

# Pharmaceutical compliance and access to medicine

Luca Genovese  
Access to Medicine Foundation

International Pharmaceutical and Medical Device Compliance Congress  
16 May 2017, Lisbon

# Overview

- The Access to Medicine Foundation
- Compliance, anti-corruption and access to medicine
- The Access to Medicine Index
- Index findings on Market Influence & 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



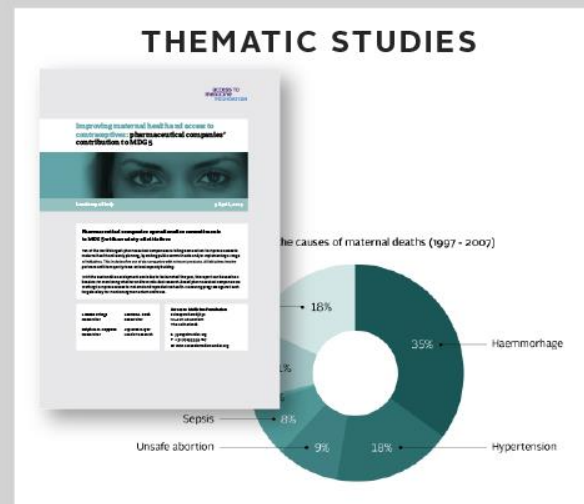
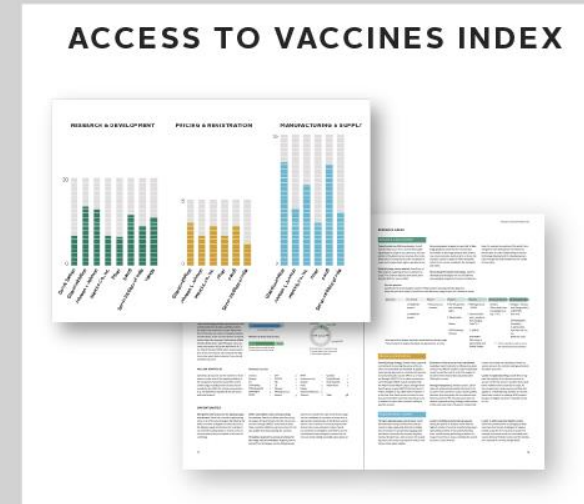
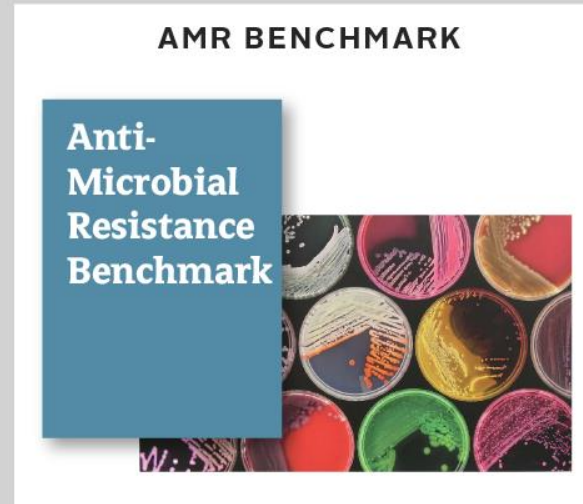
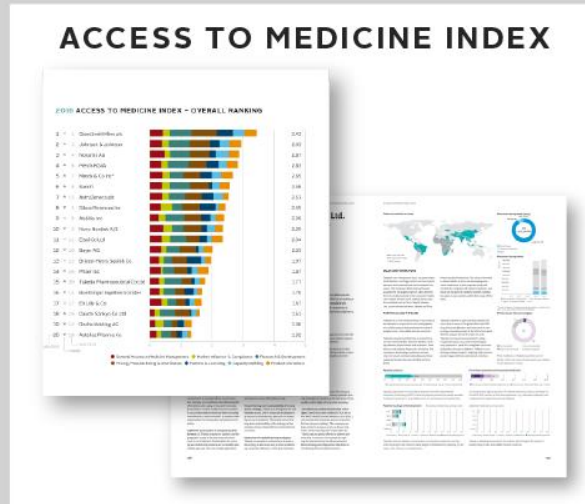
BILL & MELINDA  
GATES *foundation*

