

The 2016 Access to Medicine Index Breakfast Meeting

Jayasree K. Iyer, Executive Director, ATM Foundation

24th November 2016

HGPI, Tokyo

5 billion people
have access to medicine
2 billion to go

Availability

Accessibility

Affordability

Acceptability

The Access to Medicine Foundation

access to
medicine
FOUNDATION

- Research on, and incentives for, pharmaceutical companies and access to medicine
- Independent, non-profit organisation
- Multi-stakeholder approach



Ministry of Foreign Affairs
of the Netherlands



BILL & MELINDA
GATES *foundation*

Supported by



World's third-largest
private charity donor

Our model for change

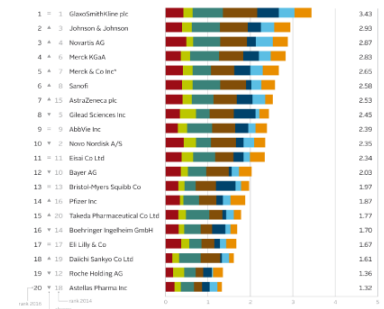
Build consensus

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.



What we do

ACCESS TO MEDICINE INDEX



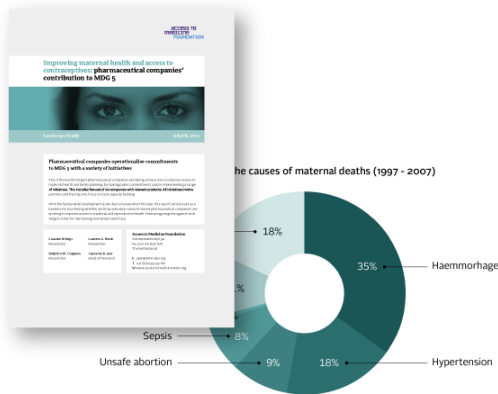
ACCESS TO VACCINES INDEX



AMR BENCHMARK

Anti-microbial Resistance Benchmark

THEMATIC STUDIES



ADVANCING THE DEBATE



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.”

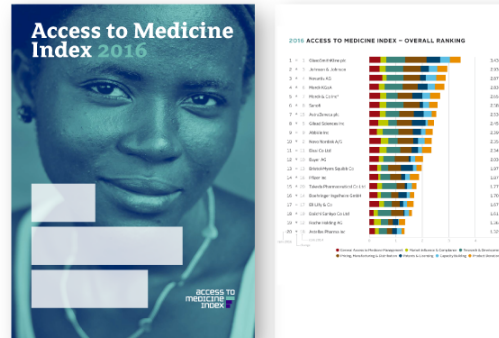
Bill Gates

Pharma Companies



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

Sir Andrew Witty, 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

Investors



“We are increasingly reviewing corporate approaches to access to medicine as a key strategic consideration.”

53 Signatory Investors

60 investors – AUM in excess of USD 5.5 trillion

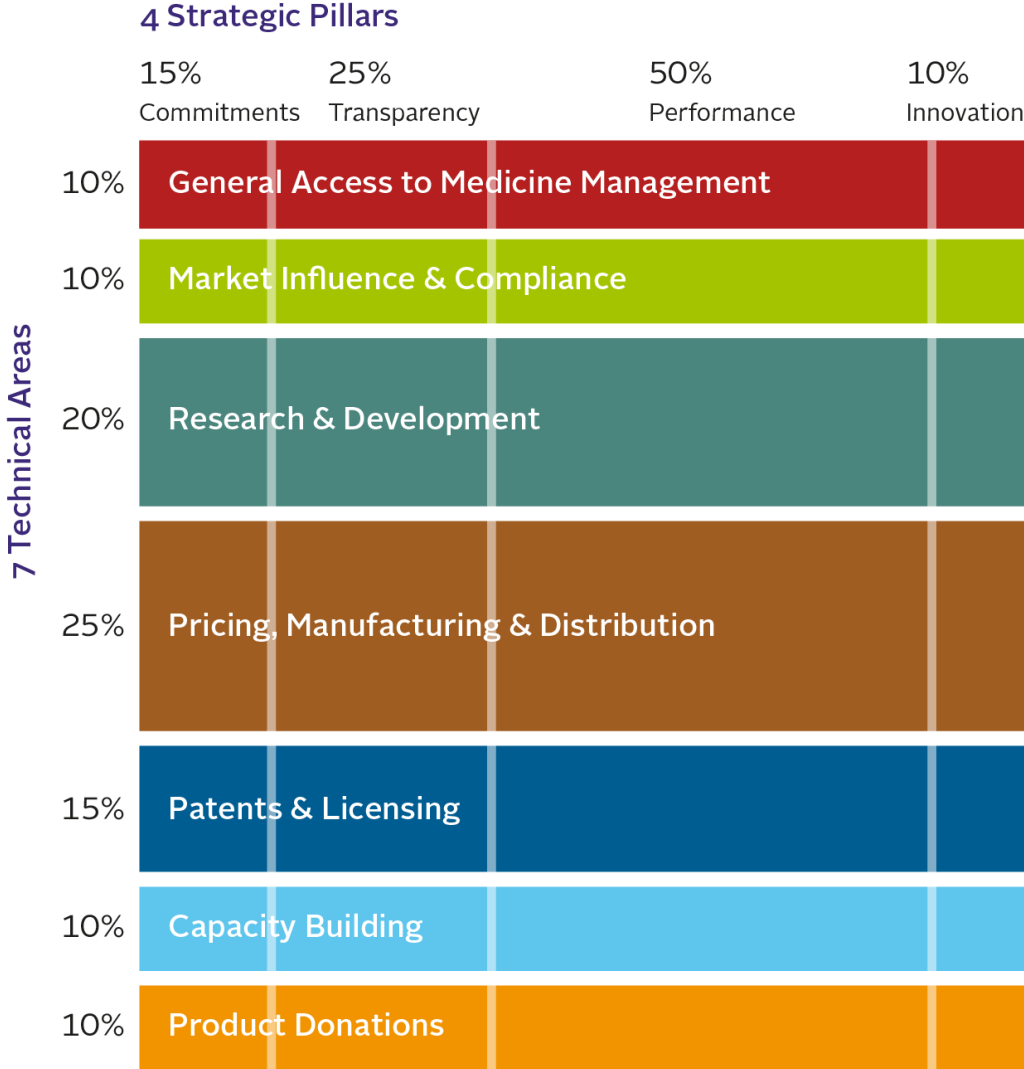
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medicine
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2016 Access to Medicine Index

