph 1).

**ii.** The 2005 Hong Kong (China) WTO Ministerial Declaration authorized LDCs to have recourse to such TRIMS performance requirements until 2020. This means that LDCs may disregard TRIMS restrictions until 2020.

**iii.** Performance requirements affecting the acquisition, use and enforcement of IP rights have to respect the TRIPS principle of non-discrimination (Articles 3 and 4).

**iv.** The effectiveness of performance requirements should be carefully assessed prior to their adoption. While local content requirements, for instance, may promote new domestic industrial activity, they may also fail to have effect where there is a lack of local capacity to make such content, e.g. APIs or other raw materials. Restricting employment for foreigners may be detrimental to technology transfer initiatives that depend on foreign inputs. Moreover, unreasonable performance requirements may damage the ability of an economy to attract investment in the longer term.

<sup>95</sup> See UNCTAD case study series, Case Study 2, Bangladesh, p. 69.

<sup>96</sup> See UNCTAD case study series, Case Study 3, Colombia, p. 104.

<sup>97</sup> See UNCTAD, Investment Policy Review of Bangladesh, p. 66.  
Available at [http://unctad.org/en/PublicationsLibrary/diaepcb2013d4\\_en.pdf](http://unctad.org/en/PublicationsLibrary/diaepcb2013d4_en.pdf) (visited 8 February 2016).



## 4.6 Investment-related policy areas

Other policy areas can make important contributions to the attraction of foreign investment.

**1.** By classifying the pharmaceutical sector as a priority for national development under Phases I and II of its Growth and Transformation Plans (GTP I & II), **Ethiopia** has made it easier for local pharmaceutical firms to qualify for incentive schemes, technological upgrading and accessing public procurement. By classifying pharmaceuticals as a priority sector, **Ghana** seeks to ensure the support of all government agencies under their respective mandates. Finally, **South Africa's** Industrial Policy Action Plan also lays priority on the pharmaceutical sector.

**2.** Combining investment incentives with the domestic EML may provide a market-based approach to encourage the production of drugs of domestic relevance (see also below, Section 6 on strategic drug selection).

**3.** Investors need a reliable and enforceable drug regulatory system and a capable drug regulatory agency to ensure quality and protection from substandard medicines and counterfeit drugs. The latter may otherwise easily undercut the price charged by compliant producers and subsequently discredit the local producers' reputation.

**4.** Section 3.2 above provides an overview of how the IP system may contribute to the promotion of local,

incremental innovation. In addition, the IP system may play an important role in attracting foreign firms. These may be originator or generic producers, or both. Developing country policy makers should employ available flexibilities under TRIPS to provide an appropriate balance between exclusive rights on the one hand and limitations and exceptions on the other hand. Section 5.1 below provides an overview of the most important TRIPS flexibilities. In the ideal scenario, IP implementation should cater to the needs of both originator and generic investors. It should reflect the specific situation of a given country. For example, the fact that **Uganda** as an LDC may disregard TRIPS obligations with respect to pharmaceutical product patents and pharmaceutical test data protection contributed to the decision by a large Indian generic firm to invest in that country.<sup>98</sup> At the same time, several originator firms have stated their intention to not file or enforce pharmaceutical patents in LDCs.<sup>99</sup>

**5.** The IP system also plays an important role in facilitating technology transfer. FDI alone may bring in capital and technology, but the local absorption of technology does not happen automatically. This requires IP laws that allow for reverse engineering and experimental uses of imported technology, within the legal boundaries of the TRIPS Agreement and its LDC-specific transition periods, where applicable.

<sup>98</sup> See UNCTAD, „Development Dimensions of Intellectual Property in Uganda: Transfer of Technology, Access to Medicines and Textbooks. Geneva, 2010, p. 40 (hereinafter UNCTAD DDIP Uganda). Available at [http://unctad.org/en/docs/diaepcb200913\\_en.pdf](http://unctad.org/en/docs/diaepcb200913_en.pdf) (visited 30 November 2015).

<sup>99</sup> See for instance for GSK at <http://www.bbc.com/news/health-35933692>, and for Roche at [http://www.roche.com/sustainability/ighc-sustainable\\_patent\\_and\\_pricing\\_policies.htm](http://www.roche.com/sustainability/ighc-sustainable_patent_and_pricing_policies.htm) (visited 10 January 2017).

## 4.7 Economies of scale

Investors look for economies of scale. Regional harmonization of drug regulatory standards, of IP flexibilities, of trade rules and tariffs are important factors to attract investment. African regional communities such as the **EAC** have advanced considerably in these regards, as illustrated by the African Medicines Regulatory Harmonization initiative, the EAC Regional Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexi-

bilities and the Approximation of National Intellectual Property Legislation, as well as the EAC Regional Protocol on Public Health Related WTO-TRIPS Flexibilities. The additional flexibility for regional trade agreements dominated by LDCs in the use of the WTO "Paragraph 6 System" is an example of expanding economies of scale through regional cooperation (see Section 5.1 below for details).

