



**TRANSPARENCY  
INTERNATIONAL**

Pharmaceuticals & Healthcare Programme

# **CORRUPTION IN THE PHARMACEUTICAL SECTOR**

## **Diagnosing the challenges**

**Transparency International** is a global movement with one vision: a world in which government, business, civil society and the daily lives of people are free from corruption. With more than 100 chapters worldwide and an international secretariat in Berlin, we are leading the fight against corruption to turn this vision into reality.

The **Pharmaceuticals & Healthcare Programme** is a new global initiative based in Transparency International UK. Applying TI's strengths and expertise, the Programme's goal is to improve global health and healthcare outcomes for the benefit of all people of all ages. It aims to achieve this by reducing corruption and promoting transparency, integrity and accountability within the pharmaceutical and healthcare sectors.

Acknowledgements: This project was funded with UK aid from the UK government. We would like to thank the UK Department for International Development (DFID) for their generous financial support to make the research possible. The views expressed do not necessarily reflect the UK government's official policies.

We would also like to thank all individuals who participated in the research interviews, as well as Robert Barrington, Craig Fagan, Joel Lexchin and Sophie Peresson for their advice and comments.

Authors: Jillian Clare Kohler - Leslie Dan Faculty of Pharmacy, University of Toronto; WHO Collaborating Centre for Governance, Transparency & Accountability in the Pharmaceutical Sector

Martha Gabriela Martinez - Leslie Dan Faculty of Pharmacy, University of Toronto

Michael Petkov and James Sale – Transparency International, Pharmaceutical & Healthcare Programme

Design: Philip Jones – Transparency International UK

© 2016 Transparency International UK. All rights reserved. Reproduction in whole or in parts is permitted, providing that full credit is given to Transparency International UK (TI-UK) and provided that any such reproduction, in whole or in parts, is not sold or incorporated in works that are sold. Written permission must be sought from Transparency International UK if any such reproduction would adapt or modify the original content.

Published June 2016.

ISBN: 978-1-910778-55-5

© Cover photo: iStock.com/4X-image

Every effort has been made to verify the accuracy of the information contained in this report. All information was believed to be correct as of June 2016. Nevertheless, Transparency International UK cannot accept responsibility for the consequences of its use for other purposes or in other contexts.

Printed on 100% recycled paper.



# Corruption in the pharmaceutical sector

## Diagnosing the challenges

# Contents

Executive summary.....	1
Abbreviations .....	2
1. Introduction.....	3
2. Methodology .....	5
How we define corruption .....	5
Data collection and analysis .....	5
3. Value chain issue analysis.....	7
Research & Development.....	8
Manufacturing .....	12
Registration .....	15
Marketing .....	17
Procurement.....	22
Distribution .....	26
4. Overarching challenges.....	28
A lack of objective data and understanding of corruption .....	29
A weak legislative and regulatory framework.....	30
The potential for undue influence from companies .....	32
A lack of leadership committed to anti-corruption efforts .....	34
5. Focus areas for action .....	35
Establishing leadership committed to addressing corruption.....	36
Adopting technology throughout the pharmaceutical value chain .....	39
Ensuring accountability through increased monitoring, enforcement and sanctions.....	41
6. Conclusion.....	44
Bibliography .....	46

# Executive summary

The launch of the Sustainable Development Goals in September 2015 signals a more comprehensive global development agenda. This plan specifies that all governments must fight corruption. For the health sector, this will mean integrating good governance into policy making and implementation to reduce the risk of corruption.

Within the health sector, pharmaceuticals stands out as sub-sector that is particularly prone to corruption. There are abundant examples globally that display how corruption in the pharmaceutical sector endangers positive health outcomes. Whether it is a pharmaceutical company bribing a doctor for prescribing its medicines irrespective of a health need or a government employee facilitating the infiltration of substandard medicines into the distribution system, public resources can be wasted and patient health put at risk.

For policy makers to implement successful anti-corruption measures there is a need to identify and understand corruption vulnerabilities in the pharmaceutical sector. To support this task this paper identifies key policy and structural issues in selected activities of the pharmaceutical value chain, along with relevant anti-corruption policies. This analysis showed that anti-corruption policies are needed throughout the pharmaceutical value chain to increase transparency around key decision points and strengthen the accountability of actors.

Four overarching challenges derived from structural issues and anti-corruption policies across the selected activities of the value chain have been identified. These are:

- **A lack of objective data and understanding of corruption** inhibited by environmental context, the complexity of issues in the sector and policy makers not viewing corruption as an issue.
- **A weak legislative and regulatory framework** because of poor investment, a lack of oversight and national regulatory frameworks that are often decentralised and reliant on self-regulation for key decision-point.
- **The potential for undue influence from companies** due to a high degree of autonomy over key decision points and unparalleled resources, on policy and regulation so profit maximisation goes beyond ethical norms and negatively impacts health outcomes and public health objectives.
- **A lack of leadership committed to anti-corruption efforts** from all actors. National leaders often only implement reforms after a crisis, with their inaction regularly hindering other actors.

Similarly, three key action areas to mitigate corruption vulnerabilities in the pharmaceutical sector are examined. These include establishing leadership committed to addressing corruption, adopting technology throughout the value chain and ensuring accountability through increased monitoring, enforcement and sanctions.

These overarching challenges and action areas are neither novel nor resource-intensive, stressing the lack of effective action in the past; as well as the difficulty of dealing with corruption in a sector that is extremely complex, has a high level of government intervention and often has regulatory systems in place that are inadequate to properly govern the value chain. Only by overcoming these challenges and focusing on these action areas will the global health community be better able to meet the health Sustainable Development Goals.



# Abbreviations

CIA – Corporate Integrity Agreement  
CME – Continued medical education  
CMS – Ghanaian Central Medical Stores  
CROs – Contract research organisations  
DFID – UK Department for International Development  
EFPIA – European Federation of Pharmaceutical Industries and Associations  
EMA – European Medicines Agency  
FDA – US Food and Drug Administration  
Global Fund – The Global Fund to Fight AIDS, TB and Malaria  
GMC – UK General Medical Council  
GMPs – Good Manufacturing Practices  
HCP – Healthcare Professional  
IATI – International Aid Transparency Initiative  
ICH – International Conference of Harmonisation  
ICMJE – The International Committee of Medical Journal Editors  
IGOs – Intergovernmental organisations  
J&J – Johnson & Johnson  
MDGs – Millennium Development Goals  
META – Medicines Transparency Alliance  
NGO – Non-governmental organisation  
NHS – UK National Health Service  
OECD – Organisation for Economic Co-operation and Development  
PhrMA – Pharmaceutical Research and Manufacturers of America  
R&D – Research and Development  
RCTs – Randomised Control Trials  
RICO – US Racketeer Influenced and Corruption Organisations Act  
SSFFC – Substandard, spurious, falsely labelled, falsified and counterfeit medicines  
SDGs – Sustainable Development Goals  
SOPs – Standard operating procedures  
UHC – Universal Health Coverage  
UNDP – United Nations Development Programme  
WHO – World Health Organisation

# 1. Introduction

Corruption can take place throughout the health sector. Effective policy responses depend on what it is and where it is taking place, whether it is at the local, regional or national levels.

Corruption negatively impacts health services and outcomes. The embezzlement of public health budgets and kickbacks in the procurement process can result in the overpayment of goods and services. This in turn may threaten a country's ability to provide universal health coverage (UHC).<sup>1</sup> Corruption diverts resources from the public sector, making it difficult to appropriately fund healthcare facilities that help ensure increased access and quality care.<sup>2</sup> Of equal importance, corruption undermines public trust in governments and public services, the willingness of healthcare professionals (HCPs) to take government instructions and warnings seriously, and patients' willingness to make use of health services. Because of corruption's significant negative effect on morbidity rates, infant and child mortality, and health spending, the impact can have life-and-death consequences.<sup>3</sup> The bottom line is that tackling corruption in the health sector is crucial for ensuring human and economic development.

Despite reports estimating that as much as 6 per cent, the equivalent of over US\$300 billion, of annual global health expenditure being lost to corruption and errors,<sup>4</sup> efforts to measure the scale of the problem and respond effectively are still few and far between. One of the challenges is that corruption and health are often viewed as two distinct public policy areas. Many global health interventions have been vertical in nature, as they focus on one specific disease at any given time, with any improvements in governance and corruption levels being a consequential effect. This not only oversimplifies the complexity of corruption, but it fails to address health sector vulnerabilities to corruption and inefficiencies that make it happen.

The global development agenda for the next 15 years is framed by the Sustainable Development Goals (SDGs), adopted in September 2015. The SDGs underscore the need to take a holistic approach to improve development outcomes, including health. The renewed focus on health system strengthening, particularly following the failure of health systems in countries severely affected by public health crises such as the West African Ebola epidemic, represents part of this shift in thinking. Improving governance to minimise healthcare corruption is vital to make gains in this area.

The inclusion of the SDG target 16.5 is significant for anti-corruption efforts globally. Calling for the substantial reduction of corruption and bribery in all their forms, this target represents a near unanimous recognition that corruption negatively impact society and development. Global leaders are firmly acknowledging that corruption is a priority issue. For example, the World Bank President, Jim Yong Kim, has denounced corruption as "public enemy number one"<sup>5</sup> and the United Nations Secretary-General, Ban Ki-moon, has emphasised that corruption is a threat to

---

<sup>1</sup> European Commission. *Study on corruption in the healthcare sector*, (2013), p.29.

<sup>2</sup> Michaud, J., Kates, J., & Oum, S., *Corruption and global health: summary of a policy roundtable* (2015). Available online: <http://kff.org/global-health-policy/issue-brief/corruption-and-global-health-summary-of-a-policy-roundtable/> [Accessed 9/9/15].

<sup>3</sup> United Nations Development Programme, *Fighting corruption in the health sector: methods, tools and good practices* (2011), p.12; Nussbaum, D. 'Preface', in Kotalik, J., & Rodriguez, D., (eds.), *Global Corruption Report 2006*. Transparency International (2006), p.xii.

<sup>4</sup> World Health Organisation, *The World Health Report* (2010), p.61.

<sup>5</sup> World Bank, *Corruption is "Public Enemy Number One" in Developing Countries, says World Bank Group President Kim* (2013). Available online: <http://www.worldbank.org/en/news/press-release/2013/12/19/corruption-developing-countries-world-bank-group-president-kim> [Accessed 17/9/15].

development, democracy and stability.<sup>6</sup> In 2010, the UK Department for International Development (DFID) noted that “tackling corruption in the health sector is essential for achieving better health outcomes.”<sup>7</sup>

The pharmaceutical sector accounts for a significant portion of health budgets globally. Almost a fifth of the entire healthcare budget across OECD countries is spent on medicines.<sup>8</sup> This could rise as the total global spend on medicines is forecasted to grow at a compound annual rate of 4-7 percent over the next five years and will reach a total of US\$1.3 trillion by 2018.<sup>9</sup>

In 2010, the World Health Organisation (WHO) reported that medicines account for three of the top ten leading sources of inefficiency in the health system and corruption is a leading source of inefficiency.<sup>10</sup> Unnecessary spending on medicines, substandard and falsified medicines infiltrating the health system, and inappropriate and ineffective medicine use have inadvertently led to a waste of resources necessary to provide quality and affordable care.

Therefore, effective and efficient medicine expenditure is crucial for the sustainability of health systems. This is particularly an issue for low- and middle-income economies where health systems are weaker and government provision is lower, placing even more pressure on patients, particularly the poorest and most vulnerable, with very high rates of out of pocket payments. Global institutions such as the WHO, the Global Fund to Fight AIDS, TB and Malaria (Global Fund) and the World Bank have increased their efforts to improve healthcare access and health outcomes by focusing on financing medicines and helping build up the capacity of the pharmaceutical sector. Combatting policy and structural issues that increase corruption vulnerabilities in the pharmaceutical sector will help prevent unnecessary medicine expenditure losses and ideally improve health outcomes for all.

For this reason, this paper focuses on analysing the pharmaceutical sector to address its vulnerabilities to corruption and inefficiencies. From the discovery and development of new medicines, to the procurement and distribution of safe, cost-effective medicines, an effective and efficient pharmaceutical sector is necessary to contain costs and move towards UHC. This paper examines six value chain activities that are considered as high priority areas by Transparency International’s Pharmaceuticals & Healthcare programme due to the prevalence and impact of corruption risks.

Furthermore, findings presented in this paper will be relevant for the wider health sector. An intervention in the pharmaceutical value chain will likely have a ripple effect on the entire health system, with improvements in the pharmaceutical sector resulting in the strengthening of health systems and the promotion of health equity.<sup>11</sup> Both the pharmaceutical and health sectors share similar policy and structural issues that make them susceptible to corruption. Equally these sectors require strong governance structures to oversee and balance multiple competing interests, stakeholders and high levels of discretion in decision-making.<sup>12</sup> Understanding where vulnerabilities lie has the potential to help policy makers identify priority areas in both sectors on which to focus research and interventions and to reduce the likelihood of corruption.

---

<sup>6</sup> United Nations, *Secretary-General warns corruption ‘threat to development, democracy and stability’, urges strong steps against it by governments, business leaders, in message on day* (2010). Available online: <http://www.un.org/press/en/2010/sgsm13292.doc.htm> [Accessed 18/9/16].

<sup>7</sup> Hussman, K., *How to note: addressing corruption in the health sector*. Department for International Development (2010), p.1.

<sup>8</sup> Organisation for Economic Cooperation and Development, *Health at a glance 2011: OECD indicators*. Organisation for Economic Cooperation and Development Publishing (2011), p.154.

<sup>9</sup> IMS Institute for Healthcare Informatics, *Global Outlook for Medicines through 2018* (2014), p.1.

<sup>10</sup> World Health Organisation, 2010, p.63.

<sup>11</sup> Bigdeli, M., et al. *Medicines in health systems: Advancing access, affordability and appropriate use*. World Health Organisation (2014), p.11.

<sup>12</sup> Ibid, p.24.



## 2. Methodology

### How we define corruption

Corruption is defined by Transparency International as the abuse of entrusted power for private gain. All countries have corruption, though the types of corruption that are prevalent can vary. The scale of corruption will also vary; it may be “petty”, as in bureaucratic processes, or “grand”, as at the policy or legislative level.

Corruption is often difficult to detect and even harder to track and verify, due to its inherent intangibility and the grey area between corruption and inefficiency. Corruption typically takes place when there is pressure to abuse power, when individuals are able to rationalise their corrupt acts through social norms and when there is a high opportunity of abusing power with minimal consequences.<sup>13</sup> Corruption does not always exist outside of legal boundaries.

Corruption can occur in both the public and private sector. This means a range of actors in the pharmaceutical sector can engage in corrupt practices, including HCPs, government officials and pharmaceutical company employees.

### Data collection and analysis

The findings in this paper are based on desk-top research and key informant interviews. The desk-top research was used to identify, summarise and highlight existing knowledge on the topic, as well as to identify gaps and inconsistencies. Over 100 documents from 2004 to 2015 that were relevant to the issue of corruption in the pharmaceutical sector were analysed (please refer to the bibliography to view a selection of these documents), which included books, peer-reviewed literature and grey literature such as reports published by international organisations and donor agencies. The literature was selected if it included one or more of the following:

- focused on the health and pharmaceutical sectors
- included some discussions of corruption and or good governance
- discussed policies and strategies to deal with corruption

Thirty-seven key informant interviews were conducted between October 2015 and January 2016 until thematic saturation was reached. Individuals were selected if they had significant expertise and knowledge of the pharmaceutical sector and/or the topic of corruption. The University of Toronto's Research Ethics Board provided ethics approval for this study. In keeping with the study requirements of the Ethics Board, the identities of the key informants are confidential. As shown in Table 1 below, the selected individuals came from a range of organisations.

---

<sup>13</sup> Hussman, 2010, p.7.

Interviews were semi-structured, open-ended and based on a list of key issues, such as what are the major policy opportunities and barriers. The interviews were predominantly conducted by phone or Skype. All interviews were transcribed and transcripts were subject to the application of content analysis. A first reading allowed the identification of major issues. Second, more readings generated a list of themes and issues as close to completion as possible. Third, a methodical coding frame was developed, rearranging the data to fit systematically into themes. This involved synthesising the data and abstracting from it then coded and interpreted using qualitative software programme, HyperResearch.

