

Pharmaceutical compliance and access to medicine

Luca Genovese
Access to Medicine Foundation

Asia Pacific Pharmaceutical and Medical Device Compliance Congress
15 September 2017, Shanghai

Overview

- The Access to Medicine Foundation
- Compliance, anti-corruption and access to medicine
- The Access to Medicine Index
- Index findings on market influence and compliance

The Access to Medicine Foundation

The Access to Medicine Foundation

- Our mission is to guide and incentivise pharmaceutical companies to improve access to medicine in low- and middle-income countries
- Independent, non-profit organisation



Ministry of Foreign Affairs
of the Netherlands



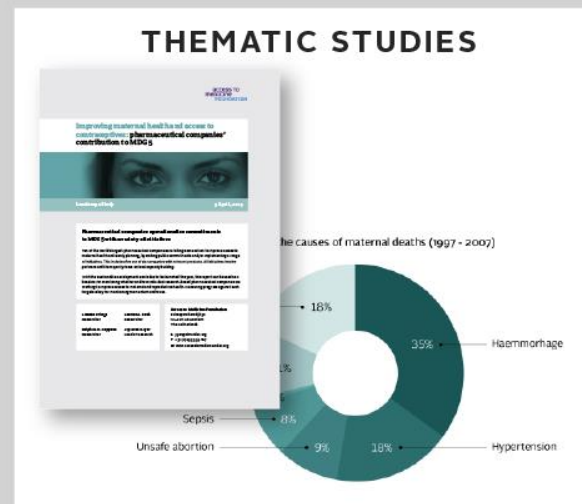
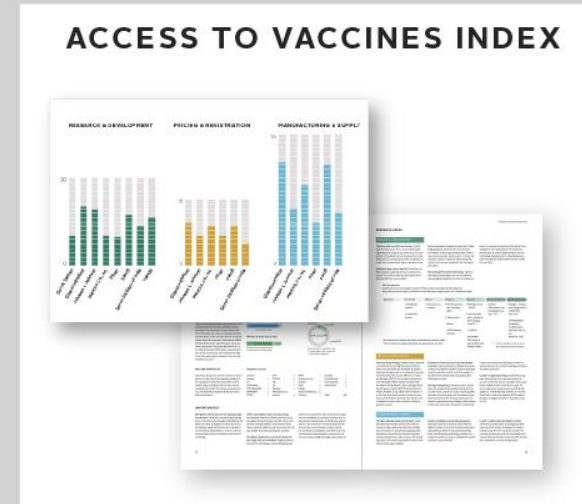
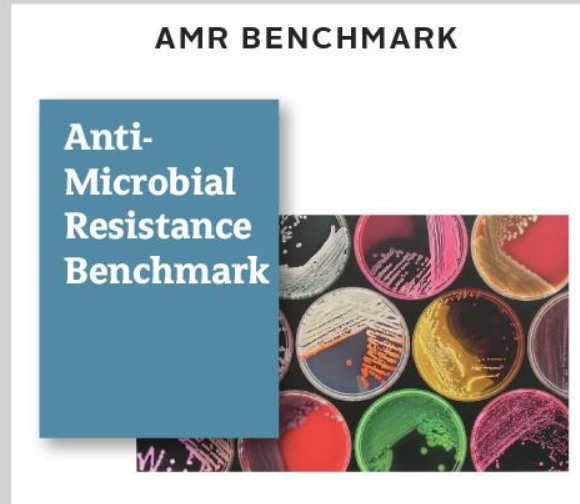
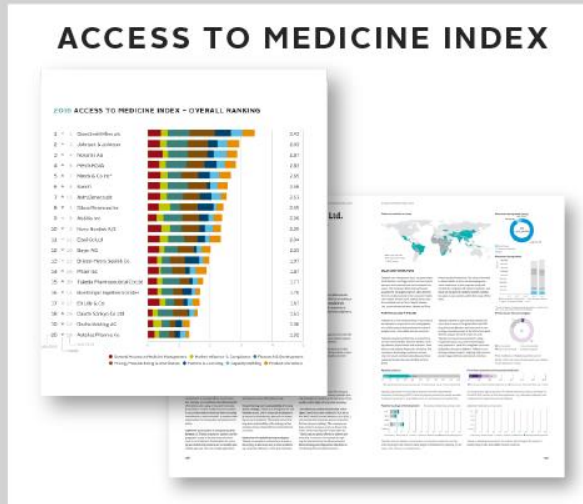
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GATES *foundation*

