

# WHAT LIES WITHIN?

Procurement processes and the risk of substandard medicines



By Dr David Torstensson and  
Dr Meir Pugatch

 STOCKHOLM NETWORK

# What Lies Within?

Procurement processes and the risk of substandard medicines

By Dr David Torstensson and Dr Meir Pugatch

Stockholm Network  
35 Britannia Row  
London N1 8QH  
[www.stockholm-network.org](http://www.stockholm-network.org)

The Stockholm Network is the leading pan-European think tank and market-oriented network. The views represented here are those of the authors and do not necessarily represent the corporate view of the Stockholm Network or its member think tanks.

Copyright © Stockholm Network 2012

The moral right of the authors has been asserted.

All rights reserved. Without limiting the rights under copyright reserved above, no part of this publication may be reproduced, stored or introduced into a retrieval system, or transmitted, in any form or by any means (electronic, mechanical, photocopying, recording or otherwise), without the prior written permission of both the copyright owner and the publisher of this book.

# Contents

## Executive Summary

### Section 1: Introduction

- 1.1 A growing threat – counterfeit and substandard medicines
- 1.2 Procurement and the distribution of substandard and counterfeit medicines

### Section 2: Defining procurement

- 2.1 Good standards of public procurement
- 2.2 Developed versus developing world and emerging markets

### Section 3: Gold standard and benchmarks for pharmaceutical procurement

- 3.1 Procurement as part of an overall pharmaceutical policy
- 3.2 Pharmaceutical procurement
  - 3.2.1 The negative consequences of poor procurement
  - 3.2.2 Systems of procurement and key actors
  - 3.2.3 Methods of procurement
  - 3.2.4 Tendering awards
  - 3.2.5 Prequalification
- 3.3 Quality assurance
  - 3.3.1 Existing guidelines and standards
  - 3.3.2 Cost over quality?
- 3.4 A gold standard?

### Section 4: Pharmaceutical procurement systems in emerging markets and the developing world

- 4.1 Argentina
  - 4.1.1 Health system overview
  - 4.1.2 Pharmaceutical profile
  - 4.1.3 Pharmaceutical procurement overview
  - 4.1.4 Strengths and weaknesses
- 4.2 Azerbaijan

- 4.2.1 Health system overview
- 4.2.2 Pharmaceutical profile
- 4.2.3 Pharmaceutical procurement overview
- 4.2.4 Strengths and weaknesses

#### 4.3 Brazil

- 4.3.1 Health system overview
- 4.3.2 Pharmaceutical profile
- 4.3.3 Pharmaceutical procurement overview
- 4.3.4 Strengths and weaknesses

#### 4.4 China

- 4.4.1 Health system overview
- 4.4.2 Pharmaceutical profile
- 4.4.3 Pharmaceutical procurement overview
- 4.4.4 Strengths and weaknesses

#### 4.5 Colombia

- 4.5.1 Health system overview
- 4.5.2 Pharmaceutical profile
- 4.5.3 Pharmaceutical procurement overview
- 4.5.4 Strengths and weaknesses

#### 4.6 India

- 4.6.1 Health system overview
- 4.6.2 Pharmaceutical profile
- 4.6.3 Pharmaceutical procurement overview
- 4.6.4 Strengths and weaknesses

#### 4.7 Poland

- 4.7.1 Health system overview
- 4.7.2 Pharmaceutical profile
- 4.7.3 Pharmaceutical procurement overview
- 4.7.4 Strengths and weaknesses

#### 4.8 Romania

- 4.8.1 Health system overview
- 4.8.2 Pharmaceutical profile

4.8.3 Pharmaceutical procurement overview

4.8.4 Strengths and weaknesses

4.9 Russia

4.9.1 Health system overview

4.9.2 Pharmaceutical profile

4.9.3 Pharmaceutical procurement overview

4.9.4 Strengths and weaknesses

4.10 Thailand

4.10.1 Health system overview

4.10.2 Pharmaceutical profile

4.10.3 Pharmaceutical procurement overview

4.10.4 Strengths and weaknesses

4.11 Turkey

4.11.1 Health system overview

4.11.2 Pharmaceutical profile

4.11.3 Pharmaceutical procurement overview

4.11.4 Strengths and weaknesses

4.12 Vietnam

4.12.1 Health system overview

4.12.2 Pharmaceutical profile

4.12.3 Pharmaceutical procurement overview

4.12.4 Strengths and weaknesses

## **Section 5: Summary, Conclusions and Policy Recommendations**

5.1 Summary

5.2 Conclusions

5.2 Policy recommendations

## **Bibliography and sources**

## Executive Summary

Substandard and counterfeit medicines are a growing health menace in both the developed and developing world. The Food and Drugs Administration (FDA) and World Health Organisation (WHO) have both estimated that in many developing countries between 25-50% of the supply chain could be made up of substandard and/or counterfeit drugs. While in developed countries the figure is usually much lower, it is nevertheless not an insignificant percentage of the total drug market. Indeed, there are a number of examples every year of substandard and counterfeit medicines being discovered in both the EU and North America.

Last year the Stockholm Network published the second paper in our series on pharmaceutical drug regulations in developing and emerging economies. This paper built on a previous 2010 publication which re-introduced the topic of substandard medicines to European policymakers. Both these papers described how the spread of substandard medicines is a serious public health issue in many emerging economies.

This paper discusses the spread of counterfeit and substandard medicines through the procurement process. Poor and/or corrupt pharmaceutical procurement practices provide an obvious and dangerous opening for the spread of both counterfeit and substandard medicines within a country's pharmaceutical supply chain. Via case studies of 12 key countries this paper details how in a number of developing economies and emerging markets, counterfeit and substandard medicines are able to penetrate the pharmaceutical supply chain through poor procurement processes.

This paper outlines how global standards and guidelines for pharmaceutical procurement are both widely available and comprehensive. Detailed examples of procurement guidelines and standards from international organisations like the WHO, World Bank and Global Fund are described. Together these examples provide an internationally recognised, agreed benchmark and point of comparison for emerging markets and developing countries. This paper summarises and formalises these guidelines into an international gold standard which describes the main features of high quality systems of pharmaceutical procurement.

Based on the evidence collected, the paper draws three conclusions:

- i) Systems of pharmaceutical procurement vary and must be viewed within the broader context of a country's respective rate of development; economic wealth; culture; levels of corruption;

existing drug regulations and implementation; penetration of substandard and counterfeit medicines within the wider health care system; and general standards of procurement.

- ii) However, even given the above caveats, there exists a gold standard for pharmaceutical procurement which both emerging and developing countries can make use of, regardless of their other differences.
- iii) Improving procurement standards and focusing on procuring the highest quality medicines is an effective way of limiting the spread and use of substandard and counterfeit medicines and therefore of protecting patients.

Based on this analysis and these conclusions, the paper provides the following policy recommendations for how governments can improve their systems of pharmaceutical procurement and drug quality standards.

- Where possible, systems of procurement should be modelled and changed to reflect the internationally established and agreed consensus on high quality procurement – as summarised in this paper's "gold standard".
- Systems of pharmaceutical procurement should prioritise quality assurance, quality verification and constant monitoring of drug supplies through such measures as drug testing and pharmacovigilance.
- Public procurement systems should, where possible, try to use their own purchasing power to deal with the problem of substandard medicines, particularly in countries in which such problems may be more frequent.

## Section I: Introduction

Last year the Stockholm Network published the second paper in our series on pharmaceutical drug regulations in developing and emerging economies, *Keeping Medicines Safe Extended A Further Study of the Regulations Guiding the Approval of Medicines in Emerging Markets (Egypt, Peru, Russia and Thailand)*. This paper built on our previous 2010 flagship publication, *Keeping Medicines Safe A Study of the Regulations Guiding the Approval of Medicines in Emerging Markets*, which re-introduced the topic of substandard medicines to European policymakers.

Both these papers described how the spread of substandard medicines is a serious public health issue in many emerging economies. The lack of robust and comprehensive systems of drug regulations as well as the lack of implementation and follow-through of existing regulations is a real problem in some of the world's biggest emerging economies.

These papers are part of the Stockholm Network's wider work on patient safety and quality of care in both private and public health systems. Since 2004 and the publication of *A Sick Business*, a pioneering look at the counterfeit drug trade, the Stockholm Network has developed a dedicated research focus that examines the spread of counterfeit and substandard medicines.

### 1.1 A growing threat – counterfeit and substandard medicines

Substandard and counterfeit medicines are a growing health menace in both the developed and developing world. The FDA and WHO have both estimated that in many developing countries between 25-50% of the supply chain could be made up of substandard and/or counterfeit drugs.<sup>1</sup> When specifically sampling for substandard medicines, surveys of anti-malarials and anti-bacterials have found that up to 40% of the total sample consisted of substandard medicines.<sup>2</sup> While in developed countries the figure is usually much lower, it is nevertheless not an insignificant percentage of the total drug market. Indeed, there are a number of

---

<sup>1</sup> Statement of Lutter, Randall W., (2005) Acting Associate Commissioner for Policy and Planning, FDA, before US Congress, November 1, 2005, <http://www.fda.gov/newsevents/testimony/ucm112670.htm> (Accessed August 2011).

<sup>2</sup> See Torstensson, D. and Pugatch, M. (2010), *Keeping Medicines Safe*, Stockholm Network, p. 9.

examples every year of substandard and counterfeit medicines being discovered in either the EU or in North America.<sup>3</sup>

Counterfeits and substandard medicines are sometimes confused and communicated as being one and the same. However, they are two distinct phenomena and it is vital to separate the two conceptually as they have different causes, symptoms and solutions. The WHO defines counterfeit medicines as:

medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source... They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a counterfeit medicine is unknown and its content unreliable. Counterfeit medicines are always illegal. They can result in treatment failure or even death.<sup>4</sup>

The crucial point contained in this definition is that counterfeit drugs are *deliberately* fraudulent and always the result of a criminal and illegitimate enterprise.<sup>5</sup> Counterfeiting, in addition to being a public health issue, is a criminal justice and law enforcement issue.

Substandard medicines, on the other hand, are different. The WHO defines substandard drugs as:

...pharmaceutical products that fail to meet either their quality standards and specifications, or both. Each pharmaceutical product that a manufacturer produces has to comply with quality assurance standards and specifications, at release and throughout its shelf-life, according to the requirements of the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable national or regional medicines regulatory authority before the product is authorized for marketing.<sup>6</sup>

As this definition suggests, substandard medicines are those which do not comply with set quality standards and/or specifications of "the territory of use". This is an important point as quality standards and specifications vary from one country to another and even within a country. For example, in India some drug regulatory responsibilities are decentralised to the regional level. Different regions have different rules and

---

<sup>3</sup> See, for example, the BBC report, "How fake drugs got into the NHS", 3 February 2009, <http://news.bbc.co.uk/2/hi/health/7865569.stm> and *USA Today*, 'Growing problem of fake drugs hurting patients, companies', September 13 2010, [http://www.usatoday.com/money/industries/health/2010-09-12-asia-counterfeit-drugs\\_N.htm](http://www.usatoday.com/money/industries/health/2010-09-12-asia-counterfeit-drugs_N.htm) (Both Accessed October 2011).

<sup>4</sup> WHO, Media Centre, Fact Sheets, "Medicines: counterfeit medicines", <http://www.who.int/mediacentre/factsheets/fs275/en/> (Accessed August 2011).

<sup>5</sup> See WHO, Counterfeit, FAQs, <http://www.who.int/medicines/services/counterfeit/faqs/QandAsUpdateJuly11.pdf> (Accessed August 2011).

<sup>6</sup> *Ibid.* Question 6, "What are substandard medicines?".

varied rates of implementation and enforcement of those rules. Thus what is substandard in one region may not be so in another.

Drug regulatory standards around the world are not uniform. What is considered as being a substandard medicine in one legal jurisdiction can quite easily be regarded as an accepted standard for other jurisdictions. There are efforts to harmonise regulations and create global minimum standards both at the WHO level as well as through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). However, by and large the drug regulatory standards in place – and implemented – in a given country vary considerably.<sup>7</sup>

The globalisation of pharmaceutical supply chains has also underlined the need for quality control in all interlinked markets. For example, after a number of cases where low quality and even hazardous drugs and foods have penetrated the US supply chain from foreign countries – including a 2008 case of heparin sodium containing a Chinese manufactured contaminant – the FDA has opened a number of permanent offices in foreign locations.<sup>8</sup> These include offices in Asia and Latin America. While the establishment of these offices has indeed been helpful, there are still concerns over the scale of enforcement and inspections activities required. For example, a 2010 GAO report on these overseas offices found that there is concern among FDA staff that the workload in these foreign offices could be overwhelming.<sup>9</sup> One area of pharmaceutical manufacturing which is of particular concern is the global import and export of Active Pharmaceutical Ingredients (APIs). APIs are the most important element of a pharmaceutical compound as they are the active substance used to treat a disease or condition. As will be discussed below, many countries do not have adequate safeguards in place to inspect and verify the quality of imported APIs. In these cases the pharmaceutical systems are vulnerable to being penetrated by substandard and counterfeit medicines.

In addition, and in sharp contrast to counterfeit medicines, substandard medicines can be produced inadvertently at the manufacturing, distribution and storage phases. Poor manufacturing, processing, transportation and storage practices can all lead to substandard quality medicines. Moreover, imperfect

---

<sup>7</sup> For a full discussion of the efforts to standardise drug regulatory standards and the varying standards and rates of implementation in a number of key emerging markets see Torstensson and Pugatch (2010).

<sup>8</sup> Rosenberg, H. (2010) "GAO Report-FDA Oversight of Imported Products Has a Long Way to Go", Frommer, Lawrence and Haug, FDA Lawyers Blog (US law firm), November 12 2010, <http://www.fdalawyersblog.com/2010/11/gao-report-fda-oversight-of-im.html> (Accessed October 2011).

<sup>9</sup> US GAO (2010), *Food and Drug Administration, Overseas Offices Have taken steps to Help Ensure Import Safety, but more Long-Term Planning is Needed*, Report to the Committee on Oversight and Government Reform, House of Representatives, GAO, p. 19.

regulations and lack of testing mean that in some countries substandard medicines receive regulatory approval.

Because substandard medicines are legally approved drugs the policy responses needed to tackle them are not primarily in the field of law enforcement or criminal justice. Instead, they cover a whole range of policy areas such as health, education, logistics, transportation and distribution infrastructure.<sup>10</sup>

## 1.2 Procurement and the spread of substandard and counterfeit medicines

The purpose of this paper is to discuss the spread of counterfeit and substandard medicines through the procurement process. The focus will primarily be on public procurement, but where appropriate, private sector procurement will also be discussed.

Poor and/or corrupt procurement practices provide an obvious opening for the spread of both counterfeit and substandard medicines. Procurement practices are influenced by a number of factors including: the design and implementation of the procurement system; levels of corruption; available public resources for procurement; experience of high-level and professional public administration; levels and consistency of enforcement; and levels of education and knowledge among health administrators and the population at large.

A number of studies and surveys of health systems in developing countries and emerging markets suggest that the risk of substandard and counterfeit medicines penetrating the supply chain is heightened when any or all of these factors are present.<sup>11</sup> Frequently, this is confined to poorer countries that do not have highly developed and professional systems of public administration and suffer comparatively high levels of corruption. However, there are also examples of counterfeits and substandard medicines having been procured by non-state actors and organisations with high levels of funding and procurement experience. For instance, a recent study by Bate has claimed that up until 2007 the Global Fund did not maintain stringent quality controls and had, in fact, spent part of its grants/funds on poor quality copied medicines.<sup>12</sup>

---

<sup>10</sup> See Torstensson and Pugatch (2010) for a full discussion in what policies are required to combat substandard drugs.

<sup>11</sup> See Erhun, W.O., OBabalola, .O. and Erhun, M.O. (2001) "Drug Regulation and Control in Nigeria: The Challenge of Counterfeit Drugs", *Journal of Health & Population in Developing Countries*, 4(2): 23-34. See also Management Sciences for Health (2008), *Assessment of Kenya Medical Supplies Agency (KEMSA)*, (funded and supported by USAID).

<sup>12</sup> Bate, R. (2008), *Making a Killing – the deadly implications of the Counterfeit Drug Trade*, AEI Press, Washington DC, p. 61-2. Bate lists as an example one batch of procurement 56% of orders went to suppliers neither WHO pre-qualified or approved by a stringent regulator such as the US FDA, Health Canada or EMA. Moreover, he argues that as of June 2007 only 7% of anti-malarials on the Global Fund's list had undergone bioequivalence testing.

In addition to areas such as effective drug registration; quality control; inspections; and improved drug regulatory capacity; improved standards of procurement is one method whereby the spread of counterfeit and substandard medicines can be limited and effectively managed. Indeed, the WHO has stated that helping countries strengthen their drug procurement is one of its key initiatives in fighting the spread of counterfeit medicines.<sup>13</sup>

The countries studied in this paper represent a cross-section of emerging and developing markets from across the world and a full spectrum of health and pharmaceutical systems. Each country description will include a brief introduction and overview of the respective health system and pharmaceutical profile. This will describe the major characteristics of the health system and the existence and market penetration of substandard medicines and counterfeits. This will then be followed by an outline and discussion of pharmaceutical procurement and the strengths and weaknesses of each respective country, leading us into a number of policy recommendations to improve the procurement of medicines and medical supplies and assist governments and policymakers in fighting the spread of counterfeit and substandard medicines.

---

<sup>13</sup> WHO, (2006a) "Counterfeit Medicines", Fact Sheet number 275, Revised February 2006, WHO Media Centre.

## Section 2: Defining public procurement

Procurement is the process by which governments, businesses and institutions purchase or contract out the provision of a specified service or good. It is an essential part of public and business administration and involves large sectors of the economy every year. The public and private policies and culture that guide the procurement process have a sizeable impact on both the quality of services obtained and the public's confidence in those services.

Public procurement in particular is of high importance as governments at all levels – central, regional and local – together frequently make up the single biggest purchaser of goods and services in an economy. For example, within the EU, public procurement accounts for just under a fifth of total output, approximately 17 % of EU GDP, that is \$2.7trillion.<sup>14</sup> The figure for OECD countries is generally thought to be the same at about 15 % of GDP.<sup>15</sup>

The high value of many public procurement projects – particularly in the field of medical supplies – means that in many countries public procurement is also an area beset with real and potential problems. Indeed, the OECD has described public procurement as the “government activity most vulnerable to corruption.”<sup>16</sup>

Survey data suggests that bribery in relation to public procurement occurs more frequently than for other public sectors or services such as in relation to taxation, the judiciary and utilities.<sup>17</sup> This is true even within the OECD which suffers comparatively low levels of corruption. Data also suggests that high levels of public procurement corruption exist in East Asia, South Asia, Sub-Saharan Africa, Eastern Europe and Latin America. In particular, this is the case for health and medicines which are, as will be outlined below, especially vulnerable to corruption.

---

<sup>14</sup> EUBusiness, “Modernising the European public procurement market – guide”, <http://www.eubusiness.com/topics/single-market/procurement-11> (Accessed August 2011).

<sup>15</sup> OECD (2007), *Integrity in Public Procurement, Good Practice from A to Z*, OECD, p. 10.