What we measure

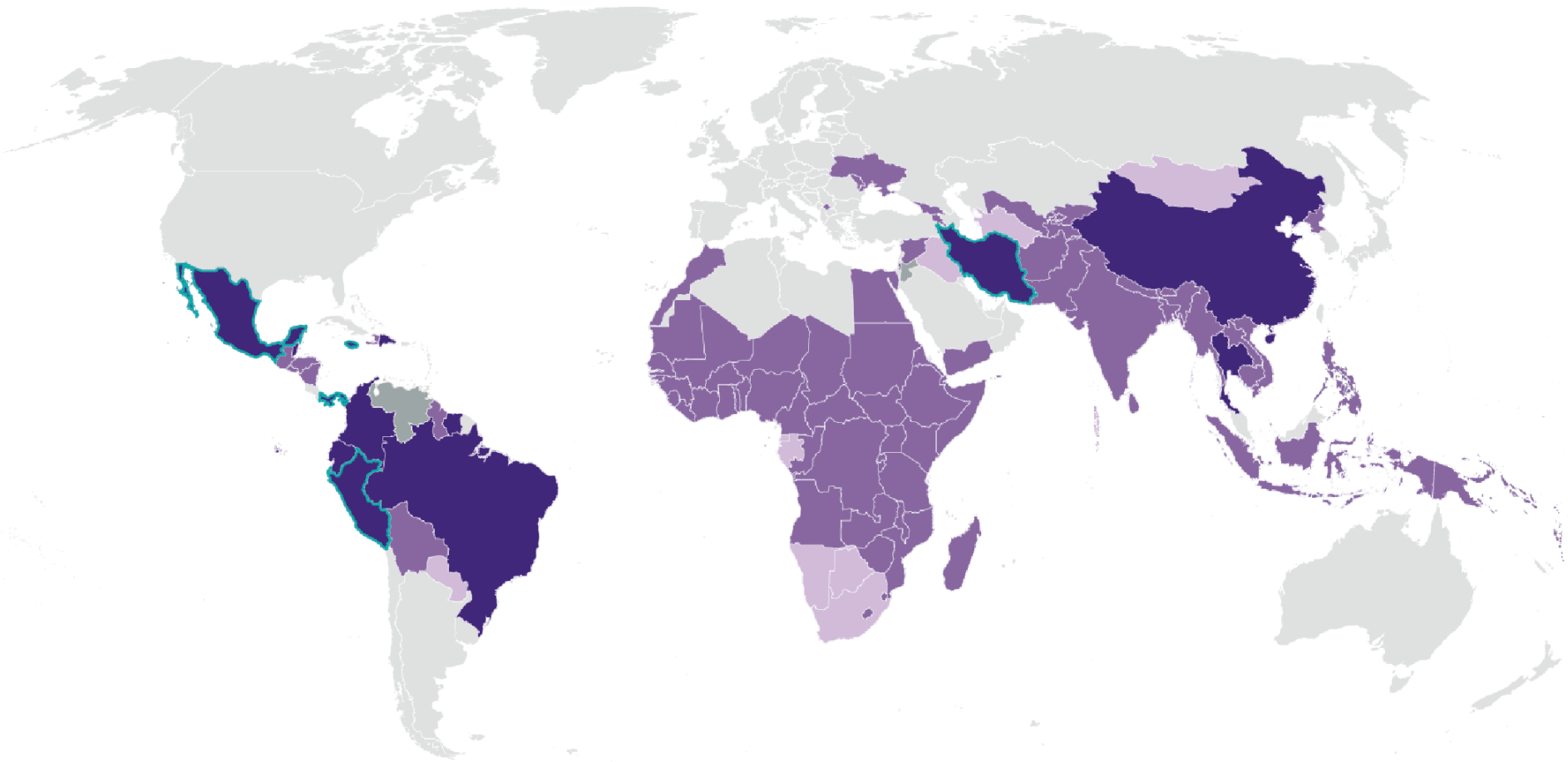
Framework for analysis



Company scope

- AbbVie Inc.
- Astellas Pharma Inc.
- AstraZeneca plc
- Bayer AG
- Boehringer Ingelheim GmbH
- Bristol-Myers Squibb Co.
- Daiichi Sankyo Co. Ltd.
- Eisai Co. Ltd.
- Eli Lilly & Co.
- Gilead Sciences Inc.
- GlaxoSmithKline plc
- Johnson & Johnson
- Merck & Co. Inc.
- Merck KGaA
- Novartis AG
- Novo Nordisk A/S
- Pfizer Inc.
- Roche Holding AG
- Sanofi
- Takeda Pharmaceutical Co. Ltd.

