



# Life Science Compliance *Update*

U.S. EDITION

Volume 3.11 | 2017

## Why It Matters

### *Pharmaceutical Compliance, Anti-corruption and Access to Medicine*

Luca Genovese and Danny Edwards,  
*The Access to Medicine Foundation*<sup>1</sup>

**Abstract:** *Access to medicine continues to be out of reach for an estimated two billion people worldwide. While it is clear that corruption plays a role in that problem, the true scope and cost of global health corruption is unknown. This article examines what pharmaceutical companies do and what role they should play in eliminating corruption as part of the equation of ensuring access.*

In the global health sector, it is estimated that \$7.35 trillion (U.S.) was spent worldwide in 2013 on the provision of health services, with a loss rate of 6.19%, equating to \$455 billion (U.S.) in losses.<sup>2</sup> The loss can be attributed to fraud, corruption, or errors.

This loss figure takes on much greater significance when juxtaposed with the opportunity-cost it means to the health of real people, and in particular to the world's most vulnerable citizens. Globally, there are an estimated 2 billion people with no access to medicine, with most of these living in low- and middle-income countries. There are various causes for this lack of access: corruption and unethical behaviour in the pharmaceutical sector can be counted amongst them.

Researchers agree that the true scope and cost of global health corruption is largely unknown.<sup>3</sup> Corruption can be invisible, difficult to detect and highly politicised, all of which require better indicators, data collection/reporting, and analysis. It is recognised however that corruption can harm people in various ways:<sup>4</sup> by forcing populations in low and middle-income countries ("LMICs") to make sub-optimal choices, such as purchasing medicines from unqualified or illegal sellers in order to save money; by compromising access when medicines are simply unavailable in the public health system; and by having to purchase less-affordable medicines in the private health sector.<sup>5</sup> In LMICs, up to 90% of spending on medicines is made on an out-of-pocket basis.<sup>6</sup> Inflated or unexpected

healthcare expenses can result in catastrophic impacts on household budgets.

Pharmaceutical companies are a significant actor in the pharmaceutical value chain. They have a clear role and responsibility to limit the incidence of corrupt acts in the areas they intersect with, and through this, to mitigate the harmful impact corruption can have on access to medicine. However, the value chain is complex, composed of many steps and many transactions involving large sums of money, and many actors from both the private and public sectors. It is an inherently difficult system to govern. Factors which can act as additional incentives for corrupt behaviour and which can frustrate the effort to limit it include:

- **Market uncertainty** – The market for pharmaceuticals can be volatile, with a limited ability to forecast demand. Companies are pressured to secure the maximum revenue possible during a limited period of market exclusivity. These factors can encourage inefficient allocation of scarce resources to medicines;
- **Conflicting interests** – Individual or commercial interests can conflict with the broader interests of the health system to safeguard public health. This can be the case when incentive structures for company sales agents are focused on achieving the sale of large volumes of medicines, regardless of whether those medicines are needed within the health system or not;

<sup>1</sup> *The Access to Medicine Foundation's mission is to stimulate and guide pharmaceutical companies to do more for the people living in low- and middle-income countries without access to medicine. The Foundation talks to experts about the actions pharmaceutical companies can and should be taking in this regard. It then analyses what specific companies are doing, and uses the findings of this research to drive change. The Foundation is an independent, non-profit organization.*

<sup>2</sup> See Jim Gee and Mark Button, *The financial cost of healthcare fraud 2015, EUROPEAN HEALTHCARE FRAUD AND CORRUPTION NETWORK (Sep. 2015)* at <https://www.pianoo.nl/sites/default/files/documents/documents/thefinancialcostofhealthcarefraud-september2015.pdf>.

<sup>3</sup> See T. K. Mackey, *The disease of corruption: Views on how to fight corruption to advance 21st century global health goals*, 14 *BMC Med.* 149 (2016).

<sup>4</sup> See *id.*; see also J.C. Kohler, *Why making the invisible visible matters for global access to medicines*, 14 *BMC Med.* 149 (2016).

<sup>5</sup> See Kohler, *supra*.