**Table 1: Types of organisation represented by key informants**

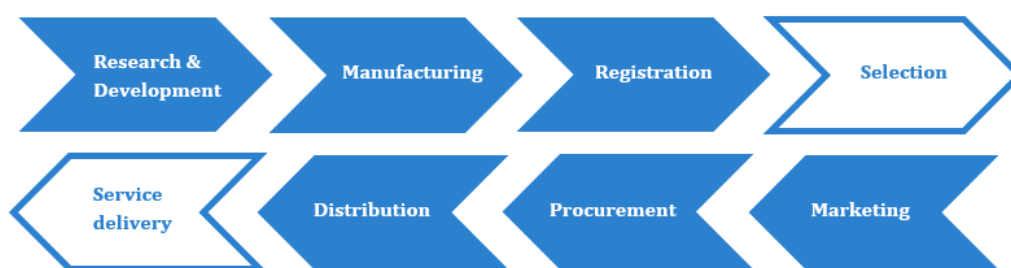
Type	Number of individuals interviewed
Academia	9
NGO	7
Government	5
Industry	5
International organisation	5
Think tank	3
Other	3

### 3. Value chain issue analysis

To better understand the corruption vulnerabilities in the pharmaceutical sector, it is necessary to analyse the structural and policy issues within it. The pharmaceutical value chain offers a framework to examine the scale and impact of these issues. The value chain sees a medicine move from its development on a laboratory bench through to its distribution to a healthcare facility, where a HCP will then prescribe the medicine to a patient.

Six activities of the value chain were selected for analysis (as shown in Figure 1) as they are considered as high priority areas due to the prevalence and impact of the corruption risks.

**Figure 1: The six activities of the pharmaceutical value chain selected for analysis**



Source: Adapted from Cohen, J.C., Mrazek, M., & Hawkins, L., 'Corruption and pharmaceuticals: strengthening good governance to improve access', in Edgardo Campos J., & Pradhan, S. (eds.), *The Many Faces of Corruption: Tackling Vulnerabilities at the Sector Level*. World Bank (2007), p.35.

Through an evaluation of policy and structural issues in the pharmaceutical sector, anti-corruption policies to mitigate these vulnerabilities are identified and discussed. Most of these policies are based on applications of good governance, which has been associated with minimising corruption and increasing efficiencies in the pharmaceutical sector. When good governance is in place: information on decision making is freely available and directly accessible to those affected by such decisions; government institutions, the private sector and civil society organisations are accountable to those affected by their decisions and; civil society involvement in decision making is strong.<sup>14</sup>

To achieve this all the policies aim to improve transparency and accountability in some way. In healthcare, transparency involves the public availability of information such as health budgets, performance indicators and the prices of medicines. Accountability requires individuals and institutions to answer to those who will be affected by decisions or actions taken by them such as internally to specific agencies or publicly to communities.<sup>15</sup>

Often these are policies that can be found globally, although these are few and far between, or are otherwise exceptional national policies. The latter can be replicated in other countries as good practice, such as transparency requirements for pharmaceutical industry and HCP interactions.

---

<sup>14</sup> United Nations Economic and Social Commission for Asia and the Pacific, *What is Good Governance?* (2009).

<sup>15</sup> Brinkerhoff, D.W., 'Accountability and health systems: toward conceptual clarity and policy relevance'. *Health Policy and Planning*, 19 (2004), p.372.

## Research & Development

The Research & Development (R&D) process is the first value chain activity and involves multiple stages. It includes the early research phase, the preclinical testing phase, three phases of clinical trials and the patent application.

Society as a whole is dependent on the pharmaceutical industry to create new medicines and monitor their effectiveness after they are released into the market. Due to the high level of risk and expenditure in R&D, R&D-based pharmaceutical companies typically take into account the potential to recoup costs and generate profits when making decisions about which medicines to develop.<sup>16</sup>

Without the proper oversight from governments in the R&D process, the financial structures that surround the development of new medicines create a risk that a company will be incentivised to prioritise profit-making over the needs of public health. Concurrently, R&D-based pharmaceutical companies have strong control over the R&D process when there are inadequate policies regulating the R&D process, which can create conflicts of interest and corruption vulnerabilities.<sup>17</sup> This combination of perverse financial incentives and significant corruption risks can lead to regulatory capture and other harmful practices, such as medicines being put into the market that are unsafe, lack efficacy and provide little or no therapeutic benefit. For example, studies in Canada, France and the Netherlands have shown a general decrease in recent years in the number of new medicines offering therapeutic advantages to previously approved drugs.<sup>18</sup>

Before a newly developed medicine can enter a market a pharmaceutical company must prove its efficacy and safety to regulatory agencies by carrying out randomised control trials (RCTs). As pharmaceutical companies rely on gaining market entry in order to recoup R&D costs, when there is a lack of oversight in clinical trial data publication a conflict of interest exists in which a pharmaceutical company may have an incentive to manipulate clinical trial data.<sup>19,20</sup> When clinical trial data is manipulated medical literature can become biased with positive findings fabricated, positive findings exaggerated or negative results hidden.<sup>21</sup> This can result in inadequate prescribing patterns because HCPs rely on clinical trial data to make decisions on which medicines to use to treat patients.<sup>22</sup>

The pharmaceutical industry is the biggest funder of RCTs and often contracts them out to academia and contract research organisations (CROs).<sup>23</sup> Research has shown that clinical trials funded by industry are more likely to produce positive results than RCTs funded by other sponsors.<sup>24</sup> One study found that 94 per cent of industry funded RCT results dealing with antidepressants were framed in a way that suggested positive results, while an analysis of those

---

<sup>16</sup> Rodwin, M., 'Five uneasy pieces to pharmaceutical policy reform'. *Journal of Law, Medicine & Ethics*, 41, 3 (2013), p.582.

<sup>17</sup> Lexchin, J., 'Those who have the gold make the evidence: how the pharmaceutical industry biases the outcomes of clinical trials of medications'. *Science and Engineering Ethics*, 18, 2 (2012), p.247.

<sup>18</sup> Light, D.W., et al., 'Institutional corruption of pharmaceuticals and the myth of safe and effective drugs'. *Journal of Law, Medicine & Ethics*, 14, 3 (2013), p.592.

<sup>19</sup> Lexchin, 2012, p.248.

<sup>20</sup> Brown, A.B., 'Understanding pharmaceutical research manipulation in the context of accounting manipulation'. *Journal of Law, Medicine and Ethics*, 41, 3 (2013), p.611.

<sup>21</sup> Lexchin, 2012, p.247.

<sup>22</sup> Lemmens, T., & Gibson, S., 'Decreasing the data deficit: improving post-market surveillance in pharmaceutical regulation'. *McGill Law Journal*, 59, 4 (2014), p.952.

<sup>23</sup> Rodwin, 2013, p.583.

<sup>24</sup> Lundh, A., et al., 'Industry sponsorship and research outcome'. *Cochrane Database Systematic Reviews*, 12, 12 (2012), p.2.

same trials by the US Food and Drug Administration (FDA) found that only 51 per cent of those RCTs had positive results.<sup>25</sup>

The practice of ghostwriting is also a risk with clinical trials. Ghostwriting involves the writing of clinical trial publications by industry and then having a highly esteemed researcher pass these findings off as their own without disclosing their actual involvement with the authorship of the article.<sup>26</sup> It is a common practice, particularly in industry led trials.<sup>27</sup> Ghostwriting is done to increase the prestige and reputation of the findings,<sup>28</sup> while simultaneously researchers are able to improve their reputation, which can lead to promotions.<sup>29</sup> Clearly this practice can result in inaccurate results being published.

## Transparency of clinical trial data

Transparency and access to information through mandatory clinical trial registration, sanctions for not registering results or providing clinical trial information, and the publication of both positive and negative results are commonly discussed as helpful tools to curb corruption.<sup>30</sup> With the European Medicines Agency (EMA) as a notable positive exception, public agencies and authorities do not require R&D-based pharmaceutical companies to make their raw data publicly available, making it impossible to verify whether the reported results are accurate.<sup>31</sup> Based on laws and regulations clinical trial data is considered to be proprietary information, which allows pharmaceutical companies to conceal important data from the public domain.

The international debate surrounding transparency in the R&D process has focused on the creation of clinical trial registries.<sup>32</sup> In many countries R&D-based pharmaceutical companies are not required to publish information on RCTs. For instance, in Canada there is no mandatory clinical trial registration unless the trials will be used in the United States. However, some examples do exist. The WHO's clinical trial database and the US ClinicalTrials.gov database demonstrate the ability to develop registries for clinical trials.

The Declaration of Helsinki is "the most widely recognised source of ethical guidance for biomedical research."<sup>33</sup> First adopted in 1964, the 2008 revision requires any clinical study involving humans to be registered in a public clinical trial register before recruitment and for the disclosure of all results.<sup>34</sup> However, what is of concern is the shift away from these guidelines. For example, the FDA has abandoned requiring the Declaration of Helsinki to be used and instead requires the Good Clinical Governance standards from the International Conference of Harmonisation (ICH).

---

<sup>25</sup> Turner, E.H., et al., 'Selective publication of antidepressant trials and its influence on apparent efficacy'. *New England Journal of Medicine*, 358 (2008), p.252.

<sup>26</sup> Lexchin, 2012, p.254.

<sup>27</sup> Gotzsche, P., et al., 'Ghost Authorship in Industry-Initiated Randomised Trials'. *PLoS Medicine*, 4, 1 (2007), p.49.

<sup>28</sup> Stern, S., & Lemmens, T., 'Legal remedies for medical ghostwriting: imposing fraud liability on guest authors of ghostwritten articles'. *PLOS Medicine*, 8, 8 (2011), p.1.

<sup>29</sup> Brown, 2013, p.615.

<sup>30</sup> Lemmens & Gibson, 2014, p.973.

<sup>31</sup> Elliott, C., & Landa, A.S., 'Commentary: what's wrong with ghostwriting?' *Bioethics*, 24, 6 (2010), p.285.

<sup>32</sup> Lemmens & Gibson, 2014, p.976.

<sup>33</sup> Carlson, R.V., et al., 'The revision of the Declaration of Helsinki: past, present and future'. *British Journal of Clinical Pharmacology*, 57, 6 (2004), p.695.

<sup>34</sup> Lemmens & Gibson, 2014, p.977.



The most rigorous legislation for disclosing clinical trial data will be introduced by the European Union in 2016. The Clinical Trials Regulation requires the public disclosure of clinical study reports within a year of the trial's completion.<sup>35</sup> This information will be accessible to researchers and even publicly available for download.<sup>36</sup> The Regulation also requires the creation of public databases that list all ongoing clinical trials along with full protocols and results to safeguard the integrity of the studies and minimise reporting bias.<sup>37</sup> Developments such as this are welcomed and demonstrate the possibility of implementing more rigorous regulations.

However, there are a number of challenges with clinical trial registries. Information for most of the medicines that are in today's market are missing, as registries often do not require the disclosure of information on RCTs that have already been conducted.<sup>38</sup> There are also issues with the lack of monitoring of the data being collected in these registries. Ensuring there is sufficient knowledge among civil society, researchers and others to access and understand information contained in these databases remains a challenge.

Furthermore, analyses of clinical trial registries demonstrate that pharmaceutical companies often violate requirements, do not file data on time or file data incompletely.<sup>39</sup> Harsher punishments for companies failing to submit legally required information into these registries must be implemented and enforced to ensure uniformity and accountability. It has also been suggested that transparency policies be implemented at an international level to ensure uniformity in data disclosure, particularly in low income countries that do not have proper regulatory systems to maintain standards.<sup>40</sup> The WHO endorsed this proposal in 2015, publicly calling for the disclosure of every clinical trial result, both past and present.<sup>41</sup>

## Other anti-corruption measures

As the pharmaceutical industry increasingly relies on universities and small start-ups to conduct initial R&D, the introduction of transparency and accountability measures in this area is pressing. The reporting of all financial contributions made by pharmaceutical companies to medical research units and academia should be mandated. This must be coupled with proper enforcement mechanisms to ensure that breaches in codes of conduct are followed by applicable sanctions.

Alternatively the design, implementation and analysis of clinical trials could be assigned to an independent institution, with the donor having no control over its progress. This would decrease the potential of perverse financial incentives and corruption vulnerabilities impacting clinical trial outcomes.

---

<sup>35</sup> New Scientist, *Only full disclosure of drug trial results will maintain trust* (2015). Available online: <https://www.newscientist.com/article/mg22730393-200-only-full-disclosure-of-drug-trial-results-will-maintain-trust/> [Accessed 19/4/16].

<sup>36</sup> Pansieri, C., et al., 'The evolution in registration of clinical trials: a chronicle of the historical calls and current initiatives promoting transparency'. *European Journal of Clinical Pharmacology*, 71, 10 (2015), p.1161.

<sup>37</sup> Pansieri et al., 2015, p.1161.

<sup>38</sup> Ibid, p.1162.

<sup>39</sup> Rodwin, 2013, p.584.

<sup>40</sup> Pansieri et al., 2015, p.1162.

<sup>41</sup> Ibid, p.1162.

Several measures are available to mitigate the prevalence of ghostwriting. The practice could be classed as fraud and prosecuted under national laws such as the US Racketeer Influenced and Corruption Organisations Act (RICO), guilty authors could be banned from future journal submissions and professional organisations could punish guilty researchers.<sup>42</sup> Most importantly journals must monitor and tackle the practice. The International Committee of Medical Journal Editors (ICMJE) has published standards for biomedical research that request detailed information on what each author has specifically contributed to the article under review, which can be used by journals in their reviewing and publishing guidelines. As many journals cannot or do not want to monitor the practice adequately,<sup>43</sup> there is a need for systemic change in this area.

### Paxil clinical trial data

In 2012, GlaxoSmithKline pleaded guilty to the unlawful promotion of the prescription drug Paxil. This was for the treatment of depression in patients under 18 years of age, despite the FDA having not approved the medicine for paediatric use. The US government claimed that GlaxoSmithKline prepared, published and distributed a misleading journal article that misrepresented a clinical trial; instead of demonstrating the efficacy of Paxil in the treatment of depression in patients under 18 years of age, the trial failed to show efficacy. At the same time the company did not make available data from two other studies in which Paxil failed to demonstrate efficacy in treating depression in patients under 18 years of age.

This case was part of a wider settlement in which the company pleaded guilty and paid US\$3 billion, the largest healthcare fraud settlement in US history, to resolve its criminal and civil liability. The company also entered into a five-year Corporate Integrity Agreement (CIA).

The original clinical trial data was re-analysed in 2015, showing that the drug was not only ineffective for treating depression but potentially unsafe, as it increased the prevalence of suicidal thoughts and behaviour.

The United States Department of Justice, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (2012). Available online: <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report> [Accessed 4/4/16].

Cha, A.E., *New analysis shows suicide link for teens on Paxil. 'Mischief' in old study claiming drug is safe* (2015). Available online: <https://www.washingtonpost.com/news/to-your-health/wp/2015/09/17/mischief-in-old-study-showing-paxil-safe-for-teens-new-analysis-shows-increased-suicide-link/> [Accessed 4/4/16].

---

<sup>42</sup> Stern & Lemmens, 2011, pp.3-4.

<sup>43</sup> Ibid, pp.2-3.

## Manufacturing

The manufacturing of safe and quality medicines is centred on Good Manufacturing Practices (GMPs). GMPs are guidelines for minimal standards for a medicine to enter the market and a requirement for the international procurement of medicines for both donor and publicly funded health programs.<sup>44</sup> These guidelines include quality management, appropriate packaging and labelling, assuring the appropriate concentration of active pharmaceutical ingredients, batch testing, laboratory controls and certificates of analysis.<sup>45</sup> Manufacturers, regulators and inspectors are responsible for ensuring that GMPs are followed and enforced; when GMPs are not, medicines run the risk of being substandard, falsified and unsafe.<sup>46</sup>

GMPs apply to manufacturers and other parties involved in the labelling and packaging of medicines.<sup>47</sup> Due to the globalisation of medicine manufacturing, the WHO has recognised GMP standards as being crucial for mitigating quality risks in pharmaceutical production and ensuring consistency in medicine quality and efficacy, such as contamination, mix-ups and false or improper labelling.<sup>48</sup>

GMPs demonstrate agreed international standards that create an economic incentive for compliance. In order for countries to be able to export their medicines GMP standards must be met. Therefore, the health of a local pharmaceutical industry can be dependent on manufacturers' ability to comply with international GMPs and conversely a drug regulatory agencies' ability to monitor and enforce compliance.<sup>49</sup>

Based around the GMPs, corruption vulnerabilities in this value chain activity include bribery by manufacturers for the certification of GMPs or to create entry barriers for competitors.<sup>50</sup> Corruption by manufacturers can also manifest in the deliberate lack of adherence to GMPs, when certificates have been awarded, to increase profits. All forms of corruption in this activity can lead to medicines that may be unsafe or of a low quality entering the health system, undermining health outcomes. The implementation of GMPs is often lax in many countries where there is limited oversight and accountability in the regulation process.