Geographic scope



Legend: Basis for inclusion

- World Bank income classification
- UN Human Development Index
- LDC (Tuvalu only)
- UN Inequality-Adjusted Human Development Index

- 5 countries newly included in the 2014 Index scope
- 2 countries removed from the Index scope

Disease scope

COMMUNICABLE DISEASES



NON-COMMUNICABLE DISEASES



NEGLECTED TROPICAL DISEASES



MATERNAL & NEONATAL HEALTH CONDITIONS



2016 Access to Medicine Index Report Highlights

A comprehensive report

access to
medicine
FOUNDATION



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KEY FINDINGS

4

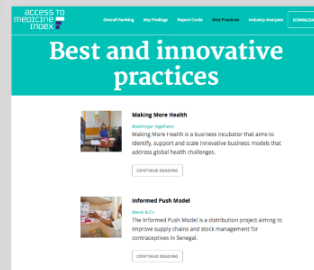
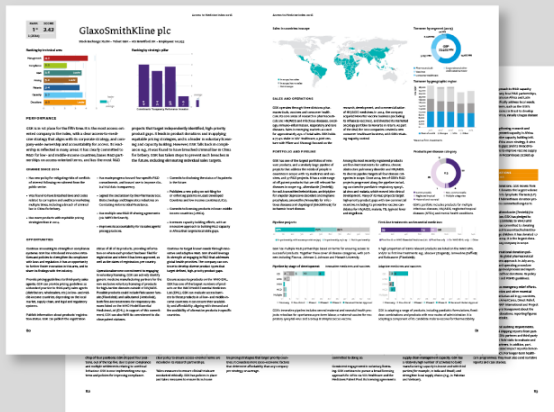
INDUSTRY ANALYSES

7

TECHNICAL AREAS

20

DETAILED COMPANY REPORT CARDS



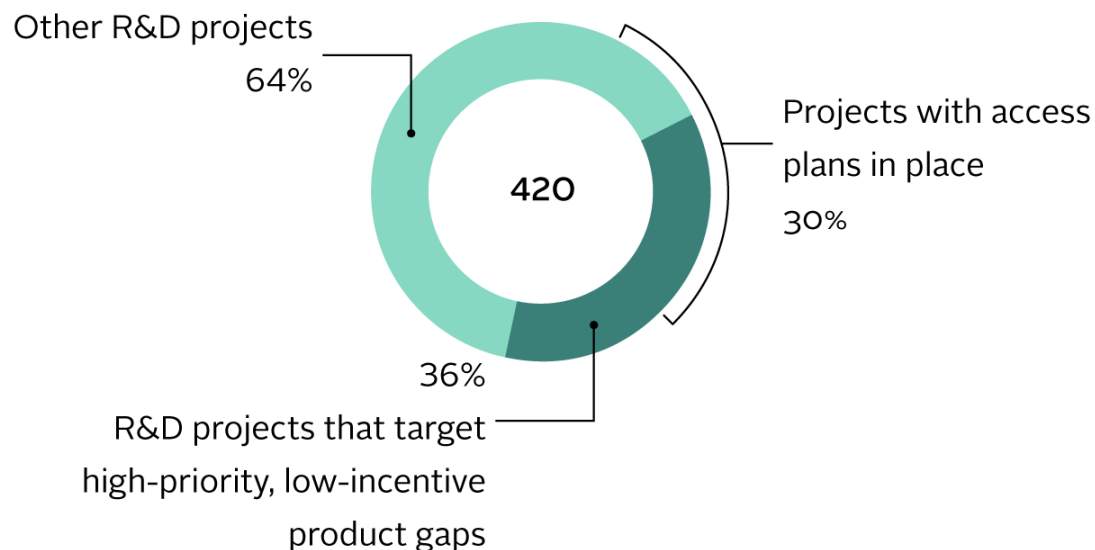
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BEST AND INNOVATIVE PRACTICES