<sup>6</sup> See World Health Organization, *WHO Guideline On Country Pharmaceutical*

- **Information asymmetry** – Patients typically lack the knowledge to understand treatments and medicines and rely on doctors, whose prescribing decisions are targeted by pharmaceutical sales agents and may not be taken with the primary consideration of the patients’ needs.<sup>7</sup>

Complicating the landscape further is the reality that in many low- and middle-income countries there are weak systems of governance in place. Poor governance marked by weak institutions, an absence of rule of law, and a lack of enforcement, creates the ideal conditions for corruption to thrive. This can further contribute to health system failure.<sup>8</sup> Despite international organisations, such as the UNDP and the World Bank assisting countries in the development of new laws and institutions, these often remain too weak.<sup>9</sup>

Considering all these points together, it becomes evident that corruption in the healthcare sector has a direct negative impact on access to medicine, and that this effect is exacerbated both by the complexity of the system and the fact that weakness in governance is more likely to exist where the need for access is greatest. As noted at the outset, pharmaceutical companies, as the developers, manufacturers, and distributors of medicines, have a role to play in the minimisation of these risks and impacts.

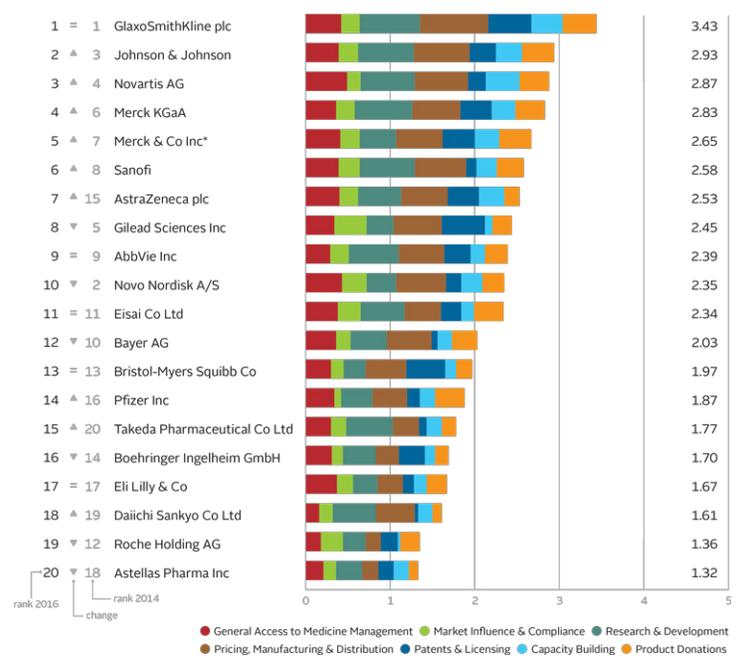
## The Access to Medicine Foundation and the Access to Medicine Index

The Access to Medicine Index analyses 20 of the top research-based pharmaceutical companies with products for high-burden diseases in low- and middle-income countries. The Index ranks these companies according to their efforts to improve access to medicine. It identifies best practices, highlights where progress is being made, and uncovers where critical action is still required. In this way, the Index provides both an incentive and a guide for pharmaceutical companies to do more for people who still lack access to medicine. The Access to Medicine Index is published every two years. (See Figure 1, The 2016 Access to Medicine Index).

Over the past decade, the Access to Medicine Foundation has developed a robust process for building consensus among a wide range of stakeholders on what society expects of pharmaceutical companies regarding access to medicine in low and middle-income countries. These expectations are then translated into metrics that form the basis of the methodology for each Access to Medicine Index, including in the research area of Market Influence & Compliance.

Throughout each methodology review, strategic guidance is provided by the Expert Review Committee (“ERC”), a panel

**Fig 1. The 2016 Access to Medicine Index – Overall Ranking**



Source: Access to Medicine Foundation

of independent experts from the WHO, governments, patient organisations, the industry, NGOs, academia, and investors, among others. Recommendations on specific topics of the Index are provided by Technical Subcommittees: panels of specialists in different aspects of access to medicine.

The Foundation’s research team also worked with experts and stakeholders from a wide range of backgrounds to ensure alternative viewpoints and technical expertise were incorporated. This included discussions with representatives of multilateral organisations, research institutions, NGOs, investors, and companies.