## “Bad” medicines

Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medicines are designed to appear identical to genuine medicines but will fail to treat the disease or condition for which they were intended.<sup>51</sup> These medicines may contain the incorrect amount of the active ingredient, no active ingredient at all or the wrong active ingredient.<sup>52</sup> The number of SSFFC medicines on the global market puts a large number of patients at risk. The WHO estimates that

---

<sup>44</sup> Brhlikova, P., et al., 'Aid conditionalities, international Good Manufacturing Practice standards and local production rights: a case study of local production in Nepal'. *Globalization and Health*, 11, 25 (2015), p.2.

<sup>45</sup> Kohler, J.C., & Ovtcharenko, N., 'Good governance for medicines initiatives: exploring lessons learned'. *U4 Issue*, 3 (2013), p.4.

<sup>46</sup> Ibid, p.3.

<sup>47</sup> Brhlikova et al., 2015, p.2.

<sup>48</sup> Ibid, p.2.

<sup>49</sup> Ibid, p.8.

<sup>50</sup> Jiao, W., *Drug Review to rid sector of corruption* (2007). Available online: [http://www.chinadaily.com.cn/cndy/2007-02/09/content\\_805232.htm](http://www.chinadaily.com.cn/cndy/2007-02/09/content_805232.htm) [Accessed 1/5/16].

<sup>51</sup> World Health Organisation, *Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products* (2016b). Available online: <http://www.who.int/mediacentre/factsheets/fs275/en/> [Accessed 4/4/16].

<sup>52</sup> Ibid.

about 25 per cent of medicines consumed in low- and middle-income countries are falsified or substandard.<sup>53</sup>

Poor-quality medicines contribute to the rising levels of antimicrobial resistance and future therapeutic failure that increase the need for new medicines to be discovered.<sup>54</sup> For example, SSFFC medicines can result in patients being switched to drugs that should be kept in reserve, because a HCP falsely assumes that the initial drug was real but ineffective. Moreover, bad medicines are detrimental to the image of the health sector and government more generally, since patients may no longer trust their ability to provide safe and effective services.<sup>55</sup>

Falsified medicines enter into markets partially because of an ineffective policy structure. Regulation for manufacturing drugs varies in effectiveness depending on the policies that are in place and the strength of the legal system that enforces such policies.<sup>56</sup> Governments need to have the capacity to implement and enforce GMPs, which is even more difficult in countries with a lack of political will and resources to ensure manufacturing sites are up to standards.<sup>57</sup> Adherence to GMPs in countries with small pharmaceutical markets is costly due to the high quality requirements.<sup>58</sup> Countries with limited resources have been found to shift from “quality monitoring” to “quality assurance”, meaning that they focus on ensuring that companies meet GMPs prior to manufacturing, but fail to monitor the quality of medicines afterwards.<sup>59</sup>

## Anti-corruption measures

Despite containing legal components GMPs are standards and do not set a legal precedence. It is crucial to anti-corruption efforts that legal frameworks at a national level that support the GMPs are robust. In many countries legal definitions based upon GMPs and legislated enforcement is lacking.<sup>60</sup>

To ensure better adherence to GMPs, authorities should conduct random, regular inspections and enforce applicable sanctions.<sup>61</sup> A policy of having multiple inspectors with rotating schedules for manufacturing sites can ensure that inspectors do not develop close relationships with those whom they are auditing. Spot testing can also be conducted to identify substandard medicines before they enter the market. This requires a sufficient number of trained and well-paid inspectors capable of conducting such testing.

---

<sup>53</sup> Cohen et al., ‘Corruption and pharmaceuticals: strengthening good governance to improve access’, in Edgardo Campos J., & Pradhan, S. (eds.), *The Many Faces of Corruption: Tackling Vulnerabilities at the Sector Level*. World Bank (2007), p.33.

<sup>54</sup> Newton, P.N., et al., ‘Counterfeit anti-infective drugs’. *The Lancet Infectious Diseases*, 6, 9 (2006), p.607.

<sup>55</sup> World Health Organisation, 2016b.

<sup>56</sup> Cohen et al., 2007, pp.36-37.

<sup>57</sup> Brhlikova et al., 2015, p.3.

<sup>58</sup> Ibid, p.6.

<sup>59</sup> Brhlikova, P., et al., ‘Good manufacturing practice in the pharmaceutical industry’. *Working paper 3, University of Edinburgh* (2007), p.20.

<sup>60</sup> Cohen et al., 2007, p.36.

<sup>61</sup> Ibid, p.37.

Other anti-corruption measures can improve the transparency of the process, such as publicly posting a list of compliant manufacturers and shaming non-compliant ones.<sup>62</sup>

The rising number of SSFFC medicines will continue unless relevant institutions at the national and international levels are prepared or compelled to cooperate in full. In part, due to a perpetually high demand to supply ratio of medicines and the inability for some supply chains to deliver medicines to all communities, the lack of laws, regulations and sanctions that hinder falsified medicine production act as incentives for individuals to produce SSFC medicines.

### The manufacture of adulterated drugs

In 2013, generic drug manufacturer Ranbaxy USA Inc., a subsidiary of Indian generic pharmaceutical manufacturer Ranbaxy Laboratories Limited, pleaded guilty to charges relating to the manufacture and distribution of adulterated medicines made in its manufacturing facilities in India. Ranbaxy USA introduced adulterated batches of medicines into the market, including Sotret, gabapentin and ciprofloxacin.

Several separate site inspections between 2006 and 2008 found incomplete testing records, an inadequate programme to assess the stability characteristics of medicines and significant GMPs deviations. Two audits conducted by consultants hired by the company in 2003 and 2005 highlighted GMPs violations.

Ranbaxy USA was aware at various times that Sotret and gabapentin had failed certain tests but failed to timely file the required reports to the FDA. The company also made false, fictitious and fraudulent statements to the FDA in Annual Reports filed in 2006 and 2007 regarding the dates of stability tests conducted on certain batches of medicines.

The company agreed to pay a criminal fine and forfeiture totalling US\$150 million and to settle civil claims under the False Claims Act and related State laws for US\$350 million.

The United States Department of Justice, *Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA* (2013a). Available online: <https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false> [Accessed 4/4/16].

---

<sup>62</sup> Cohen et al., 2007, p.38.



## Registration

The registration of medicines is the responsibility of national or regional drug regulatory agencies. Standards must be set for the licensing, marketing and usage of medicines,<sup>63</sup> as well as the enforcement of those standards to ensure the quality, efficacy and safety of medicines being released into the market.<sup>64</sup>

The registration of medicines can represent a significant cost for the pharmaceutical industry. It takes time to prepare and submit documentation, with any delays to a medicine entering a market impacting on profits. Both pharmaceutical companies and regulatory agencies with financial pressures may seek short cuts and utilise inappropriate registration procedures if they lack sufficient oversight.

Weak registration processes may be a result of underfunding, limited institutional capacity and unqualified staff.<sup>65</sup> When such problems are present, the registration process is vulnerable to corruption. For example the level of discretion that government officials have when licensing and accrediting medicines also increases the potential for abuses of power.<sup>66</sup>

Without the proper accountability mechanisms suppliers have an opportunity to bribe government officials to register their medicines without meeting the necessary requirements or to speed up the registration process; or government officials may deliberately delay the registration process in order to solicit an illegal payment from suppliers or to favour competitors.<sup>67</sup>

## Transparent and accountable regulatory agencies

Well-resourced, independent regulatory agencies responsible for the evaluation of all documents and requirements for medicines are necessary to curb corruption in the registration process.<sup>68</sup> A committee of experts with the necessary scientific, medical and technical knowledge are needed to review applications.<sup>69</sup>

Standard operating procedures (SOPs) and guidelines should explicitly outline the criteria for approving a medicine and provide guidance on exemptions, fast track registration, timeframes for processing applications and criteria for selecting external experts.<sup>70</sup> Codes of conduct for internal staff and external experts, including conflict of interest guidelines that mandate the declaration of any relationships that may influence decision-making, should be established.<sup>71</sup> An accountability body that is dedicated to monitoring and determining an appropriate course of action for ethical misconduct and internal conflicts of interest is important.<sup>72</sup>

---

<sup>63</sup> Kohler & Ovtcharenko, 2013, p.3.

<sup>64</sup> World Health Organisation, *Measuring transparency in the public pharmaceutical sector: assessment instrument* (2009), p.25.

<sup>65</sup> United Nations Development Programme, 2011, p.27.

<sup>66</sup> Vian, T., 'Review of corruption in the health sector: theory, methods and interventions'. *Health Policy and Planning*, 23, 2 (2008), p.84.

<sup>67</sup> United Nations Development Programme, 2011, p.27; Vian, 2008, p.85.

<sup>68</sup> Hussman, 2010, p.34.

<sup>69</sup> World Health Organisation, 2009, p.28.

<sup>70</sup> Ibid, p.26.

<sup>71</sup> United Nations Development Programme, 2011, p.30.

<sup>72</sup> World Health Organisation, 2009, pp.25-28.

Transparency measures, such as the creation of public online databases for medicines under review and those that are already registered, can reduce the use of unregistered medicines and expedite the registration process.<sup>73</sup> Further, publishing the registration approval procedures and regulatory agency product reviews on government websites can ensure that both industry and the public are aware of the registration process – information that can later be used to denounce any inefficiencies or corrupt activity.<sup>74</sup>

---

<sup>73</sup> United Nations Development Programme, 2011, p.29.

<sup>74</sup> Management Sciences for Health, *MDS-3: managing access to medicines and health technologies* (2012), p.6.18.

## Marketing

The marketing of medicines constitutes a large part of pharmaceutical company expenditure. Nine out of the ten largest pharmaceutical companies spent more on marketing than on R&D in 2013.<sup>75</sup> In the United States alone the pharmaceutical industry spends an estimated US\$42 billion on promotional activities that target doctors annually, which is equal to US\$61,000 per doctor on average.<sup>76</sup>

The marketing of medicines is primarily an interaction between the pharmaceutical industry and HCPs such as doctors. The relationship between industry and HCPs is important to advance research, provide continued medical education (CME) and to observe side effects.<sup>77</sup> However, due to the industry's need to recoup R&D costs and maximise profits, without strong regulatory systems and oversight mechanisms unethical marketing practices can take place. The close relationship between the pharmaceutical industry and HCPs can make it hard to detect corrupt marketing practices, since the line between violations and normal collaboration is often blurred.

Multiple marketing corruption scandals have made the headlines in the last five years. For example, in 2011 Johnson & Johnson (J&J) paid US\$70 million to settle claims it bribed doctors in Greece, Poland and Romania to prescribe its medicines.<sup>78</sup> The 2014 Access to Medicine Index Report found that 18 of the 20 largest pharmaceutical companies have been found guilty of unethical marketing practices, despite their commitment to adhere to codes of conduct and ethical marketing.<sup>79</sup> An analysis by Transparency International in February 2016 showed that of all companies subject to an ongoing and unresolved corruption related investigation by US authorities, just under ten per cent were biotechs and pharmaceuticals, and of these at least six cases related to sales and marketing practices.<sup>80</sup>

There are several methods for a corrupt pharmaceutical company to unethically market its medicines. At its most simple a pharmaceutical company can bribe a HCP directly with payments so its medicines are more likely to be prescribed. More abstrusely individuals may include a pharmaceutical company's medicine on the national list that is reimbursed by public funds, in return for an indirect bribe by being sent to inappropriate holiday destinations for lavish conferences.

Corrupt marketing practices also include pharmaceutical companies providing misleading information regarding the safety and efficacy of a medicine to influence doctors' prescribing habits and encouraging off-label, unlicensed use to increase sales.<sup>81</sup> In 2004 it was estimated that the US pharmaceutical industry spent US\$20.4 billion on pharmaceutical industry

---

<sup>75</sup> Olson, R., *Design critique: putting big pharmacy spending in perspective* (2015) Available online: <http://www.randalolson.com/2015/03/01/design-critique-putting-big-pharma-spending-in-perspective/> [Accessed 25/04/15].

<sup>76</sup> Gagnon, M.A., 'Corruption of pharmaceutical markets: addressing the misalignment of financial incentives and public health'. *Journal of Law, Medicine & Ethics*, 41, 3 (2013), p.572.

<sup>77</sup> European Commission, 2013, p.82.

<sup>78</sup> Securities and Exchange Commission, *SEC charges Johnson & Johnson with foreign bribery* (2011). Available online: <https://www.sec.gov/news/press/2011/2011-87.htm> [Accessed 25/04/16].

<sup>79</sup> Access to Medicine Index, *Public policy & market influence* (2014). Available online: <http://www.accesstomedicineindex.org/public-policy-market-influence> [Accessed 25/04/16].

<sup>80</sup> Petkov, M., Healthcare companies claim second place on the current FCPA investigation list (2016). Available online: <http://www.transparency.org.uk/healthcare-companies-claim-second-place-on-the-current-fcpa-investigation-list/> [Accessed 4/4/16].

<sup>81</sup> Fischer, C., 'Corruption in healthcare: a problem in Germany, too'. *Indian Journal of Medical Ethics*, 11, 2 (2014), p.112; Gulland, A., 'Top drug companies are making drugs more accessible but are also guilty of corruption, report says', *The BMJ*, 349 (2014), p.1.

representatives visiting HCP offices and providing information.<sup>82</sup> In the same year samples distributed by the US pharmaceutical industry were estimated to have retail value of US\$15.9 billion.<sup>83</sup> Sometimes doctors even collect samples and sell them out of their offices to patients or pharmacists. While these visits and samples can help inform doctors of newly developed drug therapies, they can also unduly influence doctors' prescribing habits.

When HCPs are misguided by false or inaccurate information, prescribing practices and health outcomes will be negatively affected.<sup>84</sup> In 2010 a study showed links between exposing doctors to information from pharmaceutical companies and higher prescribing frequency, higher costs, lower prescribing quality or no significant associations.<sup>85</sup> Often corrupt marketing practices lead to the selection and prescribing of more expensive medicines that have no therapeutic advantage over already existing ones and off-label prescribing.

The effects of improper marketing practices are often not recognised by targeted individuals. A survey of doctors in Germany found that while 77 per cent of medical students were visited by a pharmaceutical representative once a week, only 6 per cent felt that they were influenced by the information that they provided. However, they felt that 21 per cent of their colleagues' prescribing patterns were affected.<sup>86</sup> This is particularly important given the exposure medical students have to pharmaceutical representatives when they are in the process of developing a clinical attitude.<sup>87</sup>

In addition, the pharmaceutical industry voluntarily conducts most of the post-market surveillance of medicines. This is controversial as the reliability of evaluations produced by the pharmaceutical industry on its own medicines can be questionable,<sup>88</sup> as pharmaceutical companies have used post-market surveillance studies to advertise their own medicines and encourage off label use.<sup>89</sup> In countries with low levels of post-market surveillance regulation, a pharmaceutical company can use representatives to collect data on the safety and efficacy of its medicines from doctors who did not even prescribe the medicines being studied, in return for some kind of compensation.<sup>90</sup> Furthermore, the compliance with post-market surveillance standards is often not enforced, which allows pharmaceutical companies to postpone studies or forego them altogether.<sup>91</sup>

---

<sup>82</sup> Gagnon, M.A., 'The crushing cost of pills: a new estimate of pharmaceutical promotion expenditure in the United States.' *PLOS Medicine*, 5, 1 (2008), p.31.

<sup>83</sup> Ibid.

<sup>84</sup> Fischer, 2014, p.115.

<sup>85</sup> Spurling, G. K., et al., 'Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: a systematic review'. *PLoS Medicine*, 7, 10 (2010), p 1.

<sup>86</sup> Lieb, K., & Brandtönes, S., 'A survey of German physicians in private practice about contacts with pharmaceutical sales representatives'. *Dtsch Arztebl Int*, 22 (2010), p.392.

<sup>87</sup> Ibid.

<sup>88</sup> Fischer, 2014, p.113.

<sup>89</sup> Brown, 2013, p.613.

<sup>90</sup> Fischer, 2014, p.113.

<sup>91</sup> Sasich, L.D., et al., *The drug industry's performance in finishing post-marketing research (phase IV) studies* (2000). Available online: <http://www.citizen.org/hrg1520> [Accessed 25/4/16].

## Transparent and accountable industry-HCP relationships

Measures to decrease marketing corruption vulnerabilities focus on regulating and monitoring the relationship between the pharmaceutical industry and HCPs. Codes of conduct can be established at the national and international levels that call for the mandatory disclosure of conflicts of interest, such as honorariums and funding connections,<sup>92</sup> with requirements for the quantity and quality of data disclosure. Robust monitoring mechanisms to ensure that such codes are implemented properly, along with the enforcement of sanctions, are key to tackling corruption vulnerabilities in marketing practices.