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What we do



Our model for change

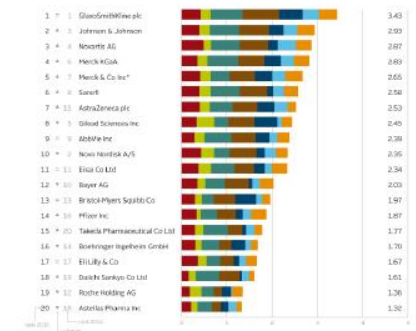
Build consensus

on what to expect from the industry and where incentives and disincentives exist.



Stimulate a “race to do well”

in key access-to-medicine areas, by creating competition on targets and topics.



Diffuse best practices

to share information and new insights into the best approaches for driving change.



Funders



“The companies at the top of the Index want to do more. The ones at the bottom see that and push forward on it.”

Bill Gates



Investors



“The Index is a useful and robust benchmark for companies, investors and stakeholders to compare a range of industry approaches to improve access to medicine.”

Yo Takatsuki
Associate Director, Governance
and Sustainable Investment
BMO Global Asset Management
(EMEA)

Pharma Companies



“The Index challenges us to think harder about how we drive innovation and enable access to our products.”

Sir Andrew Witty, former GSK CEO

Global Health



“The Index is a very important project. What gets measured, gets done.”

Dr Margaret Chan

Media



“While progress is uneven, many drug makers are, by and large, making headway. In fact, access is increasingly seen as a necessary business issue.”

Wall Street Journal

Which Big Drug Companies Are Helping the Poor? Here's the List

Global Health
By DONALD G. NELSON Jr. NOV 13, 2016



Director Access to Medicine

Er moet nog veel verbeterd worden

Basler Zeitung WIRTSCHAFT

Basel Schweiz Ausland Börse Wirtschaft Kultur Sport Auto Leben

Lob und Tadel für die Pharmakonzerne

Index überprüft das Engagement der Firmen in Entwicklungsländern

Die Pharmakonzerne sind in den letzten Jahren immer mehr in den Fokus der Öffentlichkeit geraten. Die Basler Zeitung hat sich mit dem Thema beschäftigt und überprüft das Engagement der Firmen in Entwicklungsländern. Die Pharmakonzerne sind in den letzten Jahren immer mehr in den Fokus der Öffentlichkeit geraten. Die Basler Zeitung hat sich mit dem Thema beschäftigt und überprüft das Engagement der Firmen in Entwicklungsländern.



Tuesday 15 November 2016

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GSK leads on medicines access in developing countries, but room for improvement

November 14, 2016

Access to life-saving and life-changing medicines in poorer countries is improving year on year, but there is still more to be done, according to findings of the 2016 Access to Medicines Index.

Published today, the 2016 Index sees GlaxoSmithKline top the list for a fourth time, with Johnson & Johnson, Novartis, and Merck KGaA placed second, third and fourth in the index respectively.

The index is compiled every other year by the Access to Medicine Foundation and is widely considered to be the benchmark for determining industry progress in providing vital medicines in developing countries.



Director Access to Medicine

Er moet nog veel verbeterd worden

FINANCIAL TIMES

WORLD LEADERS COMPANIES MARKETS OPINION MARKS & SPENCER

Drug prices

Big pharma failing to do enough for poor countries

Access to Medicine Index says moderate progress made in improving access to medicine



Some of the world's biggest drug companies are failing to do enough to provide medicines to poor countries, and the industry as a whole has made almost no progress in making treatments more affordable, the latest Access to Medicine Index has revealed.

The Access to Medicine Index is an annual report that ranks the world's top 100 pharmaceutical companies on their commitment to providing medicines to poor countries. The index is compiled every other year by the Access to Medicine Foundation, an independent charity based in the Netherlands.