## 4.8 Trade facilitation

Pharmaceutical products are particularly subject to a wide range of import-related trade regulations at the border, such as assessment and collection of customs duties, health and safety measures, and intellectual property anti-counterfeit controls. WTO rules on freedom of transit (Art. V GATT), importation and exportation fees and formalities (Art. VIII GATT), and publication of trade regulations (Art. X GATT) seek to facilitate trade and ensure that domestic regulations are not used as barriers to international trade. In addition, the WTO has adopted the Trade Facilitation

Agreement (TFA) in 2014, which entered into force in February 2017.<sup>100</sup>

Developing country governments are encouraged to use trade facilitation rules to improve coherence with other domestic policies to the benefit of the local pharmaceutical sector, which on the one hand depends on the importation of raw materials and on the other hand may realize economies of scale by exporting finished products.

<sup>100</sup> For more information, see [https://www.wto.org/english/tratop\\_e/tradfa\\_e/tradfa\\_e.htm](https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm) (visited 7 June 2017).

**1. Consultation procedures and accessibility of trade measures:** prior to the adoption of trade regulations, tariffs, and internal taxes, the government should consult with the domestic industry to ensure that such measures are, to the extent possible, in line with the interests of local producers.

**2. Coordinate enforcement procedures:** there should be a working procedure among the customs office, the drug regulator, standard setting bodies, competition and consumer protection agencies on the control of imported substandard or unregistered medicines and medical equipment as well as border measures against counterfeit trademarked goods. On the IP side, the TRIPS Agreement leaves it up to WTO Members whether they want to apply border measures for goods in transit. In that case, it appears appropriate to require the IP holder to demonstrate a concrete and credible likelihood of trade diversion into the national territory of the country of transit, as required by the **European Court of Justice** and subsequent **EU law**.<sup>101</sup> The **WTO** has not yet pronounced itself on the compatibility of such border measures with WTO law, pending a decision in the dispute between **India** and the **EU** and the parallel dispute initiated by **Brazil** against the EU.<sup>102</sup>

**3. Customs clearance procedures** should take account of the particularities of pharmaceutical products and ingredients, such as packaging, storage and release without delay.

#### *Final observations on Section 4*

The effectiveness of the above-mentioned direct and indirect support measures may be increased by combining them, rather than using them in isolation. **Uganda** (i.e. an LDC) has had recourse to a package of direct and indirect support measures for the benefit of a joint venture of a domestic manufacturer and an Indian generic investor for the local production of anti-retroviral (ARV) medicines and anti-malarial drugs. Incentives provided to the joint venture by the government included free land to build the plant, free set-up of the entire infrastructure, including the factory and its production facilities, roads, electricity, water as well as the payment of remuneration of the generic investor's pharmaceutical experts for their training activities with local staff to build pharmaceutical manufacturing capacities. In addition, the government agreed to procure from the new plant in Kampala ARVs worth \$30 million per year for seven years.<sup>103</sup> Furthermore, the government promised to let the joint venture benefit from a 10-year tax holiday. Finally, Uganda has implemented the pharmaceuticals-related WTO transition period for LDCs, enabling generic firms to reverse engineer and produce pharmaceutical products patented abroad. It thus took advantage of the leeway Uganda enjoys under its LDC status with respect to pharmaceutical patents and its non-GPA membership status in terms of public procurement.

<sup>101</sup> European Court of Justice, Joined Cases C446/09 and C495/09 (Philips and Nokia cases); decision of 1 December 2011. Available at <http://curia.europa.eu/juris/document/document.jsf?text=&docid=115783&pageIndex=0&doclang=en&mode=req&dir=&occ=-first&part=1&cid=3515> (visited 3 February 2016).

This is also the position adopted by the International Association for the Protection of Intellectual Property (AIPPI) in its Resolution on "Question Q230 – Infringement of trademarks by goods in transit", Congress Seoul 2012, 23 October 2012. EU Regulation 608/2013 was adopted to implement the Court's decision.

<sup>102</sup> European Union and a Member State — Seizure of Generic Drugs in Transit. DS 408 (India) and DS 409 (Brazil). Available at [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds408\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm) (visited 3 February 2016).

<sup>103</sup> See UNCTAD DDIP Uganda p. 7.



# 5. Affordability of medicines

## Outline of issues for affordability of medicines

Policy issues	Instruments	Related issues
Promotion of competition including generics	<ul style="list-style-type: none"> <li>• LDCs transition period;</li> <li>• Scope of inventions (patentability);</li> <li>• Patentability criteria;</li> <li>• Opposition procedures;</li> <li>• Regulatory review exception;</li> <li>• Parallel importation;</li> <li>• Compulsory law;</li> <li>• Competition law.</li> </ul>	Patent linkages; Data exclusivity vs market exclusivity.
Generic substitution of originator medicine	Awareness raising; Prescription policy.	Quality control of generics.
Price controls	Direct price control; Indirect price control; International reference pricing.	Balancing measures to ensure affordability and sustainability of local production.
Health financing	Private insurance; Public insurance.	Sustainability of insurance system; Price control; Generic medicine policy.