Recent measures to increase the disclosure of payment transfers between doctors and pharmaceutical company show change is possible. In 2014 the Physician Payment Sunshine Act was passed in the USA, which requires companies to disclose in an online database the payments they have made to doctors over US\$10, as well as aggregate payments of more than US\$100 to a single doctor. Like any other measure this legislation requires continued monitoring and enforcement; doctors have complained that pharmaceutical companies have submitted incorrect information on the database.<sup>93</sup> In Europe the European Federation of Pharmaceutical Industries and Associations (EFPIA) has implemented a code similar to the Sunshine Act, with data disclosure beginning in June 2016, while in the UK a “Sunshine rule” will require NHS hospitals and doctor groups to keep registers of gifts and hospitality given to staff from pharmaceutical companies.<sup>94</sup>

In each case the impacts are yet to be sufficiently analysed, so it is unclear if disclosure is a necessary and sufficient condition for change. Instead it may be more effective to ensure that conflicts of interest are avoided completely.

## Other anti-corruption measures

Increased fines and criminal penalties have been suggested for deterring unethical marketing practices. However, fines often have little financial impact compared to the profits corrupt pharmaceutical companies make from the sales generated by such practices. For example, since 1991, the industry has paid US\$30 billion in criminal fines in the US for Medicare fraud, unlawful promotion, kickbacks, monopolistic practices and failure to disclose clinical trial data, yet this is less than half of what the industry made in 2009 alone.<sup>95</sup> Nevertheless, the continued enforcement of penalties for engaging in unethical marketing activities is important to address the issue.

---

<sup>92</sup> European Commission, 2013, p.46.

<sup>93</sup> Moran, N., *Transparency measures forced on pharma* (2014). Available online: <http://www.rsc.org/chemistryworld/2014/09/pharma-fines-openness> [Accessed 25/04/16].

<sup>94</sup> Ross, T., *Jeremy Hunt: NHS bosses face jail over links to drug firms* (2015). Available online: <http://www.telegraph.co.uk/news/health/11818749/Jeremy-Hunt-NHS-bosses-face-jail-over-links-to-drug-firms.html> [Accessed 18/5/16].

<sup>95</sup> Gagnon, 2013, p.574.



To minimise the impact of corrupt marketing practices on HCPs prescribing patterns, legislation can be implemented that mandates the prescription of generic medicines in preference to brand-name medicines or the most cost-effective option. However, in studies conducted in Estonia and Spain doctors continued to prescribe brand-name medicines over generics despite legislation prohibiting such behaviour.<sup>96</sup> Such legislation should therefore come with monitoring and enforcement mechanisms to ensure compliance, along with educational programmes for patients to dissipate negative perceptions of generic medicines.

Other suggested policies include the generation of independent analyses of newly developed medicines to educate HCPs and guide their prescribing.<sup>97</sup> Countries have also begun moving towards funding public R&D laboratories for the development of new medicines and post-marketing surveillance. For example, New Zealand's Medicine and Medical Devices Safety Authority has begun conducting post-market surveillance studies through the University of Otago.<sup>98</sup>

Another alternative is using bioethical rating labels on medicines. Pharmaceutical companies with past incidents of corrupt marketing practices would receive a lower rating. This would encourage consumers to reconsider purchasing a medicine from a pharmaceutical company that is considered unethical.<sup>99</sup>

---

<sup>96</sup> European Commission, 2013, p.121.

<sup>97</sup> Fischer, 2014, p.115.

<sup>98</sup> Lemmens & Gibson, 2014, p.970.

<sup>99</sup> Miller, J.E., 'From bad pharma to good pharma: aligning market forces with good and trustworthy practices through accreditation, certification, and rating'. *The Journal of Law, Medicine & Ethics*, 41, 3 (2013), p.602.

### Marketing Risperdal for elderly dementia patients and children with mental disabilities

In 2013 it was alleged that J&J and its subsidiaries promoted medicines for uses not approved as safe and effective by the FDA and that kickbacks were paid to doctors and to the largest long-term care pharmacy provider in the USA.

Between March 2002 and December 2003 Janssen Pharmaceuticals Inc., a J&J subsidiary, introduced Risperdal, an antipsychotic drug, into the US market for unapproved use. Risperdal was for most of the time period approved only to treat schizophrenia, yet sales representatives from the company urged HCPs to use the drug on elderly dementia patients with symptoms such as anxiety, agitation and depression.

Similarly, it is suggested that between 1999 and 2005 Janssen promoted Risperdal for use in children with mental disabilities. The company instructed its sales representatives to target child psychiatrists and HCPs in mental health facilities that treated children. It is alleged that the company paid speaker fees to doctors to influence them to write prescriptions for Risperdal.

It is suggested that both J&J and Janssen were aware that Risperdal posed serious health risks for the elderly and children, but the companies downplayed these risks. The company and its subsidiaries paid more than US\$2.2 billion, one of the largest healthcare fraud settlements in US history, to resolve the criminal and civil liability. J&J also entered into a five-year Corporate Integrity Agreement (CIA).

The United States Department of Justice, *Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations* (2013b). Available online: <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations> [Accessed 4/4/16].

# Procurement

Procurement is the principal interface between the public system and medicine suppliers and aims to acquire the right quantity of drugs in the most cost-effective manner.<sup>100</sup> It is technically complex, involving multiple steps and requiring the involvement of many individuals with adequate expertise.

When medicines are effectively procured from reliable sources and are based on international guidelines, such as the WHO's Essential Medicines List, they are ideally of assured quality and readily available at a reasonable price. However, when the procurement process is compromised it can cause medicine shortages, inflated drug prices and the infiltration of falsified and substandard medicines into the health system.<sup>101</sup>

The procurement process is one of the largest expenditures in healthcare delivery, particularly in low- and middle-income countries.<sup>102</sup> Public medicine procurement is even more vulnerable to corruption than contracting in other services given that medicine volumes are typically large and the contracts are usually quite lucrative.<sup>103</sup> This is due to several factors including the difficulty in monitoring quality standards in medicine provision and the ability for suppliers to use different prices for the same medicine.<sup>104</sup> The procurement of publicly funded medicines is particularly susceptible to corruption when it is poorly documented and there is weak governance in place.

There are two main forms of corruption in medicine procurement: isolated procurement corruption and systematic procurement corruption. Isolated procurement corruption involves a very limited number of individuals, tends to be smaller in scale and attracts less attention.<sup>105</sup> Systemic procurement corruption is deeply embedded in the political functioning of the state. Such levels of corruption necessitate political involvement to ensure continued smooth operations.<sup>106</sup> Corresponding levels of governance must be in place to mitigate each form of corruption.

---

<sup>100</sup> Cohen, J.C., 'Pharmaceuticals and corruption: a risk assessment', in Kotalik, J., & Rodriguez, D., (eds.), *Global Corruption Report 2006* (Transparency International, 2006), p.81.

<sup>101</sup> Chene, M., 'Approaches to corruption in drug management'. *U4 Expert Answer*, 225 (2009), p4.

<sup>102</sup> World Health Organisation, 2009, p.87.

<sup>103</sup> United Nations Development Programme, 2011, p.30.

<sup>104</sup> Cohen, 2006, p.81.

<sup>105</sup> European Commission, 2013, p.67.

<sup>106</sup> Ibid.

Corruption can occur in all three stages of the procurement process:

- The pre-bidding stage of procurement involves a needs assessment, definition of contract characteristics and the selection of a procurement method. This stage typifies indirect procurement corruption, in which a bid is carefully drafted so that only a predetermined company can win, making it appear as if the bid was awarded on the basis of merit without technically violating any rule or procedure.<sup>107</sup>
- The second stage in procurement, the bidding stage, involves bid invitations, bid evaluations and the awarding of contracts. This stage typifies direct procurement corruption, which takes place when a particular winner is selected regardless of the offer through bribery or extortion of a public official in exchange for a bid.
- In the post-bidding stage, contract implementation and monitoring take place. Corruption at this stage can include false invoicing and changing contract agreements.

## Developing procurement guidelines and procedures

The procurement of medicines is a complicated process that can be centralised and decentralised at different levels. Many high-income countries do not have national procurement schemes or guidelines. For example, in 2010 only 30 per cent of European Union member states had developed national procurement guidelines.<sup>108</sup> This lack of minimal managerial order and oversight is a fundamental weakness in countries' public procurement systems.<sup>109</sup>

Therefore, policies for addressing corruption in procurement are often centred on ensuring guidelines are developed and implemented to ensure efficiency and oversight in procurement systems. Key features include:

- Procurement committees with clear policies and guidelines that are continually followed.
- Procurement committees with guidelines that specify the inclusion and exclusion of medicines into the list of medicines to be procured, to ensure medicines being procured are safe and cost-effective.
- Procurement committees with a conflicts of interest policy that ensures actual or potential conflicts of interest between committee members and medicine suppliers are declared and avoided if possible to minimise pre-bidding corruption.<sup>110</sup>
- Procurement committees composed of multi-disciplinary experts that are well trained, knowledgeable in pharmaceuticals and conscious of healthcare facility needs.
- Procurement committees with SOPs to hold individuals accountable in case corrupt behaviour is detected.<sup>111</sup>
- Constant technical assistance and training for procurement officials to ensure that procurement is carried out based on evidence and technical knowledge.<sup>112</sup>

---

<sup>107</sup> Ibid, p.68.

<sup>108</sup> World Health Organisation, *Fact sheet on health technologies: selected results from the baseline country survey on medical devices 2010 – European region* (2011), p.2.

<sup>109</sup> Lewis, M., 'Governance and corruption in public health care systems.' *Center for Global Development*, 78 (2006), p.21.

<sup>110</sup> World Health Organisation, 2009, p.89.

<sup>111</sup> Vian, 2008, p.86.

<sup>112</sup> United Nations Development Programme, 2011, p.34.

## E-procurement and open contracting

To ensure competitive tendering, procurement should be carried out through the use of strong procurement infrastructures such as e-procurement. Electronic bidding creates a platform through which multiple healthcare facilities can upload their tenders and where prequalified suppliers that have a proven reliability can participate. This is important as the risk of corruption increases when there is a high level of decentralisation, a low number of suppliers, a low number of bids and relatively high prices.<sup>113</sup>

Open contracting, in tandem with e-procurement, helps increase the transparency of procurement procedures and prices, as it allows for the collection for data on tenders bids, offers of tenders, terms and conditions, contract awards, supplier performance and prices paid, which can be disseminated to all healthcare facilities and the public. Efforts have been made to ensure that the procurement process is transparent to allow for comparisons to be easily made on prices paid by different facilities for the same medicine. This way healthcare facilities can make more informed decisions and can overtime lead to greater purchasing power to negotiate prices with suppliers.

Ideally, these measures will help curb price gouging, price manipulation and overpayments.<sup>114</sup> However, transparency measures should offer data that is consistently reported, reliable in terms of quality and presented in a format that can be easily used to identify potential issues and hold procurement agents accountable. This involves increasing coverage of who is required to disclose information, improving the reliability and accuracy of data, and assuring consistent and reliable access to disclosed information in a practical format.<sup>115</sup> This also includes the constant monitoring of such data to ensure accountability.

At the 2016 UK Anti-Corruption Summit Argentina, Malta, Mexico and Nigeria committed to implementing open contracting principles in the health sector.<sup>116</sup> These countries will be supported by an initiative led by Transparency International, the UK government and the Open Contracting Partnership, as well as assistance from the WHO, to develop a common approach so that open contracting becomes a default part of health sector procurement processes.

Accountability mechanisms such as sanctions and fines will also help deter unethical behaviour. Using these mechanisms involves the constant monitoring of adverse reactions to medicines, procurement performance indicators and the prices of supplies.<sup>117</sup> Experts have also suggested prequalifying suppliers and monitoring them throughout the duration of the procurement contract to ensure their performance, establishing a product defect reporting system and imposing sanctions for non-compliance. An expert committee with the necessary resources could be set up to oversee the entire procurement system, including internal and external audits, to detect corrupt behaviour and issue sanctions to guilty officials.<sup>118</sup> However, imposing sanctions for suppliers not honouring contracts may not be realistic in some settings where the number of available suppliers in a country is limited, since it can lead to stock-outs if an alternative supplier is not available.

---

<sup>113</sup> European Commission, 2013, pp.36-37.

<sup>114</sup> United Nations Development Programme, 2011, pp.32-33.

<sup>115</sup> Waning, B., & Vian, T., 'Transparency and accountability in an electronic era: the case of pharmaceutical procurements'. *U4 Brief*, 10 (2008), pp.2-3.

<sup>116</sup> Transparency International UK, *Anti-corruption summit commitments on procurement will be key for the health sector* (2016). Available online: <http://www.transparency.org.uk/press-releases/anti-corruption-summit-commitments-on-procurement-will-be-key-for-the-health-sector/> [Accessed 16/5/16].

<sup>117</sup> United Nations Development Programme, 2011, p.34.

<sup>118</sup> Hussman, 2010, p.10.



## Integrity Pacts

An anti-corruption tool used in a range of sectors is an Integrity Pact. An Integrity Pact is an agreement between the government agency offering a contract and the companies bidding for it that all parties will abstain from bribery, collusion and other corrupt practices for the extent of the contract.<sup>119</sup> To ensure accountability, an Integrity Pact includes a monitoring system typically led by civil society groups.

Transparency International has used Integrity Pacts since the 1990s in all global regions. An Integrity Pact can improve transparency and accountability in the procurement process, as well as enhance trust in government agencies. They also facilitate the uncovering of corruption and allow an actor to be punished according to the agreement. Their use in India in 2014 led to the Ministry of Defence cancelling its procurement contracts with Augusta Westland and Rolls-Royce because of bribery.<sup>120</sup>

### Ex-UN consultants rig pharmaceuticals contracts

Two former UN consultants rigged contracts to supply life-saving medicines to the Democratic Republic of Congo in return for bribes. Their company, World Response Consulting, received contracts from the UN Development Programme (UNDP) to tackle HIV and malaria in the country. The pair used their knowledge to leak details to the Danish pharmaceutical company, Missionpharma, so it could win the contract.

In return for helping the company win contracts, the men received £650,000 (US\$1 million). Evidence showed that the pair were aware that the promotion of Missionpharma needed to be hidden, with payments for the contracts “unseeable by outside eyes”. The two men hoped to make £44 million (US\$68 million) from the plot.

In 2007 the UN launched an investigation into the men and how the contracts were awarded. The men were arrested the following year. One of the pair was jailed for 15 months and the other was jailed for a year.

The Guardian, *Ex-UN consultants jailed for bribes over drugs supplied to ‘starving Africans’* (2015). Available online: <http://www.theguardian.com/uk-news/2015/sep/23/un-guido-bakker-sijbrandus-scheffer-jailed-contracts-drugs-congo> [Accessed 4/4/16].

---

<sup>119</sup> Transparency International, *Integrity Pacts*. Available online: [https://www.transparency.org/whatwedo/tools/integrity\\_pacts/3/](https://www.transparency.org/whatwedo/tools/integrity_pacts/3/) [Accessed 4/4/16].

<sup>120</sup> The Telegraph, *India terminates AgustaWestland helicopter deal* (2014). Available online: <http://www.telegraph.co.uk/finance/newsbysector/industry/defence/10545808/India-terminates-AgustaWestland-helicopter-deal.html> [Accessed 4/4/16].

## Distribution

The distribution activity involves the transportation of medicines from the manufacturer to the payer. This activity includes port clearing, receiving and inspecting, storage, inventory management, requisition of supplies, pickup and transportation, and disposal.<sup>121</sup> There are multiple distribution methods that range from multi-tiered models to direct delivery from suppliers to healthcare facilities.<sup>122</sup> Ensuring the integrity of the pharmaceutical distribution chain is important for delivering high-quality, safe medicines.

However, corruption vulnerabilities are present throughout the distribution chain. At any point where there is a lack of oversight, medicines can be stolen and sold on the black market or kept for personal use. This is a high-risk in many countries. A study in Uganda found that the resale of medicines was the greatest single source of income for healthcare personnel.<sup>123</sup>

Rampant theft will cause frequent stock-outs. This harms patients by pushing them to turn to the black market to find medicines unavailable in the public health sector, which puts them at risk of acquiring falsified or substandard medicines and paying higher prices.<sup>124</sup>

Moreover, during distribution falsified and substandard medicines can infiltrate the health system. For example, when medicines are stolen from public health facilities they can be replaced with falsified or substandard ones. Data from 2005 to 2010 from the Pharmaceutical Security Institute reports that the diversion and theft of medicines increased by 66 per cent, while the incidents of counterfeiting in the same period increased by 122 per cent.<sup>125</sup> This increased penetration of falsified and substandard medicines into legitimate medicine distribution channels has not been widely studied despite it being a well-documented problem in both low- and high-income countries.<sup>126</sup>

## Anti-corruption measures

Low wages may encourage corruption by providing individuals with a reason to rationalise theft as an alternate income source for their knowledge or services, an issue across much of the value chain. While higher salaries are often proposed to curb corruption, evidence surrounding this suggestion is inconclusive. Instead, it has been reported that employment security, recruitment and promotion criteria are more likely to influence behaviour than salary increases.<sup>127</sup>

---

<sup>121</sup> World Health Organisation, 2009, p.97.