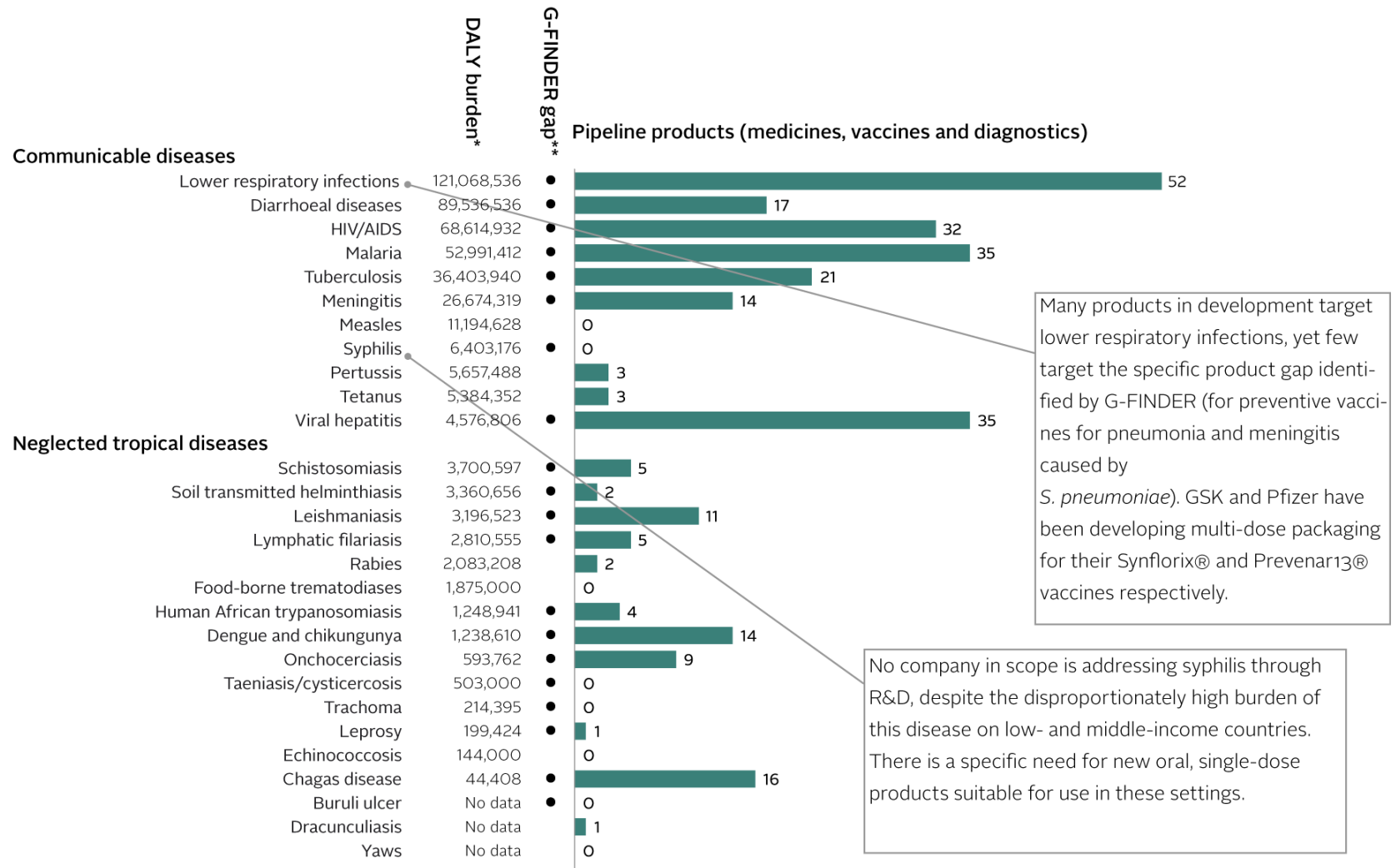
2016 Access to Medicine Index

Key Finding: R&D

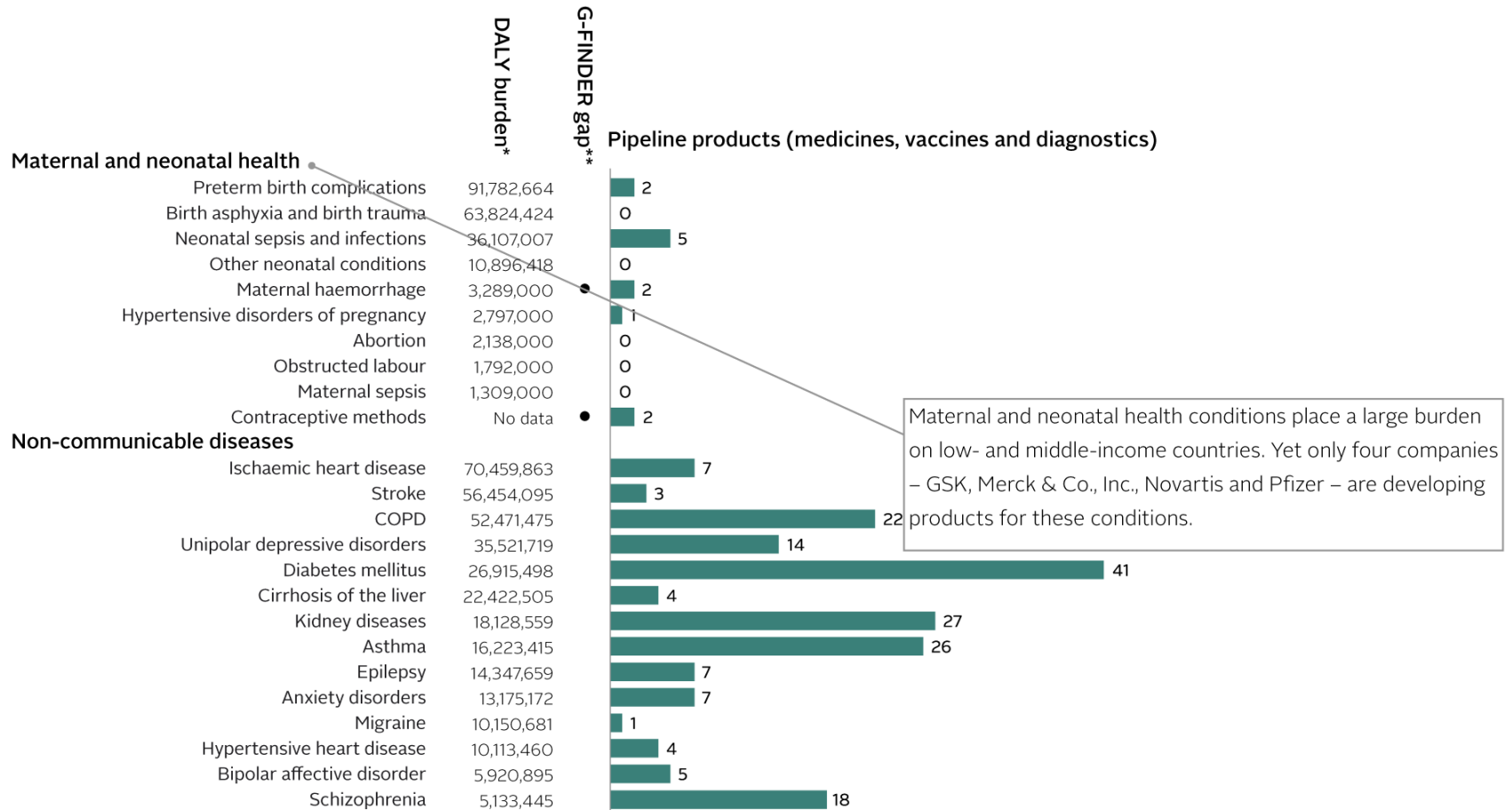
Leaders in R&D address needs and ensure access for people living in low- and middle-income countries