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Genees de wereld

Pharmaceutische bedrijven moeten hun geneesmiddelen bereikbaar maken voor arme mensen. Dat eisen deskundigen steeds vaker.

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Pharmaceuticals industry

GSK tops list of drug firms improving global access to medicine

Company leads list compiled by Access to Medicine, which measures pharmaceutical industry's efforts to spread facilities



GlaxoSmithKline has some of a longer track record in the availability of medicines in developing countries, with fellow UK drugmaker AstraZeneca ranking it in the top 10.

The new global Access to Medicine foundation, which compiles the biennial index of drug companies, ranked them while the availability of medicines is improving, the industry needs to do more on affordable pricing and the fight against

Forbes Pharma & Healthcare #PublicHealth

NOV 13, 2016 @ 09:28 PM 3,870 VIEWS

New Pharma Rankings On Global Access To Medicine Released

Judy Stone, CONTRIBUTOR

I cover infectious diseases, medicine, drug development, and ethics. FULL BIO >

Opinions expressed by Forbes Contributors are their own.

At least 2 billion people don't have access to medicines they need, according to the Access to Medicine Foundation and others.

5 billion people have access

THE LANCET

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Access to Medicine Index—what about sustainability?

changes in overall development... necessary for countries to have contingency funds to have contingency funds to have contingency funds



pharmaceutical companies... changes in overall development... necessary for countries to have contingency funds to have contingency funds to have contingency funds

Home Business Economics Banking Retail Markets Europe

Pharma lijkt toch armsten te helpen

Access to Medicine Index

in welke mate... denbedrijven zich... en voor goede doelen



08.21u - Ellen de Visser - Bron: Volkskrant

Pharmaceutical companies... changes in overall development... necessary for countries to have contingency funds to have contingency funds to have contingency funds

REUTERS

Markets World Politics Tech Commentary Breaking News Money Life >

Drugmakers improve access for poor, GSK ranked top

HEALTH NEWS | Last Nov 10, 2016 | 7:08am EDT



Pharmaceutical companies... changes in overall development... necessary for countries to have contingency funds to have contingency funds to have contingency funds

THE HINDU

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Delivery strategies rank high for Big Pharma, now

PT JYOTHI DATTA

1 Pharma Stocks to Buy 2 Top 10 Pharma Stocks 3 Top Dividend Stock

Pharmaceutical companies... changes in overall development... necessary for countries to have contingency funds to have contingency funds to have contingency funds

2016 ACCESS TO MEDICINE INDEX - OVERALL RANKING

Rank	Company	Score
1	GlaxoSmithKline	88
2	Johnson & Johnson	86
3	Novartis	84
4	Merck KGaA	82
5	AstraZeneca	80
6	Roche	78
7	Sanofi	76
8	Amgen	74
9	Abbott	72
10	Novartis	70

Big Pharma is usually seen as the villain in the healthcare story, often perceived as putting profits before patients.

But an initiative by the Netherlands-based Access to Medicine Foundation, an independent non-profit organization, is pushing the pharma big daddies to compete and collaborate on improving access to medicines.

And the Foundation does this through the Access to Medicine Index, a biennial report that assesses companies on seven criteria in corporate behaviour including pricing, patents, ethics and donations.

In its fifth report since inception, the Index put GlaxoSmithKline at the top, for the fifth time, it emerged the best in matching access activities with patient needs, the Index report said.

Close on its heels came Johnson & Johnson, Novartis and Merck KGaA.

11-16 18:08

2016 Access to Medicine Index榜单正式发布，自2008年首次发布以来，GSK连续5次蝉联榜首，今年发布的榜单中，GSK连续5次蝉联榜首，今年发布的榜单中，GSK连续5次蝉联榜首

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世界上仍然有20亿人用不起或买不到药物。为此，Access to Medicine Index

Drug firms need to tackle affordability

Aree Gulistan

Drug companies need to do more to make their products affordable to patients in low and middle income countries, an investigation by the Access to Medicine Index has found.

The Access to Medicine Index, which is published every two years and ranks companies according to how they make their products available to patients in poorer countries, found little progress in improving affordability.