<sup>122</sup> Ibid, p.97.

<sup>123</sup> Ferrinho, P., & Van Lerberghe, W., *Managing health professionals in the context of limited resources: a fine line between corruption and the need for moonlighting* (2002), p.5.

<sup>124</sup> Handfield, R., *Biopharmaceutical supply chains: distribution, regulatory, systems and structural changes ahead*. CRC Press (2012), p.179.

<sup>125</sup> Mackey, T.K., et al., 'Counterfeit drug penetration into global legitimate medicine supply chains: a global assessment.' *The American Journal of Tropical Medicine and Hygiene*, 92, 6 (2015), p.59.

<sup>126</sup> Ibid, p.59.

<sup>127</sup> Rauch, J.E., & Evans, P.B., 'Bureaucratic structure and bureaucratic performance in less developed countries'. *Journal of Public Economics*, 75, 1 (2000), p.68.

Key policies to mitigate corruption vulnerabilities during distribution include:

- Institutional checks and balances, such as dividing functions between cashiers and accountants, to help prevent fraud.<sup>128</sup>
- The physical protection and security of medicines through SOPs for medicine shipments, satellite tracking of delivery trucks and screening of all employees before and after employment.<sup>129</sup>
- Monitoring and accountability procedures such as frequent audits and whistleblowing mechanisms for the public and internal staff.

In many high-income countries the private sector is responsible for the distribution of medicines. For example, in the UK the NHS is a publicly dominated model, but the courier company DHL is contracted for the distribution. There is evidence that a private/public mix in the distribution system can work well, so long as there is sufficient oversight ensuring each institutional partner is acting correctly.

The introduction of new technologies that are able to track the distribution of medicines and prevent diversion is a useful development. As one example, pharmacies could have an e-system in place to ensure the provenance and quality of medicines they distribute. Similarly, consumers could scan a medicine label using their mobile phone and send the information to the manufacturer to ensure it is a genuine medicine.

### Fire at the Ghanaian Central Medical Stores

On 13 January 2015, a huge fire broke out at the Ghanaian Central Medical Stores (CMS), which holds medicines and supplies to be transported across the country. Because of the fire a large stock of medical supplies, and crucially records, were destroyed.

Investigations determined that the fire was deliberately started. On the date of the fire the Ghanaian Economic and Organised Crime Office had planned an investigation into the expiration of large quantities of medicines and medical items at the CMS. The fire had destroyed evidence of theft and fraud during the procurement and distribution process, involving both senior management and junior staff. For example, large quantities of Artemether Lumefantrine, an anti-malarial medicine, were stolen or diverted and sold to groups in Nigeria and Cote d'Ivoire.

Twelve individuals were identified as being part of a network at the CMS responsible for the systemic theft and fraud. A full forensic audit will be conducted by a Special Audit Task Force directed by the Minister of Health. A number of reforms will also be implemented at the CMS to reduce the risk of another similar incident, including the strengthening of the internal auditing mechanism to ensure constant monitoring of transactions.

All Ghana News, *Report identifies operational lapses at of central medical stores* (2016). Available online: <http://www.allghananews.com/health-lifestyle/68814-report-identifies-operational-lapses-at-of-central-medical-stores-full-report-attached> [Accessed 4/4/16].

---

<sup>128</sup> United Nations Development Programme, 2011, p.25.

<sup>129</sup> Ibid, p.36.

## 4. Overarching challenges

Four challenges as noted below overarch the structural issues analysed in the pharmaceutical value chain and facilitate corruption. A failure to address these challenges compounds these issues and hampers wider efforts to minimise corruption within the pharmaceutical sector. These corruption vulnerabilities increase the difficulty of governments meeting the health specific SDGs.

**A lack of objective data and understanding of corruption** – The knowledge of corruption and how to prevent it in the pharmaceutical sector is consistently low. The development of the necessary knowledge base is hampered by a tacit acceptance of corruption in some contexts, the complexity and confidentiality issues in the sector, and policy makers and decision makers not perceiving corruption as a key issue.

**A weak legislative and regulatory framework** – Legislative and regulatory frameworks for the pharmaceutical sector are weak, characterised by poor investment and a lack of oversight. This is exacerbated by the inability to produce a universal anti-corruption response, which limits uniformity between jurisdictions. Attempts at international frameworks are also hampered by the need for state sovereignty acceptance. Nationally, the regulatory framework is often decentralised and key decision-points are self-regulated, which increases corruption risks.

**The potential for undue influence from companies** – When pharmaceutical companies have autonomy over key decision points in the value chain and unparalleled resources they are exposed to high corruption vulnerabilities. This allows a pharmaceutical company to unduly influence policy and regulation so a company's profit maximisation interests can go beyond ethical norms and be prioritised over public health objectives so as to negatively impact health outcomes. This undue influence manifests in several areas including the marketing of medicines to HCPs and the CME of HCPs.

**A lack of leadership committed to anti-corruption efforts** – Many actors in the pharmaceutical sector do not display a genuine commitment to anti-corruption efforts. Often it requires a crisis for action to be taken, as national leadership can benefit from the proceeds of corruption or the level of institutional corruption can be too high for individuals to stand up. This is amplified by the undue influence that companies are capable of placing on governments. These issues are crucial as efforts led by international actors will be hampered by inaction from governments. Global institutions are not doing enough to produce global standards that can be utilised by governments, as well as civil society wanting to put pressure on uncommitted governments.

## A lack of objective data and understanding of corruption

There is a general lack of concrete data to assess the actual prevalence of corruption in the pharmaceutical sector and how it manifests itself through different key decision points. There is opaque information about corruption events and their prevalence, unless there is a large case that is brought to wide attention. While there is knowledge that corruption does take place in the pharmaceutical sector, the complexity of the issue and the systemic levels of corruption make it challenging to verify exactly where and when corruption happens at any given time.

Overarching all of this is the fact that the pharmaceutical sector, and the health sector more generally, are technical and complex. Both sectors have centralised and decentralised levels, regulatory and market dimensions, and many points of entry and stakeholders. As a result, this makes it extremely difficult to determine who is doing what and who is accountable to whom.

A lack of transparency and monitoring mechanisms in the sector can also deter the production of knowledge of where, how and to what degree corruption may be present. Corruption is difficult to identify because of its inherent intangibility and invisibility. The pharmaceutical sector is laden with issues of confidentiality and privacy, making the identification and control of corruption a challenge at best.

Probing the pharmaceutical sector for corruption also becomes challenging when there is a level of tolerance to it. Perceptions that corruption is simply the way things work or the presence of a wilful degree of blindness to it can hinder corruption from being identified. For example, bribery can be understood in a country as “how things work”. The act of a pharmaceutical company providing a gift to a ministry official for winning a large contract can be perceived as simply a gratitude payment and justified widely given low salary levels in low-income countries.

In addition, government officials and other relevant stakeholders in this sector may not perceive corruption as a critical issue that the pharmaceutical sector needs to tackle head-on. Instead, there seems to be denial and complacency that leads to belief that corruption will be “fixed” spontaneously through initiatives in other sectors. Often policy makers and donors focus their attention on addressing system leakages and inefficiencies and refrain from focusing on corruption. While understanding all system failures too readily as corruption is irresponsible, dismissing the role that corruption plays in system failures can leave these system failures largely unaddressed.

Conducting a thorough evaluation of how corruption takes place in any given pharmaceutical sector is costly. Funding that is specific to addressing corruption in the health and pharmaceutical sectors is often non-existent. Instead, donor funding has primarily focused on vertical programmes for specific diseases, such as HIV/AIDS, TB and malaria, in order to achieve direct targets for health outcomes. This vertical approach is not optimal for understanding if corruption is present because it does not aim to examine broader systemic failures, some of which may be a result of corruption.

While the adoption of the SDGs encourages a more holistic approach to health system strengthening, funding for anti-corruption research and interventions should also be encouraged to help governments assess the prevalence of corruption and exactly where and how it is happening in their pharmaceutical sectors. This will not only help create baseline data that can be used to evaluate the success of future interventions, but it will lead to a health systems approach that is well targeted, context specific and based on evidence.

## A weak legislative and regulatory framework

Ensuring strong legislative and drug regulatory frameworks are in place to effectively govern the pharmaceutical sector is essential and certainly not a new finding. A clear legal and judicial system allows governments to hold individuals and the private sector accountable for their behaviour. Strong legislative and regulatory frameworks at the national, regional and global levels are important for establishing a strong and consistent baseline upon which future policies that minimise vulnerabilities to corruption can be developed.<sup>130</sup>

Despite the longstanding awareness of the need for strong legislative and regulatory frameworks, it remains a challenge when mitigating the structural and policy issues in the pharmaceutical sector. It is one of the most regulated sectors in many countries, yet the legislative and regulatory framework is characterised by multiple failures, poor investment and a lack of oversight.

Efforts by international organisations, such as the UNDP and the World Bank, have focused on strengthening countries' legislative and regulatory frameworks by assisting in the development of new laws and institutions.<sup>131</sup> But efforts have not been sufficient; existing laws and institutions are often too weak, leaving a legal system's vulnerabilities to non-compliance that can essentially make new and existing laws futile.<sup>132</sup> As a result countries that have weak levels of governance to begin with are further limited by their inability to effectively ensure that government institutions carry out existing and new laws.

A challenge in drafting anti-corruption legislation is the lack of a globally agreed upon definition of corruption. Further, corruption may be understood as having context specific properties as it manifests itself in different ways depending on the environment in which the pharmaceutical sector operates.<sup>133</sup> There is no simple universal, all-purpose anti-corruption legislative framework for the pharmaceutical sector. This poses a challenge in drafting legislation that specifically targets corruption and establishes uniformity across jurisdictions to combat corruption at the transnational level. Uniformity across legislations is crucial for deterring transnational actors from engaging in corrupt behaviour, particularly in the pharmaceutical sector.<sup>134</sup>

A further difficulty with international legislation is the need for ratification, implementation and enforcement by national governments that may have limited interest in doing so. International laws' dependence on state sovereignty for its implementation continues to be an issue for ensuring uniformity in anti-corruption legislation across nations. This is particularly problematic in the pharmaceutical sector given the transnational nature of value chain activities.

---

<sup>130</sup> Toebe, B., 'Human rights and health sector corruption', in Harrington, J., & Stuttford, M., (eds.), *Global Health and Human Rights*. Routledge (2010), p.113.

<sup>131</sup> United Nations Development Programme, *Strengthening the rule of law in crisis-affected and fragile situations: Global Programme Annual Report 2014*. United Nations Development Programme (2014); World Bank, *Reforming public institutions and strengthening governance*. World Bank (2000).

<sup>132</sup> Morita, S., & Zaelke, D., *The Rule of Law, Good Governance & Sustainable Development*. Submission to the Seventh International Conference on Environmental Compliance and Enforcement (2005).

<sup>133</sup> Savedoff, W.D. & Hussmann, K., 'Why are health systems prone to corruption?', in Kotalik, J., & Rodriguez, D., (eds.), *Global Corruption Report 2006*. Transparency International (2006), p.14.

<sup>134</sup> European Commission, 2013, p.102.

Nationally, the regulatory framework is often decentralised. This makes it difficult to ensure all critical decision points are adequately regulated. In several areas the pharmaceutical industry is expected to self-regulate, with numerous resultant risks. For example, in most countries marketing practices by pharmaceutical companies are often regulated by industry-association codes that are self-regulated and how well these are enforced can be unclear.

Countries will continue to face specific challenges along each of the value chain activities in the pharmaceutical sector. Governments must set standards for the licensing, marketing and usage of medicines, as well as the enforcement of those standards through legislation to ensure quality, efficacy and safety.<sup>135</sup> Setting these standards will help minimise vulnerabilities to corruption.

---

<sup>135</sup> World Health Organisation, 2009, p.22; Kohler & Ovtcharenko, 2013, p.3, 8, 19.



## The potential for undue influence from companies

The pharmaceutical industry, whether at the international or national levels, producing brand-name or generic medicines, plays a crucial role in developing and supplying medicines. To fulfil this important role pharmaceutical companies, along with other actors such as HCPs, are given a large degree of autonomy to act with integrity and honesty.

However, strong control over key processes combined with huge resources and big profits to be made make the pharmaceutical industry particularly vulnerable to corruption. Pharmaceutical companies have the opportunity to use their influence and resources to exploit weak governance structures and divert policy and institutions away from public health objectives and towards their own profit maximising interests. While there is nothing wrong with profit maximisation that abides with legal norms,<sup>136</sup> if it goes beyond ethical norms, has a negative impact on health outcomes and limits the potential for governments to provide quality and affordable care, it is a serious issue.

Pharmaceutical companies can unduly influence national political systems through their large spending power. Pharmaceutical companies often fund candidates that support their position on key issues. Outside of elections, the pharmaceutical industry spends vast sums of money lobbying. Estimates suggest that in 2009 the industry association Pharmaceutical Research and Manufacturers of America (PhRMA), as well as one of the member companies Pfizer, each spent over US\$25 million.<sup>137</sup> Such funding can shape policy debates to favour a pharmaceutical company's profit maximisation priorities and negatively impact public health objectives.

Undue influence from pharmaceutical companies at the national level can occur discretely through other actors. Patient groups wield a strong voice within the health sector as a whole. Many patient groups receive considerable financing from industry due to a lack of other funding sources.<sup>138</sup> Such power can allow a pharmaceutical company to exert undue influence on cash-strapped patient groups. As a result policy debates can be distorted and institutions can be diverted away from their intended purpose of improving public health outcomes, as patient groups promote the benefits of a new medicine while downplaying the side effects.

Another example of the way that pharmaceutical companies can use their resources and influence in a way to maximise their profit interests can be seen in the commercialisation of drug information to HCPs. Through the use of pharmaceutical representatives, pharmaceutical companies can directly reach out to doctors to market their medicines, often encouraging them to prescribe newer, more expensive medicines that often lack innovation and do not provide therapeutics advantages over older drugs.<sup>139</sup> This has an obvious public health impact, particularly as medicine costs rise and public health spending plateaus.

---

<sup>136</sup> Cohen et al., 2007, p.31.

<sup>137</sup> Gurciullo, B., *Pharmaceutical industry, under scrutiny for prices, has history of big political wins* (2015). Available online: <https://www.opensecrets.org/news/2015/10/pharmaceutical-industry-under-scrutiny-for-prices-has-history-of-big-political-wins/> [Accessed 18/05/16].

<sup>138</sup> Rose, S.L., 'Patient advocacy organizations: institutional conflicts of interest, trust, and trustworthiness.' *The Journal of Law, Medicines and Ethics*, 41, 3 (2013), p.681.

<sup>139</sup> Gagnon, 2013, pp.571-572.

Similarly, the desire to increase profits may encourage a pharmaceutical company to exploit its autonomy and influence to market its medicines through the CME of HCPs. The pharmaceutical industry contributes a large proportion of CME funding and uses this influence to market medicines.<sup>140</sup> While the pharmaceutical industry's contributions to CME are important for providing CME for HCPs, without proper oversight to regulate the role of industry on what is being taught, HCPs can be encouraged to prescribe less effective and more costly medicines to increase profits at the expense of health budgets and patients.

---

<sup>140</sup> Rodwin, 2013, p.585.

## A lack of leadership committed to anti-corruption efforts

Genuine commitment to anti-corruption policies by heads of governments, senior government officials and regulatory agencies is currently absent in many countries. Countries are able to sign anti-corruption agreements without actively overseeing if or how these are implemented. Unfortunately, it often requires a crisis for a government to introduce new legislation, strengthen regulation and increase enforcement.

Strong leadership in the public and private sectors that is committed to anti-corruption efforts is often absent due to the high level of institutional corruption within governments and global and national institutions. Pushing for change can be challenging in environments where leadership is compromised by the illicit gains that are to be made from corrupt activity. Individuals may also hesitate to act against corruption when it is deeply embedded in the system due to the negative consequences it can bring to their careers and even their well-being, thus deterring strong leadership from emerging.

Through its integral role in health systems the pharmaceutical industry has the ability to unduly influence national and international political systems, allowing pharmaceutical companies to prevent the introduction of policies that will mitigate corruption yet impact company profits in the short term. Governments may be hesitant to implement policies that go against industry's commercial interests when there are economic gains to be made for the country from having policies to attract foreign investment from pharmaceutical companies. Therefore, leadership that shows a commitment to tackling corruption must not only come from governments, but also from the pharmaceutical industry.