Efforts to meet product R&D needs are uneven



Efforts to meet product R&D needs are uneven



*See 2015 Methodology for the 2016 Access to Medicine Index.

**The G-FINDER tool from Policy Cures identifies high-priority product gaps where there is both a need for new products and insufficient commercial incentive to drive R&D.

Over one third of product gaps with low commercial incentive being addressed

ATMI Disease	Specific disease target	Medicines	Vaccines (Preventive)	Vaccines (Therapeutic)	Diagnostics	Microbicides	Vector Control Products	Devices (for reproductive health only)
Buruli ulcer		●	●					
Chagas disease		15	●	1	●		●	
Dengue and chikungunya	Dengue	9			●		●	
Human African trypanosomiasis		4	●		●		●	
Leishmaniasis		11	●	●	●			
Leprosy		1			●			
Lymphatic filariasis		5			●		●	
Onchocerciasis		9	●		●		●	
Schistosomiasis		5	●		●		●	
Soil transmitted helminthiasis	Ascariasis	2						
	Hookworm diseases	2	●					
	Strongyloidiasis	1	●		●			
Taeniasis/cysticercosis		●				●		
Trachoma			●		●			

- High-priority, low-incentive product gap, unaddressed by companies in scope
 - High-priority, low-incentive product gap, addressed by companies in scope. Includes number of R&D projects.
- Blank cell: no high-priority, low-incentive product gap identified by G-FINDER

*Specific product gap identified, e.g., for a new administration route to be developed, or serotypes to be targeted.

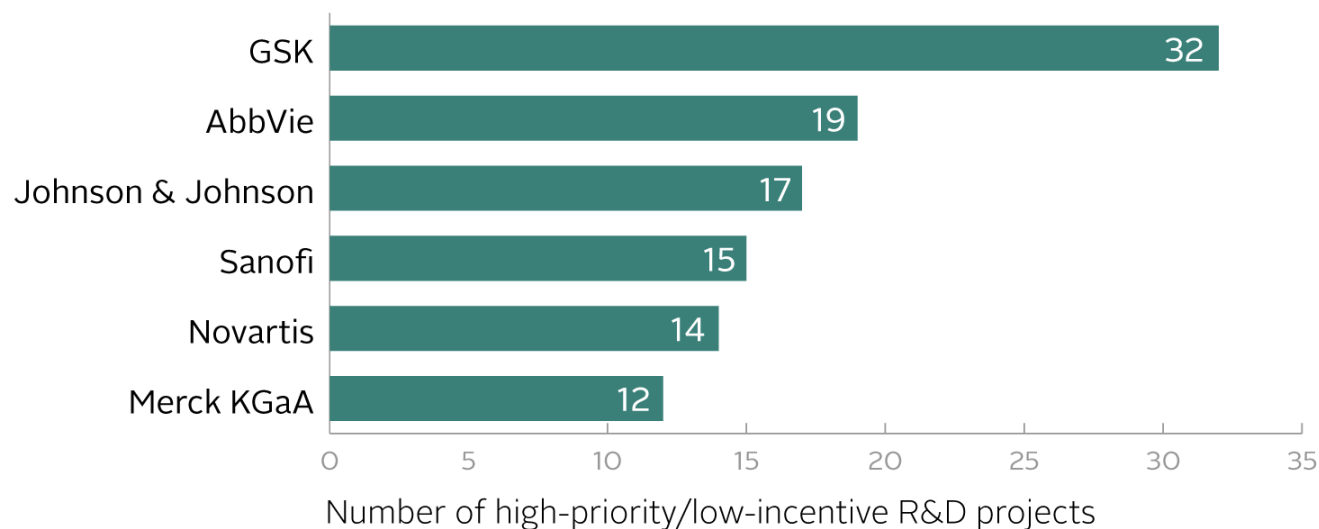
Over one third of product gaps with low commercial incentive being addressed