Ensuring medicines affordability requires the coordination of various different policies that may have an impact on price, such as promotion of competition, including early generic/biosimilar market entry; generic substitution of originator products; price controls; and implementation of

health insurance schemes. Typically, these measures will apply to both local producers and importers of generics. In conjunction with the industrial policy measures discussed under Section 4, however, they can be particularly beneficial to local manufacturers.

## 5.1 Promotion of competition, including generics

A number of important policy tools exist to promote competition in the pharmaceutical sector. These comprise measures to improve the sustainability of local manufacturing (e.g. government procurement policies), capacity building for local producers to ensure quality, and the intelligent use of trade instruments and investment promotion as outlined under Section 4, above. Intellectual property rights such as patents and the protection of pharmaceutical test data may also contribute to a pro-competitive environment by providing incentives for investment in drug development. Second-tier IP rights such as compensatory liability regimes, trade secrets and, to some extent,

utility models (see Section 3.2, above) may specifically benefit developing country-based producers engaged in incremental innovation. At the same time, generic competition plays an important role in lowering drug prices. Policy makers should strike an appropriate balance between exclusive rights and exceptions to and limitations of these rights. How to strike that balance depends on each country's specific situation. In industrial history, countries with less developed technological capacities in pharmaceutical development have tended to provide for less expansive exclusive rights, thereby leaving room for generic producers to "invent around" an exclusive right.<sup>104</sup>

<sup>104</sup> See UNCTAD-ICTSD, "Intellectual Property Rights: Implications for Development". Policy Discussion Paper, 2003, Chapter 1 on the relatively late introduction of pharmaceutical product patent protection in countries such as France, Germany, Switzerland and others. Available at <http://www.ictsd.org/themes/innovation-and-ip/research/intellectual-property-rights-implications-for-development> (visited on 15 December 2016).



The purpose of this Section is to provide policy makers with a list of tools available under international IP treaties, and in particular the TRIPS Agreement, usually referred to as "flexibilities". They provide an important means to strike an appropriate balance between the degree of protection desirable for the establishment of a local generic industry on the one hand and the need for international cooperation on the other hand, including with generic investors and IP holders, which in many cases has been conducive to effective transfer of technological know-how.<sup>105</sup>

**1.** A number of LDCs still have not introduced in domestic laws the TRIPS transition period that authorizes them to disregard until 2033 the implementation of TRIPS obligations on patents and undisclosed information (pharmaceutical test data protection) related to pharmaceutical products. While most LDC-based producers do not have the capacity to engage in the production of patent-eligible products, foreign generic investors like, for example, Indian firms are needed in LDCs to assist in the building of domestic productive capacities. The prospect of being allowed to make generic copies of recent medicines that are or will be patented in a country like India may provide big generic firms with an interesting incentive to invest in local production in LDCs. An example is **Uganda**, which has attracted investment from India, *inter alia* through the exclusion of pharmaceutical products from patent protection.<sup>106</sup> It is clear that for such investments to effectively promote local capacities, the national IP regime alone is not sufficient, but needs to be complemented by incentives for the investor to transfer know-how to the local industry on a sustainable basis, e.g. by enabling economies of scale and effective drug regulation.

**2.** A narrow definition of patentable "inventions" leaves natural substances and even their extractions in the public domain, thus improving the conditions for generic competition. An exclusion from patentability of methods of medical treatment avoids an obligation on the part of physicians to pay licensing fees to carry out their every-day work, which would increase the costs of their services. In addition, this exclusion could be interpreted as prohibiting patents on new ways of using known pharmaceutical products, if this serves the needs of the do-

mestic industry. Finally, an exclusion of trivial improvements of existing drugs from the notion of patentable "inventions" may reduce the costs incurred by public health systems and patients by ensuring that patent holders do not seek to exclude generic competition on the basis of such trivial improvements. In **India**, for example, the patent office rejects patents on product improvements, unless the patent applicant demonstrates improved therapeutic efficacy.<sup>107</sup> Where patentability is excluded, second-tier IP tools as discussed under Section 3 above should be available to encourage local producers to invest in incremental innovation.

**3.** Alternatively, patenting of trivial improvements over the prior art can also be restricted through a policy of applying patentability requirements narrowly. The TRIPS Agreement does not define novelty, inventive step and industrial application and therefore leaves room for interpretation. Again, the requirement of therapeutic efficacy may be used to define the contours of what is considered an "inventive step" or a useful product of "industrial application" in the area of pharmaceuticals.

**4.** The availability of pre- and post-grant opposition procedures facilitates the challenging of patents or applications as compared to much more costly litigation before a country's national courts.