<sup>16</sup> *Ibid.* p. 3.

<sup>17</sup> *Ibid.* p. 9.

## 2.1 Good standards of public procurement

Introducing high standards of public procurement is a necessary, albeit insufficient, measure for combating the spread of counterfeit and substandard medicines. (As will be discussed below, the *implementation* and *enforcement* of public procurement standards is just as important as introducing the standards in the first place.) General standards of public procurement in a given country or region have a significant influence on pharmaceutical and medical procurement. Most obviously it is unusual for a country with poor general public procurement standards to have high standards of health and medical procurement. For example, the authorities in Poland in the early to mid 2000s launched a government-wide anti-corruption campaign which, while not sector specific, did help reduce the prevalence of corruption in the health sector.<sup>18</sup>

What defines good standards of public procurement? The OECD has argued that ensuring good procurement is a balancing act between providing high levels of transparency and accountability on the one hand, and administrative efficiency and securing taxpayer value on the other. While providing transparency is essential to ensuring adequate levels of public confidence and competition in public procurement, transparency requirements also impose direct costs on procurement agencies and bidders. As a result, high levels of transparency frequently increase the overall cost of the procurement process. As will be seen, in countries with limited public means this can be problematic. The OECD recommends that an effective system of public procurement needs to make transparent “what sufficiently enables corruption control.”<sup>19</sup>

In addition, systems of public procurement need to ensure that procurement officials have a degree of professionalism and ethical behaviour which secures value for taxpayer money. Procurement is not simply an administrative function, but a process through which taxpayer value and strategic public administration decisions are made.<sup>20</sup>

Systems of public procurement need to be held to account by governments, bidders and the general public. This can be achieved largely through a system of controls, internal and external audits as well as transparent and fair systems of appeal and resolution. The procurement process itself also needs to be viewed as being

---

<sup>18</sup> Lewis, M. (2006), “Tackling Healthcare Corruption and Governance Woes in Developing Countries”, *CGD Brief*, Center for Global Development 2006, p. 6.

<sup>19</sup> *Ibid.* p. 12

<sup>20</sup> *Ibid.*

accountable. To achieve this, governments are increasingly involving stakeholders outside government including bidders, the wider public and procurement officials themselves.<sup>21</sup>

Finally, and as will be outlined in more detail in section 3.3, it is essential for patient safety that procurement authorities always seek to purchase and verify products with the highest levels of quality available (particularly in relation to medical and pharmaceutical procurement).

## 2.2 Developed versus developing world and emerging markets

While public procurement processes are, in theory, essentially the same the world over, there are a number of important differences between procurement in the developed and developing world in practice. Developing countries have:

- fewer financial resources than developed countries;
- smaller sometimes non-existent pharmaceutical manufacturing base which means they are often dependent on importing medicines or at least active ingredients;
- less developed infrastructure including IT and monitoring equipment;
- poor enforcement capabilities;
- less experienced and specialised health staff; and
- often have a wider and more difficult set of problems to deal with such as corruption and political instability.

Analysts at the World Bank have highlighted these problems and the way in which poor procurement practises are influenced by the overall environment:

Significant problems also exist in pharmaceutical procurement and distribution systems. The cause of these problems include market failures (such as insufficient drug information) and government failures (associated with limited management capacity, weak management information systems, and poor warehouses and storage systems). **The problems are compounded in some countries by widespread corruption in public sector procurement and distribution systems, including in the health sector. The inefficient use of resources in public procurement and distributions systems represents an important motivation for health sector reform efforts.** [Emphasis added]<sup>22</sup>

---

<sup>21</sup> Ibid.

<sup>22</sup> Govindaraj, R., Reich, M.R., and Cohen, Jillian C. (2000), *World Bank Pharmaceuticals*, HNP Discussion Paper, World Bank, September 2000, p. 11.

While the World Bank is mainly describing developing countries, many emerging markets also have many of these problems.

## Section 3: Gold standard and benchmarks for pharmaceutical procurement

### 3.1 Procurement as part of an overall pharmaceutical policy

Pharmaceutical procurement is not an isolated part of an overall national pharmaceutical policy. It forms one important element that, together with other rules and regulations, ensures that patients are supplied with high quality, safe and effective medicines. The most important elements that determine the quality and safety levels of a pharmaceutical supply chain include:

- i) drug registration;
- ii) distribution and storage;
- iii) national pricing and reimbursement policies;
- iv) pharmacovigilance
- v) systems of enforcement; and
- vi) the existence of national pharmaceutical plans such as an Essential Drugs List (EDL).

Drug Regulatory Authorities (DRA) [the national and regional authorities that regulate and overlook the quality, safety and efficacy of pharmaceutical products] and the quality, design and enforcement of drug regulatory standards have a tremendous impact on the prevalence of substandard and counterfeit medicines.<sup>23</sup> Ensuring that medicines and medical products meet high quality, safety and efficacy requirements is an essential element to any anti-counterfeiting strategy as well as maintaining a market of high quality medicines. This is a particularly acute problem in developing world countries which often do not have the regulatory capacity to ensure the quality of medicines. A World Bank report succinctly captured this fundamental problem: "Developing country governments have difficulty in assuring the quality of pharmaceuticals in the public sector and on the private market. Governments confront problems of counterfeit drugs and poor manufacturing processes, as well as difficulties in the regulation of prescribing practices and informal sales of drugs."<sup>24</sup>

---

<sup>23</sup> Torstensson and Pugatch (2010)

<sup>24</sup> Govindaraj (2000), p. 9.

The distribution and storage systems in place directly affect the quality and safety of pharmaceuticals. Storing drugs at either too high or too low temperatures may have a detrimental impact on the active ingredient or the excipient compounds used. For example, vaccines must be stored at either refrigerated temperatures (2-8 degrees centigrade) or, if frozen, between -50 and -15 degrees centigrade.<sup>25</sup>

National pricing and reimbursement policies within a public health system also affect procurement practices. For example, in both Poland and Romania, government agencies in negotiation with pharmaceutical manufacturers determine reimbursement rates as well as impose price controls on selected medicines and industries such as pharmacists and drug wholesalers. This limits the type of medicines that the public health system can procure and patients can access. Depending on the strength of other characteristics of the supply system (including quality assurance and control) this could potentially lead to substandard medicines being introduced into the supply chain.

Pharmacovigilance is the ability of a drug regulatory authority to track and act on the information collected in the last phase (phase IV) of the clinical trials that are used to test the safety of a medicine. These post-marketing studies contain vital information on how a population responds to a new drug. Pharmacovigilance includes the institutional and structural capacity of a country to detect any adverse effects, having the necessary reporting mechanisms in place and effectively stopping the further use of a medicine or treatment. An additional important element is the extent to which pharmaceutical manufacturers, suppliers and distributors are expected and/or legally mandated to proactively communicate adverse drug reactions to the relevant health authorities. Pharmacovigilance is a vital means of combating the use of counterfeit and substandard medicines. A number of academic and international studies have found that implementing and maintaining systems of pharmacovigilance is an absolutely essential part of any pharmaceutical market.<sup>26</sup> And it is of particular importance in countries which are heavily affected by counterfeit and substandard drugs.

Finally, procurement decisions and the characteristics of systems are also influenced by broader pharmaceutical policies such as the existence of an EDL. An EDL is a list of essential medicines and drugs that the WHO has determined a health system needs to provide its citizens. The construction of an EDL

---

<sup>25</sup> Centre for Disease Control and Prevention, *Vaccine storage & handling guide, Protect your Vaccine – Protect your Patients*, October 2011, <http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf> (Accessed October 2011).

<sup>26</sup> See for example Torstensson and Pugatch (2010). WHO, *The Importance of Pharmacovigilance – Safety Monitoring of Medicinal Products*, (2002), Geneva. See also Wise, L. et al (2009), "New approaches to drug safety: a pharmacovigilance tool kit", *Nature Reviews Drug Discovery*, Vol 8, October 2009, pp. 779-782.

and the decisions about which types of drugs are included should be informed by the disease and morbidity patterns of each individual country. EDLs have been identified as a basic stepping stone for pharmaceutical policy by the WHO since the 1970s.<sup>27</sup> They form the basis of many countries' national pharmaceutical and procurement policies.

### 3.2 Pharmaceutical procurement

At its most basic level, medical procurement is about making sure that hospitals, health centres, health professionals and patients all have access to the right type of medical supplies, in the right quantities, at the right place and time when they are needed. Procurement is part of an overall process of planning, purchasing, storing and distributing medicines. The World Bank provides a good working definition of pharmaceutical procurement:

Precisely defined, procurement can be presented as one step in the process of ensuring that good quality cost-effective commodities are available to support health sector services...Procurement follows on from selection—the informed determination of the most suitable items to obtain for the health system—and precedes the distribution (or allocation, in the case of medical equipment) of the products to the dispensing unit and subsequent rational use by the consumer. Underlying the whole process is the national legislative and regulatory framework.<sup>28</sup>

The World Bank's definition is useful in that it narrows the issue of procurement down as well as highlighting how procurement is part of an overall process of quality control and pharmaceutical policy. This is an important point and will be returned to in section 4 when individual countries systems of procurement are discussed.

What are the goals of medical procurement? According to the WHO any system of pharmaceutical procurement should have four operational goals:

1. Procure the most cost-effective drugs in the right quantities;
2. Select reliable suppliers of high-quality products;
3. Ensure timely delivery; and

---

<sup>27</sup> See WHO, Medicines: essential medicines, <http://www.who.int/mediacentre/factsheets/fs325/en/index.html> (Accessed September 2011).

<sup>28</sup> World Bank (2000), *TECHNICAL NOTE Procurement of Health Sector Goods*, Washington DC May 2000, p. 5.

4. Achieve the lowest possible total cost.<sup>29</sup>

The WHO has argued that to achieve these objectives organisations should: establish an essential drugs list; accurately estimate the quantities needed for the drugs list; make use of quality assurance programmes involving both surveillance and testing of purchased drugs; and ensure that the combined cost of the procurement should always be as low as possible.<sup>30</sup>

Other international agencies and NGOs have similar goals in mind for procurement. The Global Fund, for example, states that the primary goal of its procurement and supply policies is **to ensure the efficient procurement, distribution and use of health products meeting agreed quality standards at the lowest possible price and in accordance with national and international laws.** [Emphasis added]<sup>31</sup>

Both these examples illustrate how international organisations emphasise the need for both buying high quality drugs but doing so in the most cost efficient manner. Yet as our country case studies show, in many cases there is a tension between these two aims. Indeed, there are a number of examples where the relevant procurement authorities are lacking in the expertise and resources needed for continuous testing and monitoring of drug quality. (This is also discussed below in section 3.3.3 on quality assurance.)

### 3.2.1 The negative consequences of poor procurement

The importance of good pharmaceutical procurement policies is illustrated by the negative consequences dysfunctional or poor procurement practices have on patients and health systems. Below table 1 summarises some of the more common problems of dysfunctions and their potential consequences.

---

<sup>29</sup> WHO (1999), *Operational Principles for good pharmaceutical procurement*, Essential Drugs and Medicines Policy, Interagency Pharmaceutical Coordination Group, Geneva 1999, p. 7-8. The conflict between cost and quality will be discussed separately below.

<sup>30</sup> The combined cost being defined as the total of: purchase price of drugs; hidden costs such as poor quality, poor distribution, poor supplier performance etc; inventory costs; operating costs of management and administration of procurement and distribution system.

<sup>31</sup> Global Fund (2009), *Guide to the Global Fund's policies on Procurement and Supply Management*, November 2009, p. 6.

Table 1: Common problems and consequences of poor pharmaceutical procurement<sup>32</sup>

Problem or dysfunction	Potential negative effect or consequence
<u>Corruption</u>	Drug shortages; poor quality medicines being used; loss of public trust in health system.
<u>Lack of training and professionalism</u>	Delays in handling bids and procurement decisions; poor decisions being made.
<u>Pressure to buy from local suppliers</u>	Decisions made on basis on origin of supply not quality of drug.
<u>Quality standards not enforced or in place</u>	Leads to procurement of substandard and/or counterfeit medicines.
<u>Lack of funds</u>	Payments not made; drug shortages; disruption to supply chain.

Poor procurement can lead to shortages of medicines and essential medical supplies; infiltration of the medical supply with substandard and counterfeit medicines; and, ultimately, the failure of a health system to respond to the needs of patients.

Corruption can contribute to poor procurement standards. As medical and pharmaceutical procurement involves what are relatively high-value products as well as substantial government funds, it attracts more attention and is more threatened by corruption and misappropriation. This is especially true for developing countries where, according to the World Bank, corruption is the “single greatest obstacle to economic and social development”.<sup>33</sup>

For example, in Cambodia and Uganda corruption eats up a substantial part of the health and pharmaceuticals budgets – in the former an estimated 5% of the health budget has been lost to corruption and in the latter two-thirds of medicines supplies have been misappropriated.<sup>34</sup> This problem is compounded by the fact that poorer countries often spend a higher proportion of their health budgets on

<sup>32</sup> Seiter, A. (2010), *A Practical Approach to Pharmaceutical Policy*, World Bank, p. 47.

<sup>33</sup> WHO (2006b), *Measuring Transparency in Medicines Registration, Selection and Procurement – Four Country Assessment Studies*, WHO, p. 1.

<sup>34</sup> Ibid.

pharmaceuticals.<sup>35</sup> For example, South Africa in 2002 spent 24% of its total health expenditure on drugs, whereas Mali spent 66%.<sup>36</sup>

### 3.2.2 Systems of procurement and key actors

There are a number of models or systems of medical procurement. Frequently these involve not only the purchase of medicines but also their distribution and storage. The WHO has sketched out some of the most commonly used drug supply systems. (It should be noted that most countries' systems of drugs supply and procurement are dependent on the specific health variables and characteristics of that country. That is, most systems of procurement are unique to each country. Nevertheless, the below categories provide an analytical starting point from which to discuss the shape and design of systems of procurement.) As defined by the WHO and World Bank, the models are:

- Central Medical Stores (CMS);
- Autonomous supply agency (ASA);
- Direct delivery system;
- Primary distributor system; and
- Fully private supply.<sup>37</sup>

CMS is the traditional procurement, storage and distribution model. In this system a central government buys, stores, owns and distributes medicines. Financially, technically and man-power wise it is a very demanding option.

The ASA system works through a centralised supply system but overall management responsibility is devolved to a separate board. The ASA has evolved as a result of the growing inefficiency and inadequacy of the CMS approach. The rationale behind the ASA is that their quasi-independent status and devolved management is more efficient and achieves greater value for money and improved drug availability than the CMS. While the ASA provides a modicum of decentralisation and independence from central government it is still, generally, under the purview of a Ministry of Health (MoH)

---

<sup>35</sup> Enemark, U., Alban, A., Vasquez, E., *Purchasing Pharmaceuticals*, (2004), Health, Nutrition and Population (HNP) Discussion Paper, World Bank, p. 4.

<sup>36</sup> Ibid.

<sup>37</sup> WHO (1998), "Drug Supply Choices: what works best?", WHO, *Essential Drugs Monitor*, No 25-26 (1998). Similar categories are also presented in World Bank (2000), p. 7. The below discussion and outline of each category is based on these two sources.

and central government. Many ASAs frequently become a CMS in disguise, plagued by similar problems.

A direct delivery system is a decentralised supply and distribution system in which central government tenders and handles the bidding process but does not get involved in the distribution, storage or supply of medicines. Problems of direct supply systems involve separation of accounts for each local facility. This can result in debts accumulating if over-ordering takes place.

The primary distributor system is a non CMS system where the government drug procurement office establishes contracts with a single primary distributor which distributes and stores all drugs bought to major facilities. It is similar to the direct delivery system but a key difference is that suppliers do not deliver the drugs. Instead, distribution is contracted out to one specific drug logistics company. Procurement contracts, however, are still negotiated centrally.

The final system is one in which the private sector fully caters for pharmaceutical demand. Critics of this system often point to the issue of equal access to care if the cost burden is entirely placed on the individual.

Systems of procurement reflect and will be the product of the characteristics of a country's socio-economic make-up and development as well as more specifically the type of overall health system in place. This includes the type of health actors (payers, providers etc.) that are prevalent in the system. As there is no one uniform system of pharmaceutical procurement, neither is there only one body or actor that can procure pharmaceuticals. Instead the procurement of medicines can be carried out by a number of actors including:

- a central government (such as a MoH or procurement agency);
- regional, local, provincial, and state governments;
- through consortia of hospitals either locally or regionally;
- at the individual hospital level;
- by private health insurers or through drug insurance plans, as in Latin America;
- through public sector drug revolving funds;
- through community drug financing; or

- through international procurement agreements between different countries and direct negotiations with drug manufacturers.<sup>38</sup>

Many developing and emerging market economies use mixed systems of procurement, with some drugs being procured centrally and others at the local or regional level. For some medicines, such as HIV/AIDS antiretrovirals, centralised procurement will be used. For other drugs this is done either at the local or regional level, for example, in Brazil.

There are advantages and disadvantages to both systems. With a higher degree of centralisation, there is a greater likelihood that competent and sufficient numbers of professional procurement staff will be available than at the local or regional level. Furthermore, larger quantities can be procured for a whole health system. This increases the likelihood that a lower price per product can be achieved. Disadvantages of centralised procurement are that it can be bureaucratic, inflexible and not responsive to local needs. It also places a high premium on the abilities of a procurement agency to accurately forecast both the quantity and types of medicines needed.

Decentralisation, on the other hand, allows individual providers to contract locally and gives hospitals, health centres and doctors the flexibility of tailoring their procurement processes to specific local needs. However, there is often a lack of capacity at the regional and local level as a result of there not being enough qualified local staff or competent managers. Decentralisation also increases the risk of local corruption. In addition, stable and timely financing can often be lacking. Finally, decentralisation is frequently associated with higher per unit costs as smaller drug quantities are procured.<sup>39</sup>

The World Bank views centralised tendering as more often than not being the best option with some functions devolved to a regional or local level.<sup>40</sup> For example, the actual bidding and tendering could be managed centrally, while local bodies and hospitals could order health sector goods from the suppliers selected through a centrally managed bid process.

---

<sup>38</sup> These different types of procurement actors are discussed in Enemark et al, (2004) p. 7.

<sup>39</sup> WHO, (1998)

<sup>40</sup> World Bank (2000), pp. 15-6.

### 3.2.3 Methods of procurement

The initial step for procurement to take place is normally for a tender to be issued. Tendering is the process whereby a procurement agency invites potential suppliers to bid for a government contract. As defined by the WHO there are 4 different kinds of procurement methods:

- Open tender;
- Restricted tender;
- Competitive negotiations; and
- Direct procurement.<sup>41</sup>

Open tenders are formal procedures whereby bids are invited from a variety of pharmaceutical companies. The advantage of this type of tendering is that a wide variety of manufacturers can bid for a contract. However, the WHO has argued that when open tenders are too often issued, too many bids are submitted and the DRA or procurement agency cannot properly evaluate all bids within the time allocated.

Restricted tender is a bidding process which is open only to pre-qualified suppliers. This is thought to work best for smaller countries with limited procurement capacity. While the initial screening process of selecting qualified suppliers is time-consuming, once a list has been established subsequent bidding processes are less demanding.