ATMI Disease	Specific disease target	Medicines	Vaccines (Preventive)	Vaccines (Therapeutic)	Diagnostics	Microbicides	Vector Control Products	Devices (for reproductive health only)
Contraceptive methods	Reproductive health products*	2						●
Diarrhoeal diseases	Cholera*	●	●		●			
	Cryptosporidiosis*	1	●		●			
	Enterotoxigenic E. coli infection		1		●			
	Giardiasis [Iambliasis]				●			
	Rotaviral enteritis*		1					
	Shigellosis*	●	2		●			
	Typhoid and paratyphoid fevers	●	2		●			
	Other intestinal E. coli infections		●		●			
HIV/AIDS*		17	3		3	●		
Lower respiratory infections	Due to S. pneumoniae*		5		●			
Malaria		30	3		2	●		
Maternal haemorrhage	Postpartum haemorrhage*	2						
Meningitis	Due to N. meningitidis*		●		●			
	Due to S. pneumoniae*		5		●			
Syphilis*		●						
Tuberculosis		19	2	●	●			
Viral hepatitis	Hepatitis C genotypes 4, 5, 6*	12	1		●			

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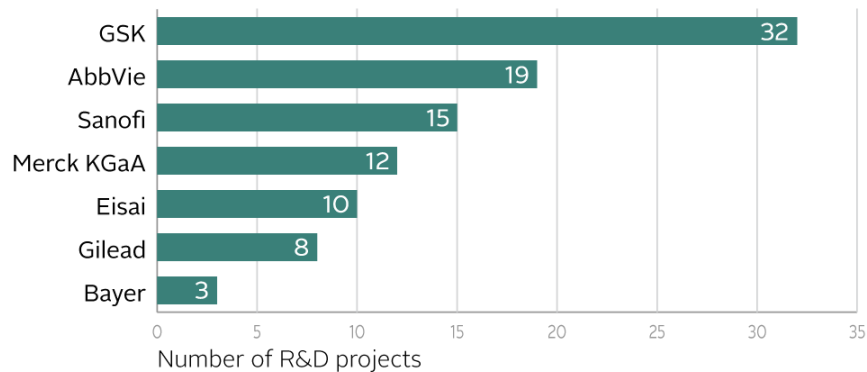
*Specific product gap identified, e.g., for a new administration route to be developed, or serotypes to be targeted.

Collaborative research models appear effective in engaging the industry in developing urgently needed products with low commercial potential

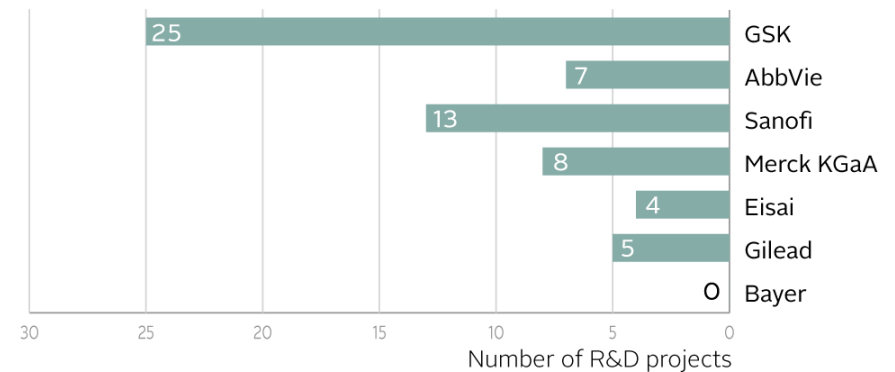


Seven companies have the strongest focus on high-priority product gaps with low commercial incentive

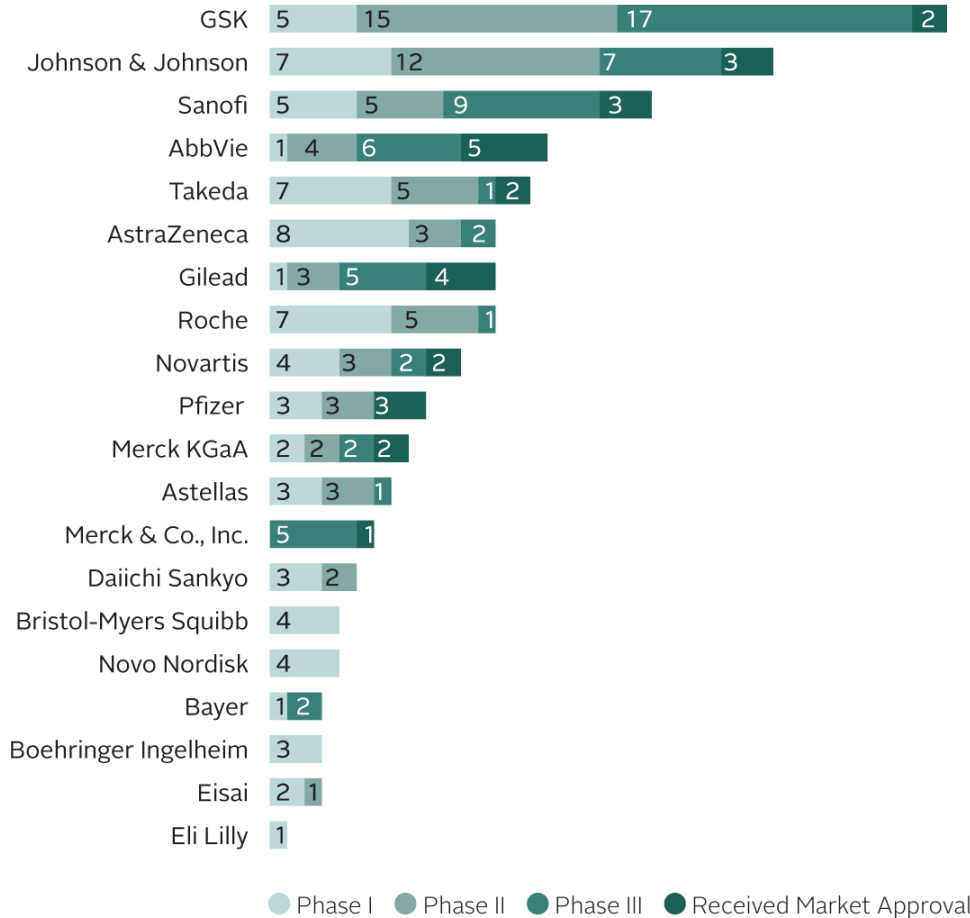
R&D for high-priority, low-incentive product gaps