The Access to Medicine Index analyses the level of engagement by pharmaceutical companies in addressing corruption, as well as the kinds of commitment they make to existing guidelines, how they enforce and audit the standards of behaviour they apply, the level of information they share about incidents they have been implicated in and the follow-up action taken.

The 2016 Access to Medicine Index indicated that the efforts of large R&D based pharmaceutical companies to improve ac-

7 See M. Baily, *Comments on Berndt, Cockburn, Griliches, Pharmaceutical Innovations and Market Dynamic, Brookings Papers on Economic Activity: Microeconomics, Brookings Institution (Washington, D.C. 1997).*

8 See Kolher, *supra*.

9 See Transparency International, *Corruption in the Pharmaceutical Sector, (Jun. 2016) available at <http://www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/#.WeuYCRNSwjc>.*

cess to their medicines in low- and middle-income countries can be put at risk by misconduct and the unethical behaviour of their employees, the third parties they interact with in the manufacture, distribution and sales of their medicines, and of the many other actors they interact with in the value chain. In addition, the 2016 Access to Medicine Index described some of the steps they can take to mitigate the risk of corruption occurring (See Figure 2, The Compliance Chain).

## Research Findings From the 2016 Access to Medicine Index

The 2016 Access to Medicine Index found that company approaches to the management of compliance through, for example, developing codes of practice in line with international standards, and the application of these to third parties, did not correspond with an absence of corrupt incidents.<sup>10</sup>

**Fig 2. The Compliance Chain**



Source: Access to Medicine Foundation

## Why This Matters for Pharmaceutical Companies, and What Role They Can Play

A primary part of the fight against corruption in the pharmaceutical system is the implementation of stringent governance mechanisms. This is the primary responsibility of national and local governments. However, pharmaceutical companies also have a clear role to play to support these efforts and to minimise the risk of unethical practices. Companies are increasingly present or are expanding into low- and middle-income country markets where, as we have noted, governance systems may be weaker.

In the area of Market Influence & Compliance, the Foundation identified that stakeholders expect that in low- and middle-income country contexts pharmaceutical companies apply the most stringent compliance standards that they would apply in well-regulated markets, such as the U.S. and the EU. Alongside these standards, and especially where regulatory controls are weak, stakeholders expect the implementation of stringent and effective company compliance systems to ensure that those standards are enforced.

All 20 companies evaluated have in place a code (or codes) of conduct to prevent the risks of corruption and unethical marketing practices. Ten companies evaluated (AstraZeneca, Bristol-Myers Squibb, Gilead, GSK, Johnson & Johnson, Merck KGaA, Merck & Co., Inc., Novo Nordisk, Pfizer, and Takeda) have mechanisms through which they can enforce those codes on third parties (through, for example, contractual agreements). This practice ensures the broader outreach of company codes, and minimises the risk of engaging and doing business with third parties that may not align with company standards of behaviour.

Seven companies (AstraZeneca, Bayer, Eisai, Eli Lilly, GSK, Merck KGaA and Novartis) are using incentives for their salesforce which are

not driven exclusively by sales volumes. These companies incentivise sales agents using parameters which measure their performance, such as the technical knowledge they show regarding products and the quality of service they provide to their counterparts, aimed at minimising the potential negative effects of target-driven sales on the rational prescribing practices of health care practitioners.

Companies also engage in a range of market-influencing activities in order to build the acceptance and use of their products. These can – when deployed inappropriately – unduly influence politicians to propose regulations harmful for access to medicine, and influence public officials and/or healthcare professionals to make purchasing and prescribing decisions on grounds other than the best evidence, putting patient safety and access to medicine at risk.

To allow stakeholders to scrutinise these activities and decide whether these interactions are appropriate and ensure companies can be held accountable, companies can publicly share the financial contributions they make, and the policy positions they hold. This kind of transparency can also

<sup>10</sup> See Access to Medicine Foundation, Access to Medicine Index 2016, available at <https://accesstomedicineindex.org/>.

help minimise the occurrence of misconduct in marketing and lobbying practices by holding both payer and recipient accountable to the public: this is one reason why the Access to Medicine Index includes an analysis of transparency of marketing and lobbying practices next to its analysis of compliance systems of pharmaceutical companies.