Competitive negotiations involve approaching a few companies directly and receiving bids from them.

Direct procurement is the direct purchasing from a single supplier. According to the WHO, while this is the easiest form of tendering it is also the most expensive route. This may work in emergency situations, but is not cost-effective.

Table 2 summarises these four types of tendering and their respective advantages and disadvantages as outlined by the WHO.

---

<sup>41</sup> WHO (2002), *Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies*, section 4. <http://apps.who.int/medicinedocs/en/d/Jh2999e/1.html#Jh2999e.1> (Accessed July 2011). The description of each category is taken from this document.

**Table 2: Tendering methods<sup>42</sup>**

Procurement method	Advantages	Disadvantages
<u>Open tender</u>	Many bids, some with low prices; new suppliers can be identified.	High workload required in evaluating bids and selected suppliers.
<u>Restricted tender</u>	Fewer bids, pre-qualified suppliers, quality easier to ensure.	Fewer bids, more limited options. A system of suppliers must be in place.
<u>Competitive negotiations</u>	Suppliers generally well-known, less evaluation work.	Generally higher prices.
<u>Direct procurement</u>	Easy and quick.	High prices.

### 3.2.4 Tendering awards

Apart from deciding on the method of the bid, tendering also involves deciding to use:

- fixed tender quantities (including estimated quantities);
- split or single awards;
- mandatory use of local agents in international tenders;
- annual or bi-annual tenders versus multiple tenders during the year; and
- pre-qualification of suppliers to be invited for restricted tenders.<sup>43</sup>

There are two main types of fixed tender options: fixed quantity and estimated quantity.

Fixed-quantity, scheduled delivery purchasing contracts provides a fixed quantity of medicines over a scheduled period of time. This carries with it the risks of either over-purchasing or under-purchasing medicines. There is very little flexibility in terms of cancelling contracts or returning drugs if over-purchasing. Fixed-quantity requires a relatively high level of skill from the relevant procurement agency of forecasting what the medical needs of the relevant population/patient group served will be.

Estimated quantity, on the other hand is a periodic order-contract. The quantity of drugs is based on estimates with orders placed periodically and contract prices are negotiated per drug. Under this option the supplier carries most of the risks.

---

<sup>42</sup> Ibid. This table is quoted verbatim.

<sup>43</sup> WHO, (2002) sections 5-9.

Split or single awards involves the use of either one or several suppliers for one contract. Single award has the advantage of placing responsibility and accountability with only one supplier. Using several suppliers through split awards increases the administrative burden of monitoring the supply chain, but it does reduce the risk of catastrophic supply failure as medicines are being procured from different sources.

The use of local agents in international tenders is made mandatory by local or national procurement legislation in many countries. This type of local preferencing can take many shapes; in some cases allowing local suppliers to meet lower quality standards than international bidders. This is a practice which has been criticised by the World Bank. It has argued that as only a small minority of drugs are manufactured in developing countries, all domestic bids should be evaluated against and on the same basis as international ones:

Procurement opportunities cannot be reserved only for local manufacturers, and if they participate in ICB, LIB, or NCB procurement, they must be held to the same quality and other standards as other bidders. If domestic producers meet the standards, the Bank allows borrowers to provide a small margin of preference in the evaluation of bids, applying the preference to goods manufactured in the country of the borrower.<sup>44</sup>

The number of tenders during a year will vary and depends primarily on the capabilities of the national DRA, local and international suppliers, and the capabilities of the procurement agency.

### 3.2.5 Pre-qualification

The pre-qualification of suppliers to be invited for restricted tenders can be an important element of providing high quality procurement. If done properly, pre-qualification can both ensure that high quality drugs are procured as well as making the procurement process as efficient as possible.

Essentially, pre-qualification is a way of conducting one open tender with the goal of screening bids and whittling down the number of potential suppliers to a set number. This pre-qualified pool of suppliers can then be used for both current and future bids. To achieve maximum efficiency the initial screening process or pre-qualification must be rigorous, reliable and kept up-to-date. This latter point is of real importance as the reliability of suppliers and the quality of the medicines supplied must be continuously monitored.

---

<sup>44</sup> World Bank (2000), p. 12.

The merit of pre-qualification as a method of tendering is something on which there is near universal agreement among international agencies. For example, the World Bank in its *Technical Note* on the procurement of medicines has stated that: "The Bank supports prequalification for the procurement of health sector goods, including pharmaceuticals, vaccines, and condoms. Prequalification contributes significantly to the purchase of high-quality products while maintaining the desired competitive nature of the procurement process."<sup>45</sup>

Moreover, the WHO, the United Nations (UN) Children's Fund, the UN Development Programme and the UN Population Fund also support pre-qualification. In their 2007 joint publication with the World Bank, *A Model Quality Assurance System for Procurement Agencies*, these agencies argued that pre-qualification was a vital part of efficient procurement and the overall quality assurance process.<sup>46</sup> This publication identified two main parts of pre-qualification:

- **Product-related assessment:** This refers to the procurement agency procuring the correct product, and assessing whether the proposed manufacturer is offering a product that meets adequate and predetermined safety, efficacy and quality criteria.
- **Manufacturer-related assessment:** This refers to the confirmation that the manufacturer can actually manufacture the product as specified and in accordance with Good Manufacturing Practices (GMP). Crucially, the manufacturer must be able to consistently produce drugs of the same high quality standard so that there is no drop-off in quality from batch to batch.<sup>47</sup>

In addition to these assessments, *A Model Quality Assurance System* claims that an essential principle of procurement procedures should be reliability and reliance of procurement agencies on their national drug regulators.<sup>48</sup> While in theory this is indeed good practice, in the real world national DRAs differ both in their overall quality as well as the reliability and quality of their assessments. In India the split between central and provincial functions of DRAs and the resulting differences of rules, regulations and enforcement are at the heart of the country's difficulties with counterfeit (as well as substandard) medicines.<sup>49</sup> Moreover, in many

---

<sup>45</sup> Ibid., pp. 15-6.

<sup>46</sup> WHO, UN Children's Fund, UN Development Programme, UN Population Fund, World Bank, (2007) *A Model Quality Assurance System for Procurement Agencies*, WHO 2007, p. 25

<sup>47</sup> Ibid.

<sup>48</sup> Ibid. p. 25.

<sup>49</sup> Torstensson and Pugatch (2010), pp. 26-32.

countries significant numbers of drugs are *not* registered with the authorities. For example, 30% of drugs in Brazil and 19% of drugs in Nigeria are not registered at all.<sup>50</sup>

This wider issue of quality assurance – regardless of which method of procurement is used – is fundamental.

### 3.3 Quality assurance

Quality assurance should be central to any system of public procurement. Making sure that the medicines procured are of high quality, safe and effective should be at the heart of any procurement agency throughout the whole procurement process.

#### 3.3.1 Existing guidelines and standards

Many international aid and health agencies as well as NGOs in their published procurement guidelines emphasise the importance of quality control. For example, the WHO recently published a guide to procuring artemisinin-based antimalarial medicines in which quality was stressed as a key consideration:

Quality is one of the most important considerations in the manufacture and procurement of medicines. The aim of having quality assurance measures in place all along the supply chain is to ensure that each procured batch of a finished pharmaceutical product (FPP) meets approved manufacturing quality standards. Poor quality medicines affect the health and lives of patients, damage the credibility of health-care programmes and increase the burden on the health-care system.<sup>51</sup>

The WHO guide emphasised how important the quality of artemisinin-based antimalarials was to the drug having its intended effect “as the use of ineffective or unsafe substandard products in the treatment of malaria may be harmful...parasites are exposed to low levels of antimalarial medicines in the blood, resistant parasites will survive and multiply, favouring the emergence and spread of resistant strains.”<sup>52</sup> The guide concluded that “the quality of artemisinin-based antimalarial products is therefore not negotiable and must be the first consideration in procurement.”<sup>53</sup>

---

<sup>50</sup> Bate, R. (2010), *Drug Registration – a necessary but not sufficient condition for good quality drugs – a preliminary analysis of 12 countries*, Africa Fighting Malaria Working Paper, October 2010, pp. 2-3.

<sup>51</sup> WHO Global Malaria Programme (2010), *Good Procurement Practices for artemisinin-based antimalarial medicines*, p. 1.

<sup>52</sup> Ibid.

<sup>53</sup> Ibid.

Significantly, this guide also stressed the importance of continuous monitoring of the supply chain within the procurement process. Because of the unique characteristics of antimalarials it argued that it was crucial that each individual batch of medicine was tested and the quality assured and maintained throughout the supply chain.<sup>54</sup> The guide describes how verification of the quality assurance measures applied to a product during its lifetime through product documentation and separate quality control testing is of the essence.<sup>55</sup>

Similarly, the 2007 joint publication by the WHO and others, *A Model Quality Assurance System for Procurement Agencies*, emphasised the importance of quality assurance in the procurement process. It stated quite clearly how high quality assurance programmes are needed to limit the amount of substandard and counterfeit medicines entering the supply chain: “Without a quality assurance system, organizations risk sourcing substandard, counterfeit or contaminated pharmaceutical products, leading to complaints about products and product recalls, wastage of money and serious health risks to patients.”<sup>56</sup>

In its own publications the WHO has also repeatedly emphasised the need for quality assurance throughout the procurement process. This is to be achieved by: selecting reliable suppliers of quality drugs; using existing mechanisms like the WHO Certification Scheme; establishing a program of defect reporting; and through targeted quality control testing.<sup>57</sup>

The World Bank has also emphasised the importance of quality assurance in its *Technical Note*. The Bank describes quality assurance as an “essential component of the procurement process”.<sup>58</sup>

Similarly, the Global Fund requires recipient countries to adhere to international and national standards of quality, including DRA registration and approval. Additional quality assurance guidelines also exist for antiretrovirals, antimalarial, and medicines for tuberculosis. These products must also be: pre-qualified under the WHO Prequalification Programme; authorised for use by a stringent DRA, such as, the FDA, EMA, or Health Canada; or recommended by the Global Fund’s Expert Review Panel.<sup>59</sup> Illustrating the wider point of the importance of continued vigilance and implementation the Fund also requires post-purchase monitoring

---

<sup>54</sup> Ibid.

<sup>55</sup> Ibid. p. 4.

<sup>56</sup> WHO, UN Children’s Fund, UN Development Programme, UN Population Fund, World Bank (2007) p. 5.

<sup>57</sup> WHO, (1999), p. 9.

<sup>58</sup> World Bank, (2000) p. 17.

<sup>59</sup> Global Fund (2009), *Guide to the Global Fund’s policies on Procurement and Supply Management*, November 2009, p. 16.

and testing of quality at various points in the supply chain. Samples must be sent and analysed by the national DRA, WHO approved labs or Global Fund contracted labs.<sup>60</sup>

### 3.3.2 Cost over quality?

Public health bodies are often charged with obtaining the highest possible taxpayer value in their procurement, yet are also expected to purchase the highest quality products. Within pharmaceutical procurement there is a fundamental tension between limiting cost on the one hand and buying high quality products. This is a difficult balancing act, particularly in developing and emerging markets where public financial means can be quite limited.

Indeed, even in the above cited guidelines which stress the importance of quality, cost-containment is at many times given an equal emphasis. For example, the WHO in its *Operational Principles* states that procurement and distribution systems must achieve the “lowest possible total cost”.<sup>61</sup> While this guide also includes the issue of poor quality and the hidden cost of purchasing inferior quality medicines, this strongly suggests that cost should really be the key concern for procurement agencies.

Nevertheless, the overwhelming emphasis by the WHO and others is that quality should never be compromised due to higher initial costs. In fact, sourcing a poorer quality medicine at what appears to be a lower initial cost may actually in the end be of a higher total cost due to hidden costs imposed on the health system. As the WHO states:

As is often the case, the determining factor for awarding a tender is price. Quality must be a more important consideration due to the fact that substandard products give rise to health hazards as well as financial losses to the procurement agency. While products of assured quality may be priced higher, they may be cheaper in the long run...purchase of cheaper pharmaceuticals without quality assurance invariably result in losses as follows: (1) expiration of stocks soon after delivery because of too short shelf-life; (2) substandard drugs and (3) health hazards.<sup>62</sup>

---

<sup>60</sup> Ibid.

<sup>61</sup> WHO, (1999), pp. 7-8.

<sup>62</sup> WHO, (2000), section 11.

### 3.4 A gold standard?

The sources used in this paper have either come from leading international institutions such as the WHO, UN and World Bank or prominent NGOs such as the Global Fund. From this material and the above discussion of pharmaceutical procurement it is possible to piece together a gold standard or set of best practices. Table 3 summarises these practices and provides a brief description of each. Where there has sometimes been a lack of clarity in the existing guidelines (for example, on the issue of quality assurance) the below gold standard includes a clearer emphasis on the need for procuring, verifying and monitoring the quality of purchased medicines and medical products. The table has been divided into three sections – pre-procurement; procurement; and post-procurement.

**Table 3: Pharmaceutical procurement best practices<sup>63</sup>**

<b>Pre-procurement stage</b>
- Ensure adequate procurement infrastructure in place.
- Ensure health professional and technical capacity is high among officials.
- Use written quality manual and written standardised operating procedures (SOPs).
- Use of pre-screening and pre-qualification is recommended for procurement agencies with limited capabilities.
- Pre-qualification must include quality assurance and quality testing through product-related and manufacture related assessments, including testing of batches.
- Have Management Information System (MIS) in place to monitor actual supply and payment of drugs as well as post-supply quality.
- Estimates of medicines needed should be based on reliable scientific estimates like past consumption, morbidity-based and extrapolated consumption techniques.
- Separate duties of pre-procurement process.
<b>Procurement stage</b>
- Procurement should be transparent, following formal written procedures and clear public selection criteria.
- International competitive bidding (ICB) ensures economy efficiency and transparency and should be used.
- Separate duties of selection, product specification and adjudication.
- Quality assessment of drugs upon receipt including lab testing, inspection of shipments and certificate of analysis of delivered products.
- Domestic preferencing should not compromise quality standards.
- Ensure technical specifications are right (e.g. dosage, storage, shelf-life, delivery expectations etc) in Bidding Documents.
<b>Post-procurement stage</b>
- Continue to monitor quality of received drugs through independent testing.
- Establish and use pharmacovigilance and ADR reporting facilities.
- Conduct independent and transparent audits of procurement and supplier performance.
- Regular new tenders should open to new bidders.

<sup>63</sup> These best practices are based on all sources used and listed throughout section 3.

## Section 4: Pharmaceutical procurement systems in emerging markets and the developing world

### 4.1 Argentina

Argentina is one of the largest economies in South America. Having experienced a devastating recession in the early 2000s, the economy rebounded in the mid to late 2000s and – the 2008-9 financial crisis notwithstanding – has achieved annual GDP growth rates of 8% and above.<sup>64</sup>

#### 4.1.1 Health system

The Argentine health system is largely decentralised with most health provision delegated to the provincial and regional levels. The public health system provides coverage of the total population through both primary and secondary health units.<sup>65</sup> The quality of this coverage is patchy with some analysts likening public coverage to in effect being uninsured.<sup>66</sup> Local social workers (*Obras Sociales*) are regional and local health care providers.

Public funding covers 54% of total health expenditure with the majority being through general taxation.<sup>67</sup> As a percentage of total government expenditure, health care represents 13.9%.<sup>68</sup>

#### 4.1.2 Pharmaceutical Profile

A defining feature of the Argentine pharmaceutical market is the extent to which local manufacturers dominate the supply of drugs. Seven out of the top ten best selling brands are manufactured domestically.<sup>69</sup> Moreover, the top 10 domestic manufacturers account for nearly 50% of total sales.<sup>70</sup>

---

<sup>64</sup> Torstensson and Pugatch (2010), pp. 36-7

<sup>65</sup> Ministry of Health, Argentina (2010), *Argentina Pharmaceutical Profile*, p. 4. This profile is part of a larger project of pharmaceutical profiles supported by the WHO and Global Fund. See: [http://www.who.int/medicines/areas/coordination/coordination\\_assessment/en/index2.html](http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index2.html) (Accessed August 2011)

<sup>66</sup> IMS Health, Country Profiles, IMS Argentina, <http://imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnnextoid=cc48bf6b12e19210VgnVCM100000ed152ca2RCRD&cpsexcurrchannel=1> (Accessed October 2011)

<sup>67</sup> Torstensson and Pugatch (2010) pp. 36-7.

<sup>68</sup> Ministry of Health, Argentina (2010) p. 4.

<sup>69</sup> IMS Health, Argentina, (2011)

<sup>70</sup> Ibid.

Argentina's pharmaceutical profile has been shaped in large measure by the economic crisis of the early 2000s with a national drug policy introduced in 2002.<sup>71</sup> This established an EDL and a public programme for the provision of medicines: *Remediar*. The *Remediar* program provides ambulatory drugs at no cost and pharmaceuticals for specific disease categories including HIV/AIDS, malaria, Sexually Transmitted Diseases (STDs), and tuberculosis.<sup>72</sup> The reforms of the early 2000s also introduced compulsory generic prescription.

The national DRA is the Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) which has responsibility for ensuring the quality and effectiveness of medicines and medical devices. It is an independent agency reliant on the MoH for technical guidelines and scientific standards.<sup>73</sup>

Argentina (like many Latin American countries) has three drug classifications: i) innovative or original, ii) generics, and iii) similars. Category one drugs are used as reference drugs for both generics and similars. The crucial difference between similars and generics is that the latter undergo bioequivalence testing and the former do not. They simply need to contain the same active ingredient, concentration, pharmaceutical form and dosage, but can differ in size, shape, packaging and period of activity. The use of similars is encouraged by the Argentine government with many health officials drawing little distinction between the similars and bioequivalent tested generics.<sup>74</sup>

The similar drugs have been heavily criticised for being of lesser and unproven quality in comparison with bioequivalent tested generics.<sup>75</sup> In Brazil, this criticism and the realisation that many of these similars were substandard drugs is one of the factors which lead to ANVISA (the national DRA) imposing new requirements for bioequivalence testing for all generic drugs.<sup>76</sup> This is not the case in Argentina, however.

ANMAT does not have a comprehensive system of pharmacovigilance. Indeed, there are no legal provisions in health legislation mandating ANMAT or any other government agency to implement a system of pharmacovigilance.<sup>77</sup> Instead much of the emphasis is on the pharmaceutical industry and holders of market authorisation to monitor the safety of their products. The ANMAT pharmacovigilance centre which is in

---

<sup>71</sup> Torstensson and Pugatch (2010) pp. 36-8.

<sup>72</sup> Ministry of Health, Argentina, (2010), p. 13.

<sup>73</sup> Torstensson and Pugatch, (2010), pp. 36-8.

<sup>74</sup> Ibid. pp. 38-9.

<sup>75</sup> Ibid.

<sup>76</sup> Bate (2010), p. 3.