R&D for product gaps not identified as having low commercial incentive



Only a few commercially-promising projects have plans for access in place



Projects that target multiple diseases or are being developed by multiple companies are counted more than once

Access provisions are set earlier when projects are conducted in partnership

R&D in partnership



In-house R&D



- Affordable pricing
- Donation programmes
- Local clinical trial sites
- Registration targets
- Responsible IP-management
- Sufficient supply
- WHO prequalification
- No evidence of current access

2016 Access to Medicine Index

Key Finding: Capacity Building

Leading companies systematically address local needs

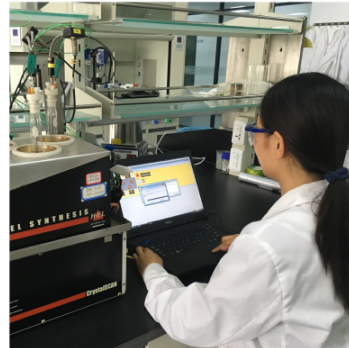
	R&D	MANUFACTURING	SUPPLY CHAIN MANAGEMENT	PHARMACOVIGILANCE
ACTIVITY	Companies are more active than in 2014, with a similar proportion of long-term initiatives. Four companies directly target local skills gaps.	Most companies build capacity in-house and with others. Three commit to assessing third-party training needs.	Many best practice initiatives but large scope for better information-sharing, e.g., to report suspected falsified medicines	Majority of companies update their safety labels globally, but sharing safety data is less common.
LEADERS	GSK, Merck & Co., Inc., Merck KGaA, Novartis	AstraZeneca, Daiichi Sankyo, Johnson & Johnson, Merck KGaA	GSK, Johnson & Johnson, Merck & Co., Inc., Novartis, Sanofi	AbbVie, Bayer, GSK, Johnson & Johnson, Novartis
ACTIVE NUMBER	15	18	14	16
GEOGRAPHIC FOCUS	China, Brazil, Kenya and South Africa	China, India and Brazil	Sub-Saharan Africa	Latin America

Leading companies systematically address local needs

R&D



MANUFACTURING



SUPPLY CHAIN
MANAGEMENT



PHARMACOVIGILANCE



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Key Finding: Business Models

Commercial business models address lower income populations

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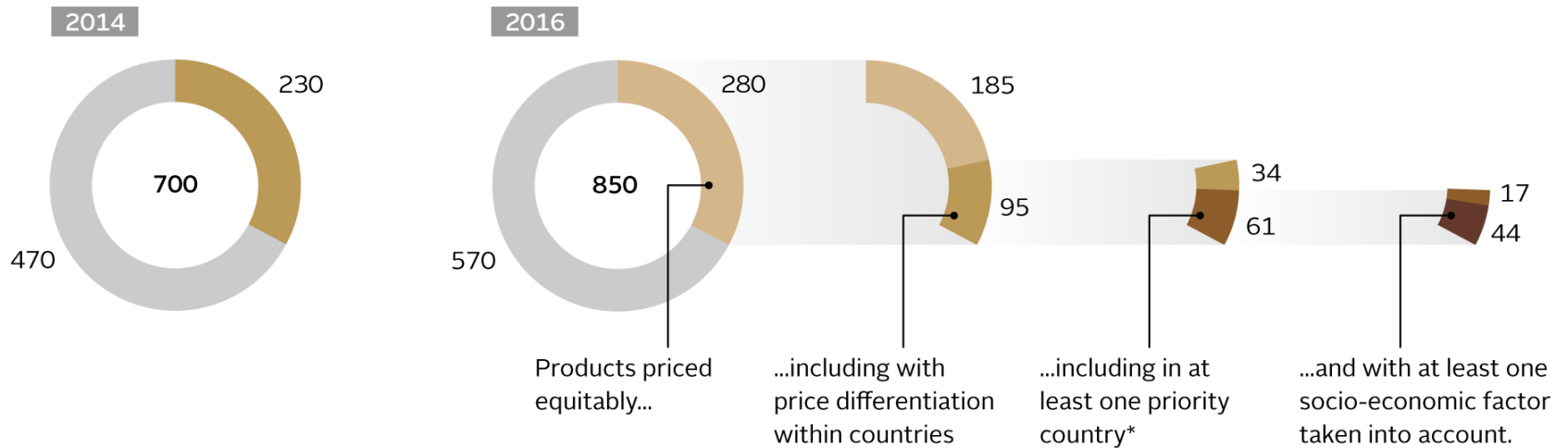
Commercial business models address lower income populations