**5.** If the patent holder has the right to prevent a generic competitor from using the patented substance for requesting marketing approval during the patent term, the generic producer may only file the request after patent expiry. The time needed for regulatory approval would provide the owner of the expired patent with a *de facto* additional period of market exclusivity. A specific regulatory review exception, under which countries may exempt from patent protection any acts reasonably related to the submission of a request for generic approval, enables the generic competitor to secure marketing approval during the patent term and enter the market immediately upon patent expiry. The consistency of this exception with the TRIPS Agreement has been confirmed by a **WTO** dispute settlement panel.<sup>108</sup> Securing marketing approval during the term of the patent is

<sup>105</sup> For a detailed legal analysis of the following flexibilities, including examples of national legislation, see UNCTAD, "Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide" (hereinafter UNCTAD Reference Guide). Available at [http://unctad.org/en/Docs/diaepcb2009d19\\_en.pdf](http://unctad.org/en/Docs/diaepcb2009d19_en.pdf) (visited on 16 November 2015). For an illustration of how both IP protection and its exceptions and limitations have contributed to the transfer of pharmaceutical know-how, see UNCTAD case study series.

<sup>106</sup> See UNCTAD case study series, Case study 8, Uganda. [http://unctad.org/en/PublicationsLibrary/diaepcb2011d7\\_en.pdf](http://unctad.org/en/PublicationsLibrary/diaepcb2011d7_en.pdf)

<sup>107</sup> Novartis AG v. Union of India & Others, Supreme Court of India, 1 April 2013, decision based on Article 3(d) of the Indian Patents Act.

<sup>108</sup> See Canada - Patent Protection of Pharmaceutical Products, [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds114\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm) (accessed on 12 November 2015).



an essential condition for generic producers to successfully challenge a pharmaceutical patent.<sup>109</sup>

**6.** The effectiveness of the regulatory review exception may be jeopardized by the adoption of **exclusive rights in pharmaceutical test data** (data exclusivity) and under regimes of patent linkage, i.e. where the DRA is prevented by law from approving generic copies as long as the original medicine is protected by a patent. Data exclusivity may prevent the DRA from approving or even examining a generic drug on the basis of the originator's test data. The TRIPS Agreement mandates neither exclusivity in test data nor patent linkage (see below Box 4 for options for developing countries on negotiation and implementation of data exclusivity and patent linkages). As these tools may delay the market entry of generic medicines, developing countries should be cautious to accept them under domestic law, but may be obligated to do so under preferential trade and investment agreements (PTIAs).

**a.** In that case, before agreeing on test data exclusivity or patent linkage, developing country negotiators of PTIAs should liaise with the national Health Ministry to seek feedback or should even integrate Health Ministry colleagues within the negotiating team to ensure that public health concerns are taken into account in the negotiations. **Vietnam**, for example, included the Ministry of Health in the delegation to negotiate the Trans-Pacific Partnership (TPP) Agreement.

**b.** In general, developing countries may want to be cautious to engage in TRIPS-plus commitments in PTIAs. Prior to PTIA negotiations, a government should collect economic data as evidence of the economic impact generated by a PTIA. Various developing countries have made compromises on the flexibilities available under TRIPS in exchange for improved access to their PTIA partners' agricultural or textile markets. Such moves should be carefully coordinated among the relevant ministries, such as Trade and Health. Vietnam for example

succeeded in negotiating various transition periods (up to 12 years) for the implementation of TPP obligations in the area of IP.<sup>110</sup>

**c.** If a developing country cannot avoid a commitment to data or market exclusivity and patent linkages under a PTIA, the government should consult with national stakeholders to review possibilities of mitigating the impact of such exclusivity under domestic legislation. UNCTAD has made a number of suggestions in this context.<sup>111</sup>

**7.** If a government decides to make affordable parallel imports of patented medicines and ingredients available, there is a need to ensure coherence among the national patent law and the drug regulatory law in that regard. Even where the national patent law allows parallel imports, imported medicines still require regulatory approval. Domestic drug regulatory laws should facilitate such approval, e.g. by recognizing foreign approvals of the imported products by qualified authorities in case the domestic patent holder decides not to register the product. From the industrial development perspective, it may be necessary to closely consult with local producers to what extent they may benefit from parallel imports (e.g. affordable active pharmaceutical ingredients (APIs) needed for production), and to what extent parallel imports may make their products uncompetitive (e.g. finished products at prices lower than the domestic producer can offer under its license from the patent holder). Again, this requires cautious balancing of potentially competing interests, i.e. those related to industrial development and health security on the one hand, and those related to immediate access on the other.

**8.** The TRIPS Agreement authorizes Members to determine the grounds for the granting of a compulsory license or government use license, e.g. in case the price charged for a patented medicine is too high for the national public health system.<sup>112</sup>

<sup>109</sup> For instance, between 2000 and 2007, generic producers prevailed in 62 per cent of the final judgments rendered by European courts in patent litigation cases between originator and generic companies. See Competition Directorate General of the European Commission, "Pharmaceutical Sector Inquiry", Final Report, 8 July 2009, p. 12 (para. 3.2.2.) Available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>.