Strengthening national leadership for anti-corruption efforts will have the most impact in reducing corruption vulnerabilities and ensure long-term sustainability. Research has shown that anti-corruption efforts led by aid agencies are often ineffective when the national political context is not favourable.<sup>141</sup> It is up to governments to oversee industry and prioritise public health objectives by setting and enforcing good regulations and policies.

Whilst effective change needs to take place at the national level, the lack of global governance on key issues is hampering progress. National authorities and civil society can be emboldened by the actions of global institutions who can set global standards and best practices that cascade to the national level. Where national policy makers are reluctant to improve legislation and regulation, civil society can use the actions of global institutions to add weight to their argument and demand change.

---

<sup>141</sup> Disch, A., et al., 'Anti-corruption approaches: a literature review'. *Norwegian Agency for Development Cooperation* (2009), p.19; Persson, A., et al., 'Why anticorruption reforms fail – systemic corruption as a collective action problem'. *Governance: an international journal of policy, administration, and institutions*, 26, 3 (2013), p.453.

## 5. Focus areas for action

Three broad areas that capture some of the issues analysed in the value chain were identified in the research for mitigating corruption in the pharmaceutical sector. By minimising corruption vulnerabilities in the pharmaceutical sector governments will be in a stronger position to improve health outcomes and meet the SDGs.

**Establishing leadership committed to addressing corruption** - All actors must display a genuine commitment to tackling corruption. Cooperation is key within and between governments, the pharmaceutical industry, global institutions and civil society organisations. This collaboration can be facilitated through the use of multi-stakeholder alliances. In this regard governments are the most important driver of change. They must show strong commitment to anti-corruption efforts, including a stance of no impunity for all corrupt actors. Donors can assist in driving change at the national level, global institutions must improve their accountability so they are better able to provide global leadership and the pharmaceutical industry can lead and engage with governments.

**Adopting technology throughout the pharmaceutical value chain** – Government agencies must adopt technology to reduce the opportunity for corruption by minimising actor agency and the need for face-to-face interactions. The increased use of digital record keeping facilitates the production and access of records that aids the discovery of corruption. Much of this information is readily available, diminishing asymmetrical information at key decision points that facilitates corruption. Other actors, such as HCPs and patients, can use technology for novel purposes to confirm the quality and standard of a medicine.

**Ensuring accountability through increased monitoring, enforcement and sanctions** – Actors in the pharmaceutical sector must be held accountable for their actions. Governments must implement processes to track activities and provide civil society organisations with access to data so they are able to act as watchdogs. Governments must also do more to ensure all regulation and legislation is actively enforced to ensure corrupt pharmaceutical companies are investigated and punished, with evidence suggesting that in many cases the level of fines must be raised. Similarly, professional and academic institutions must apply appropriate sanctions against corrupt HCPs and researchers.

## Establishing leadership committed to addressing corruption

Current leadership in the pharmaceutical sector is too weak and fragmented to address corruption in a meaningful way. Systemic change will not be achieved by a small number of individuals and organisations working independently. Strong, purposeful leadership is needed at multiple levels and from a broad range of actors to create systemic change.

To achieve anti-corruption progress in the pharmaceutical sector, as with all sectors, it is essential that all actors display a strong obligation to action. For governments this will require a long-term political commitment to addressing corruption, while for global institutions this means providing strong assistance and direction to other actors. Overall, local, national and international actors must collaborate to ensure anti-corruption efforts are effective.

## Increased cooperation between actors

The sharing of information among different levels of government, as well as between governments, must take place. This will require efforts to forge global, regional and national level multistakeholder collaborations particularly with regards to falsified and substandard medicines. The development of an independent health sector anti-corruption organisation to facilitate these efforts should be explored and considered. Information pertaining to the coordination of standards, relevant audits, investigations and enforcement when breaches occur must be shared.

Multi-stakeholder alliances are particularly effective at bringing actors together to achieve anti-corruption success. The All Trials campaign is a good example of what can be achieved using such an approach. With the support of a broad coalition of over 600 organisations, including pharmaceutical companies, the campaign persuaded the European Medical Agency to make scrutiny of clinical trial data much easier.<sup>142</sup>

In particular, the WHO must continue to work with other actors including NGOs. For an issue like corruption there are numerous NGOs that have experience working in this area and which are not constrained by the same political considerations as the WHO. The organisation should coordinate such actors to ensure these activities are carried out most effectively. The organisation must also support initiatives that show real progress through its extensive global network of contacts and broad technical expertise.

## Genuine action from governments

The key actor to drive change in the sector is national governments. To genuinely diminish corruption in the pharmaceutical sector national governments must show commitment to tackling the issues that facilitate corruption. This includes cleaning up the pharmaceutical sector by adopting a stance of no-impunity for all corrupt actors in the pharmaceutical sector, including companies, government officials and HCPs. Regardless of a company's revenue, an official's seniority or a HCP's prestige, anyone suspected of corruption must be investigated and appropriate sanctions applied. It is only with a well-functioning pharmaceutical sector with clean actors that governments will be best placed to meet the SDGs and provide affordable and safe medicines.

---

<sup>142</sup> AllTrials, *EMA removes some restrictions from its data sharing policy* (2014). Available online: <http://www.alltrials.net/news/ema-removes-some-restrictions-from-its-data-sharing-policy/> [Accessed 20/4/16].

Various countries are showing a commitment to increasing transparency in the pharmaceutical sector. For example, the United States Government in its 2017 Budget is showing a positive direction by including the provision to "require drug manufacturers to publicly disclose certain information, including research and development costs, discounts, and other data as determined through regulation."<sup>143</sup> However, the issue remains if and how this will be implemented.

## Donors have a role to drive anti-corruption efforts

Global institutions and cooperative governments can apply pressure on unwilling governments to create enabling environments for civil society to actively participate in the external oversight of the pharmaceutical sector. The donor community can support the anti-corruption initiatives of governments through official development assistance. In the health sector, Performance Based Financing has been used to tackle corruption and drive efficiencies. In this model, the recipient is provided with the funding only after agreed upon activities are carried out, helping to strengthen accountability. The international community has committed to this approach through agreements such as the Paris Declaration on Aid Effectiveness in 2005 and the 2008 Accra Agenda for Action.

Similarly, arguments have recently been made that donor agencies should focus on project results when giving aid and expand the use of pay-for-results programmes.<sup>144</sup> This will allow donor agencies to determine if corruption was the cause for a project failing, to evaluate the function of control processes in practice and to help measure countries' level of suitability for aid receipt.<sup>145</sup> Further studies must be conducted to evaluate the utility of such funding mechanisms.

## Independent and autonomous global institutions

To coordinate the global pharmaceutical sector and provide strong governance global institutions such as the WHO must increase its own levels of accountability and transparency. Actors must trust the organisation to act with integrity and believe it will place public health priorities above private interests.

The current funding structure of WHO has caused some health and development experts to express concern. This criticism has in part been attributed to the WHO's decreased level of independence and autonomy that has resulted from its dependence on powerful independent funders that provide voluntary contributions.<sup>146</sup>

The organisation has accepted the need to transform its organisational culture and strengthen compliance. It has introduced a web portal and oversight mechanisms.<sup>147</sup> Web portal seems like a positive development. In particular, it is encouraging that the WHO Director-General has announced the commitment for the organisation to join the International Aid Transparency

---

<sup>143</sup> Office of Management and Budget, *Budget of the US Government: Fiscal Year 2017* (2016), p.66.

<sup>144</sup> Savedoff, W., *Anti-corruption strategies in foreign aid: from controls to results*. Center for Global Development, Policy Paper 76 (2016), p.12.

<sup>145</sup> Ibid.

<sup>146</sup> Sridhar, D., & Clinton, C., 'Overseeing global health'. *Finance & Development*, 51, 4 (2014), p.27.

<sup>147</sup> World Health Organisation, *WHO Financing Dialogue 2015: meeting report*. World Health Organisation (2015).

Initiative (IATI) by the end of 2016.<sup>148</sup> With an information disclosure policy currently under development it is necessary to wait to see the results and how far the disclosure goes.

Key global institutions alongside the WHO must assist in the development of agreeable standards and governance tools that can be adopted and adapted by countries. These standards and tools must be designed in tandem with national governments to ensure their effective design and implementation, along with sufficient political support. Crucially, these actions need to be supported in their implementation, training and monitoring by global institutions.

## Using industry power for progress

Lastly, those within the pharmaceutical industry brave enough to lead change will have a dramatic effect. While some pharmaceutical companies are contributing to positive changes within the sector, the industry as a whole can use its unique position to engage with governments on the issue of corruption in the pharmaceutical sector and make the economic argument for corruption's negative effect on business.

---

<sup>148</sup> World Health Organisation, *Financing of Programme budget 2016–2017* (2016a), p.2.



## Adopting technology throughout the pharmaceutical value chain

The adoption of appropriate technology throughout the pharmaceutical value chain can be an effective tool to minimise some of the policy and structural issues enabling corruption in the pharmaceutical sector. Technology can prevent actors from using corrupt practices, allows corruption to be discovered by opening health system operations to scrutiny and diminishes asymmetrical information at key decision points that facilitates corruption.

Organisations like the World Bank have been recommending the adoption of information technology and citizen empowerment as a strategy for increasing transparency and minimising vulnerabilities to corruption.<sup>149</sup> The Medicines Transparency Alliance (MeTA) has focused on ensuring better availability of drug pricing in its pilot countries. For example Peru's MeTA established the online Medicines Pricing Observatory as a mechanism for decreasing drug prices, increasing access to medicines and detecting falsified and substandard medicines.<sup>150</sup>

### Government adoption of technology

The need for “gatekeepers” and unregulated discretion for processes along the pharmaceutical value chain can be reduced by government agencies utilising technology. While it is impossible to completely eliminate face-to-face interactions between actors in the pharmaceutical sector, technology can help reduce or completely eliminate the role of human agents and avenues for opportunistic behaviour by digitalising routine procedures. Through public sector drug pricing portals, behaviour uncertainty is reduced, since managers are no longer able to falsify or distort information, which often results in bribes.<sup>151</sup> Decreasing such behaviour and the chance for private gain will reduce the likelihood of actors using corrupt practices.

Technology facilitates recordkeeping and information management in the pharmaceutical sector. Digital recordkeeping means audits can be carried out more easily and systematically, allowing government officials to verify that money is not being diverted out of the system and identifying what is corruption and what is an inefficiency.<sup>152</sup> For example, the tendering process of a hospital can be monitored through an information technology system that keeps track of drug prices, suppliers, types of medicines being purchased and transactions.<sup>153</sup> In low- and middle-income countries that use highly decentralised paper-based systems, technology will greatly increase the ability to monitor and audit the system. Not only will corruption be discovered, allowing authorities to punish those responsible, but actors will be discouraged from engaging in corrupt behaviour in the future.

---

<sup>149</sup> World Bank, *Corruption Fight Aided by Technology* (2014). Available online:

<http://blogs.worldbank.org/voices/corruption-fight-aided-technology> [Accessed 8/12/14].

<sup>150</sup> Ministerio de Salud Peru, *Observatorio de Productos Farmaceuticos: Sistema Nacional de Informacion de Precios*. Available online: <http://observatorio.digemid.minsa.gob.pe> [Accessed 18/5/15].

<sup>151</sup> Prasad, A., & Shivarajan, S., 'Understanding the role of technology in reducing corruption: a transaction cost approach'. *Journal of Public Affairs*, 15, 1 (2015), p.19.

<sup>152</sup> Hussman, 2010, p.26.

<sup>153</sup> Cohen, J.C., & Montoya, J.C., *Using technology to fight corruption in pharmaceutical purchasing: lessons learned from the Chilean experience*. World Bank Institute (2001), p.3.

The introduction of technology in the pharmaceutical sector generates readily available data that can help inform actors during decision-making and diminish asymmetrical information that facilitates corruption. For example, the use of e-procurement and open contracting makes key information throughout the procurement process transparent and available for public scrutiny. Furthermore, through increased access to real time information on contract awards and evaluation procurement agents are able to get better deals from suppliers, which in the long term leads to lower prices.<sup>154</sup> With medicines taking up a large proportion of national health budgets, lower medicine prices will have a huge impact on governments' ability to achieve UHC.

## Adoption of technology by HCPs and patients

Similarly, new technologies can be adopted by other actors to increase the safety of the distribution of medicines. Patients and HCPs can scan medicines labelled with unique identifiers and send the information to manufacturers to verify their authenticity, facilitating the detection of falsified and substandard medicines. This can help prevent the distribution and use of SSFFC medicines by patients, as well as minimise the diversion of medicines out of the supply chain.

---

<sup>154</sup> Cohen & Montoya, 2001, p.5.

## Ensuring accountability through increased monitoring, enforcement and sanctions

From fines for guilty pharmaceutical companies being too low, to suspensions for corrupt doctors not being issued, actors in the pharmaceutical sector are often not being held accountable for committing corrupt practices. Low levels of accountability result from insufficient performance monitoring, unclear laws and regulations to punish corrupt behaviour, inadequate resources to enforce laws and regulations, and a lack of political and institutional commitment to punish corrupt actors. Therefore, increasing accountability will mean increasing the monitoring and evaluation of performance with efficient information systems and the enforcement of sanctions for non-compliance with laws and regulations.<sup>155</sup>

### Official performance monitoring supported by civil society

To monitor and evaluate the health and pharmaceutical sectors, governments must establish internal control mechanisms and the necessary infrastructure to track all activities and generate performance data. An independent health sector anti-corruption organisation could develop the criteria and standards for internal control mechanisms, apply pressure on governments and intergovernmental organisations to meet these standards and publish the required data. This will facilitate the monitoring of the pharmaceutical sector, which can be carried out by the same organisation or others.

While having internal control mechanisms will allow for the creation of data that will facilitate the tracking of corrupt activity and increase transparency, it alone is not enough to ensure that vulnerabilities to corruption are minimised.<sup>156</sup> The creation of data must be combined with the monitoring of such data. This involves increasing the coverage of who discloses information, improving the reliability and accuracy of data, and ensuring easy accessibility to such data to identify potential issues and hold responsible agents accountable.<sup>157</sup> For example, open contracting is the publishing of key data from health public procurement contracts by default. This will facilitate the monitoring and evaluation of performance indicators against targets and expectations in a way that is effective and reliable.<sup>158</sup> It will also create data that can be used to prosecute corrupt individuals.

Civil society can play a major role in monitoring critical processes within the pharmaceutical sector, as governments are ultimately accountable to citizens. Civil society participation can include acting as watchdog organisations, creating complaint procedures and leading awareness raising campaigns.<sup>159</sup> For this to take place citizens must have the necessary data in an understandable and accessible format. Setting up whistleblowing mechanisms for citizens must come with proper protection, particularly for those working in procurement, healthcare facilities, service providers and medicine suppliers.<sup>160</sup>

---

<sup>155</sup> Brinkerhoff, 2004, p.372.

<sup>156</sup> Ibid, p 372.

<sup>157</sup> Waning & Vian, 2008, p.2.

<sup>158</sup> Cohen et al., 2007, p 48.

<sup>159</sup> European Commission, 2013, p.131.

<sup>160</sup> Transparency International, 'Executive Summary', in Kotalik, J., & Rodriguez, D., (eds.), *Global Corruption Report 2006* (Transparency International, 2006), p.xx.

## Enforcing legislation and applying sanctions to companies

Ensuring accountability is limited by the continued lack of enforcement of laws and regulations. While US authorities currently investigate and punish pharmaceutical sector companies for corrupt practices most vigorously, in many emerging markets local and national companies are not regulated by strong legislation and if they are it can often be weak and lack the scope to effectively prosecute corrupt individuals. Moreover, rigorous, impartial prosecution often does not take place due to a lack of the necessary resources, expertise and legal backing to safeguard legal institutions' autonomy and impartiality to enforce the rule of law. To successfully fight corruption in the pharmaceutical sector all countries must investigate and prosecute equally every individual and organisation involved suspected of corruption. This means providing the necessary resources to public institutions involved in investigations and prosecutions, as well as providing political support to their independent decisions.