There are currently 100 products on the market for the 16 most vulnerable countries in low and middle income countries. Companies are developing another 100, which includes about 100 products that have entered the market since 2014 and 15 that have not even entered the market but are expected to do so in the next few years.

The index found that just 4% (six) of the 100 products had pricing strategies that took into account the ability to pay a common reference price in the highest poverty. Most of these products were manufactured by the three companies: GSK, AstraZeneca, and Sanofi.

The report said that since 2014 access companies had published more on expanded pricing to meet or improve upon their current pricing in low and middle income countries, such as Mexico and Thailand, where most of the world's poorest people live, were not included.

But the report also noted that GSK was the only company that had published more on expanded pricing to meet or improve upon their current pricing in low and middle income countries, such as Mexico and Thailand, where most of the world's poorest people live, were not included.

However, although companies were making progress on expanded pricing to meet or improve upon their current pricing in low and middle income countries, such as Mexico and Thailand, where most of the world's poorest people live, were not included.

NOS News Sport Lezingen

'Triaat dat mensen na lang horen dat hun medicijn er

BRUNO VAN DER BRUG



De invloed van de zogenoemde Index of Access to Medicine onmiskenbaar, maar het wil nog niet vlotter met het toegenome medicijnen voor mensen in arme landen. Dat blijkt uit de vanc gepubliceerde vijfde editie van de ranglijst.

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60 investors: AUM in excess of USD 5.5 trillion

access to
MEDICINE
FOUNDATION



Compliance, anti-corruption and access to medicine

WHO's Access to medicine framework (2004)



Source: WHO

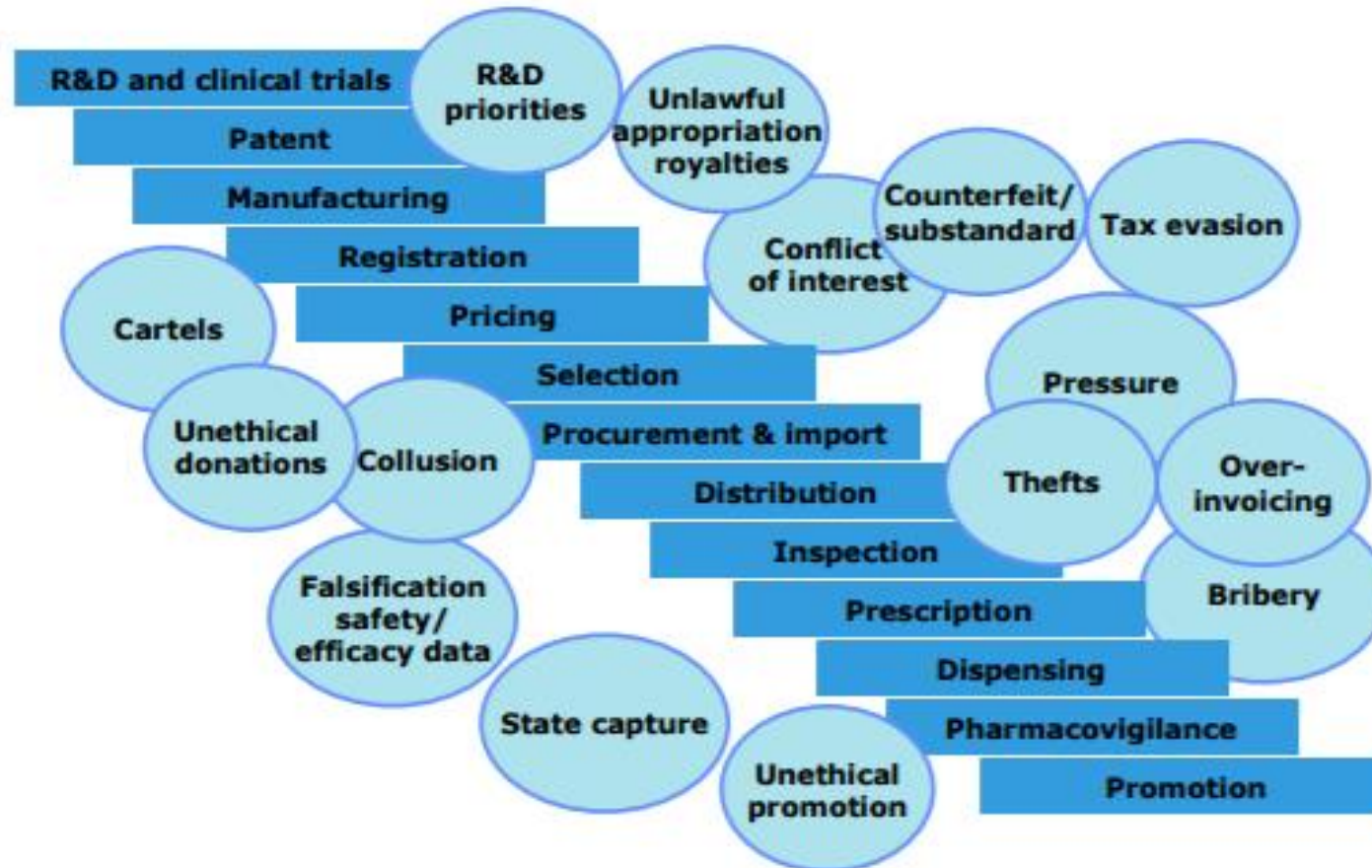
Why compliance and anti-corruption matter for access to medicine?