The United States offers the first generic producer to successfully challenge a pharmaceutical patent a six-month period of market exclusivity, under the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act") of 1984. See <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069964.htm> (visited on 8 February 2016).

<sup>110</sup> Article 18.83.4(f) of the TPP. Note that the status of the TPP as of the date of publication of this report was not clear.

<sup>111</sup> UNCTAD Reference Guide, pp. 180 -182.

<sup>112</sup> For details, also on the procedural requirements to be respected, see UNCTAD Reference Guide, pp. 118 -144.

## Box 4:

# Negotiation and/or implementation options on data exclusivity

Although the TRIPS Agreement does not mandate data exclusivity, developing countries may be obliged to introduce these "TRIPS-plus" provisions under bilateral or regional PTIAs.

Two alternatives to data exclusivity regimes exist, namely, "use and pay" systems and market exclusivity approaches:

1. Use and pay system: Some developed country PTIA partners such as the **European Free Trade Association (EFTA)** have shown flexibility in relation to the protection of test data. For instance, the **EFTA-Republic of Korea PTIA** in Annex XIII (Article 3) authorizes an alternative to data exclusivity, i.e. compensation of the data originator for the reliance by generic producers on the protected data.<sup>120</sup>

Local producers could benefit from such flexibility, provided they are in a position to offer quality at affordable prices.

- a) Health authorities should liaise with the national patent office to check the patent status of medicines on the national list of essential medicines (see in particular the **Thai** example, Box 2, above).
- b) Health authorities should also make sure domestic capacity to produce under a compulsory/government use license is available. If this is not the case, a compulsory license may also be issued to import the needed product from abroad.
- c) During the price negotiations with the patent holder, it is up to the authority in charge of drug procurement to use the availability of a government use license as a negotiating tool, provided all legal requirements are met. In the end, the grant of a government use license may not even be required.
- d) There should be guidelines for the determination of remuneration fees payable to the patent holder under a compulsory license. For example, the go-

vernment of **Ecuador** in 2010 granted a compulsory license on ritonavir and calculated royalties for the patent holder in accordance with the "Tiered Royalty Method" developed by UNDP and WHO.<sup>113</sup>

- e) Domestic legislation needs to ensure that exclusive rights in pharmaceutical test data (see above) do not stand in the way of the effective use of compulsory/government use licenses. Some WTO Members like **Chile** have provided a waiver of data exclusivity in case of compulsory licenses to ensure the DRA may approve the compulsory licensee's generic product.<sup>114</sup> The **EU** also provides a similar waiver, but limits this to the case of a specific license for export to WTO Members without sufficient domestic pharmaceutical manufacturing capacities.<sup>115</sup>

9. Certain practices by patent holders may under certain circumstances constitute an abuse of dominance under domestic competition law. Examples are the charging of excessive medicines' prices or the refusal of granting a license to a

<sup>113</sup> See UNCTAD Reference Guide, pp. 141, 141.

<sup>114</sup> See UNCTAD Reference Guide, pp. 181, 182.

<sup>115</sup> Ibid, p. 182.

2. Data exclusivity arguably differs from *market* exclusivity. Some PTIAs such as NAFTA, for instance, use language that directly prohibits the reliance on originator test data *in support of an application* for approval of generic products.<sup>121</sup> Such language could be interpreted as preventing a DRA from examining a generic application until the term of protection for the test data has expired. This would create a *de facto* monopoly for the data originator during the time needed by the DRA to examine the generic request. While such interpretation should be rejected as abusive, it seems advisable to avoid this language altogether and instead follow other PTIAs that only prohibit the *marketing* of generic drugs based on originator test data. This surely leaves the DRA free to complete generic approval procedures during the term of exclusivity and authorize generic marketing immediately upon expiry of the term of protection. The majority of US PTIAs employ this language.<sup>122</sup> Likewise, many other PTIAs between developed and developing countries only refer to market exclusivity. This can make an important difference for generic competition and drugs affordability in the market.

Source: UNCTAD, 2017.

competitor to access a technology that is essential for the development of a new product ("essential facility", e.g. various active ingredients needed to make a fixed-dose combination).<sup>116</sup> Governments should ensure that:

**a)** Compulsory licenses are available as a remedy for anti-competitive behavior/abuse of dominance under domestic competition law.

**b)** Domestic competition law is in place to define key terms such as abuse of dominance through excessive prices and essential facilities, as is done under **South Africa's** Competition Act.<sup>117</sup> Countries like **Cambodia, Ghana** and others for the time being have neither enacted competition rules nor have they an experienced competition authority and are therefore especially vulnerable to abuses of dominant market positions.<sup>118</sup>

**c)** National competition authorities understand the interface between IP and competition in the area of pharmaceuticals.