While the use of fines can be useful to combat corruption, its effectiveness on deterring multinational pharmaceutical companies from engaging in corrupt behaviour has been debated. Strong evidence has shown that fines issued to pharmaceutical companies by US authorities have been ineffectual. The level of fine a pharmaceutical company pays in the United States is often a very small percentage of the market share it has gained from the corrupt practices.<sup>161</sup> For example, in 2012 GlaxoSmithKline settled for US\$3 billion after pleading guilty to charges of unlawful promotion and failure to report safety data for medicines such as Avandia, Paxil and Wellbutrin; in the same period its sales on all three medicines totalled US\$28 billion.<sup>162</sup>

There are also cases where a pharmaceutical company has received a fine or settled a claim from the US authorities, only several years later to be investigated for similar corrupt practices; this is despite many companies entering into CIAs. For example, in 2002 Pfizer entered into a five-year CIA. Then in 2004 a subsidiary settled for illegal marketing and in 2009 Pfizer settled illegal promotion claims.<sup>163</sup>

To ensure that fines do discourage pharmaceutical companies from engaging in corrupt activities, the penalties issued by the authorities could be modified to seek disgorgement of all profits generated from illegal conduct.<sup>164</sup> As many corruption cases occur when a pharmaceutical company has prioritised profit-making over the needs of public health, a fine that impacts a company's bottom line should be extremely effective in countering corrupt practices, as it removes the financial incentive.

## Applying sanctions to HCPs and researchers

HCPs must be held accountable by professional associations. For example, the UK General Medical Council (GMC) was accused of taking no action in 2012 when it was given evidence that doctors were accepting incentives from private healthcare facilities to give preference to its facilities to treat or refer patients. Only after a later investigation by the Competition and Markets Authority did the GMC write a warning to all licensed doctors.<sup>165</sup> This shows a concerning level of inaction from the GMC on a very serious matter. Professional associations must play an active role in enforcing strong regulations for HCPs.

---

<sup>161</sup> These fines do not take into account class action suits and shareholder derivative litigation

<sup>162</sup> Gagnon, 2013, p.575.

<sup>163</sup> Rodwin, M., 'Do we need stronger sanctions to ensure legal compliance by pharmaceutical firms?' *Food and Drug Law Journal*, 70 (2015), p.437.

<sup>164</sup> Ibid, p.444.

<sup>165</sup> Dyer, C., *Doctors must not accept inducements for referrals, GMC says*. The BMJ (2015).

Similarly, academic institutions must effectively enforce codes of conduct, conflict of interest procedures and other relevant policies for HCPs and researchers and apply appropriate punishment. Increasing funding pressures does not excuse universities from displaying what some say is a systemic unwillingness for universities to punish corrupt behaviour.<sup>166</sup> While universities need to increase their integrity by investigating misconduct, punishing guilty researchers and correcting the research record, a regulatory body that oversees research institutions may be needed in many countries.<sup>167</sup>

---

<sup>166</sup> Wilmschurst, P., *Dishonesty in Medical Research*. Medico-Legal Society. Available online: [http://www.medico-legalsociety.org.uk/articles/dishonesty\\_in\\_medical\\_research.pdf](http://www.medico-legalsociety.org.uk/articles/dishonesty_in_medical_research.pdf) [Accessed 22/4/16].

<sup>167</sup> Smith, R., *Statutory regulation needed to expose and stop medical fraud*. The BMJ (2016).

## 6. Conclusion

As the world enters a new global development agenda with the launch of the SDGs, many of the underlying policy and structural issues throughout the pharmaceutical sector value chain remain. From transparency issues during R&D to unethical drug promotion in marketing practices, key issues caused by corruption and inefficiency continue to undermine health outcomes.

Over the last ten years, global institutions have produced programmes and policies to address some of these issues. Yet, these policies are few and far between and have led to the continued presence of vulnerabilities to corruption throughout the pharmaceutical value chain. This is due to a number of recurrent challenges that make it difficult for governments to create anti-corruption policies. Decentralisation in legislative and regulatory frameworks, compounded by the fact that it is extremely difficult to create global legislation because of the contextual nature of corruption make it problematic to provide strong governance in the pharmaceutical sector. In addition, the high degree of autonomy afforded to the pharmaceutical industry, the industry's vast financial resources, the drivers for maximising profits at the expense of healthcare outcomes and the incentives for HCPs to act unethically, create a breeding ground for corruption to take place. As in any sector, the more ethical companies are disadvantaged, the greater the risk that all companies operate with unethical business practices. This is further facilitated by the lack of government oversight and leadership committed to fighting corruption, including national and international stakeholders.

In particular, corruption in the pharmaceutical sector is not yet treated as a distinct issue by key institutions. There remains a lack of funding for anti-corruption research and interventions, creating a lack of data necessary to understand the complexity of the issue and develop well-tailored anti-corruption initiatives. Often, corruption in the pharmaceutical sector is addressed indirectly through interventions that target other sectors and issues, such as procurement policy and general issues related to state-based corruption. Although international organisations have produced reports focusing solely on corruption in the pharmaceutical sector, we continue to lack an institutional space for discussing this specific issue.

However, the SDGs could be a turning point for pushing corruption in health to the forefront. In contrast to the MDGs, the SDGs are adopting a holistic approach to improving health outcomes and this serves the issue of corruption and health well. The inclusion of Goal 16.5 shows that a key part of improving health systems is strong, effective governance, which anti-corruption policies must be a part of.

Policies must be put in place and enforced that tackle issues throughout the value chain and increase transparency and accountability. Indeed legislation already in place must be enforced, so guilty parties are proportionately punished to deter others from engaging in corrupt practices.

In most cases the adoption of appropriate technology can play a crucial part in supporting such policies. Not only can technology aid in the prevention and discovery of pharmaceutical sector corruption, it can also diminish information asymmetries at key decision points.

In order for such policies to be adopted there must be strong leadership and political will. Only with governments collaborating and global institutions providing clear accountable oversight of the pharmaceutical sector, will it be possible to introduce policies that mitigate institutional corruption. Civil society must play its role in ensuring governments are transparent and accountable and government officials must act with their population's health as the number one concern. Industry must use its knowledge and considerable resources as part of multi-stakeholder initiatives that tackle corruption in the sector.

While the pharmaceutical sector can benefit from general anti-corruption policies and laws, there is a need for targeted and case specific interventions at the local level that are globally reinforced by international legislation on healthcare corruption specifically. There is no universal, all-purpose approach to mitigating corruption in the pharmaceutical sector. Policy makers need to give careful attention as to what strategies would work most effectively in view of the specific risks identified by use of evidence-based data. Only then will each country be able to achieve progress in the health and anti-corruption SDGs.



# Bibliography

- Access to Medicine Index, *Public policy & market influence* (2014). Available online: <http://www.accesstomedicineindex.org/public-policy-market-influence> [Accessed 25/04/16].
- All Ghana News, *Report identities operational lapses at of central medical stores* (2016). Available online: <http://www.allghananews.com/health-lifestyle/68814-report-identifies-operational-lapses-at-of-central-medical-stores-full-report-attached> [Accessed 4/4/16].
- AllTrials, *EMA removes some restrictions from its data sharing policy* (2014). Available online: <http://www.alltrials.net/news/ema-removes-some-restrictions-from-its-data-sharing-policy/> [Accessed 20/4/16].
- Bigdeli, M., Peters, D.H., & Wagner, A.K., *Medicines in health systems: Advancing access, affordability and appropriate use*. World Health Organisation (2014). Available online: [http://www.who.int/alliance-hpsr/resources/FR\\_webfinal\\_v1.pdf](http://www.who.int/alliance-hpsr/resources/FR_webfinal_v1.pdf) [Accessed 4/4/16].
- Brhlikova, P., Harper, I., & Pollock, A., 'Good manufacturing practice in the pharmaceutical industry'. Working paper 3, University of Edinburgh (2007). Available online: [http://www.csas.ed.ac.uk/\\_data/assets/pdf\\_file/0011/38828/GMPinPharmaIndustry.pdf](http://www.csas.ed.ac.uk/_data/assets/pdf_file/0011/38828/GMPinPharmaIndustry.pdf) [Accessed 4/4/16].
- Brhlikova, P., Harper, I., Subedi, M., Bhattarai, S., Rawal, N., & Pollock, A.M., 'Aid conditionalities, international Good Manufacturing Practice standards and local production rights: a case study of local production in Nepal'. *Globalization and Health*, 11, 25 (2015), pp.1-10. Available online: [http://www.research.ed.ac.uk/portal/files/21616169/Brhlikova\\_Harper\\_et\\_al\\_Aid\\_conditionalities\\_2015.pdf](http://www.research.ed.ac.uk/portal/files/21616169/Brhlikova_Harper_et_al_Aid_conditionalities_2015.pdf) [Accessed 4/4/16].
- Brinkerhoff, D.W., 'Accountability and health systems: Toward conceptual clarity and policy relevance'. *Health Policy and Planning*, 19, 6 (2004), pp.371-379. Available online: <http://heapol.oxfordjournals.org/content/19/6/371.full.pdf+html> [Accessed 4/4/16].
- Brown, A.B., 'Understanding pharmaceutical research manipulation in the context of accounting manipulation'. *Journal of Law, Medicine and Ethics*, 41, 3 (2013), pp.611-619. Available online: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2286446](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2286446) [Accessed 4/4/16].
- Carlson, R.V., Boyd, K.M., & Webb, D.J., 'The revision of the Declaration of Helsinki: past, present and future'. *British Journal of Clinical Pharmacology*, 57, 6 (2004), pp.695-713. Available online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1884510/pdf/bcp0057-0695.pdf> [Accessed 4/4/16].
- Cha, A.E., *New analysis shows suicide link for teens on Paxil. 'Mischief' in old study claiming drug is safe* (2015). Available online: <https://www.washingtonpost.com/news/to-your-health/wp/2015/09/17/mischief-in-old-study-showing-paxil-safe-for-teens-new-analysis-shows-increased-suicide-link/> [Accessed 4/4/16].
- Chene, M., 'Approaches to corruption in drug management'. *U4 Expert Answer*, 225 (2009), pp.1-10. Available online: <http://www.u4.no/publications/approaches-to-corruption-in-drug-management/downloadasset/418> [Accessed 20/5/16].

Cohen, J.C., & Montoya, J.C., *Using technology to fight corruption in pharmaceutical purchasing: lessons learned from the Chilean experience*. World Bank Institute (2001). Available online: [http://info.worldbank.org/etools/docs/library/48617/oj\\_chile.pdf](http://info.worldbank.org/etools/docs/library/48617/oj_chile.pdf) [Accessed 4/4/16].

Cohen, J.C., 'Pharmaceuticals and corruption: a risk assessment', in Kotalik, J., & Rodriguez, D., (eds.), *Global Corruption Report 2006* (Transparency International, 2006). Available online: [http://files.transparency.org/content/download/473/1950/file/2006\\_GCR\\_HealthSector\\_EN.pdf](http://files.transparency.org/content/download/473/1950/file/2006_GCR_HealthSector_EN.pdf) [Accessed 4/4/16].

Cohen, J.C., Mrazek, M., & Hawkins, L., 'Corruption and pharmaceuticals: strengthening good governance to improve access', in Edgardo Campos J., & Pradhan, S. (eds.), *The Many Faces of Corruption: Tackling Vulnerabilities at the Sector Level*. World Bank (2007), pp.29-62. Available online: <https://openknowledge.worldbank.org/bitstream/handle/10986/6848/399850REPLACEMENT1010FICIALOUSE0Only1.pdf?sequence=1> [Accessed 4/4/16].

Disch, A., Vigeland, E., & Sundet, G., 'Anti-corruption approaches: a literature review'. *Norwegian Agency for Development Cooperation* (2009). Available online: [http://www.sida.se/contentassets/3f5c8afd51a6414d9f6c8f8425fb935b/anti-corruption-approaches-a-literature-review\\_3153.pdf](http://www.sida.se/contentassets/3f5c8afd51a6414d9f6c8f8425fb935b/anti-corruption-approaches-a-literature-review_3153.pdf) [Accessed 4/4/16].

Dyer, C., *Doctors must not accept inducements for referrals, GMC says*. The BMJ (2015). Available online: <http://www.bmj.com/content/350/bmj.h2098> [Accessed 4/4/16].

Elliott, C., & Landa, A.S., 'Commentary: what's wrong with ghostwriting?' *Bioethics*, 24, 6 (2010), pp.284–286. Available online: <http://onlinelibrary.wiley.com/doi/10.1111/j.1467-8519.2010.01828.x/epdf> [Accessed 4/4/16].

European Commission. *Study on corruption in the healthcare sector*, (2013). Available online: [http://ec.europa.eu/dgs/home-affairs/what-is-new/news/news/docs/20131219\\_study\\_on\\_corruption\\_in\\_the\\_healthcare\\_sector\\_en.pdf](http://ec.europa.eu/dgs/home-affairs/what-is-new/news/news/docs/20131219_study_on_corruption_in_the_healthcare_sector_en.pdf) [Accessed 9/9/15].

Ferrinho, P., & Van Lerberghe, W., *Managing health professionals in the context of limited resources: a fine line between corruption and the need for moonlighting* (2002). Available online: [http://www-wds.worldbank.org/external/default/WDSContentServer/IW3P/IB/2003/10/15/000160016\\_20031015122817/additional/310436360\\_20050276101642.pdf](http://www-wds.worldbank.org/external/default/WDSContentServer/IW3P/IB/2003/10/15/000160016_20031015122817/additional/310436360_20050276101642.pdf) [Accessed 1/5/16].

Fischer, C., 'Corruption in healthcare: a problem in Germany, too'. *Indian Journal of Medical Ethics*, 11, 2 (2014), pp.110-117. Available online: <http://www.issuesinmedicaethics.org/index.php/ijme/article/download/1930/4194> [Accessed 4/4/16].

Gagnon, M.A., 'The crushing cost of pills: a new estimate of pharmaceutical promotion expenditure in the United States'. *PLOS Medicine*, 5, 1 (2008), pp.29-33. Available online: <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050001> [Accessed 25/04/16].

Gagnon, M.A., 'Corruption of pharmaceutical markets: addressing the misalignment of financial incentives and public health'. *Journal of Law, Medicine & Ethics*, 41, 3 (2013), pp.571-580. Available online: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2286415](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2286415) [Accessed 4/4/16].

Gøtzsche, P., Hrobjartsson, A., Johansen, H.K., Haahr, M.T., Altman, D.G., & Chan, A., 'Ghost Authorship in Industry-Initiated Randomised Trials'. *PLoS Medicine*, 4, 1 (2007), pp.47-52. Available online: <http://journals.plos.org/plosmedicine/article/asset?id=10.1371%2Fjournal.pmed.0040019.PDF> [Accessed 4/4/16].

Gulland, A., 'Top drug companies are making drugs more accessible but are also guilty of corruption, report says'. *The BMJ*, 349 (2014). Available online: <http://www.bmj.com/content/349/bmj.g6834> [Accessed 4/4/16].

Gurciullo, B., *Pharmaceutical industry, under scrutiny for prices, has history of big political wins* (2015). Available online: <https://www.opensecrets.org/news/2015/10/pharmaceutical-industry-under-scrutiny-for-prices-has-history-of-big-political-wins/> [Accessed 18/05/16].

Handfield, R., *Biopharmaceutical supply chains: distribution, regulatory, systems and structural changes ahead*. CRC Press (2012).

Hussman, K. *How to note: addressing corruption in the health sector*. Department for International Development (2010). Available online: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/67659/How-to-Note-corruption-health.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/67659/How-to-Note-corruption-health.pdf) [Accessed 9/9/15].

IMS Institute for Healthcare Informatics, *Global Outlook for Medicines through 2018* (2014). Available online: [http://static.correofarmaceutico.com/docs/2014/12/01/informe\\_ims.pdf](http://static.correofarmaceutico.com/docs/2014/12/01/informe_ims.pdf) [Accessed 11/9/15].

Jiao, W., *Drug Review to rid sector of corruption* (2007). Available online: [http://www.chinadaily.com.cn/cndy/2007-02/09/content\\_805232.htm](http://www.chinadaily.com.cn/cndy/2007-02/09/content_805232.htm) [Accessed 1/5/16].

Kohler, J.C., & Ovtcharenko, N., 'Good governance for medicines initiatives: exploring lessons learned'. *U4 Issue*, 3 (2013). Available online: <http://www.u4.no/publications/good-governance-for-medicines-initiatives-exploring-lessons-learned/downloadasset/3355> [Accessed 4/4/16].

Lemmens, T., & Gibson, S., 'Decreasing the data deficit: improving post-market surveillance in pharmaceutical regulation'. *McGill Law Journal*, 59, 4 (2014), pp.943-988. Available online: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2535621](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2535621) [Accessed 4/4/16].

Lewis, M., 'Governance and corruption in public health care systems.' *Center for Global Development*, 78 (2006), pp.1-57. Available online: [http://www1.worldbank.org/publicsector/anticorrupt/Corruption%20WP\\_78.pdf](http://www1.worldbank.org/publicsector/anticorrupt/Corruption%20WP_78.pdf) [Accessed 4/4/16].

Lexchin, J., 'Those who have the gold make the evidence: how the pharmaceutical industry biases the outcomes of clinical trials of medications'. *Science and Engineering Ethics*, 18, 2 (2012), pp.247-261. Available online: <http://link.springer.com/article/10.1007%2Fs11948-011-9265-3> [Accessed 4/4/16].