- Corruption and misconduct in the health sector directly impact on global health outcomes in general, and on access to medicine in particular
 - *WB: up to USD 300 million of annual global health expenditure is lost in corruption*
 - *WHO: medicines account for 3 of the top 10 leading sources of inefficiency in health systems – corruption being a leading source of inefficiency*

Why compliance and anti-corruption matter for access to medicine? (cont.)

- Traditionally, focus for access to medicine has been on pricing, infrastructure, IP rights
- Growing attention on consequences of corruption and misconduct as a further barrier to access to medicine, especially in low-middle income countries:
 - Unavailability of medicines in public sector due to money diversion
 - Further impoverishment of the poor for purchasing expensive medicines from private sector

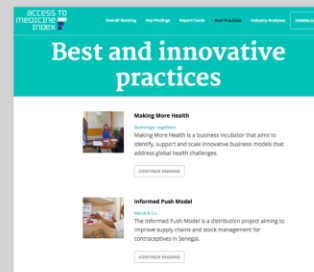
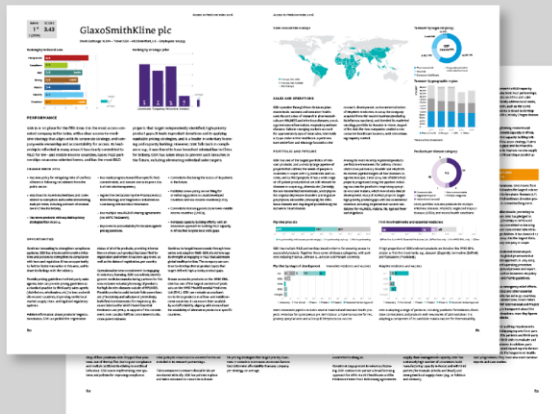
The medicines chain is a system inherently challenging to govern