**10.** The WTO "Paragraph 6 System" provides for procedures to facilitate the export of medicines made under a compulsory license to countries with insufficient local manufacturing capacities upon notification to the WTO.<sup>119</sup> It further facilitates the reexportation of medicines produced under the Paragraph 6 System among Parties to a regional trade agreement mainly composed of LDCs without any further notifications. The additional flexibility to regional trade agreements is provided with the objective of promoting regional pharmaceutical production.

<sup>116</sup> For details, see Beatriz Conde Gallego, „Unilateral refusal to license indispensable intellectual property rights - US and EU approaches“, in Research Handbook on Intellectual Property and Competition Law (editor Josef Drexler), Edward Elgar, 2008, pp. 215-238.

<sup>117</sup> Sections 7 and 8, Competition Act of 1998. South Africa's Department of Trade and Industry (dti) and the Competition Commission will jointly develop guidelines on IP and competition to provide further clarification on the interface between these two sets of law. Information received from the dti, December 2016.

<sup>118</sup> Cambodia and Ghana as of 2016 have draft competition laws awaiting adoption.

<sup>119</sup> Decision of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO General Council, WT/L/540 of 2 September 2003, and Amendment of the TRIPS Agreement, General Council, WT/L/641 of 8 December 2005.

<sup>120</sup> EFTA-Republic of Korea PTIA (accessed on 13 February 2015). <http://www.efta.int/free-trade/free-trade-agreements/media/documents/legal-texts/free-trade-relations/republic-of-korea/anne-tes-rou-jd/DA1CC4D735464D1B9ACB81C45FEC1446.pdf>

<sup>121</sup> See Article 1711(6) of NAFTA.

<sup>122</sup> See, for instance, Article 15.10.1 of the Central America-Dominican Republic-United States Free Trade Agreement (DR-CAFTA). See also Article 18.50.1 of the TPP. Available at USTR, <https://ustr.gov/tradeagreements/free-trade-agreements/trans-pacific-partnership> (last visited, 19 May 2017)

## 5.2 Promotion of generic substitution of originator medicines

To the extent that affordable and quality-complying generic medicines are available, it is appropriate to promote the substitution of more expensive originator products with those generics. While the above-mentioned TRIPS flexibilities prepare the legal framework to enable the early market entry of generic products, other policies need to be in place to address the practical problem that medical doctors and patients may be subject to advertising efforts from originator firms to discourage the use of generic pharmaceuticals even after patent expiry. A number of measures should be considered to promote effective generic substitution.

**a)** Governments may adopt awareness raising campaigns via social media as well as direct distribution of information to physicians regarding the substitutability of originator drugs through generics.

**b)** A prerequisite for the success of such campaigns is the capacity of the national DRA to effectively examine drug safety, efficacy and quality. Quality assurance documents should be published to build generic reputation.

**c)** In some countries, medical doctors and pharmacies are required to prescribe and dispense generic equivalents when available. Governments may wish to consider financial and other incentives in this regard.

## 5.3 Price controls

The majority of new medicines continue being made in a number of developed countries such as the **United States, Switzerland, France, the United Kingdom, Japan and Germany**. Medical R&D as well as intellectual property frameworks in those countries enable the private sector to be in charge of both downstream drug development and marketing. By introducing the obligation to make patents available for pharmaceutical products, the TRIPS Agreement (Article 27.1) has exported this R&D model to almost

all WTO Members. As recalled in the WTO Declaration on the TRIPS Agreement and Public Health, IP rights provide important incentives to invest in costly drug development, but also raise concern about their effect on drug prices.<sup>123</sup> In order to limit expenses in that regard, many countries rely on various systems of price controls, which are not regulated under TRIPS. The systems most frequently used vary according to the degree of government intervention:<sup>124</sup>

<sup>123</sup> WTO, 2001, Doha Ministerial Declaration of the WTO on TRIPS and Public Health, World Trade Organisation, WT/MIN(01)/DEC/2, Ministerial Conference, Fourth Session, Doha, 9 - 14 November 2001, para. 3.

<sup>124</sup> On the following, see WTO, WIPO, WHO, pp. 157-159.

**1.** The most direct forms of intervention are those where the government sets the price and prevents sales at any other price, or directly negotiates the price with the industry. In **Canada**, the Patented Medicines Prices Review Board has the right to order price reductions or the offset of revenues deemed excessive.<sup>125</sup> In **Colombia**, the National Pricing Commission fixes maximum retail prices. In a 2009/2010 case involving the substances lopinavir and ritonavir (used in HIV/AIDS drugs), the drug supplier was obliged by the Pricing Commission to sell the product at the fixed price.<sup>126</sup> As the product was on the national essential medicines list, health insurers were required to reimburse its cost to patients, which in turn made it necessary for the government to fix a maximum price.<sup>127</sup>