Lieb, K., & Brandtönes, S., 'A survey of German physicians in private practice about contacts with pharmaceutical sales representatives'. *Dtsch Arztebl Int*, 22 (2010), pp.392-398. Available online: [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2890067/pdf/Dtsch\\_Arztebl\\_Int-107-0392.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2890067/pdf/Dtsch_Arztebl_Int-107-0392.pdf) [Accessed 18/5/16].

Light, D.W., Lexchin, J., & Darrow, J.J., 'Institutional corruption of pharmaceuticals and the myth of safe and effective drugs'. *Journal of Law, Medicine & Ethics*, 41, 3 (2013), pp.590-610.

Available online: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2282014](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2282014) [Accessed 4/4/16].

Lundh, A., Sismondo, S., Lexchin, J., Busuioc, O.A., & Bero, L., 'Industry sponsorship and research outcome'. *Cochrane Database Systematic Reviews*, 12, 12 (2012). Available online: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.MR000033.pub2/full> [Accessed 4/4/16].

Mackey, T.K., Liang, B.A., York, P., & Kubic, T., 'Counterfeit drug penetration into global legitimate medicine supply chains: a global assessment.' *The American Journal of Tropical Medicine and Hygiene*, 92, 6 (2015), pp.59-67. Available online: [http://www.ajtmh.org/content/92/6\\_Suppl/59.full.pdf+html](http://www.ajtmh.org/content/92/6_Suppl/59.full.pdf+html) [Accessed 4/4/16].

Management Sciences for Health, *MDS-3: managing access to medicines and health technologies* (2012). Available online: <http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf> [Accessed 1/5/16].

Michaud, J., Kates, J., & Oum, S., *Corruption and global health: summary of a policy roundtable* (2015). Available online: <http://kff.org/global-health-policy/issue-brief/corruption-and-global-health-summary-of-a-policy-roundtable/> [Accessed 9/9/15].

Miller, J.E., 'From bad pharma to good pharma: aligning market forces with good and trustworthy practices through accreditation, certification, and rating'. *The Journal of Law, Medicine & Ethics*, 41, 3 (2013), pp.601-610. Available online: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2293629](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2293629) [Accessed 4/4/16].

Ministerio de Salud Peru, *Observatorio de Productos Farmaceuticos: Sistema Nacional de Informacion de Precios*. Available online: <http://observatorio.digemid.minsa.gob.pe> [Accessed 18/5/15].

Moran, N., *Transparency measures forced on pharma* (2014). Available online: <http://www.rsc.org/chemistryworld/2014/09/pharma-fines-openness> [Accessed 25/4/16].

Morita, S., & Zaelke, D., *The Rule of Law, Good Governance & Sustainable Development*. Submission to the Seventh International Conference on Environmental Compliance and Enforcement (2005). Available online: [http://www.inece.org/conference/7/vol1/05\\_Sachiko\\_Zaelke.pdf](http://www.inece.org/conference/7/vol1/05_Sachiko_Zaelke.pdf) [Accessed 4/4/16].

New Scientist, *Only full disclosure of drug trial results will maintain trust* (2015). Available online: <https://www.newscientist.com/article/mg22730393-200-only-full-disclosure-of-drug-trial-results-will-maintain-trust/> [Accessed 19/4/16].

Newton, P.N., Green, M.D., Fernández, F.M., Day, N.P., & White, N.J., 'Counterfeit anti-infective drugs'. *The Lancet Infectious Diseases*, 6, 9 (2006), pp.602-613. Available online: [http://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099\(06\)70581-3.pdf](http://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(06)70581-3.pdf) [Accessed 4/4/16].

Nussbaum, D., 'Preface', in Kotalik, J., & Rodriguez, D., (eds.), *Global Corruption Report 2006*. Transparency International (2006). Available online: [http://files.transparency.org/content/download/473/1950/file/2006\\_GCR\\_HealthSector\\_EN.pdf](http://files.transparency.org/content/download/473/1950/file/2006_GCR_HealthSector_EN.pdf) [Accessed 4/4/16].

Office of Management and Budget, *Budget of the US Government: Fiscal Year 2017* (2016). Available online:

<https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/budget.pdf>  
[Accessed 20/4/16].

Olson, R., *Design critique: putting big pharmacy spending in perspective* (2015). Available online: <http://www.randalolson.com/2015/03/01/design-critique-putting-big-pharma-spending-in-perspective/> [Accessed 25/04/15].

Organisation for Economic Cooperation and Development, *Health at a glance 2011: OECD indicators*. Organisation for Economic Cooperation and Development Publishing (2011). Available online: <http://www.oecd.org/els/health-systems/49105858.pdf> [Accessed 4/4/16].

Pansieri, C., Pandolfini, C., & Bonati, M., 'The evolution in registration of clinical trials: a chronicle of the historical calls and current initiatives promoting transparency'. *European Journal of Clinical Pharmacology*, 71, 10 (2015), pp.1159–1164. Available online: <http://link.springer.com/article/10.1007%2Fs00228-015-1897-9> [Accessed 4/4/16].

Persson, A., Rothstein, B., & Teorell, J., 'Why anticorruption reforms fail – systemic corruption as a collective action problem'. *Governance: an international journal of policy, administration, and institutions*, 26, 3 (2013), pp.449–471. Available online: <http://onlinelibrary.wiley.com/doi/10.1111/j.1468-0491.2012.01604.x/abstract> [Accessed 4/4/16].

Petkov, M., *Healthcare companies claim second place on the current FCPA investigation list* (2016). Available online: <http://www.transparency.org.uk/healthcare-companies-claim-second-place-on-the-current-fcpa-investigation-list/> [Accessed 4/4/16].

Prasad, A., & Shivarajan, S., 'Understanding the role of technology in reducing corruption: a transaction cost approach'. *Journal of Public Affairs*, 15, 1 (2015), pp.22–39. Available online: <http://onlinelibrary.wiley.com/doi/10.1002/pa.1484/abstract> [Accessed 4/4/16].

Rauch, J.E., & Evans, P.B., 'Bureaucratic structure and bureaucratic performance in less developed countries'. *Journal of Public Economics*, 75, 1 (2000), pp.49–71. Available online: <http://www.sciencedirect.com/science/article/pii/S0047272799000444> [Accessed 4/4/16].

Rodwin, M., 'Five uneasy pieces to pharmaceutical policy reform'. *Journal of Law, Medicine & Ethics*, 41, 3 (2013), pp.581–589. Available online: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2295002](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2295002) [Accessed 4/4/16].

Rodwin, M., 'Do we need stronger sanctions to ensure legal compliance by pharmaceutical firms?' *Food and Drug Law Journal*, 70 (2015), pp.435–452. Available online: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2654884](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2654884) [Accessed 4/4/16].

Rose, S.L., 'Patient advocacy organizations: institutional conflicts of interest, trust, and trustworthiness.' *The Journal of Law, Medicines and Ethics*, 41, 3 (2013), pp.680–687. Available online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4107906/pdf/nihms603977.pdf> [Accessed 4/4/16].

Ross, T., *Jeremy Hunt: NHS bosses face jail over links to drug firms* (2015). Available online: <http://www.telegraph.co.uk/news/health/11818749/Jeremy-Hunt-NHS-bosses-face-jail-over-links-to-drug-firms.html> [Accessed 18/5/16].

Sasich, L.D., Lurie, P., & Wolfe, S.M., *The drug industry's performance in finishing post-marketing research (phase IV) studies* (2000). Available online: <http://www.citizen.org/hrg1520> [Accessed 25/4/16].

Savedoff, W.D. & Hussmann, K., 'Why are health systems prone to corruption?', in Kotalik, J., & Rodriguez, D., (eds.), *Global Corruption Report 2006*. Transparency International (2006). Available online: [http://files.transparency.org/content/download/473/1950/file/2006\\_GCR\\_HealthSector\\_EN.pdf](http://files.transparency.org/content/download/473/1950/file/2006_GCR_HealthSector_EN.pdf) [4/4/16].

Savedoff, W., *Anti-corruption strategies in foreign aid: from controls to results*. Center for Global Development, Policy Paper 76 (2016), pp.1-17. Available online: <http://www.cgdev.org/sites/default/files/CGD-policy-paper-Savedoff-anticorruption-agenda.pdf> [Accessed 4/4/16].

Securities and Exchange Commission, *SEC charges Johnson & Johnson with foreign bribery* (2011). Available online: <https://www.sec.gov/news/press/2011/2011-87.htm> [Accessed 25/04/16].

Smith, R., *Statutory regulation needed to expose and stop medical fraud*. The BMJ (2016). Available online: <http://www.bmj.com/content/352/bmj.i293> [Accessed 4/4/16].

Spurling, G. K., Mansfield, P. R., Montgomery, B. D., Lexchin, J., Doust, J., Othman, N., & Vitry, A. I. 'Information from pharmaceutical companies and the quality, quantity, and cost of physicians prescribing: a systematic review'. *PLoS Medicine*, 7, 10 (2010), pp.1-22. Available online: <http://journals.plos.org/plosmedicine/article/asset?id=10.1371%2Fjournal.pmed.1000352.PDF> [4/4/16].

Sridhar, D., & Clinton, C., 'Overseeing global health'. *Finance & Development*, 51, 4 (2014), pp.26-29. Available online: <http://www.imf.org/external/pubs/ft/fandd/2014/12/pdf/sridhar.pdf> [Accessed 4/4/16].

Stern, S., & Lemmens, T., 'Legal remedies for medical ghostwriting: imposing fraud liability on guest authors of ghostwritten articles'. *PLOS Medicine*, 8, 8 (2011), pp.1-5. Available online: <http://journals.plos.org/plosmedicine/article/asset?id=10.1371%2Fjournal.pmed.1001070.PDF> [Accessed 4/4/16].

The Guardian, *Ex-UN consultants jailed for bribes over drugs supplied to 'starving Africans'* (2015). Available online: <http://www.theguardian.com/uk-news/2015/sep/23/un-guido-bakker-sijbrandus-scheffer-jailed-contracts-drugs-congo> [Accessed 4/4/16].

The Telegraph, *India terminates AgustaWestland helicopter deal* (2014). Available online: <http://www.telegraph.co.uk/finance/newsbysector/industry/defence/10545808/India-terminates-AgustaWestland-helicopter-deal.html> [Accessed 4/4/16].

Toebes, B., 'Human rights and health sector corruption', in Harrington, J., & Stuttaford, M., (eds.), *Global Health and Human Rights*. Routledge (2010), pp.102-134.

Transparency International, *Integrity Pacts*. Available online: [https://www.transparency.org/whatwedo/tools/integrity\\_pacts/3/](https://www.transparency.org/whatwedo/tools/integrity_pacts/3/) [Accessed 4/4/16].

Transparency International, 'Executive Summary', in Kotalik, J., & Rodriguez, D., (eds.), *Global Corruption Report 2006* (Transparency International, 2006). Available online: [http://files.transparency.org/content/download/473/1950/file/2006\\_GCR\\_HealthSector\\_EN.pdf](http://files.transparency.org/content/download/473/1950/file/2006_GCR_HealthSector_EN.pdf) [4/4/16].



Transparency International UK, *Anti-corruption summit commitments on procurement will be key for the health sector* (2016). Available online: <http://www.transparency.org.uk/press-releases/anti-corruption-summit-commitments-on-procurement-will-be-key-for-the-health-sector/> [Accessed 16/5/16].

Turner, E.H., Matthews, A.M., Linardatos, E., Tell, R.A., & Rosenthal, R., 'Selective publication of antidepressant trials and its influence on apparent efficacy'. *New England Journal of Medicine*, 358 (2008), pp.252-260. Available online: <http://www.nejm.org/doi/pdf/10.1056/NEJMsa065779> [Accessed 4/4/16].

United Nations Development Programme, *Fighting corruption in the health sector: methods, tools and good practices* (2011). Available online: [http://www.undp.org/content/undp/en/home/librarypage/democratic-governance/anti-corruption/fighting\\_corruptioninthehealthsector.html](http://www.undp.org/content/undp/en/home/librarypage/democratic-governance/anti-corruption/fighting_corruptioninthehealthsector.html) [Accessed 11/9/15].

United Nations Development Programme, *Strengthening the rule of law in crisis-affected and fragile situations: Global Programme Annual Report 2014*. United Nations Development Programme (2014). Available online: [http://www.undp.org/content/dam/undp/library/Democratic%20Governance/Access%20to%20Justice%20and%20Rule%20of%20Law/Global\\_Programme\\_Rule\\_of\\_Law-Annual\\_Report\\_2014.pdf?download](http://www.undp.org/content/dam/undp/library/Democratic%20Governance/Access%20to%20Justice%20and%20Rule%20of%20Law/Global_Programme_Rule_of_Law-Annual_Report_2014.pdf?download) [Accessed 4/4/16].

United Nations Economic and Social Commission for Asia and the Pacific, *What is Good Governance?* (2009). Available online: <http://www.unescap.org/sites/default/files/good-governance.pdf> [Accessed 14/2/14].

United Nations, *Secretary-General warns corruption 'threat to development, democracy and stability', urges strong steps against it by governments, business leaders, in message on day* (2010). Available online: <http://www.un.org/press/en/2010/sgsm13292.doc.htm> [Accessed 18/9/16].

United States Department of Justice, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (2012). Available online: <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report> [Accessed 4/4/16].

United States Department of Justice, *Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA* (2013a). Available online: <https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false> [Accessed 4/4/16].

United States Department of Justice, *Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations* (2013b). Available online: <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations> [Accessed 4/4/16].

Vian, T., 'Review of corruption in the health sector: theory, methods and interventions'. *Health Policy and Planning*, 23, 2 (2008), pp.83–94. Available online: <http://heapol.oxfordjournals.org/content/23/2/83.full.pdf+html> [Accessed 4/4/16].

Waning, B., & Vian, T., 'Transparency and accountability in an electronic era: the case of pharmaceutical procurements'. *U4 Brief*, 10 (2008), pp.1-4. Available online:



<http://www.u4.no/publications/transparency-and-accountability-in-an-electronic-era-the-case-of-pharmaceutical-procurements/downloadasset/97> [Accessed 4/4/16].

Wilmshurst, P., *Dishonesty in Medical Research*. Medico-Legal Society. Available online: [http://www.medico-legalsociety.org.uk/articles/dishonesty\\_in\\_medical\\_research.pdf](http://www.medico-legalsociety.org.uk/articles/dishonesty_in_medical_research.pdf) [Accessed 22/4/16].

World Bank, *Reforming public institutions and strengthening governance*. World Bank (2000). Available online: <http://www1.worldbank.org/publicsector/Reforming.pdf> [Accessed 4/4/16].

World Bank, *Corruption is "Public Enemy Number One" in Developing Countries, says World Bank Group President Kim* (2013). Available online: <http://www.worldbank.org/en/news/press-release/2013/12/19/corruption-developing-countries-world-bank-group-president-kim> [Accessed 17/9/15].

World Bank, *Corruption Fight Aided by Technology* (2014). Available online: <http://blogs.worldbank.org/voices/corruption-fight-aided-technology> [Accessed 8/12/14].

World Health Organisation, *Measuring transparency in the public pharmaceutical sector: assessment instrument* (2009). Available online: <http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspENG.PDF> [Accessed 19/4/16].

World Health Organisation, *The World Health Report* (2010). Available online: [http://www.who.int/whr/2010/whr10\\_en.pdf?ua=1](http://www.who.int/whr/2010/whr10_en.pdf?ua=1) [Accessed 9/9/15].

World Health Organisation, *Fact sheet on health technologies: selected results from the baseline country survey on medical devices 2010 – European region* (2011). Available online: [http://www.euro.who.int/\\_data/assets/pdf\\_file/0011/140051/Fact\\_sheet\\_HT\\_2011.pdf](http://www.euro.who.int/_data/assets/pdf_file/0011/140051/Fact_sheet_HT_2011.pdf) [Accessed 4/4/16].

World Health Organisation, *WHO Financing Dialogue 2015: meeting report*. World Health Organisation (2015). Available online: [http://www.who.int/about/resources\\_planning/financing\\_dialogue/Meeting-report-final.pdf](http://www.who.int/about/resources_planning/financing_dialogue/Meeting-report-final.pdf) [Accessed 26/4/16].

World Health Organisation, *Financing of Programme budget 2016–2017* (2016a). Available online: [http://apps.who.int/gb/ebwha/pdf\\_files/EB138/B138\\_42-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB138/B138_42-en.pdf) [Accessed 26/4/16].

World Health Organisation, *Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products* (2016b). Available online: <http://www.who.int/mediacentre/factsheets/fs275/en/> [Accessed 4/4/16].