Source: Baghdadi-Sabeti, G. And Serhan, F. 2010

The Access to Medicine Index

A comprehensive report



4

KEY FINDINGS

4

INDUSTRY ANALYSES

7

TECHNICAL AREAS

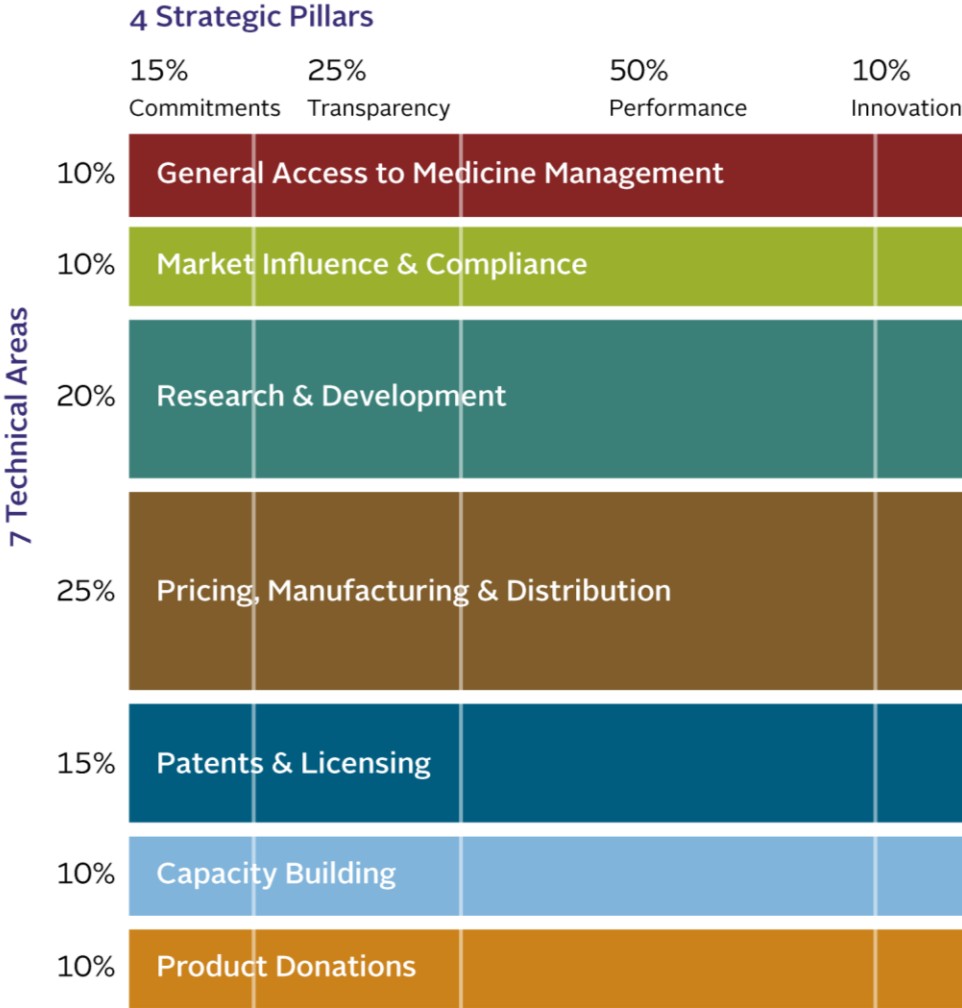
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DETAILED COMPANY REPORT CARDS