**2.** Less direct ways of controlling the price are for instance by linking marketing approvals to prices or by limiting insurance coverage to certain maximum retail prices.<sup>128</sup> In **Colombia**, a number of medicines at least during a certain period (2004-2010) were no longer subject to direct price fixing but to a more liberal regime under which the government only determined the criteria and methodology based upon which producers were allowed to set the maximum retail price. Under an even more liberal approach, the government between 2006 and 2010 let the producers freely set the retail price and only obliged them to explain the price setting methodology and indicate any price variations.<sup>129</sup>

**3.** Prices are usually set by reference to comparable medicines abroad (external reference pricing, ERP) or on the domestic market (internal reference pricing). The purpose is to derive a benchmark or reference price for the purpose of setting or negotiating medicine prices. While ERP has been shown to be associated with lower medicines prices, concerns have been expressed about the unexpected and negative impacts of ERP. In

particular, pharmaceutical producers might be tempted to introduce new medicines at high entry prices in countries without price controls, thus setting a high reference price for countries using ERP.<sup>130</sup>

While the predominant goal of price controls is to keep medicines' prices at affordable levels for patients and the public health service, it is recommended that there should be a clear policy on the interface between price controls and the promotion of local producers. In particular price controls need to strike a balance between the need to ensure affordable prices and the need by economic actors for economic sustainability of their production.

► In order to ensure long-term availability of medicines (see above, Section 4 on availability and sustainable supply), local producers have to make investments to upgrade their production sites in terms of GMP and the quality of their products to meet regulatory safety, efficacy and quality requirements. The establishment of low mandatory drug prices (e.g. for purposes of procurement and health insurance reimbursement schemes) should not discourage local producers from making such long-term investments. Striking the right balance in this context requires continuous coordination between health and industry stakeholders, especially the relevant government agencies and the private sector.

► Such balance may be struck by limiting price controls to certain categories of products or by allowing producers to set the price within a range determined by the government. In **Indonesia**, only 150 out of 369 generic<sup>131</sup> medicines on the national EML are generally subject to reference pricing. The remainder of the essential drugs is only controlled as to purchases by the public sector.<sup>132</sup> **Canada** and **Mexico**, by contrast, limit price controls to patented pharmaceuticals.<sup>133</sup>

<sup>125</sup> See <http://pmprb-cepmb.gc.ca/home> (visited 26 May 2016).

<sup>126</sup> See UNCTAD case study series, Case Study 3 Colombia, p. 114/115.

<sup>127</sup> See WTO, WIPO, WHO, p. 158 / Box 4.4.

<sup>128</sup> Ibid.

<sup>129</sup> See UNCTAD case study series, Case study 3, Colombia, p. 114.

<sup>130</sup> For more details, see Leopold, C. Mantel-Teeuwisse, AK; Seyfang, L; Vogler, S; de Joncheere, K; Laing, RO; Leuffkens, H. (2012), Impact of External Price Referencing on Medicine Prices – A Price Comparison Among 14 European Countries, *South Med Rev.* 2012 December; 5(2): 34–41. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3606937/> (visited on 8 June 2017).

<sup>131</sup> According to WIPO's Statistical Country Profiles, the overall number of patents including pharmaceuticals granted in Indonesia between 2000 and 2014 is very limited. [http://www.wipo.int/ipstats/en/statistics/country\\_profile/profile.jsp?code=ID](http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=ID) (visited on 26 May 2016). This may have convinced the government to subject even generic products to price controls.

<sup>132</sup> See UNCTAD, case study series, Case Study 5 Indonesia, p. 181.

<sup>133</sup> See WTO, WIPO, WHO, p. 157.



## 5.4 Health financing

Sustainable Development Goal 3 *inter alia* calls for universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.<sup>134</sup> Accordingly, medical treatment should be available to individuals without putting them at risk of financial hardship. Any form of health financing should therefore be built upon the concept of a "risk pool", whereby funds are collected from the general public to cover the risk that some become sick and need access to cost-intensive health care. A risk pool may be funded either through taxes or an insurance system.<sup>135</sup> Funding of the pool may come from public or private sources. For instance, a majority of the population in the **United States** relies on private insurance companies,

to which insured patients pay a premium. Public funding of the risk pool may be generated through payments that are mostly employment-dependent (both employer and employee) as in **France** and **Germany**, or through general taxation, as in **Australia**. **Japan** has traditionally put much emphasis on universal health coverage for all its residents through its public national health insurance. The public medical insurance program in **Indonesia** covers the poorest segments of the population, making up 15 per cent of national health spending. 70 per cent of health expenses are borne by patients out of pocket, while employers take care of the remaining 15 per cent through private corporate health insurance schemes.<sup>136</sup> **Thailand's** universal public healthcare scheme extends to 78 per cent of the population that had previously not

<sup>134</sup> See United Nations, Sustainable Development Goals, 2016, Goal 3: Ensure healthy lives and promote well-being for all at all ages, available at <http://www.un.org/sustainabledevelopment/health/> (visited on 30 May 2016).