<sup>77</sup> Ministry of Health, Argentina (2010), p. 12.

existence is relatively small and is hampered by its reliance (outside a small number of medicines) on industry reporting ADRs.<sup>78</sup>

#### 4.1.3 Pharmaceutical procurement overview

Pharmaceutical procurement is both centralised and decentralised. Procurement for drug programmes within *Remediar* is done centrally through a procurement agency within the MoH.<sup>79</sup> Provincial health funds and providers procure medicines separately, as do public hospitals. In addition, the procurement of \$1 million of generic medicines for the *Remediar* programme has been delegated to the UNOPS Argentina Operation Centre.<sup>80</sup>

Procurement bids are publicly available whereas awards are not. This raises transparency issues and the possibility of uncompetitive tendering.

Argentina also does not impose a program of pre-qualification of bidders. This raises the question of what type of quality control mechanisms are in place and whether drugs are screened to the same standards for each round of bids.

Crucially, the quality standards applied are those set by ANMAT (and in some cases the Inter-American Development Bank which supports the *Remediar* program). Given that ANMAT gives regulatory approval and market authorisation to similars there is a risk that substandard medicines are being purchased through the public procurement process.

Within the procurement process priority is given to local suppliers, including manufacturers of similars. As the World Bank pointed out in its *Technical Note*, local preferencing in which quality standards are lowered for domestic producers (which is the case for similars which are not tested for bioequivalence) is not conducive to procuring the highest quality medicines.<sup>81</sup>

---

<sup>78</sup> Torstensson and Pugatch, (2010), p. 39.

<sup>79</sup> Ministry of Health, Argentina (2010), p. 16.

<sup>80</sup> UNOPS (2010), "Medicines for Argentina's public health service", January 8 2010, <http://www.unops.org/english/whatwedo/news/Pages/Medicines-for-Argentina%e2%80%99s-public-health-service.aspx> (Accessed October 2011).

<sup>81</sup> See above Section 3: Gold standard and benchmarks for pharmaceutical procurement.

There have been reported cases of corruption in medical non-pharmaceutical procurement including within the second largest network of hospitals in the country, run by the City Government of Buenos Aires.<sup>82</sup> During the mid 1990s, the city began a program of collecting and publicising the prices paid by each individual hospital for a basket of common medical supplies. At the time of publication each individual hospital procured medical supplies on its own using the city budget. The collection showed wide discrepancies in prices paid for the same products, suggesting corruption in procurement practices. The result of this programme was an initial noticeable drop in prices, but a subsequent rise once no enforcement mechanisms were implemented.<sup>83</sup>

#### 4.1.4 Strengths and weaknesses

Public procurement in Argentina does not seem to suffer from a particularly high degree of corruption or poor management practices. There are some deficiencies in procurement practices, such as local preferencing and, in some cases, a lack of transparency, but overall the major impediment to high quality procurement is the existence and regulatory approval of similars. Unlike counterfeit medicines or substandard medicines in other countries that do not meet regulatory quality standards, similars constitute a category of medicines that, although meeting national Argentine regulatory standards, pose a significant risk of being substandard.

Table 4 summarises the strengths and weakness of the Argentine system of procurement:

---

<sup>82</sup> Savedoff, W. (2008) "The impact of information and accountability on hospital procurement corruption in Argentina and Bolivia", *U4 Brief*, No. 7, May 2008. Available from U4, Anti-corruption Resource Center, [www.u4.no](http://www.u4.no) (Accessed August 2011)

<sup>83</sup> Ibid.

**Table 4: Argentina: strengths and weakness**

<b>Strengths</b>
- Centralised procurement of essential medicines.
- Outsourcing of some generic procurement to the UNOPS.
- Transparency of awards and public bidding.
<b>Weaknesses</b>
- No prequalification.
- Domestic preferencing with de facto lesser quality requirements.
- Regulatory and public acceptance of similars is likely to lead to substandard medicines being publicly procured.
- Relatively underdeveloped and poorly designed system of pharmacovigilance.

## **4.2 Azerbaijan**

The Republic of Azerbaijan is a major exporter of hydrocarbons which have been the basis for much of the country's economic growth. Since the late 1990s Azerbaijan has experienced relative high levels of economic growth. Only in 2010 did GDP growth drop to 3.7% from over 9% in 2009.

### 4.2.1 Health system

The Azerbaijani public health system is both highly centralised and decentralised. It is centralised in the sense that national health policy is set and major decisions are taken within and by the Ministry of Health (MoH).<sup>84</sup> However, the provision of care is largely localised with funding not coming from the MoH. Instead it is allocated by local governments who in turn receive their financing through district health authorities which receives money directly from the Ministry of Finance.

Public spending on health, albeit rising, is still relatively low and stands at 3.8% of the total 2010 public budget. Out-of-pocket (OOP) expenditure accounts for the vast majority of health expenditure. The most

---

<sup>84</sup> Ibrahimov, F. et al, (2010) *Azerbaijan, Health System Review*, from the WHO and European Observatory on Health Systems and Policies series *Health Systems in Transition*, pp. 11-4.

recent figures from 2010 show 89% of Azeri health spending through OOP.<sup>85</sup> Access to publicly provided medicines is also limited, with a high proportion of drugs being purchased through OOP expenditure.<sup>86</sup>

Reforms to the health system are underway with the aim of improving both the delivery and management of services. Proposals have been put forward to introduce contracting and new payment mechanisms, as well as mandatory health insurance.<sup>87</sup>

#### 4.2.2 Pharmaceutical Profile

The regulation of pharmaceuticals has been re-organised several times in the last few years. Currently there are three different governmental agencies within the MoH that are responsible for the procurement, licensing and registration of pharmaceuticals.

The Innovation and Supply Centre is responsible for medical and pharmaceutical procurement. The licensing of pharmaceutical entities is carried out by the Licensing Department. Responsibility for drug registration and ensuring quality of medicines is lodged with the Analytical Expertise Centre for Medicines (AECM).<sup>88</sup> In addition to drug testing the AECM also carries out quality inspections of pharmacists and wholesalers. Since 2006 the AECM staff have received full training from the WHO.<sup>89</sup>

Azerbaijan has a very limited domestic pharmaceutical manufacturing capability with only 3 licensed manufacturers. None of these manufacturers have an independent R&D capability or the ability to produce active pharmaceutical ingredients (APIs).<sup>90</sup> As of 2009 these manufacturers held under 4% of the total domestic pharmaceutical market.<sup>91</sup>

Azerbaijan is thus reliant to a large extent on imported pharmaceuticals. The AECM is the agency responsible for inspections of imported medicines. Current regulations state that one sample from each

---

<sup>85</sup> Ministry of Health, Azerbaijan, (2011), *Pharmaceutical Profile*, WHO. This profile is part of a larger project of pharmaceutical profiles supported by the WHO and Global Fund.

<sup>86</sup> World Bank, (2005) *Azerbaijan Health Sector Review Note, Vol 2*, 2005, p. 162.

<http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/ECAEXT/AZERBAIJANEXTN/0,,contentMDK:20842242~pagePK:141137~piPK:141127~theSitePK:301914,00.html> (Accessed October 2010)

<sup>87</sup> Ibrahimov et al (2010), pp. xvi-xvii.

<sup>88</sup> Ibid. p. 80.

<sup>89</sup> Ibid.

<sup>90</sup> Ministry of Health, Azerbaijan, (2011), p. 11.

<sup>91</sup> Ibid.

batch imported should be inspected.<sup>92</sup> However, anecdotal evidence suggests that up to 70% of imports do not pass through customs and are not inspected.<sup>93</sup> Similar regulations are in place for distributors who are required to have a license and adhere to Good Distribution Practices.<sup>94</sup>

The existing system of pharmacovigilance is quite rudimentary. A national pharmacovigilance centre does exist, but it has not published any reports or an ADR bulletin. Post-marketing surveillance is mandated for both the AECM as well as market authorisation holders. There is no national ADR or pharmacovigilance committee or the like to provide communication in the event of a crisis.

Counterfeit and substandard medicines have been found in Azerbaijan. They are a significant problem as some estimates suggest (the most recent from 2005) that up to 50% of drugs on the market are not registered with the AECM.<sup>95</sup> According to the World Bank's 2005 *Health Sector Review Note*, substandard and counterfeit drugs have entered Azerbaijan from Russia, Turkey and India.<sup>96</sup> These drugs risk permeating the legitimate supply chain as an estimated 50% of pharmaceutical sales volume is made up of unregulated market traders.<sup>97</sup> Efforts to combat this through the use of anti-counterfeiting and substandard hologram seals of approval have not been successful.<sup>98</sup> The latest information compiled by the US Pharmacopeia in August 2011 shows that 12 pharmacies out of over 230 inspected were closed due to selling low quality drugs.<sup>99</sup>

#### 4.2.3 Pharmaceutical procurement overview

Procurement of public medicines is primarily done through the AECM which receives requests from the MoH or from specialists.<sup>100</sup> Some procurement does take place at the local level for regional health programmes.<sup>101</sup> Tender documents and awards are publicly available with tendering being based on pre-qualification.

---

<sup>92</sup> Ibid. p. 15.

<sup>93</sup> World Bank, (2005), p. 163.

<sup>94</sup> Ministry of Health, Azerbaijan, (2011), p. 16.

<sup>95</sup> World Bank, (2005), pp.170-1.

<sup>96</sup> Ibid. p. 162.

<sup>97</sup> Ibid. p. 163.

<sup>98</sup> Ibid.

<sup>99</sup> US Pharmacopeia, *Media Reports on Medicine Quality: Focusing on USAID-assisted Countries*, August 2011, <http://www.usp.org/pdf/EN/PQM/mediaReportsFinal.pdf> (Accessed October 2011)

<sup>100</sup> Ibrahimov et al, (2010), pp. 82-3.

<sup>101</sup> Ministry of Health, Azerbaijan, (2011), p. 23.

Public sector procurement is guided by the 2001 Law on Public Procurement. This legislation states that all public procurement over AZM250million (approximately \$320million) must be conducted through open tender. As the total 2010 budget for public health was approximately \$584million, it is however unlikely that much of this was done through open tendering.<sup>102</sup>

Azeri public procurement practices have been criticised by anti-corruption watchdogs and international institutions. The OECD's latest Anti-Corruption Network report on Azerbaijan lists a number of deficiencies in the country's system of public procurement.<sup>103</sup> This includes a high share of single source procurement, high participation fees, and limited ability of the State Procurement Agency to review and overturn corrupt or poor procurement.<sup>104</sup> The Business Anti-Corruption Portal also lists corruption as a major problem in public procurement with a lack of enforcement mechanisms for corrupt behaviour.<sup>105</sup>

#### 4.2.4 Strengths and weaknesses

Azerbaijan has long-standing issues with counterfeit and substandard medicines. Many medicines sold and traded are not registered with the relevant drug authorities and while measures have been introduced to limit the spread of counterfeit and substandard medicines these have not eradicated the practice. Similarly, the lack of enforcement and inspections of the quality of imported medicines allows potentially substandard and low quality drugs to enter the supply chain. Like many other countries in this study the quality of medicines procured is reflected by the overall quality of the medicines within the medical supply chain.

---

<sup>102</sup> The total public budget was \$14.6billion. Of this just under 4% represented health expenditure. See CIA, Factbook, Economy, <https://www.cia.gov/library/publications/the-world-factbook/geos/aj.html> (Accessed October 2011). And above cited figures from Ministry of Health, Azerbaijan, (2011).

<sup>103</sup> Anti-Corruption division, OECD, *Second Round of Monitoring, Azerbaijan*, 2010, pp. 40-1. <http://www.oecd.org/dataoecd/8/11/44996103.pdf> (Accessed October 2011).

<sup>104</sup> Ibid.

<sup>105</sup> Business Anti-Corruption Portal, Azerbaijan Country Profile, <http://www.business-anti-corruption.com/country-profiles/europe-central-asia/azerbaijan/corruption-levels/public-procurement-and-contracting/> (Accessed October 2011).

**Table 5: Azerbaijan: strengths and weakness**

<b>Strengths</b>
- Centralised procurement of essential medicines.
- Prequalification used.
- Transparency of awards and public bidding in theory.
<b>Weaknesses</b>
- Poor system of pharmacovigilance.
- Poor record of quality control and registration of drugs on domestic market. In particular testing and monitoring of imported pharmaceuticals appears to be quite poor.
- Poor accountability in public procurement.

### 4.3 Brazil

Together with China and India, the emergence of Brazil has been one of the major economic stories of the first decade of the 21<sup>st</sup> century. The Brazilian economy is now considered one of the most dynamic and important in the world. Since the late 1990s it has recorded steady GDP growth at just under 3% per year, growing at an estimated 7.5% in 2010.<sup>106</sup>

#### 4.3.1 Health system

In Brazil, health care is a constitutional right. The public system of care, *Sistema Único de Saúde* (SUS), provides services free at the point of use. Roughly half of Brazil's population make use of the SUS, and the other half are covered through private health insurance. While the federal government through the Brazilian MoH sets national health policy, the day-to-day running of the SUS has largely been delegated from the federal level to states and municipalities which manage and administer local health services. This has led to a wide variety in how national health policies are implemented, health services delivered and the standards of procurement and pharmaceutical profile of individual districts.

---

<sup>106</sup> Torstensson and Pugatch, (2010), p. 33 and CIA Factbook, Brazil, <https://www.cia.gov/library/publications/the-world-factbook/geos/br.html> (Accessed September 2011).

#### 4.3.2 Pharmaceutical profile

The Brazilian pharmaceutical market is one of the fastest growing in the world and is the largest in South America.<sup>107</sup> IMS Health estimated that in 2009 the total pharmaceutical market was worth over \$17billion; roughly the same size as the Indian market with a fifth of India's population.<sup>108</sup>

Brazilian pharmaceutical policy has traditionally been committed to non-research based medicines. Historically this was achieved through the promotion of a copied-drugs industry built during the 1980s. These drugs are today known as similars and constitute a substantial share of the Brazilian drug market. Crucially, many of these similars are still freely available on the Brazilian market. Indeed, as in Argentina, there is currently a regulatory distinction between 3 different types of pharmaceuticals: Similar Drug Product, Generic Drug and Reference Drug Product.<sup>109</sup>

Unlike Argentina, Brazil has introduced measures to effectively curtail the use and distribution of similars, replacing them with bioequivalent tested generic drugs by 2013-14. Regulations introduced in 2003 require all similar drugs to submit bioavailability data, pharmaceutical equivalence tests and a copy of GMP certificate issued by the national DRA, ANVISA.<sup>110</sup> While this requirement was in 2009 somewhat watered down, phasing out the use of similar drugs would be a significant achievement in the fight against substandard medicines.

These similars have long been a source of substandard and low quality pharmaceuticals. Following the introduction of the 2003 bioequivalence regulations, 21 similar products were immediately removed from the market by ANVISA.<sup>111</sup> Quality studies of the similars drugs find substantial rates of low quality medicines. For instance, analysis of ferrous sulphate pills and oral solutions over a four year period found close to 40% of samples with significant discrepancies in quality, including grade of the principal active ingredient and precipitation.<sup>112</sup> Other local studies have found similar results. One survey, in the southern state of Santa Catarina, found that 5 of 7 lots of similars had quality problems.<sup>113</sup>

---

<sup>107</sup> Torstensson and Pugatch, (2010) p. 33.

<sup>108</sup> IMS Health, Country Profiles, IMS Brazil, <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnnextoid=819e58a2d5e85210VgnVCM100000ed152ca2RCRD> (Accessed September 2011).

<sup>109</sup> Torstensson and Pugatch (2010), p. 35.

<sup>110</sup> Ibid. pp. 34-5.

<sup>111</sup> Ibid. p. 47.

<sup>112</sup> Bevilacqua, G. et al (2011), "Procurement of generic medicines in a medium size municipality", *Rev Saude Publica*; 45(3), p. 2.

<sup>113</sup> Ibid.

While ANVISA's regulatory push for the wider use of bioequivalence tested generics in local procurement practices is an important step, it is equally important that this is also implemented on the ground.

#### 4.3.3 Pharmaceutical procurement overview

Procurement takes place at the federal, state and local level with the vast majority at the municipal level through Municipal Health Secretariats.<sup>114</sup> The federal government is only responsible for the procurement of certain treatments and medicines such as HIV/AIDS antiretrovirals.

Purchasing is done primarily through public tendering from private suppliers or, occasionally, direct purchasing from public pharmaceutical laboratories.<sup>115</sup> Procurement guidelines have been issued at the federal level by the MoH.<sup>116</sup> Brazil has a strict generics medicine policy which (since the 2003 regulatory changes) encourages the procurement of bioequivalent tested generics. However, the results of this policy have so far been mixed. Evidence suggests that Brazilian public procurement is still dominated by similars. A 2009 study of the type of medicines available at the local level suggests only a quarter of publicly procured medicines are bioequivalent tested generics, with the vast majority of the remaining three-quarters being similars.<sup>117</sup> Significantly, unlike much other research on Brazil, this study covered all regions, not just one or two.<sup>118</sup>

Why is this? Simply put, similars are much cheaper to procure than bioequivalent generics. Indeed, research shows how the changes to generics policy and the national move away from similars raise costs substantially for local pharmaceutical procurement. For example, studies of municipal procurement in Santa Catarina state found that in 2007 and 2008 60% of medicines procured had increased in cost as a result of the requirements to procure bioequivalent tested generics.<sup>119</sup> This study also found that the failure rate of medicines procured increased significantly, suggesting that the similars procured prior to 2008 were in fact of lower quality.<sup>120</sup> Indeed, this raises the issue of interchangeability and whether or not similars are

---

<sup>114</sup> US Department of Commerce (2004), *ExportMED Brazil*, 2004, p. 10.

<http://www.trade.gov/td/health/BrazilExportMEDFINAL.pdf> (Accessed July 2011).

<sup>115</sup> WHO (2010), "Lessons learnt from conducting a medicine price survey in multiple regions of Brazil", *Essential Medicines Monitor*, Issue 4, April 2010, p. 3.

<sup>116</sup> Ministério da Saúde, (2006) *Acquisição de Medicamentos para Assistência Farmacêutica no SUS*, Brasília 2006 (Brazilian Ministry of Health, Guidelines of pharmaceutical procurement). Stockholm Network translation from Portuguese to English, 2011.

<sup>117</sup> Bevilacqua et al, (2011), p. 2.

<sup>118</sup> *Ibid.*

<sup>119</sup> *Ibid.* p. 4.

<sup>120</sup> *Ibid.* p. 3.

biologically or clinically interchangeable. As price is still a significant, if not deciding, factor influencing local procurement the lower cost of similars in comparison to bioequivalent generics helps explain the continued high level of procurement of similars in Brazil.

#### 4.3.4 Strengths and weaknesses

Public procurement in Brazil is changing in line with changes to its pharmaceutical environment. The decision in 2003 to require similars to produce bioequivalence testing and thus replace these copied drugs with higher quality bioequivalent tested generics was an important step towards limiting the spread and use of substandard medicines. However, because many similars have been allowed to stay on the market until 2014 and given local procurement practices sharp focus on cost, similars still make up the majority of medicines procured in the public health system. The issue of quality over cost – as outlined above in section 3 – must be more effectively addressed by Brazil and particularly by local municipalities in their procurement practices.

A greater focus must also be placed on pharmacovigilance. While the institutional pharmacovigilance framework has expanded with ANVISA now allowing health professionals and industry to report ADRs through its website, it is unclear that medical professionals and industry is making greater use of these tools.<sup>121</sup> More evidence is needed that pharmacovigilance is a real priority for health professionals and all sectors of the pharmaceutical industry.