When analysing the ways companies manage their financial contributions to political parties and/or politicians, the Index found that only two companies – Merck KGaA and GSK - have a public statement about a prohibition on such payments, while another ten companies declared to the Index (but not publicly) that they did not make these payments in countries within the geographic scope of the Index (107 low- and middle-income countries). Almost none of the companies disclosed payments made to healthcare practitioners anywhere it is not required by law or by trade association requirements. One exception to this is Merck & Co., Inc., which discloses on its website some marketing-related payments to medical associations, clinics and patient organisations where this is not a legal requirement.

Aside from the actions identified above, companies can and do take a range of other complementary actions aimed at minimising the risk of corruption in their workforce and with the third parties they interact with. Figure 2 shows a series of good practices identified by the 2016 Index. Through the steps of hiring, on-boarding, and evaluating work performance, companies can implement a series of initiatives to enhance their compliance systems. Three examples are detailed here:

- Takeda is piloting an ethical screening process that it applies to prospective employees during recruitment. It consists of a questionnaire designed to identify potential areas of concerns, and scenarios for testing applicants' ethical decision-making processes.
- To mitigate against potential conflicts of interest, GSK introduced a global policy to implement a “cooling off” period for staff hired from the public sector. These staff are not permitted to work on any project from their previous role for six months. This includes a ban on engaging with former colleagues still working on those projects. This restriction is aligned with existing rules for U.S. hires, as described in the U.S. Government wide post-employment statute, 18 U.S.C. 207.
- Gilead distributes a pocket guide to its business partners to strengthen their compliance mechanisms. This detailed tool was introduced in 2014 and focuses on a wide variety of interactions and activities with physicians and government officials. This approach reflects Gilead's business model, which largely relies on third-party distributors. Gilead also offers in-person compliance courses, featuring case-based scenarios to business partners in multiple regions.

## New Measurements in the 2018 Access to Medicine Index

As part of the 2017 review of the Access to Medicine Index methodology, the Access to Medicine Index Research team engaged with a range of organisations and experts in the field of pharmaceutical compliance and anti-corruption, including Alex Almici, from the University of Brescia, Sarah Steingrüber, from the Pharmaceuticals and Healthcare Programme of Transparency International, and Joel Lexchin from York University. The methodology review was supported with the oversight and advice of Michele Forzley from Forzley & Associates and Jillian Kohler from the University of Toronto, who together compose the Technical Subcommittee for the Index area of analysis on Market Influence & Compliance.<sup>11</sup>

The Access to Medicine Index Research team mapped some of the actions companies can take to minimise the risk of corrupt action occurring. This review focused on the quality and composition of internal control frameworks. Internal control is a process designed to provide reasonable assurance regarding the achievement of company objectives relating to operations, reporting, and – importantly - compliance.

Based on research in this area, and discussions held with experts, the Index will measure both processes (fraud-specific risk assessments, live or ongoing monitoring, segregation of duties) and structures (roles and responsibilities for compliance, committees and reporting lines) that can be part of these frameworks, and whether companies apply these frameworks in all countries where they have operations, and to their third parties. An in-depth analysis of the composition and quality of internal control frameworks will allow the Index to compare and differentiate the compliance systems of the pharmaceutical companies it ranks. This builds on measures introduced in 2016 related to auditing mechanisms, which are one of the internal controls of compliance systems.

The new methodology that will support the analysis for the 2018 Access to Medicine Index was recently published and is freely downloadable at.<sup>12</sup> The 2018 Access to Medicine Index will be published at the end of 2018.

<sup>11</sup> See Committee of Sponsoring Organizations of the Treadway Commission, *Internal Control – Integrated Framework*, (2013) available at [https://na.theiaa.org/standards-guidance/topics/Documents/Executive\\_Summary.pdf](https://na.theiaa.org/standards-guidance/topics/Documents/Executive_Summary.pdf).

<sup>12</sup> Download here [www.accesstomedicineindex.org](http://www.accesstomedicineindex.org).

Copyright © 2016, Life Science Compliance Update This publication may not be reproduced in any form without express consent of the publisher. Reprints of this publication can be obtained by contacting:

**Life Science Compliance Update**  
Visit [www.lifescicompliance.com](http://www.lifescicompliance.com)