<sup>135</sup> See [http://www.who.int/health\\_financing/en/](http://www.who.int/health_financing/en/) (visited 8 February 2016).

<sup>136</sup> See UNCTAD case study series, Case Study 5, Indonesia, p. 177.





been covered under the social security scheme for private sector employees and the Thai Government employee health care scheme. Health insurance coverage in Thailand has thus succeeded in covering about 98 per cent of the population.<sup>137</sup> While this has limited out of pocket expenses for patients, it has also contributed to making Thailand's public spending on health higher than in its neighboring countries.<sup>138</sup> The social health protection system in **Rwanda** consists of Community-based Health Insurance (CBHI) schemes for formal and informal sector members that covered 91 per cent of the population in Rwanda in 2011 providing access to basic health care services and medication at a discount rate. The Rwandan CBHI scheme is funded from various sources, i.e. member contributions, government subsidies, external donors, etc. Member contributions made up 66 per cent of the overall funding in 2012/13. Premiums are divided into six categories, where the two poorest ones are entirely subsidized by the government. CBHI schemes have been expanding in African and other developing countries.<sup>139</sup> For reasons of sustainability of their insurance systems,

countries are interested in maintaining the prices of procured medicines at an affordable level. Other policies discussed in this Tool Box therefore play an important role in ensuring the long-term acceptance of a given insurance system by the public (i.e. the contributors). Such policies are for example the use of price controls (see above), the promotion of generic medicines (see above), and the use of a country's essential medicines list to guide reimbursement decisions under health insurance schemes (see below, Section 6 on strategic drug selection). Tax-based health financing systems require close coordination between the Ministry of Health and the Ministry of Finance to determine the tax base for reimbursable medicines as well as the generation of resources to enable access by the poor segments of the population. Facilitated reimbursement may provide an incentive to domestic producers to focus on those drugs. Thus, the public through the funding of reimbursement schemes indirectly creates demand in the area of what the Ministry of Health considers essential medicines.

<sup>137</sup> Ibid, Case Study 7, Thailand, p. 235.

<sup>138</sup> Ibid, pp. 234/235, referring to 2.7 per cent of GDP in Thailand as compared to 1.9 per cent in Malaysia, 1.2 per cent in Indonesia, and 1.3 per cent in the Philippines. Thai public health spending appears very low as compared to that in developed countries, e.g. 9 per cent in France, 8.7 per cent in Germany and 8.3 per cent in the United States (figures from 2014, see at <http://data.worldbank.org/indicator/SH.XPD.PUBL.ZS> ; visited on 7 September 2016).

<sup>139</sup> For details, see ILO, 2016, Progress towards Universal Health Coverage, ILO Social Protection Department, April 2016, Geneva.



## 6. Strategic drug selection

### Outline of issues for strategic drug selection

Policy issues	Instruments
Ensure availability of essential medicines	Tie industrial policy measures to essential medicine list; Overall impact on society as a criterion in government procurement of drugs; Reimbursement based on essential medicine list.
Ensure drug quality	Make reimbursement under health insurances dependent on drug quality.

From a public health perspective, local production is only successful if it enhances access to medicines that addresses countries' important public health concerns. A local production policy should therefore commit industrial policy makers to agreeing on certain measures that will encourage the development of drugs for which there might otherwise be no market, such as anti-malaria treatments. The WHO EML provides a

selection of medicines from which countries may choose the ones that are most relevant to their health systems and include them on their national EML. This list may be used by the government to decide which medicines (not necessarily all of the listed ones) qualify for specific government support in terms of reimbursement, facilitating their production or importation. Accordingly, a government may wish to:



1. Tie industrial policy measures such as preferential tariffs, taxes, subsidies, procurement regimes and other support measures to the local production of those medicines that are included in the national EML.
2. Guide reimbursement decisions under health insurance schemes according to the inclusion of a drug on the national EML.
3. Guide reimbursement decisions under health insurance schemes according to an independent assessment of the quality and efficiency of a drug. In **Germany** the *Institute for Quality and Efficiency in Health Care (IQWiG)*, which is independent from any government agency and the private sector, examines the advantages

and disadvantages of medical services, drugs, medical devices, etc. Its publicly available reports are the basis for inter alia decisions regarding the reimbursement of medical interventions.<sup>140</sup>

Influencing firms' investment decisions through industrial policy measures may be particularly relevant where local production is pursued through the private sector. Dependency on market forces is less pertinent where the local producer is owned by the government, such as **Thailand's** Government Pharmaceutical Organization (GPO). Finally, it is important to note in this context that no country can produce all essential medicines domestically.

<sup>140</sup> For details, see German Institute for Quality and Efficiency in Health Care (IQWiG), 2016 available at <https://www.iqwig.de/en/about-us/responsibilities-and-objectives-of-iqwig.2946.html> (visited on 26 October 2016).

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