Finally, public procurement in Brazil has been heavily criticised for being corrupt with bribery being widespread. The last decade has seen a number of high-profile scandals involving members of Congress and the government accused of corrupt behaviour in relation to the award of public contracts.<sup>122</sup> With regards to medical procurement, in the mid 2000s several members of the Brazilian Congress were accused of rigging procurement contracts for ambulances and receiving bribes in return.<sup>123</sup>

---

<sup>121</sup> See the section on pharmacovigilance on ANVISA's website: <http://www.anvisa.gov.br/hotsite/notivisa/index.htm> (Accessed October 2011).

<sup>122</sup> *Reuters*, "Factbox: Brazil's political corruption scandals", May 22 2007, <http://www.reuters.com/article/2007/05/22/us-brazil-corruption-factbox-idUSN2242608620070522> (Accessed October 2011).

<sup>123</sup> See: <http://www.business-anti-corruption.com/country-profiles/latin-america-the-caribbean/brazil/corruption-levels/public-procurement-and-contracting/> and *Reuters*, "Factbox: Brazil's political corruption scandals", May 22 2007, <http://www.reuters.com/article/2007/05/22/us-brazil-corruption-factbox-idUSN2242608620070522> (Both sites accessed October 2011).

Table 6: Brazil: strengths and weakness

Strengths
- Requirement that local bodies procure bioequivalent tested generics.
- Greater focus on pharmacovigilance by ANVISA.
- Transparency of awards and public bidding in theory.
Weaknesses
- Similar majority of drugs procured in public health system.
- Not clear that pharmacovigilance is being used in practice.
- Wide-spread corruption in public procurement.

## 4.4 China

China is now the world's second largest economy having averaged almost 10% growth since 2008.<sup>124</sup> China is one of the most dynamic and attractive places to invest in and is viewed by many as the future engine of the world economy.

### 4.4.1 Health system

Chinese health care was, up until the 1980s, modelled on a Soviet-style, highly centralised system of free care at the point of use. During the opening up and privatisation of the Chinese economy during the 1980s and 1990s public health care was in effect also privatised and public expenditure on health care was drastically reduced.<sup>125</sup>

In 2008 the system was again fundamentally reformed as part of the Chinese government's wider economic stimulus. A universal system of health insurance was introduced and over \$130 billion invested in upgrading public health care facilities.<sup>126</sup> As part of this national effort, an essential drugs list was also introduced.<sup>127</sup>

<sup>124</sup> CIA Factbook, [China](https://www.cia.gov/library/publications/the-world-factbook/geos/ch.html), <https://www.cia.gov/library/publications/the-world-factbook/geos/ch.html> (Accessed October 2011).

<sup>125</sup> Blumenthal, D. et al, (2005) "Privatization and its Discontents – The Evolving Chinese Health Care System", *New England Journal of Medicine*, 353: 11, pp.1165-6.

<sup>126</sup> *Science Insider*, "China's Health Care Reform Looks to Science", June 27 2011, <http://news.sciencemag.org/scienceinsider/2011/06/chinas-health-care-reform-looks.html> (Accessed July 2011).

<sup>127</sup> *China View*, "China unveils action plan for universal access to basic health care", April 7 2009, [http://news.xinhuanet.com/english/2009-04/07/content\\_11141889.htm](http://news.xinhuanet.com/english/2009-04/07/content_11141889.htm) (Accessed July 2011).

#### 4.4.2 Pharmaceutical profile

The domestic pharmaceutical market is one of the fastest-growing in the world with an estimated value of \$30billion.<sup>128</sup>

The Chinese pharmaceutical market has long been associated with very high levels of both counterfeit and substandard medicines. Indeed, China is in many respects the world leader in counterfeit medicines. For instance, in 2006 close to half of all seizures of counterfeit Viagra were made in China.<sup>129</sup> In addition, both substandard and counterfeit medicines manufactured in China have spread to other parts of the world, even Europe and North America.

Most seriously, China's national DRA, the State Food and Drug Administration (SFDA), was in 2005 involved in very serious corruption charges. The then head of the SFDA was arrested for having taken bribes for approving untested medicines and was subsequently executed by the Chinese authorities.<sup>130</sup> The SFDA has since been reformed with a greater emphasis placed on transparency of the regulatory process as well as ensuring the quality and safety of medicines. Yet whether or not these new regulations are actually implemented and followed in practice is a separate issue. Indeed, the main challenge to Chinese policymakers is to ensure compliance and full implementation of policies aimed at combating substandard and counterfeit medicines. This is also true for pharmacovigilance. China has, on paper, a relatively well-developed system of pharmacovigilance with local ADR monitoring stations and centres set up throughout the country. By its own assessment China is approaching the expected level of ADR reporting of 400 cases per million people.<sup>131</sup>

#### 4.4.3 Pharmaceutical procurement overview

As part of the wider health reform package in 2008, pharmaceutical procurement was also fundamentally changed. Prior to 2008, drug procurement had largely been regional and localised with most provinces contracting out to wholesalers and distributors. Hospitals and health clinics had up until the health reforms

---

<sup>128</sup> Torstensson and Pugatch, (2010) p. 22.

<sup>129</sup> US Pharmacopoeia Drug Quality and Information Program, (2009), *Matrix of Drug Quality Reports Affecting USAID-assisted Countries*, June 2009, p. 18.

<sup>130</sup> Torstensson and Pugatch, (2010), pp. 22-3.

<sup>131</sup> *Ibid.* p. 24.

used prescribing practices and income from drug sales to supplement their relatively low levels of central government funding.<sup>132</sup> Mark-ups of 15% were the norm.<sup>133</sup>

Today procurement is still regional but is run through a centralised on-line drug procurement system.<sup>134</sup> The provincial government oversees the procurement process which aims to be completely transparent. Bidding is to take place once per year with wholesalers and distributors effectively cut out of the tendering process. Crucially, hospitals no longer have a direct relationship with wholesalers or distributors. Instead, contracting is done directly with manufacturers who are responsible for distribution either themselves or through pre-qualified distributors.

Quality assurance and control has been part of the reform effort with the original policy document on procurement, "Opinion on Strengthening the Centralized Procurement of Drugs by Medical Institutions", co-drafted by the SFDA, the Chinese MoH and other government stakeholders.<sup>135</sup> This document suggested that procurement should be guided by the principle "quality first, price reasonable".<sup>136</sup> The SFDA has also introduced tougher measures for ensuring GMP and enforcement.

The key question is whether or not this will be implemented in practice. The widespread use and infiltration of substandard and counterfeit medicines in China is testament to the lack of quality oversight and assurance throughout the pharmaceutical supply cycle. More evidence is required to see if the recent procurement system reforms have also had an impact on increasing the quality of drugs.

#### 4.4.4 Strengths and weaknesses

The changes to pharmaceutical procurement introduced in the 2008-9 health reform have fundamentally altered the way in which medical procurement is conducted. This includes: the introduction of an EDL; centralisation of procurement; elimination of hospital and health centre mark-ups; creation of an online, transparent system of bidding and oversight; elimination of direct relationships between hospitals and wholesalers and distributors; and the increase in quality assurance measures by the SFDA.

---

<sup>132</sup> English.news.cn, "China's health reform cuts drug prices, but still fights pain", April 23 2011, [http://news.xinhuanet.com/english2010/china/2011-04/23/c\\_13842651.htm](http://news.xinhuanet.com/english2010/china/2011-04/23/c_13842651.htm) (Accessed July 2011)

<sup>133</sup> Ibid.

<sup>134</sup> GBI Pharma (2010) (China based pharmaceutical consultancy, market intelligence firm) "Cure for Procurement...", *China Pharmaceutical and Biotechnology Review*, Vol 36, March 2010, pp. 3-4.

<sup>135</sup> Ibid, p. 3.

<sup>136</sup> Ibid, p. 5.

The key question is whether or not the implementation of this new system and wider efforts by the SFDA to increase quality will have a significant impact on the wide-spread use of substandard and counterfeit medicines. As is illustrated by the corruption trial and subsequent execution of the previous head of the SFDA, corruption in China is pervasive and can reach the highest levels of government.

**Table 7: China: strengths and weakness**

<b>Strengths</b>
- Centralisation of procurement.
- Introduction of greater standardisation and transparency to local hospital procurement.
- Use of EDL.
<b>Weaknesses</b>
- Quality of overall medicines supply is still an overwhelming concern.
- Will quality safeguards be used and implemented?
- Wide-spread corruption in public procurement.

#### 4.5 Colombia

Colombia is the third largest economy in Latin America, behind Brazil and Argentina. The country has suffered from a long standing conflict between government and insurgents led by the Revolutionary Armed Forces of Colombia (FARC) guerrillas. Since the early to mid 2000s new security policies championed by the then President, Álvaro Uribe, have significantly improved the security situation and the country's economic prospects.

Since 2003 Colombia's GDP has posted sustained high rates of growth, averaging 5.3% between 2003 and 2008.<sup>137</sup> While growth rates dropped to 0.9% in 2009, the Colombian economy did not contract and has bounced back in 2010 growing by an impressive estimated 4.4%.<sup>138</sup>

<sup>137</sup> Invest in Colombia, "Emerging Countries the opportunity", <http://www.investincolombia.com.co/emerging-countries/emerging-countries-2010> (Accessed October 2011).

<sup>138</sup> CIA Factbook, Colombia, <https://www.cia.gov/library/publications/the-world-factbook/geos/co.html> (Accessed October 2011)

#### 4.5.1 Health system overview

In 1993, Colombia fundamentally reformed its health care system by introducing mandatory health insurance. Prior to these reforms a majority of Colombian health expenditure had been through OOP spending. The reforms decentralised health care services to the municipal level while simultaneously introducing a mandatory universal insurance scheme provided through private and not-for profit insurers with government subsidies. The reform package is widely viewed as being a success with coverage extending to 85% of the population and a significant increase in the amount of health services used by the poor.<sup>139</sup>

Since the introduction of the reforms OOP spending dipped from a high of 3.3% of GDP in 1993 to 1.2% of GDP in 2003.<sup>140</sup> During the same period social insurance expenditure increased from 1.6% of GDP to 4.3%.<sup>141</sup> Total expenditure on health as a percentage of GDP stood at 7.8% in 2003.<sup>142</sup>

#### 4.5.2 Pharmaceutical profile

Colombia is a medium-sized pharmaceutical market in Latin America with only moderate growth rates expected over the next 5 years.<sup>143</sup> In conjunction with the health care reforms Colombia established an EDL in 2002. The registration, testing of medicines and overall responsibility for safety and quality lies with the National Institute of Food and Drug Monitoring (INVIMA).

Counterfeit medicines make up a substantial portion of the overall drug supply. In 2004 the Association of Colombian Pharmaceutical Industries (ASINFAR) estimated that 5% of the pharmaceutical market was counterfeit.<sup>144</sup>

Like Argentina, Brazil and many other South American countries a large proportion of medicines manufactured and consumed in Colombia are so-called similars. They traditionally represent the majority of

---

<sup>139</sup> Glassman, A., Giuffrida, A., Escobar, E. and Giedion, U. eds., (2010) *From Few to Many Ten Years of Health Insurance Expansion in Colombia*, Brookings Institution Press, pp. 1-2.

<sup>140</sup> *Ibid.* p. 164.

<sup>141</sup> *Ibid.*

<sup>142</sup> *Ibid.*

<sup>143</sup> Espicom, "The Pharmaceutical Market: Colombia", June 30 2011,

[http://www.espicom.com/prodcat2.nsf/Product\\_ID\\_Lookup/00000334?OpenDocument](http://www.espicom.com/prodcat2.nsf/Product_ID_Lookup/00000334?OpenDocument) (Accessed October 2011).

<sup>144</sup> WHO, Counterfeit Medicines, [http://www.who.int/medicines/services/counterfeit/impact/impactF\\_S/en/index1.html](http://www.who.int/medicines/services/counterfeit/impact/impactF_S/en/index1.html) (Accessed October 2011).

drugs sold according to sales volume.<sup>145</sup> Case study analysis of the testing requirements for 96 active ingredients show that as of 2007 Colombia had the lowest number of bioequivalence testing requirements of all countries in Latin America at 5.<sup>146</sup> Contrary to this, data from INVIMA suggests that poor quality medicines in Colombia are becoming rarer. Data gathered through the national pharmacovigilance program points to only 4.2% of drugs not complying with quality standards.<sup>147</sup> Similarly, figures show that INVIMA received only a small number of quality complaints (67 in total) between 2007 and 2009.

However, the INVIMA figures assume that the national system of pharmacovigilance is adequately reporting all ADRs and that quality testing of similars is being done. Academic studies and surveys of the Colombian pharmaceutical market indicate that quality is in many cases lacking. For example, in interviews with local manufacturers and INVIMA a 2008 study found that no domestic pharmaceutical producer would meet WHO GMP standards.<sup>148</sup>

#### 4.5.3 Pharmaceutical procurement overview

Since the decentralisation of the provision and management of health care, individual hospitals and local providers procure medicines locally. Colombia also takes part in regional procurement pools. For example, Colombia has been a procuring party in the purchase of HIV/AIDS antiretrovirals. This has taken place through the 10-country Caribbean and Latin American regional procurement body set up through negotiations held in Lima in 2002-3.<sup>149</sup> Significantly, these medicines are only procured from manufacturers that meet WHO pre-qualification quality standards and guidelines.<sup>150</sup>

There have been notable cases of corruption involving hospital procurement. For example, case study analysis by Transparency International has shown that in 1998 32 public hospitals had overpaid \$2million for procuring drugs.<sup>151</sup> Indexing of the risk of corruption by Transparency International's local chapter,

---

<sup>145</sup> Homedes, N. et al, (2005), *Generic Drug Policies in Latin America*, March 2005 HNP Discussion Paper, World Bank, pp. 9-10.

<sup>146</sup> Niazi, S.K. (2007), *Handbook of Bioequivalence testing*, Informa Healthcare, p. 51.

<sup>147</sup> Acosta, Angela (2011) IFARMA (a local think tank/research consultancy), "Regulatory Capacities in Quality Assurance of Medicines: and outlook from LA and INVIMA", Roundtable III: Role of Medicine Regulatory Authorities in developing countries and how to strengthen regulatory capacity, MSF conference 2011. From: <http://www.slideshare.net/apacostas/presentation-aa> (Accessed October 2011).

<sup>148</sup> Ryan, M.P. and Ramos, T., (2008) *Seeking Health Competitiveness, Embracing Free Trade with the United States, Pharmaceuticals, Intellectual Property Rights, Bilateral Trade Diplomacy, and Development Strategies in Jordan and Colombia*, George Washington University Law School, p. 22.

<sup>149</sup> Enemark et al, (2004), p. 30. See also Wagstaff, A. and Claeson, M. (2004) *The Millennium Development Goals for Health*, World Bank, p. 124.

<sup>150</sup> Enemark et al, (2004), p. 30.

<sup>151</sup> Transparency International, (2006), *Global Corruption Report 2006 Corruption in Health*, 2006 p. 51.

Transparencia por Colombia, also suggests that in 59% of health sector public institutions the risk for corruption is high.<sup>152</sup>

#### 4.5.4 Strengths and weaknesses

Like other Latin American countries, the quality of drugs procured in Colombia's health care system is largely dependent on the quality of pharmaceuticals within the supply chain. Academic studies suggest that no domestic pharmaceutical manufacturer adheres to internationally recognised GMP. Unlike Brazil, Colombia has not implemented a plan of requiring bioequivalence testing on its large similar drug market.

**Table 8: Colombia: strengths and weakness**

<u>Strengths</u>
- Health care reforms of 1990s has moved a majority of the population into social insurance.
- Use of EDL.
<u>Weaknesses</u>
- Quality of similars is open to question.
- Not clear if pharmacovigilance program is effectively reflecting all ADRs and monitoring quality of similar drugs in use. Lack of GMP certification indicates quality is lacking.
- Corruption in public procurement.

#### 4.6 India

The Indian economy is one of the fastest growing and most dynamic economies in the world. Since 1997 India has averaged close to 7% growth in its GDP per year, including the recession of 2008-9.<sup>153</sup> For 2010 the economy is estimated to have grown at a blistering 10.4%.<sup>154</sup>

<sup>152</sup> Ibid. pp. 339-40.

<sup>153</sup> Torstensson and Pugatch, (2010), p. 26.

<sup>154</sup> CIA Factbook, India, <https://www.cia.gov/library/publications/the-world-factbook/geos/in.html> (Accessed October 2011)

#### 4.6.1 Health system overview

India's system of health care is highly fragmented with services being provided and paid for at both the federal and state level. Only about 20% of the population have health insurance with the remainder relying either on private providers and OOP payment or the over-stretched public health system.<sup>155</sup>

As a percentage of GDP, Indian health expenditure is estimated at 6%.<sup>156</sup> Over 70% of this spending is private and OOP.<sup>157</sup> The lack of health insurance and high rate of OOP spending has resulted in health expenditure being a leading cause of indebtedness and poverty.<sup>158</sup>

#### 4.6.2 Pharmaceutical overview

India's pharmaceutical market has shown strong rates of growth, with nominal sales of pharmaceuticals between 1996 and 2006 increasing by 9% per year.<sup>159</sup> India is also a world leader in the manufacture of generic drugs, supplying both the developed and developing world. Indian firms' share of the global generics market is substantial at around 20%.<sup>160</sup>

India drug regulations have not been developed in a centralised and deliberate fashion. At the central government level regulation and responsibility for pharmaceuticals is divided between a number of agencies and ministries with the Central Drugs Standard Control (CDSC) being the most important as the DRA.<sup>161</sup> Many important drug regulatory functions – such as drug manufacturing, sale and distribution – have been delegated to the state level.<sup>162</sup> This has resulted in wide disparity in the quality and safety of medicines throughout India; some states have adequate regulatory capabilities while others are lacking.

The lack of consistency in quality control has led to a number of substandard drugs entering the pharmaceutical supply chain.<sup>163</sup> A 2007 OECD study estimated that 75% of the world's total supply of

---

<sup>155</sup> World Bank, "World Bank Support for the Health Sector in India", April 2010, <http://www.worldbank.org.in/WBSITE/EXTERNAL/COUNTRIES/SOUTHASIAEXT/INDIAEXTN/0,,contentMDK:21476175~pagePK:141137~piPK:141127~theSitePK:295584,00.html> (Accessed October 2011)

<sup>156</sup> PwC, (2010), *Healthcare in India*, Emerging market report 2007, PwC LLP 2007, p. 1.

<sup>157</sup> World Bank, (2010).

<sup>158</sup> Ibid.

<sup>159</sup> Torstensson and Pugatch, (2010), p. 26.

<sup>160</sup> Ibid. p. 27.

<sup>161</sup> Ibid. p. 29.

<sup>162</sup> Ibid. p. 30.

<sup>163</sup> Ibid.

counterfeit and/or substandard drugs came from India. In 2007 Indian vaccines were banned from the WHO's pre-qualification list over quality concerns and a track record of poor manufacturing practices.