Supported by



World's third-largest  
private charity donor

# What we do



# Our model for change

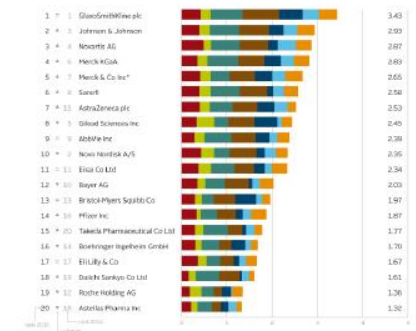
## Build consensus

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.



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

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



## Basler Zeitung WIRTSCHAFT FINANCIAL TIMES

Basel Schweiz Ausland Börse Wirtschaft Kultur Sport Auto Leben  
Unternehmen Konjunktur Geld Konsense Börse Verbots Wirtshaltung Blasmusiken

### Lob und Tadel für die Pharmakonzerne

Index überprüft das Engagement der Firmen in Entwicklungsländern  
Die Pharmakonzerne sind im vergangenen Jahr für den Index der Access to Medicine Foundation (ATMI) in die Liste der Top 100 der Pharmakonzerne aufgenommen worden. Die Liste ist ein Maßstab für die Pharmakonzerne, die sich in den letzten Jahren für die Verbesserung des Zugangs zu Arzneimitteln in den Entwicklungsländern eingesetzt haben. Die Liste ist ein Maßstab für die Pharmakonzerne, die sich in den letzten Jahren für die Verbesserung des Zugangs zu Arzneimitteln in den Entwicklungsländern eingesetzt haben.



Tuesday 15 November 2016

Home News Views & analysis Deep Dive White papers



### 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.

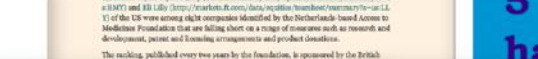


## Director Access to Medicine

Er moet nog veel verbeterd worden

### Drug prices Big pharma failing to do enough for poor countries

Access to Medicine Index says moderate progress made in improving access to medicine  
The Access to Medicine Index (AMI) has published its 2016 report, which ranks the top 100 pharmaceutical companies on their commitment to improving access to medicines in low- and middle-income countries. The report shows that while there has been some progress, the industry as a whole is still failing to do enough for poor countries. The report also highlights the need for more sustainable and equitable access to medicines in these countries.



## nrc.next

Home Journals Specialties The Lancet Clinic Global Health



### Genees de wereld

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

Pharmaceutical companies must make their medicines accessible to poor people, investors are increasingly demanding

Pharmaceutical companies must make their medicines accessible to poor people, investors are increasingly demanding

Pharmaceutical companies must make their medicines accessible to poor people, investors are increasingly demanding

### 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 support 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 non-profit 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

Pharmaceutical industry is making progress in providing medicines to poor countries, but still has a long way to go, according to the Access to Medicine Index.



Home News Markets Companies Money & Banking Economy Info-tech Opinions

## THE LANCET

Online First Current Issue All Issues Special Issues Multimedia > Info

### Access to Medicine Index—what about sustainability?



changes in overall development, patient and financing arrangements and product innovation.

changes in overall development, patient and financing arrangements and product innovation.

changes in overall development, patient and financing arrangements and product innovation.

changes in overall development, patient and financing arrangements and product innovation.

changes in overall development, patient and financing arrangements and product innovation.

changes in overall development, patient and financing arrangements and product innovation.