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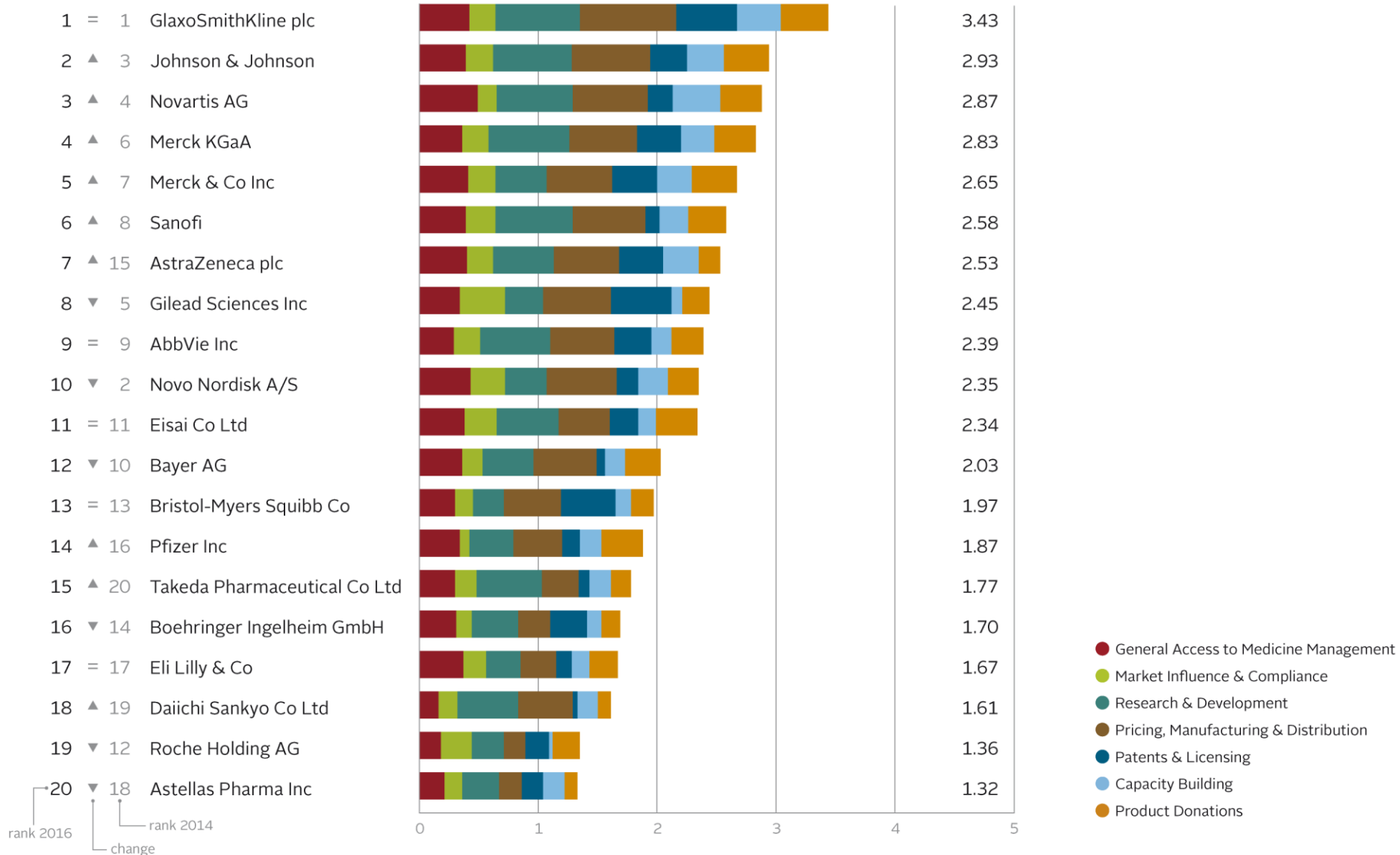
BEST AND INNOVATIVE PRACTICES

Framework for analysis



2016 Access to Medicine Index

OVERALL RANKING



Findings on Market Influence & Compliance

Market Influence & Compliance: Overall findings

- The 2016 Index found that strong commitments in implementing compliance systems do not correspond with good performance in terms of compliant and ethical behaviour:
 - Further research on causes is needed
 - **Stakeholders** expect stringent and effective compliance systems for companies expanding into low- and middle-income country markets → regulatory frameworks and prosecutorial systems may be unable to react appropriately to cases of misconduct

Market Influence & Compliance: Finding on commitments

- Ethical behaviour: codes of conduct on marketing and anti-corruption
 - **All companies** have a code of conduct for ethical marketing
 - **7 companies** clearly enforce their codes of conduct on third parties
 - **7 companies** have sales incentives not driven by sales targets

Market Influence & Compliance: Finding on transparency

- Contributions to political parties and/or politicians
 - **2 companies** have a public statement on not making these payments
 - Other **10 companies** declare (not publicly) to not make these payments in countries in scope
- Payments to HCPs
 - **No company** discloses this information where it is not required by law – **one company** discloses some marketing related payments to medical associations, clinics and patients organisations

Market Influence & Compliance: Finding on breaches of laws and codes

- **4 companies** with no breaches during the period of analysis (2014-2016)
- A total of **51 breaches** were identified:
 - 31 breaches of **industry codes** of conduct
 - 20 breaches of **national laws**

Good practices: the compliance chain



Methodology review for the 2018 Access to Medicine Index

- Stakeholders point toward need for strong internal control frameworks, including e.g.:
 - Structures (leadership, roles & responsibilities, reporting lines)
 - Processes (fraud-risk assessments, auditing mechanisms, segregation of duties, whistle-blower facilities)

Thank you

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[@AtMIndex; @lucagenoves](#)

www.accesstomedicinefoundation.org