Corruption and misappropriation of resources within Indian public administration is also a major concern. With regard to procurement, the history of Delhi is instructive. Prior to the mid 1990s the availability of quality drugs through the public health care system was limited and corruption was widespread.<sup>164</sup> Together with a local NGO the government of Delhi and WHO implemented a series of reforms aimed at improving procurement practices, transparency, the efficiency of procurement and quality of medicines. The Delhi reforms included among other things: establishing an EDL; centralising procurement; quality assuring medicines and suppliers; and continuous monitoring of the programme.<sup>165</sup> Since its inception the programme has been widely regarded as a success and is being used as a model for other Indian states.

Pharmacovigilance and quality monitoring programs are relatively limited with India only in 2003 launching a national program of pharmacovigilance.<sup>166</sup> The low levels of post-marketing surveillance is also compounded by the delegation of licensing and quality inspection to the state level as well as responsibility for the monitoring of quality of drugs manufactured within the state.<sup>167</sup>

#### 4.6.3 Pharmaceutical procurement overview

Procurement takes place at three levels: central through the federal government; state, through state governments; and at the local district level within a state.<sup>168</sup>

At the central level pharmaceutical procurement is conducted through the Directorate of procurement under the Ministry of Health and Family Welfare. The Directorate is assisted by the Empowered Procurement Wing (EPW). The EPW has developed a number of specific guidelines on procurement practices and a management information system (ProMis). The EPW oversees the direct procurement of medicines used in so-called vertical programs and national projects such as contraceptives, vaccines, TB

---

<sup>164</sup> Rao, P.R. et al (2011), *Impact of TRIPS on Pharmaceutical Prices with specific focus on generics in India*, WHO and Ministry of Health & Family Welfare, India, 2006, p. 70.

<sup>165</sup> Editorial, "Implementing rational drug use: A success story", *Indian Journal of Pharmacology*, April 2006, Vol 38, Issue 2, pp. 93-4.

<sup>166</sup> Torstensson and Pugatch, (2010), p. 32.

<sup>167</sup> Ibid. p. 30.

<sup>168</sup> Selvaraj, S. et al, (2010) *Improving Governance and Accountability in India's Medicine Supply System*, Public Health Foundation of India (public-private research institute, for details see: <http://www.phfi.org/about-us>), March 2010, p. 38.

control, and malaria control.<sup>169</sup> The EPW also oversees the procurement of medicines at the state and district level.

At the state level procurement procedures and capabilities vary. Some states use pooled procurement and a state version of an EDL together with clear and transparent tendering documents. For example, the state of Tamil Nadu issues detailed descriptions of the tendering process and what is required by suppliers in terms of quality control and continuous quality assurance.<sup>170</sup>

The manner in which procurement is divided between the state and local level varies. For instance, in the state of Chhattisgarh the State Health Society (SHS) is responsible for the centralised procurement of medical equipment while drugs and consumables are purchased at the local level.<sup>171</sup> The SHS, however, does not have a dedicated procurement division or team of procurement professionals. Other states, such as Rajasthan, have dedicated State Procurement Offices (SPOs).<sup>172</sup> Moreover, in Rajasthan local health care facilities procure drugs themselves, but do so with the rate contracts fixed by the SPO.<sup>173</sup>

On the issue of quality assurance and control, some states have begun using a two-bid process: a technical and a commercial bid. In Rajasthan, commercial bids are only evaluated once a technical bid document has been approved.<sup>174</sup> States also use independent quality verification and in some cases require GMP certification prior to purchase. See, for example, the state of Tamil Nadu and Andhra Pradesh.<sup>175</sup>

#### 4.6.4 Strengths and weaknesses

As with its drug regulations, Indian procurement practices are highly fragmented and vary in both quality and design from state to state. The high level of substandard drugs within the pharmaceutical supply cycle and the lack of quality controls in many procurement systems mean that quality assurance is a real issue. There are some examples of states that have launched new programs of procurement that include quality assurance and monitoring. Where in place these seem to have been successful and where properly implemented have improved access to quality medicines.

---

<sup>169</sup> Department of Health & Family Welfare, Government of India, "Office Memorandum", October 28 2005, from the EPW website: <http://mohfw-epw.gov.in/> (Accessed October 2011)

<sup>170</sup> Selvaraj et al, (2010), pp. 48-50.

<sup>171</sup> Ibid. p. 39.

<sup>172</sup> Ibid.

<sup>173</sup> Ibid.

<sup>174</sup> Ibid. pp. 41-2

<sup>175</sup> Rao et al, (2006), pp. 71-5.

**Table 9: India: strengths and weakness**

<b>Strengths</b>
- Centralised national procurement through the EPW and implementation of a MIS in 2005 is a good step towards ensuring higher quality procurement.
- Many states have implemented procurement reforms and improving quality assurance programs.
<b>Weaknesses</b>
- High level of substandard and counterfeit medicines within drug supply.
- Poor levels of pharmacovigilance
- Wide-spread corruption in procurement.
- Standards of quality control are not consistent for exported versus drugs manufactured for domestic sale.

#### 4.7 Poland

Since its accession to the EU in 2004 the Polish economy has been one of the most successful of the former communist bloc and has grown strongly. In fact, Poland was the only EU country not to contract or stagnate during the financial crisis and subsequent global recession. In 2008 it posted GDP growth of 5.1%, in 2009 1.7% and for 2010 an estimated 3.8%.<sup>176</sup>

##### 4.7.1 Health system overview

Prior to 1991 the Polish health system was – like most communist states – based on the Semashko model.<sup>177</sup> But in 1999, following the fall of communism the health care system was fundamentally reformed. These reforms moved it away from being a state-centred system of financing and provision and created an internal health care market with a separation of purchasers and providers. This system was then reformed again in 2003 when 17 sickness funds established in 1999 failed to stay solvent. A new National Health Fund was set up which contracts health services on behalf of the public.

<sup>176</sup> CIA Factbook, Poland, <https://www.cia.gov/library/publications/the-world-factbook/geos/pl.html> (Accessed October 2011)

<sup>177</sup> This model being the quintessentially centrally controlled and state run system of healthcare that was in place in most of the Soviet Union and Eastern Europe under communism.

Polish expenditure on health care as a percentage of GDP for 2009 was 7.4%, below the OECD average.<sup>178</sup> This is, however, a substantial increase from ten years earlier when the figure was 5.7%. As of 2009 public expenditure makes up the majority of this spending at 72.2%.<sup>179</sup>

#### 4.7.2 Pharmaceutical system overview

The Polish pharmaceutical market is one of the biggest in Central and Eastern Europe and is expected to grow strongly over the next few years.<sup>180</sup> Most drugs consumed and sold are domestically manufactured; the majority being generics.<sup>181</sup>

Like all other EU member states, the Polish pharmaceutical market is highly regulated with price and reimbursement controls in place and determined by the state. Pharmaceutical price and reimbursement lists are set by the Drug Management Team of the MoH for essential medicines with price caps on wholesalers and pharmacist mark-ups established. Reference pricing is used. As of 2002 just over 50% of all drugs on the market were reimbursed.<sup>182</sup>

Recently the Polish government passed a Drug Reimbursement Act which aims to cut drug reimbursement spending. It includes a number of cost-containment provisions, such as capping the drug reimbursement expenditure to a fixed percentage of the overall public health budget.<sup>183</sup>

Polish health care has been subject to accusations of corruption. For example, in 2001 academic surveys found that informal payments had become a part of the health care system, being a way of obtaining the services of reputable and specialist providers.<sup>184</sup> A government-wide anti-corruption campaign launched in the early 2000s had a noticeable impact on reducing corruption in health care.<sup>185</sup> By and large this campaign contributed to reducing overall levels of corruption in the public sector.

---

<sup>178</sup> OECD, OECD Health Data 2011 - Frequently Requested Data, OECD 2011.

<sup>179</sup> Ibid.

<sup>180</sup> Espicom, "The Pharmaceutical Market: Poland",

[http://www.espicom.com/Prodcat2.nsf/Product\\_ID\\_Lookup/00000363?OpenDocument](http://www.espicom.com/Prodcat2.nsf/Product_ID_Lookup/00000363?OpenDocument) (Accessed October 2011)

<sup>181</sup> Gericke, C. et al, (2005) *Health Systems in Transition Poland*, European Observatory on Health Systems and Policies, Vol 7, No 5, p. 82.

<sup>182</sup> Ibid. p. 83. See also SCRIP Reports (2007), "European Pharmaceutical Distribution: Key Players, Challenges and Future Strategies", p. 103.

<sup>183</sup> Espicom, "The Pharmaceutical Market: Poland".

<sup>184</sup> Lewis, M. (2006a), *Governance and Corruption in Public Health Care Systems*, Center for Global Development, Working Paper number 78, January 2006, p. 30

<sup>185</sup> Lewis, M. (2006b) "Tackling Healthcare Corruption and Governance Woes in Developing Countries", CGD Brief, Center for Global Development, May 2006, p. 6.

Poland has also been affected by increasing inflows of counterfeit medicines. For instance, in 2008 figures from Polish customs showed a 100-fold increase in packages intercepted over previous years.<sup>186</sup>

#### 4.7.3 Pharmaceutical procurement overview

Public procurement in Poland – like in all EU member states – is, with some exceptions, regulated by EU Directive 2004/18/EC. Polish law on public procurement is thus both detailed and contains numerous provisions on transparency and the types of tendering allowed.<sup>187</sup> For example, it specifies how awards over certain thresholds must be publicised both in the Official Journal of the European Union as well as in the Polish Public Procurement Bulletin.<sup>188</sup> Similarly, the tendering procedure used for contracts with a value over €5million for services or €10million in works must be approved by the President of the Polish Public Procurement Office.

Pharmaceutical procurement takes place at the individual hospital level, not through central or district tendering. By and large the tendering process is determined by the cost of the drug.<sup>189</sup> Medical procurement (with pharmaceutical procurement in particular) has been accused of wide-spread corruption.<sup>190</sup> In 2008 the Polish National Chamber of Commerce (KIG) warned of the collusion between hospitals and preferred providers. In particular, tendering documents were said to be unclear and the process convoluted.<sup>191</sup>

#### 4.7.4 Strengths and weaknesses

Poland is an EU member state and therefore all public tendering and procurement is legally bound by the rules and regulations stipulated in EU directives. While health care in Poland has been subject to accusations of corruption it does not seem to be endemic or unusually high. Indeed, as mentioned, there is evidence to suggest that the government-wide anti-corruption reforms of the mid 2000s reduced graft in health. Still, as

---

<sup>186</sup> PMR, “Confiscated counterfeit drugs soar 100-fold”, January 25 2009, <http://www.pharmapoland.com/68670/Confiscated-counterfeit-drugs-soar-100-fold.shtml> (Accessed October 2011).

<sup>187</sup> European Tender Information System (2006), “Public Procurement in Poland”, October 2006.

<sup>188</sup> Ibid.

<sup>189</sup> Adamski, J. et al, (2008), “Cost containment in the pharmaceutical sector: innovative approaches for contracting while ensuring fair access to drugs”, Peer Review July 2008, DG Employment, Social Affairs and Inclusion initiative, <http://www.peer-review-social-inclusion.eu/peer-reviews/2008/cost-containment-in-the-pharmaceutical-sector-innovative-approaches-to-contracting-while-ensuring-fair-access-to-drugs> (Accessed September 2011).

<sup>190</sup> See: PMR (2008), “KIG demands changes in hospital procurement”, July 23 2008, <http://www.pharmapoland.com/62802/KIG-demands-changes-in-hospital-procurement.shtml> (Accessed October 2011).

<sup>191</sup> Ibid.

both the allegations by the KIG illustrate and the decentralised nature of Polish procurement, corrupt practices at the individual hospital level may still occur.

With regard to pharmacovigilance, as in other EU member states the EMA has monitoring responsibility for centrally authorised medicines, which includes Poland's pharmaceutical market.<sup>192</sup>

**Table 10: Poland: strengths and weakness**

<b>Strengths</b>
- As an EU member State all public procurement must follow EU laws and regulations.
- EMA responsible for important aspects of pharmacovigilance.
- Relatively advanced system of health care and social insurance.
<b>Weaknesses</b>
- Corruption in health care an issue during the 2000s; recent allegations have been made about hospital procurement.
- Counterfeit medicines an increasing problem.
- Decentralised procurement at hospital level raises structural risk of corruption and wide variety in quality assurance procedures.

## 4.8 Romania

Romania is one of the poorest EU member states. Since its accession together with Bulgaria in 2007 the country has been marred by accusations of corruption and a slow-down in the implementation of EU directives and reforms. Its economy has suffered badly during the recession. In 2009 GDP shrank by 7.1% and in 2010 the economy is estimated to have contracted by a further 1.3%.<sup>193</sup>

### 4.8.1 Health system overview

Romania's health care system has moved away from a tax-based centralised Semashko-style system to a social insurance model. Reforms in 1997 and 2006 created a social insurance model with government

<sup>192</sup> EMA, "Pharmacovigilance Working Party", [http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMP/people\\_listing\\_000019.jsp&mid=WC0b01ac0580028d92&jenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMP/people_listing_000019.jsp&mid=WC0b01ac0580028d92&jenabled=true) (Accessed October 2011).

<sup>193</sup> CIA Factbook, Romania, <https://www.cia.gov/library/publications/the-world-factbook/geos/ro.html> (Accessed October 2011)

playing a leading role in the contracting and purchasing of care. The National Health Insurance Fund (NHIF) administers and regulates the health insurance system.<sup>194</sup> Local District Health Insurance Funds (DHIF) contract health services with public and private providers.<sup>195</sup>

As a percentage of GDP health expenditure is relatively low at 4.4% for the latest available year (2005).<sup>196</sup>

#### 4.8.2 Pharmaceutical system overview

The Romanian pharmaceutical market is a medium-sized Central and Eastern European market and recorded substantial growth rates during the mid to late 2000s. This growth has stagnated somewhat since then as the economic recession, increased parallel exporting and decreases in prescribing has taken its toll.<sup>197</sup>

Reference pricing is in place for pharmaceuticals and co-payments are required for most drugs.<sup>198</sup> Co-payments work according to a tiered formulary with higher payments for branded drugs and lower payments for generics. Only certain diseases and types of medicines are provided without a co-payment and free of charge.

Allegations of corruption have beset Romania and its health care sector. A recent article in the magazine *The Diplomat* stated that: “the problem of medical staff soliciting bribes from patients is endemic, and there are also suspicions of kickbacks between some hospital procurement staff and private providers of medical equipment and pharmaceuticals.”<sup>199</sup>

Recently, the Romanian President Traian Basescu said that outstanding debts for drug reimbursement which the Romanian National Health Insurance House (CNAS) owes pharmacies and hospitals should not be settled until poor local procurement practices had been reformed.<sup>200</sup> Moreover, the most recent report by the EU Commission, published in July 2011, on the progress of Romanian reforms suggested that

---

<sup>194</sup> Vlădescu, C. et al, (2008) “Romania Health System Review”, *Health Systems in Transition*, Vol. 10, No 3, 2008, p. xvi.

<sup>195</sup> Ibid.

<sup>196</sup> Ibid. p. xvii.

<sup>197</sup> Roland Berger Management Consultants, “Romanian pharmaceutical market”, <http://rbd.doingbusiness.ro/en/5/evolutia-principalelor-sectoare-economice/all/510/romanian-pharmaceutical-market>

<sup>198</sup> Vlădescu et al, (2008), pp. 125-6.

<sup>199</sup> *The Diplomat*, “Romanian healthcare system awaits life-saving cash injection”, *Bucharest*, Vol 7, No 7 September, <http://www.thediplomat.ro/articol.php?id=2192> (Accessed October 2011).

<sup>200</sup> PMR, “Romanian President advises not to settle outstanding payments for drug reimbursement”, July 22 2011, <http://www.ceepharm.com/107609/Romanian-President-advises-not-to-settle-outstanding-payments-for-drug-reimbursement.shtml> (Accessed September 2011).

improvements to good practice and to strengthen integrity and accountability were still lacking in the health sector.<sup>201</sup>

#### 4.8.3 Pharmaceutical procurement overview

As in Poland and other EU member states, all public procurement is guided by EU law and regulations. Procurement in Romania is both centralised and decentralised. Most medical and pharmaceutical procurement takes place at the local hospital level where it is subject to public procurement legislation and EU law.<sup>202</sup> For certain types of drugs and high-technology equipment, procurement takes place at the central level with the Ministry of Public Health, the purchasing party.<sup>203</sup> The Ministry of Public Health is also partly responsible for procuring drugs used in ambulatory care.<sup>204</sup>

A system of pharmaceutical tendering is in use since 2002. Tendering is used for virtually all drug procurement: in hospital care, public functions (e.g. pharmaceuticals for pandemic plans), and also for ambulatory care.<sup>205</sup>

Tendering occurs annually and is issued on a country-wide, not EU-wide, basis.<sup>206</sup> Tender results are published by the Ministry of Communications and Information Technology. With regard to tendering criteria used, EU law (EC Directive 2004/18) outlines two main criteria to be used in public procurement:

- a) most economically advantageous with “various criteria linked to the subject-matter of the public contract in question, for example, quality, price technical merit...cost effectiveness” etc.; or
- b) the lowest price only.<sup>207</sup>

Member states therefore have a choice between judging and awarding tenders based on price alone or using a broader set of criteria, including quality. In a 2010 survey of EU member states' drug procurement policies, Romania listed category b, lowest price among bidders, as its guiding criteria.<sup>208</sup>

---

<sup>201</sup> European Commission, 'On Progress in Romania under the Co-operation and Verification Mechanism', July 2011, Supporting Technical Document.

<sup>202</sup> Vlădescu et al, (2008), p. 122.

<sup>203</sup> Ibid. p. 55.

<sup>204</sup> Leopold, C. et al, (2008) *Tendering of pharmaceuticals in EU Member States and EEA countries, Results from the Survey*, June 2008, Commissioned by the European Social Insurance Platform, p. 10.

<sup>205</sup> Ibid. p. 7.

<sup>206</sup> Ibid. pp. 15-6.

<sup>207</sup> Ibid. p. 14.

<sup>208</sup> Ibid. p. 16.

#### 4.8.4 Strengths and weaknesses

For a developed country Romania has serious problems with corruption and the public procurement of pharmaceuticals is one area where the system is liable to corruption. Recent comments by the Romanian President indicate as much and suggest this is an area of pending reform.

**Table 11: Romania: strengths and weakness**

<b><u>Strengths</u></b>
- As an EU member State all public procurement must follow EU laws and regulations.
- EMA responsible for important aspects of pharmacovigilance.
<b><u>Weaknesses</u></b>
- Corruption in health care and health procurement is still a serious issue; in particular recent allegations have been made about hospital procurement by the President.
- Wide-spread corruption through public administration as highlighted by EU verification reports.
- Decentralised procurement at hospital level raises structural risk of corruption and wide variety in quality assurance procedures.