### Pharma lijkt toch armsten te helpen

Access to Medicine Index in welke mate



08.21u - Ellen de Visser - Bron: Volkskrant

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

## REUTERS

Markets World Politics Tech Commentary Breaking News Money Life >

### Drugmakers improve access for poor, GSK ranked top

The Access to Medicine Index, which is published every two years and ranks companies according to how they assist their patients in low- and middle-income countries, ranked GSK as the top performer in its report card on global access to medicines.

The index found that just 4% (44) of the 100 products that were ranked were available in low- and middle-income countries. Companies are developing another 420, which includes about 100 products that have entered the market since 2014 and 150 that have not.

The index found that just 4% (44) of the 100 products that were ranked were available in low- and middle-income countries. Companies are developing another 420, which includes about 100 products that have entered the market since 2014 and 150 that have not.



Pharmaceutical industry is making progress in providing medicines to poor countries, but still has a long way to go, according to the Access to Medicine Index.



Home News Markets Companies Money & Banking Economy Info-tech Opinions

## THE HINDU

Home News Markets Companies Money & Banking Economy Info-tech Opinions

### 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

### 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	Roche	80
6	Sanofi	78
7	AstraZeneca	76
8	AbbVie	74
9	Amgen	72
10	Novartis	70
11	Novartis	68
12	Novartis	66
13	Novartis	64
14	Novartis	62
15	Novartis	60
16	Novartis	58
17	Novartis	56
18	Novartis	54
19	Novartis	52
20	Novartis	50
21	Novartis	48
22	Novartis	46
23	Novartis	44
24	Novartis	42
25	Novartis	40
26	Novartis	38
27	Novartis	36
28	Novartis	34
29	Novartis	32
30	Novartis	30

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

### Pharma lijkt toch armsten te helpen

Access to Medicine Index in welke mate



08.21u - Ellen de Visser - Bron: Volkskrant

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

## REUTERS

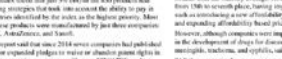
Markets World Politics Tech Commentary Breaking News Money Life >

### Drug firms need to tackle affordability

The Access to Medicine Index, which is published every two years and ranks companies according to how they assist their patients in low- and middle-income countries, ranked GSK as the top performer in its report card on global access to medicines.

The index found that just 4% (44) of the 100 products that were ranked were available in low- and middle-income countries. Companies are developing another 420, which includes about 100 products that have entered the market since 2014 and 150 that have not.

The index found that just 4% (44) of the 100 products that were ranked were available in low- and middle-income countries. Companies are developing another 420, which includes about 100 products that have entered the market since 2014 and 150 that have not.



Pharmaceutical industry is making progress in providing medicines to poor countries, but still has a long way to go, according to the Access to Medicine Index.



Home News Markets Companies Money & Banking Economy Info-tech Opinions

## THE HINDU

Home News Markets Companies Money & Banking Economy Info-tech Opinions

### 'Triaat dat mensen na lang horen dat hun medicijn er



Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

Pharmaceutical companies are working on reaching medicines where needed but need to do much more, finds Access to Medicine Index