#### **4.9 Russia**

Benefiting from strong global demand for oil and gas and the accompanying high prices of hydrocarbons, the Russian economy during the mid to late 2000s grew at an impressive pace. In 2006 GDP grew by 7.7%, in 2007 this increased to 8.1% falling slightly to 5.6% in 2008.<sup>209</sup> However, the 2008-9 financial crisis and subsequent recession has hit Russia hard with GDP falling by 7.9% in 2009.<sup>210</sup>

##### 4.9.1 Health system overview

Prior to 1991 healthcare was highly centralised and the MoH, in effect, regulated, managed and oversaw health care throughout the Soviet Union. In 1991 the healthcare system was decentralised and now works

<sup>209</sup> The World Bank in Russia, (2009), "Russian Economic Report", No 19, June 2009, p. 2.

<sup>210</sup> Galbraith Wight, *Russian Healthcare System Report*, 2010, p. 2.

on three distinct levels: the federal, regional (oblast-level) and municipal (rayon-level).<sup>211</sup> In addition, there is a large “parallel” system of health care through various other federal departments and ministries. This accounts for roughly 15% of all outpatient facilities and 6% of inpatient facilities.<sup>212</sup>

Mandatory health insurance was introduced in 1993 but implementation has been relatively limited. Financing remains problematic and private sector insurance third party payers have yet to emerge in all regions.<sup>213</sup>

Total expenditure on health care is in comparison with the OECD average rather low, at 5.3% of GDP for 2006.<sup>214</sup> Public expenditure on health is also relatively low. For 2008 this amounted to an estimated 3.6% of GDP.<sup>215</sup>

#### 4.9.2 Pharmaceutical systems overview

The Russian pharmaceutical market grew at a rapid rate between 2003 and 2008 with an increase of 19% in the compound annual growth rate.<sup>216</sup> A majority of the market is made up of the retail, non-government subsidised sector.<sup>217</sup> While Russia has had an EDL in place for some time and public health regulations stipulate that provision of drugs should be free of charge under certain conditions (for in-hospital treatment and for essential drugs) more often than not this is not the case. For example, OOP household spending on drugs account for 30% of total health expenditure; far above the average rate for OECD countries.<sup>218</sup> Survey data also shows that 95% of those who bought medical drugs paid OOP.<sup>219</sup> Moreover, the existing outpatient drug program (through the mandatory health insurance programme) covers only 10% of the population, but only half of those covered choose to take the coverage instead of a cash-back option introduced in 2005.<sup>220</sup>

---

<sup>211</sup> Tragakes, E. and Lessof, S. (2003), “Russian Federation”, *Healthcare systems in Transition*, European Observatory on Health Systems and Policies, pp. 28-9.

<sup>212</sup> *Ibid.* p. 38.

<sup>213</sup> *Ibid.* p. 41.

<sup>214</sup> Galbraith Wight, (2010), p. 2.

<sup>215</sup> The World Bank in Russia, (2009), p. 15.

<sup>216</sup> Galbraith Wight, (2010), p. 2.

<sup>217</sup> *Ibid.*

<sup>218</sup> The World Bank in Russia, (2009), p. 15.

<sup>219</sup> *Ibid.* p. 16.

<sup>220</sup> *Ibid.*

Russia has significant problems with the quality and regulation of its pharmaceutical market. Estimates suggest that substandards and counterfeits account for around 12% of the total Russian drug supply.<sup>221</sup> Public awareness of this problem is growing. For instance, a 2008 opinion poll showed that roughly 40% of Russians were concerned that they were being exposed to substandard or low quality medicines.<sup>222</sup>

Furthermore, in 2006 *The Lancet* described widespread Russian practices whereby drugs manufacturers, who operate legitimate pharmaceutical production businesses by day, would dedicate time at night to “producing extra quantities of a certified drug that does not pass through quality control, or sophisticated copies of well-known drugs are produced, often with reduced levels of expensive active ingredients”. It also said that 70% of substandard medicines and counterfeits in Russia were produced domestically, and an estimated 70% of them were copies of foreign medications.<sup>223</sup>

These illicit practices aside, there are wider quality concerns within pharmaceutical manufacturing. To begin with, very few Russian pharmaceutical manufacturers adhere to internationally recognised standards of GMP. There are presently 400 Russian pharmaceutical companies operating in the country, of which just 40 meet international GMP standards.<sup>224</sup> While the Russian government has introduced legislation requiring international GMP and GCP compliance by 2014, there is some doubt over the extent to which this will be implemented and vigorously enforced.<sup>225</sup>

Finally, corruption in the Russian pharmaceutical and health care market is widespread. Studies suggest that \$2.5billion was paid in bribes per year for receiving nominally free services.<sup>226</sup> Informal payments within the health sector constituted the largest single share of this graft.<sup>227</sup>

#### 4.9.3 Pharmaceutical procurement overview

Pharmaceutical procurement is highly fragmented and there is great variety in the quality of products procured from region to region and hospital to hospital. Broadly speaking, most procurement is done at the

---

<sup>221</sup> Bate (2008), p. 21.

<sup>222</sup> Healy and Pugatch, (2011) p. 25.

<sup>223</sup> “Russia cracks down on counterfeit drugs” in *The Lancet* (28/10/2006). See [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(06\)69619-0/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(06)69619-0/fulltext).

<sup>224</sup> “New Russian Pharmaceutical Bill Passed on Final Reading” in IHS Global Insight (26/03/10). See <http://www.ihsglobalinsight.com/SDA/SDADetail18459.htm>.

<sup>225</sup> Healy and Pugatch, (2011) p. 25.

<sup>226</sup> Tragakes and Lessof, (2003), p. 105.

<sup>227</sup> Ibid.

regional, local, insurer and hospital level. Hospital procurement is done either through a regional hospital budget or by the territorial mandatory health insurance funds (a body under the Mandatory Health Insurance Fund, MHIF, set up in the early 1990s).<sup>228</sup> Insurers issue tenders that pharmacies, wholesalers or distributors can bid on.<sup>229</sup>

Systems of hospital procurement vary from region to region; some regions such as Komi have had some success in centralising pharmaceutical procurement and increasing access and lowering cost.<sup>230</sup> Yet, overall, drug procurement of substandard and counterfeit medicines will be heavily affected by local corruption, poor administrative routines and the poor state of the domestic Russian pharmaceutical industry where, as mentioned, very few manufacturers are GMP compliant and counterfeiting is rife.

Moreover, pricing and the cost of medication also varies from region to region. For example, federal regulations impose price regulations and mark up limits on both retailers and wholesaler's of 30% and 25% respectively.<sup>231</sup> However, survey analysis suggests that there is wide variation in the end price from region to region with average prices in Moscow (the most expensive region) being over three times as expensive as the cheapest region Kemerov.<sup>232</sup> Many view the main cause for this disparity in the delegation of enforcing the mark-up limits to regional authorities.<sup>233</sup> The Russian government has launched a number of initiatives to reduce this disparity; vesting sole authority with the MoH for price regulation being one of the most important.<sup>234</sup>

For some types of medicines, such as orphan drugs, the state provides funding and procures drugs directly.<sup>235</sup> For example the 7 Nosology (7N) program is such a program with a budget of close to \$800m annually.<sup>236</sup>

---

<sup>228</sup> Ibid. p. 151.

<sup>229</sup> Ibid.

<sup>230</sup> expo.rus.medserv.com, "Russia: The challenge of access to medicines", <http://expo.rusmedserv.com/articl2.html> (Accessed October 2011).

<sup>231</sup> Zasimova, Liudmila (2010), "Public policy and access to new drugs: evidence form Russian pharmaceutical market", Pan European Institute, p. 16. <http://www.tse.fi/FI/yksikot/erillislaitokset/pei/Documents/Julkaisut/Zasimova%20final.pdf>

<sup>232</sup> Ibid. p. 17.

<sup>233</sup> Ibid.

<sup>234</sup> Ibid.

<sup>235</sup> pharma.focusreports.net, Interview with Viktor Geisler, Country Division Head, Bayer Pharmaceuticals, Russia, <http://www.pharma.focusreports.net/index.php#state=InterviewDetail&id=1344> (Accessed November 2011).

<sup>236</sup> IHS Global Insight, "Russian Healthcare Law Amendments Will Increase Orphan Drugs Access; Debate on Drug Insurance Provision Continues", 22 September 2011, <http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065930370> (Accessed November 2011).

The Russian government has recently updated and altered the way it reimburses medicines. The draft Vital and Essential Drug (ZHNVLDP) released earlier this year shows a number of new medicines and products being reimbursed, including high-cost oncology products.<sup>237</sup>

#### 4.9.4 Strengths and weakness

The Russian health care system is marred by corruption, counterfeiting and substandard drugs. Quality standards are quite poor and there are doubts that government efforts to improve quality and accessibility – through an expanded EDL and tougher GMP requirements – will be fully implemented.

**Table 12: Russia: strengths and weakness**

<u>Strengths</u>
- New regulations require manufacturers to be GMP compliant.
- A system of pharmacovigilance was introduced in the mid 2000s with additional regional monitoring centres introduced subsequently.
<u>Weaknesses</u>
- Corruption in health care and public services a major public policy issue.
- Counterfeit medicines an increasing problem with examples of legitimate suppliers producing counterfeits as a side venture.
- Poor quality track record, both in actual drug regulations (lack of GMP) and implementation and enforcement.

#### **4.10 Thailand**

Despite recent political upheaval and prolonged periods of public protests and uncertainty, the Thai economy has been relatively strong. In 2008 GDP grew by 2.5% and while the economy contracted by 2.3% in 2009 it bounced back in 2010 growing by and estimated 7.8%.<sup>238</sup>

<sup>237</sup> IHS Global Insight, "Russia's Draft 2012 Essential Drugs List Includes Many New Innovative Products, Several Oncology Drugs", 10 July 2011, <http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065930427> (Accessed November 2011).

<sup>238</sup> CIA Factbook, Thailand, <https://www.cia.gov/library/publications/the-world-factbook/geos/th.html> (Accessed October 2011)

#### 4.10.1 Health system overview

Access to health care and universal healthcare coverage was mandated in both the 1997 constitution as well as in 2002 health care legislation. The latter introduced a tax-funded health insurance scheme, the Universal Coverage System (UC). UC covers around three-quarters of the population, with the remainder covered by public civil service or social health insurance schemes.<sup>239</sup>

Thai spending on healthcare is relatively low, in 2007 it accounted for 3.7% of GDP.<sup>240</sup> The majority of this (73%) is made up of government spending.<sup>241</sup>

#### 4.10.2 Pharmaceutical system overview

The Thai pharmaceutical market is growing rapidly and is expected to be the seventh largest pharmaceutical market in the Asia Pacific region by the middle of this decade.<sup>242</sup>

The Thai pharmaceutical industry consists mainly of local manufacturers of finished drugs based on imported APIs. Fewer than 10 Thai companies are involved in the production of raw material that could be used in the production of medicines and almost all of these raw materials are intermediate ingredients. Most chemical compounds required for transformation into finished drugs – that is, about 95% of compounds used in the country - are imported.<sup>243</sup>

In 2005, there were 162 firms involved in pharmaceutical manufacturing, 90% of which were private companies. A notable exception is the Government Pharmaceutical Organisation (GPO) which is one of the largest pharmaceutical producers. As a government supported entity the GPO is mandated to provide low-cost drugs to public hospitals. In providing this service, the GPO is exempt from registration and GMP requirements and maintains an exclusive position in supplying government hospitals with products on the EDL.<sup>244</sup> Significantly, the GPO monitors the quality of its products itself.<sup>245</sup>

---

<sup>239</sup> Healy and Pugatch, (2011) p. 26.

<sup>240</sup> Thai National Health Accounts, "Sustainable Updates", <http://whothailand.healthrepository.org/handle/123456789/547> (Accessed October 2011)

<sup>241</sup> Ibid.

<sup>242</sup> Espicom, "The Pharmaceutical Market: Thailand",

[http://www.espicom.com/prodcat2.nsf/Product\\_ID\\_Lookup/00000377?OpenDocument](http://www.espicom.com/prodcat2.nsf/Product_ID_Lookup/00000377?OpenDocument) (Accessed October 2011)

<sup>243</sup> Healy and Pugatch, (2011), pp. 26-30

<sup>244</sup> Ibid.

<sup>245</sup> WHO, (1998) Essential Drugs Monitor, No 25-26 , p. 5.

Thailand has had a National Drugs policy in place since 1981. The Drug Act was revised in 2003 and now, for example, requires all manufacturers – except the GPO – to have GMP certification.<sup>246</sup> Thailand also requires bioequivalence testing for registration of generics.<sup>247</sup>

Corruption in the health and pharmaceutical sector has been observed. The GPO, for instance, was in the early 2000s accused by the Thai auditor-general of excessively marking up its medicines and selling 60% of its drugs at above market rate.<sup>248</sup>

In 2004 Thailand signed up to the WHO's Good Governance for Medicines (GGM) programme. This programme is designed to introduce best practices, increase transparency and reduce corruption within the health sector.<sup>249</sup> According to the WHO Thailand has since made significant improvements, listing an increase in best practice procurement as one of them.<sup>250</sup> Still, problems remain. For example, Thai drug regulatory officials do not have to declare any conflicts of interests or fill out any COI forms before evaluating medicines.<sup>251</sup>

With regard to substandard and counterfeit medicines Thailand has significant problems. In 2004, the WHO estimated that 8.5% of all medicines on the Thai market were substandard.<sup>252</sup> A 1997 study of malaria drugs (chloroquine) and selected antibacterials showed that 40% of samples from Thailand were substandard with respect to British Pharmacopoeia limits, with some amoxicillin drugs showing zero quantities of active ingredient.<sup>253</sup> A further study by Dondorp et al, which looked at antimalarials (artemisinin derivatives and mefloquine) throughout Southeast Asia, found that 53% of drugs analysed that were labelled "artesunate" did not in fact contain any artesunate in them, whilst among the 44 mefloquine samples looked at, 9% contained less than a tenth of the expected amount of active ingredient.<sup>254</sup>

---

<sup>246</sup> WHO and HAI, Thailand, "Medicine prices, availability, affordability, & price components", 2003

<sup>247</sup> Sooksriwong, C. et al, "Medicine Prices in Thailand: A result of no medicine pricing policy", *Southern Med Review*, (2009) 2;2: pp. 10-14, p. 10.

<sup>248</sup> Healy and Pugatch, (2011), p. 30.

<sup>249</sup> WHO Good Governance for Medicines Programme (2010), *Country Case studies and best practices*.

<sup>250</sup> *Ibid.* p. 19.

<sup>251</sup> WHO, (2006), *Measuring Transparency in Medicines Registration, Selection and Procurement – Four Country Assessment Studies*, p. 8.

<sup>252</sup> US Pharmacopeia 2004, p. 23.

<sup>253</sup> Shakoor, O. et al (1997). *Assessment of the incidence of substandard drugs in developing countries*. (Tropical Medicine and International Health, Volume 2 No 9 PP. 839-845 September 1997). See <http://onlinelibrary.wiley.com/doi/10.1046/j.1365-3156.1997.d01-403.x/pdf>. (Accessed July 2011)

<sup>254</sup> Healy and Pugatch, (2011), pp. 26-30

#### 4.10.3 Pharmaceutical procurement overview

Thai drug procurement has been fundamentally changed over the past fifteen years. In 1994 drug procurement was moved to the provincial level with Thailand's 75 provinces taking charge of drug procurement for all district hospitals. This delegation was inspired by a local initiative in Nakorn Ratchasima province in 1990. Here district hospitals set up a collective bargaining system which agreed on the equivalent of an EDL and collectively negotiated with selected (pre-screened) drug suppliers. Tenders were given on an annual basis based on price.<sup>255</sup> As part of the reform quality control procedures (pre and post purchase) were improved with only GMP certified factories being allowed to compete for contracts; post purchase sampling and testing of essential drugs were carried out at Regional Medical Centres. These improved quality control procedures led to a reduction of substandard medicines in the regional supply chain from 30 to 15%.<sup>256</sup>

Other provinces followed in 1992 and in 1994 central government proposed a national policy. This was only taken up by a handful of provinces and not until the financial and economic crisis of 1997-8 did Thai provinces begin to fully implement the system. Ministry of Public Health Inspector Generals were dispatched to overlook the implementation of the new rules. By 1998 success was measured by 67 out of the 75 provinces having implemented the new purchasing mechanism. Together they had reduced expenditure by 25%.<sup>257</sup> Subsequent studies support this. A 2009 price comparison survey between private and public-sector procured medicines argues that hospital group purchasing is responsible for the significant difference between private and public sector drug prices.<sup>258</sup>

Still, Thailand has problems with its system of procurement. In a 2006 WHO assessment Thailand scored reasonably in relation to transparency but was listed as having deficiencies in the following areas:

- contract specifications for purchases under 100,000 baht in value not being made publicly available;
- tenders under 100,000 baht not being publicised; and
- adjudication criteria mostly not being publicly available or included in tender packages.<sup>259</sup>

---

<sup>255</sup> WHO, (1998), p. 5.

<sup>256</sup> Ibid.

<sup>257</sup> Ibid.

<sup>258</sup> Sooksriwong et al, (2009), pp. 12-3.

<sup>259</sup> WHO, (2006), p. 15.

Furthermore, the WHO in this assessment did not view audits of procurement agencies as being comprehensive enough.<sup>260</sup> Finally, the assessment suggested that Thai lot testing standards are quite poor with only the Department of Medical Sciences and a handful of individual hospitals performing some sampling when purchasing from new suppliers.<sup>261</sup>

#### 4.10.4 Strengths and weaknesses

Thailand's system of quality assurance and drug procurement has undergone significant changes and, according to the WHO, made significant improvements. Procured drugs in the public health system are now of higher quality and procured at a lower cost than before. The requirement for bioequivalence testing for generics and GMP certification for all domestic manufacturers are also significant improvements.

Nevertheless, there are areas of concern. These include the implementation of quality assurance mechanisms throughout the procurement cycle as well as the quality of GPO medicines. Equally, not requiring the GPO to adhere to GMP and allowing it to self-review and test its medicines raises serious questions about the quality of these medicines.

**Table 13: Thailand: strengths and weakness**

<b><u>Strengths</u></b>
- Has systematically improved hospital procurement and reduced the presence of substandard medicines.
- Joined the WHO GGM program and has implemented a number of best practices.
- Bioequivalence testing required for generics and GMP for the majority of manufacturers.
<b><u>Weaknesses</u></b>
- Not requiring the GPO to adhere to GMP.
- Counterfeit and substandard medicines make up a substantial share of the drug supply. Some studies show up to 40% of sampled drugs being substandard.

<sup>260</sup> Ibid. p. 16.

<sup>261</sup> Ibid. p. 18.

## 4.1.1 Turkey

Turkey has over the past decade emerged as an economic power. GDP growth has hovered around 5% a year from the early 2000s up until the financial crisis of 2009 when it contracted by 4.7%.<sup>262</sup> In 2010 the economy bounced back strongly and grew by an estimated 8.2%.<sup>263</sup>

### 4.1.1.1 Health system overview

Turkish health care was fundamentally reformed in 2003 with the introduction of the Health Transformation Programme (HTP). The most important of the HTP reforms was to centralise health care and create a single-payer system of health insurance.<sup>264</sup> These reforms were a reaction to the deteriorating fiscal situation of the public social security system.

### 4.1.1.2 Pharmaceutical system overview

Buoyed on by rising living standards and a growing economy the Turkish pharmaceutical market has shown strong growth in recent years almost doubling in value from €3.3billion to €5.2billion between 2002 and 2006.<sup>265</sup>

However, both substandard and counterfeit medicines make up a significant share of the Turkish pharmaceutical market. Some experts have claimed it is the fourth largest market in the world measured by number of arrests.<sup>266</sup> Furthermore, quality assurance has proven to be difficult in a market where bartering medicines between small-scale pharmacists is a common practice.<sup>267</sup>

Significantly, Turkey does not require GMP certification to internationally accepted standards.<sup>268</sup> This suggests that the majority of Turkish pharmaceutical manufacturers – which do not have contracts or work for multinational firms – do not adhere to international GMP standards.<sup>269</sup>

---

<sup>262</sup> Torstensson and Pugatch, (2010), p. 40. See CIA Factbook, Turkey for 2009 GDP figures, <https://www.cia.gov/library/publications/the-world-factbook/geos/tu.html> (Accessed October 2011)

<sup>263</sup> Ibid. CIA Factbook.

<sup>264</sup> Ibid. p. 40.

<sup>265</sup> Torstensson and Pugatch, (2010) p. 41.

<sup>266</sup> Ibid. p. 48.

<sup>267</sup> Ibid. p. 49.

<sup>268</sup> Celik, Y. and Seiter, A. (2008), "Turkey Pharmaceutical Sector Analysis", The World Bank, p. 18.

<sup>269</sup> Ibid.

#### 4.1.1.3 Pharmaceutical procurement overview

Turkey has in recent years embarked on series of ambitious reforms to its system of public procurement to bring it in line with EC law and European standards. Recent Sigma assessments (2009 and 2010) by the OECD and EU argue that Turkey is making good progress in formulating good procurement policies and practices.<sup>270</sup>

General procurement procedures and guidelines have been produced in the Public Tendering Act (Act No 4734), State Bidding Law and Public Tender Law (PTL), which all hospitals are required by law to follow. The PTL outlines in some detail the methods, values and procedures to be used in any tendering.<sup>271</sup> For example, most bidding is restricted to open bids or pre-qualified, restricted tendering.<sup>272</sup> The Sigma assessments show that the overwhelming number of public tendering is done by open bidding.<sup>273</sup>

However, the PTL does allow for domestic preferencing.<sup>274</sup> Specifically, there is a price advantage of up to 15% for domestic contractors offering domestic products. Foreign companies can also be excluded from the procurement process if the value of the contract is below a given threshold.<sup>275</sup> The 2009 Sigma report criticised this aspect of the PPL, saying that because of this and other issues it had “concerns...about the compatibility of the PPL with current EU legislation”.<sup>276</sup>

With regard to drug procurement Turkey has decentralised this down to the individual hospital level.<sup>277</sup> Since January 2008 all hospitals must provide patients with drugs for free and can be fined if they fail to do so.<sup>278</sup> It is not clear if this rule is being implemented or if quality assurance programs have suffered as a result of this requirement. Hospitals generally tend to purchase drugs directly from wholesalers or manufacturers. Given that Turkish manufacturers are not required to adhere to GMP standards, there is a high risk that low quality yet regulatory approved drugs are being procured through the public procurement system.

---

<sup>270</sup> See: OECD and EU, SIGMA Assessment, “Turkey Public Procurement, Assessment May 2009” and OECD and EU, SIGMA Assessment, “Turkey Public Procurement, Assessment 2010”.

<sup>271</sup> Global Legal Group, “Public Procurement 2011”, chapter 30 Turkey, p. 191.

<sup>272</sup> *Ibid.*

<sup>273</sup> OECD and EU, SIGMA Assessment, “Turkey Public Procurement, Assessment 2010”, p. 4.

<sup>274</sup> OECD and EU, SIGMA Assessment, “Turkey Public Procurement, Assessment 2009”, p. 6.

<sup>275</sup> *Ibid.*

<sup>276</sup> *Ibid.*

<sup>277</sup> *Ibid.* p. 10.

<sup>278</sup> Celik et al, (2008) p. 10.

#### 4.11.4 Strengths and weaknesses

The Turkish system of public procurement is moving in the right direction. Both the OECD and EU have expressed satisfaction with the improvements and changes made to the PTL and related institutions. There are some problems relating to domestic preferencing and discrimination against foreign companies.

With regards to pharmaceutical procurement the evidence is not clear on how procurement at the individual hospital level is progressing or what quality assurance measures are in place. The lack of GMP requirement suggests that – as in other countries – low quality drugs may be procured even when best practice procurement is followed.

**Table 14: Turkey: strengths and weakness**

<b>Strengths</b>
- General system of public procurement is viewed by the EU and OECD as being of a high standard.
<b>Weaknesses</b>
- No official requirement to adhere to international GMP standards.
- Counterfeit and substandard medicines make up a substantial share of the drug supply.

#### **4.12 Vietnam**

The Vietnamese economy has become one of the faster growing economies of Southeast Asia. GDP growth has exceeded 6% in two out of the last three years only slowing down to 5.3% in 2009.<sup>279</sup>

##### 4.12.1 Health system overview

A decentralisation reform program during the 1990s and 2000s – with specific changes in the 1996 and 2002 State Budget laws – resulted in a fundamental shift in health care implementation and management from the central to provincial level.<sup>280</sup> Primary care is now, by and large, locally run and administered with

<sup>279</sup> CIA Factbook, Vietnam, <https://www.cia.gov/library/publications/the-world-factbook/geos/vm.html> (Accessed October 2011).

<sup>280</sup> Lieberman, S. et al, (2005), "Decentralizing health: Lessons from Indonesia, the Philippines, and Vietnam", from *East Asia decentralizes: making local government work*, World Bank, p. 158.

the central government remaining responsible for research and other niche areas such as speciality hospitals. Under this new decentralised system province-level People's Councils and health care facilities themselves have much greater autonomy and control over their budgets.<sup>281</sup> Vietnam has had an essential drugs list since 1985.

Total expenditure on health has grown from an average of 4.9% of GDP during the late 1990s and early 2000s to 6.2% in 2007.<sup>282</sup>

Like other developing countries a large proportion of health expenditure is made up of OOP spending. For 2007 this was estimated to be over 60% of total health expenditure.<sup>283</sup>

Self-prescription is very common as access to medical care and advice is quite expensive; the average consultation costs close to 10% of the average monthly salary.<sup>284</sup>

#### 4.12.2 Pharmaceutical system overview

The Vietnamese pharmaceutical market is one of the smaller in Southeast Asia with an estimated worth of \$1 billion.<sup>285</sup> However, it is viewed by market analysts as having high levels of growth potential demonstrated by a 15% annual growth rate during the mid to late 2000s.<sup>286</sup>

There are strict limitations on foreign competition and manufacturers' presence in the country. Vietnam has a stated policy of encouraging domestic pharmaceutical manufacturing and aims to see 60% of local medicines consumed produced domestically.<sup>287</sup>

Like Thailand and the other countries of the Mekong Delta (Myanmar, Laos, Cambodia and China), Vietnam suffers from high rates of counterfeit and substandard drugs. For example, randomly selected samples of drugs cited by the WHO showed 8% failed laboratory quality testing with particularly high rates for

---

<sup>281</sup> Ibid.

<sup>282</sup> See: Lieberman et al, (2005), p. 161 and WHO Representative Office in Viet Nam, "Background", [http://www.wpro.who.int/vietnam/sites/dhs/health\\_financing/](http://www.wpro.who.int/vietnam/sites/dhs/health_financing/) (Accessed October 2011)

<sup>283</sup> Ibid.

<sup>284</sup> JACCAR Equity Research Vietnam, (2008), (JACCAR is the private holding company of the chairman of BOURBON a French marine services company), "Sector Report Pharma", p. 25.

<sup>285</sup> Ibid. p. 5.

<sup>286</sup> Ibid.

<sup>287</sup> Ibid. p. 10.

rifampicin and contrimoxazole at just over and under a quarter of sampled lots, respectively.<sup>288</sup> Equally, counterfeit medicines permeate the drug supply.<sup>289</sup>

Domestic manufacturers are required by law to comply with WHO GMP standards; there is no evidence showing whether or not this is widely being implemented or enforced today.<sup>290</sup> In 2008 less than one third of Vietnamese manufacturers were GMP compliant. Market analysts view the GMP requirement (if enforced) as inevitably leading to a number of manufacturers being forced to shut down their production.

Domestic manufacturing focuses on generic and quite basic medicines. No high-value complex compounds are worked on in Vietnam and few, if any, APIs or other raw materials are produced there. Indeed, nearly 90% of raw materials, including most APIs, are imported, mainly from China. Quality control of these materials varies with some reports suggesting that the largest manufacturers maintain relatively high levels of quality assurance. Still, quality standards will inevitably be affected by most manufacturers not being WHO GMP compliant.<sup>291</sup>

#### 4.12.3 Pharmaceutical procurement overview

Medical and drug procurement is largely decentralised with individual hospitals and regions responsible for their own procurement. Hospitals issue calls for tender once or twice a year. As there is virtually no joint or regional pooling, each individual hospital applies its own system of bidding. Crucially, each individual hospital has a network of distributors and pharmaceutical manufacturers that it has an established relationship with. Analysts suggest that this is often the key factor in determining procurement contracts and that bribery can eat up to 30% of total revenue.<sup>292</sup>

Pharmacy procurement is similar to hospital procurement in that the personal relationship between the sales representative and purchasing party is instrumental in successful procurement. Pharmacies are largely small, privately owned and run businesses. Less than 1% of GPP are currently Good Pharmacies Practice (GPP) certified.<sup>293</sup> The Government is now requiring all pharmacies to conform to International

---

<sup>288</sup> WHO Regional Office for the Western Pacific (2003), *Essential Drugs and Medicines Policy*, WPRO-EDM, II, 1, May 2003, p. 9.

<sup>289</sup> *Ibid.*

<sup>290</sup> JACCAR Equity Research Vietnam (2008), p. 15.

<sup>291</sup> *Ibid.* p. 21.

<sup>292</sup> *Ibid.*

<sup>293</sup> *Ibid.*

Pharmaceutical Federation GPP requirements, but it is not clear whether these rules are being followed or stringently enforced.<sup>294</sup>

#### 4.12.4 Strengths and weaknesses

Vietnam suffers from many of the basic problems affecting developing countries' health care systems: high prevalence of substandards and counterfeit medicines; underdeveloped health care funding mechanisms; large regional and provincial variation in access and quality of care; inefficient decentralised and highly varied procurement policies; and corruption.

**Table 15: Vietnam: strengths and weakness**

<b><u>Strengths</u></b>
- Reforms to require GMP and GPP are good first step in raising the quality level of pharmaceutical supply chain
<b><u>Weaknesses</u></b>
- Wide-spread corruption in procurement and distribution.
- Counterfeit and substandard medicines make up a substantial share of the drug supply.
- Discrimination against foreign companies and high barriers in effort to increase domestic manufacturers' share of market limits drug supply and availability of high quality foreign drugs.

---

<sup>294</sup> Ibid.

## Section 5: Summary, Conclusions and Policy Recommendations

### 5.1 Summary

This paper has sought to discuss the issue of quality of medicines within the context of pharmaceutical procurement. It began by outlining the existence and spread of substandard and counterfeit medicines in both the developed and developing world. The paper then moved on to the issue of procurement – and public procurement in particular – and described how this is an area of the pharmaceutical supply chain which is highly vulnerable to corruption. Section 3 of the paper outlined how global standards and guidelines of pharmaceutical procurement are both widely available and comprehensive. Detailed examples of procurement guidelines and standards from international organisations like the WHO, World Bank and Global Fund were described. Together these examples provides an internationally recognised and agreed benchmark and point of comparison for emerging market and developing countries; an international gold standard. The final section, section 4, looked at the health and procurement systems of 12 developing and emerging economies. The section described each countries strengths and weaknesses, specifically in relation to procurement and the presence and regulation of substandard and counterfeit medicines.

### 5.2 Conclusions

Based on this analysis there are a number of important conclusions:

- Countries' systems of pharmaceutical procurement vary and must be viewed within the broader context of their respective rates of development; economic wealth; culture; levels of corruption; existing drug regulations and implementation; penetration of substandard and counterfeit medicines within the wider health care system; and general standards of procurement.
- However, even given the above there exists a gold standard for pharmaceutical procurement which both emerging and developing countries can make use of regardless of their other differences.
- Improving procurement standards and focusing on procuring the highest quality medicines is an effective way of limiting the spread and use of substandard and counterfeit medicines.

### 5.3 Policy Recommendations

The above conclusions and the analysis that underpins them have been distilled into a set of Policy Recommendations outlined in the below table.

**Table 16: Policy Recommendations**

- Where possible systems of procurement should be modelled and changed to reflect the internationally established and agreed consensus on high quality procurement; as summarised in this paper's "gold standard".
- Systems of pharmaceutical procurement should prioritise quality assurance, quality verification and constant monitoring of drug supplies through such measures as drug testing and pharmacovigilance.
- Public procurement systems should where possible try to use their own purchasing power to deal with the problem of substandard medicines, particularly in countries in which such problems may be more frequent.

While these recommendations are necessary and important steps to improving standards of pharmaceutical procurement, they are not a silver bullet in limiting the spread of substandard and counterfeit drugs. A country's system of procurement is only one factor in determining the overall presence of substandard medicines within the pharmaceutical supply chain. Even a "perfect" system of procurement cannot, and would not, stem the flow of substandard and counterfeit medicines in a country which already suffers from the wide-spread proliferation of substandard and counterfeit medicines.

To be effective, good standards of pharmaceutical procurement need to be part of wider governmental and regulatory efforts aimed at ensuring the quality and safety of medicines. For example: using and establishing levels of GMP and GCP; independent and frequent regulatory inspections; introduction of comprehensive systems of pharmacovigilance; well-developed drug regulatory authorities; standardised quality and safety criteria for pharmaceuticals; and the proper implementation and consistent monitoring of safety and quality throughout the pharmaceutical supply chain.

Establishing a system of drug procurement and national drug regulations that deliver high quality, safe and effective medicines to patients is not an easy or straight-forward task. Yet it is a vital one that governments

and policymakers around the world should do their utmost to achieve. Substandard and poor quality medicines affect the poorest people and the poorest nations in the world disproportionately.

The evidence collected in this paper, along with the conclusions policy recommendations aims to give governments, policymakers and members of civil society a broad and effective tool in thinking about quality within the context of pharmaceutical procurement with the ultimate goal of securing better outcomes for patients the world over.

## Bibliography

### Publications

Bate, Roger (2010) *Drug Registration – a necessary but not sufficient condition for good quality drugs – a preliminary analysis of 12 countries*, Africa Fighting Malaria Working Paper, AEI, Washington DC.

Bate, Roger (2008), *Making a Killing – the deadly implications of the Counterfeit Drug Trade*, AEI Press, Washington DC.

Bevilacqua, Gabriela and Farias, Maren Rocha (2011) "Procurement of generic medicines in a medium size municipality" in *Rev Saude Publica*

Blumenthal, David and Hsiao, William (2005), "Privatization and its Discontents – The Evolving Chinese Health Care System" in *New England Journal of Medicine*

Celik, Yusuf and Seiter, Andreas, (2008), "Turkey Pharmaceutical Sector Analysis", World Bank, Ankara.

Enemark, Ulrike, Alban, Anita and Vasquez, Enrique (2004), *Purchasing Pharmaceuticals* World Bank, Washington DC.

Erhun, WO, Babalola OO and Erhun MO (2001), "Drug Regulation and Control in Nigeria: The Challenge of Counterfeit Drugs" in *Journal of Health & Population in Developing Countries*

Glassman, Amanda, Giuffrida, Antonio, Escobar, Maria-Luisa and Giedion, Ursula eds. (2010) *From Few to Many Ten Years of Health Insurance Expansion in Colombia*, Brookings, Washington DC.

Homedes, Núria, López Linares, Roberto and Ugalde, Antonio (2005), *Generic Drug Policies in Latin America*, World Bank, Washington DC.

JACCAR Equity Research Vietnam (2008), *Sector Report Pharma*, JACCAR Equity Research, Vietnam.

Leopold, Christine (2008), *Tendering of pharmaceuticals in EU Member States and EEA countries, Results from the Survey*, ÖBIG, Vienna.

Lewis, Maureen (2006) "Tackling Healthcare Corruption and Governance Woes in Developing Countries", in *CGD Brief*

Lieberman, Samuel, Capuno, Joseph J., and Minh, Hoang Van (2008), "Decentralizing health: Lessons from Indonesia, the Philippines, and Vietnam", from *East Asia decentralizes: making local government work*, World Bank.

Management Sciences for Health (2008), *Assessment of Kenya Medical Supplies Agency (KEMSA)*.

SK Niazi, (2007), *Handbook of Bioequivalence testing*, Informa Healthcare.

Rao, Rama (2006) *Impact of TRIPS on Pharmaceutical Prices with specific focus on generics in India*, WHO and Ministry of Health & Family Welfare India, Punjab.

Ryan, Michael and Ramos, Teresita (2007) *Seeking Health Competitiveness, Embracing Free Trade with the United States, Pharmaceuticals, Intellectual Property Rights, Bilateral Trade Diplomacy, and Development Strategies in Jordan and Colombia*, George Washington University Law School, Washington DC.

Seiter, Andreas (2010), *A Practical Approach to Pharmaceutical Policy*, World Bank, Washington DC.

Selvaraj, Sakthivel (2010) *Improving Governance and Accountability in India's Medicine Supply System*, Public Health Foundation of India, New Delhi.

Shakoor, Omar (1997), "Assessment of the incidence of substandard drugs in developing countries" in *Tropical Medicine and International Health*, (September 1997).

Sooksriwong, Cha-oncin, (2009), "Medicine Prices in Thailand: A result of no medicine pricing policy", in *Southern Med Review*

Torstensson, David and Pugatch, Meir (2008), *Keeping Medicines Safe*, Stockholm Network, London.

Tragakes, Ellie and Lessof, Suszy (2003) "Russian Federation" in *Healthcare systems in Transition*, European Observatory on Health Systems and Policies, London.

Wagstaff, Adam and Claeson, Mariam (2004) *The Millennium Development Goals for Health*, World Bank, Washington DC.

Wise, Lesley, Parkinson, John, Raine, June and Breckenridge, Alasdair (2009), "New approaches to drug safety: a pharmacovigilance tool kit", in *Nature Reviews Drug Discovery*, (October 2009).

Zasimova, Liudmila (2010) *Public policy and access to new drugs: evidence form Russian pharmaceutical market*, Pan European Institute, Turku.

#### Official Source

Argentina Ministry of Health

Azerbaijan Ministry of Health

Brazil Ministry of Health

Brazil National Health Surveillance Agency

CIA Factbook

European Commission

European Observatory on Health Systems and Policies

Federal Drug and Food Administration

Global Fund

Organisation for Economic Co-operation and Development

United Nations Children's Fund

United Nations Development Programme

United Nations Office for Project Services

United Nations Population Fund

United States Centre for Disease Control and Prevention

United States Department of Commerce

United States Government Accountability Office (GAO)

United States Pharmacopeia

World Bank

World Health Organization