# 60 investors: AUM in excess of USD 5.5 trillion





# 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 mln 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*

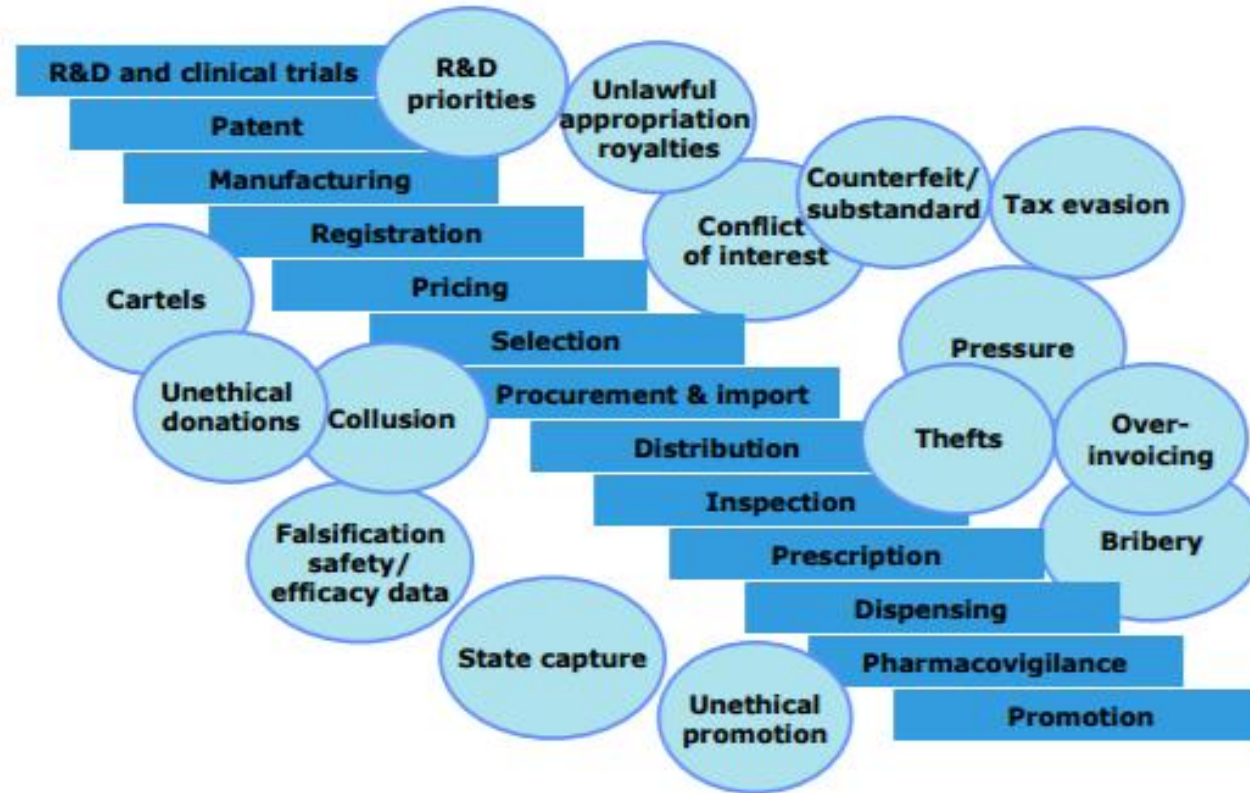
# Why compliance and anti-corruption matter for access to medicine

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 meds from private sector

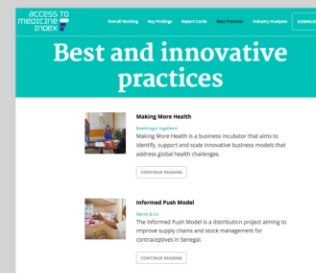
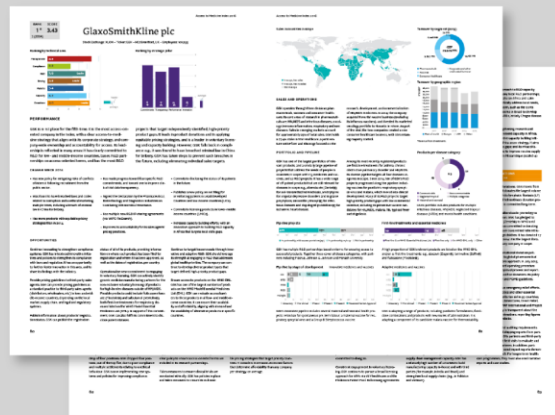
# The medicines chain is a system inherently challenging to govern



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

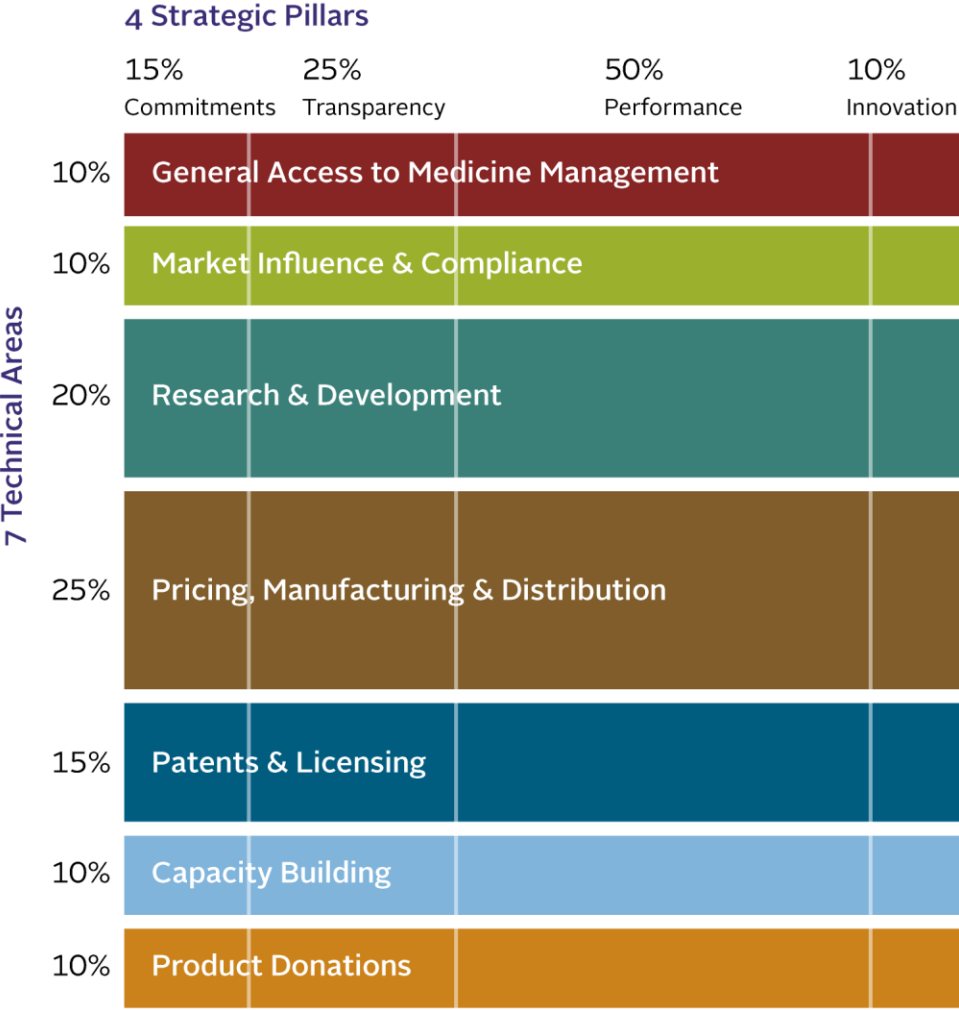
20

DETAILED COMPANY REPORT CARDS

57

BEST AND INNOVATIVE PRACTICES

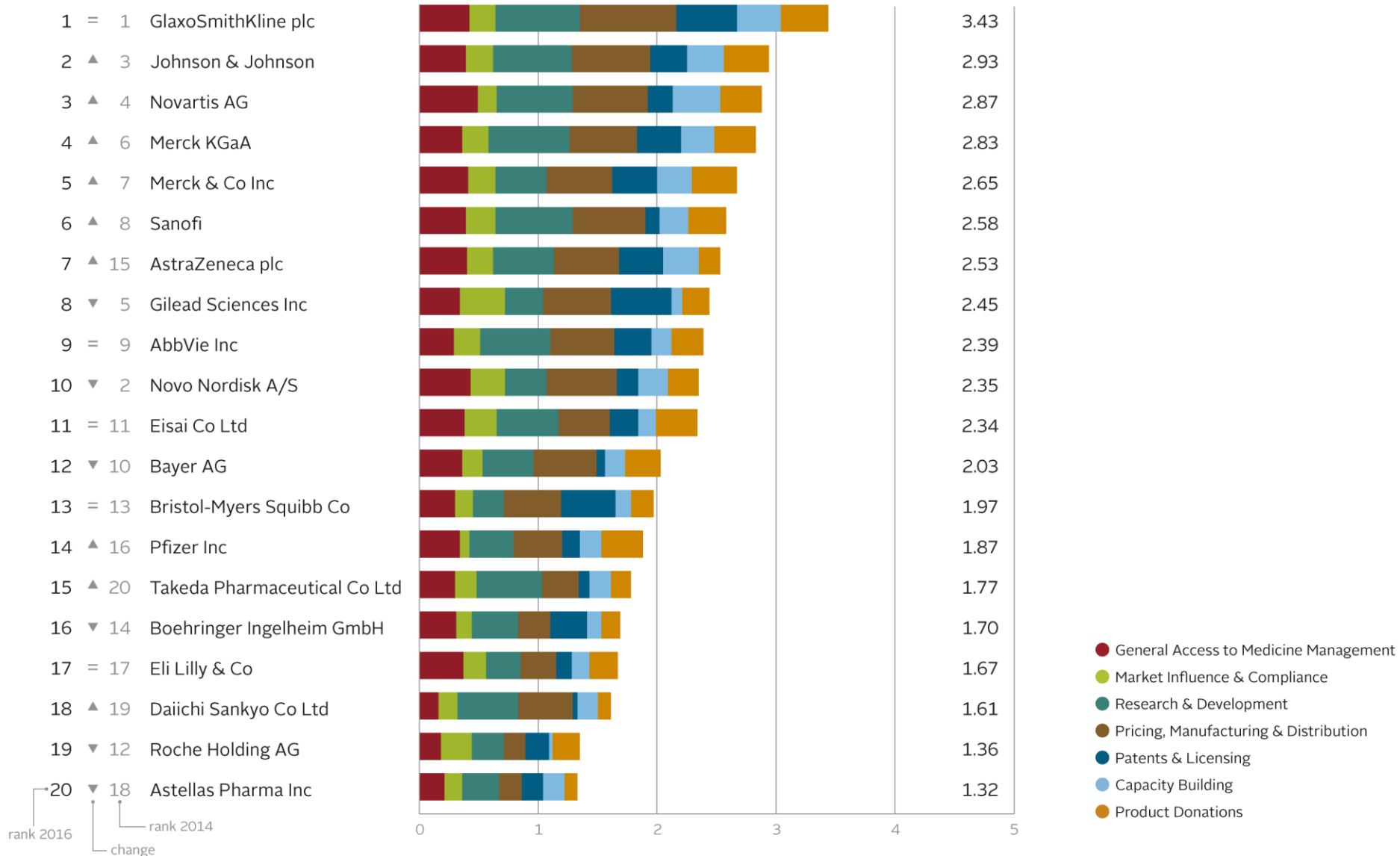
# Framework for analysis





# 2016 Access to Medicine Index

## OVERALL RANKING



*“The Access to Medicine Index  
is a very important project.  
What gets measured, gets done.”*

*Dr. Margaret Chan  
Director-General World Health Organization*



# Focus on Market Influence & Compliance

# Market Influence & Compliance: Overall finding

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 (settlements) during the period of analysis (2014-2016)
- Total of **51 breaches** (settlements) 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

For the 2018 Index, we will increase our focus on internal control frameworks, investigating both:

- Structures (leadership; roles & responsibilities; reporting lines)
- Processes (fraud-risk assessment; auditing mechanisms; segregation of duties; whistle-blower facilities)

Thank you

[lgenovese@atmindex.org](mailto:lgenovese@atmindex.org)

[@AtMIndex](https://twitter.com/AtMIndex)

[www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)