Company	Name	Geographic scope	Disease scope
Boehringer Ingelheim	PreCare	Kenya	Stroke
	Coupon/Loyalty Programme	Kenya	Stroke
Eli Lilly	Lilly Expanded Access for People (LEAP)	China	Diabetes
Novartis	Novartis Access	Initially Kenya and Ethiopia	Cardiovascular diseases, diabetes, respiratory illnesses, breast cancer
	Community-based Hypertension Improvement Project (ComHIP)	Ghana	Hypertension
Merck KGaA	Su-Swastha	Rural India	Cough, cold and allergies; immunity and malnutrition; diabetic neuropathy; diarrhoea; and dermatology.
Pfizer	Global Established Products portfolio (business unit)	Global	Multiple diseases

2016 Access to Medicine Index

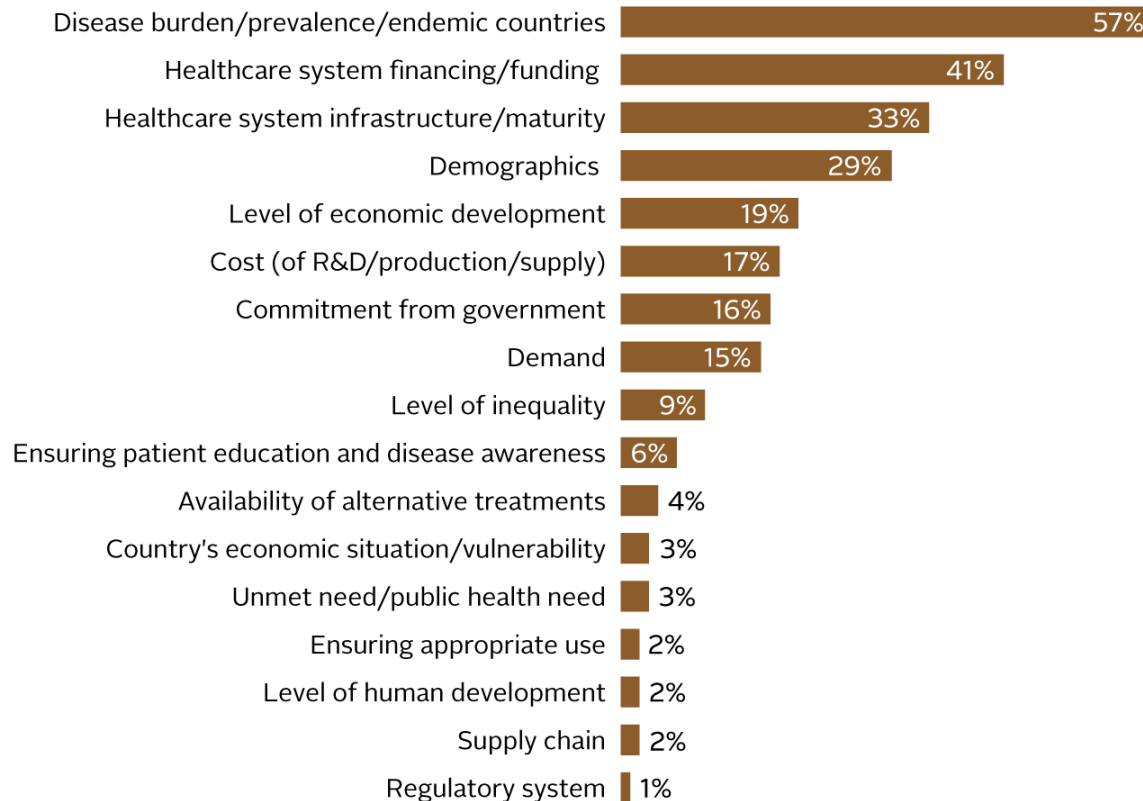
Key Finding: Product Deployment

True needs-based pricing is limited

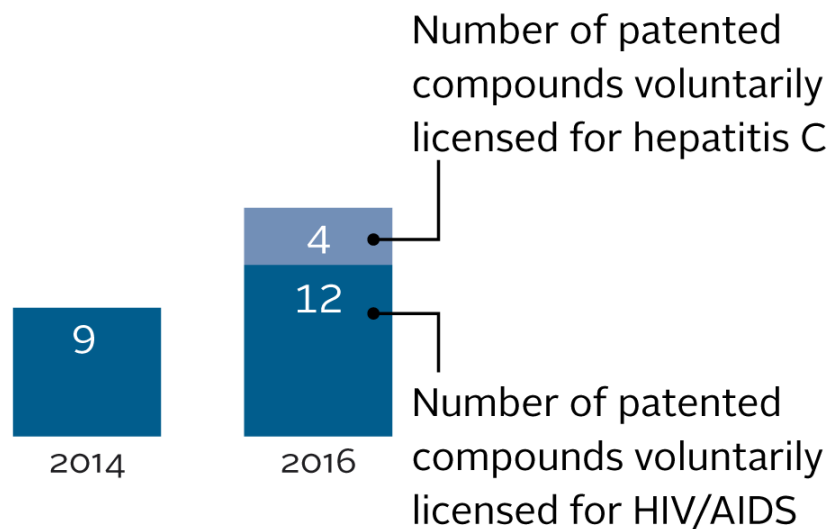


Leaders take multiple socio-economic factors into account when pricing their products

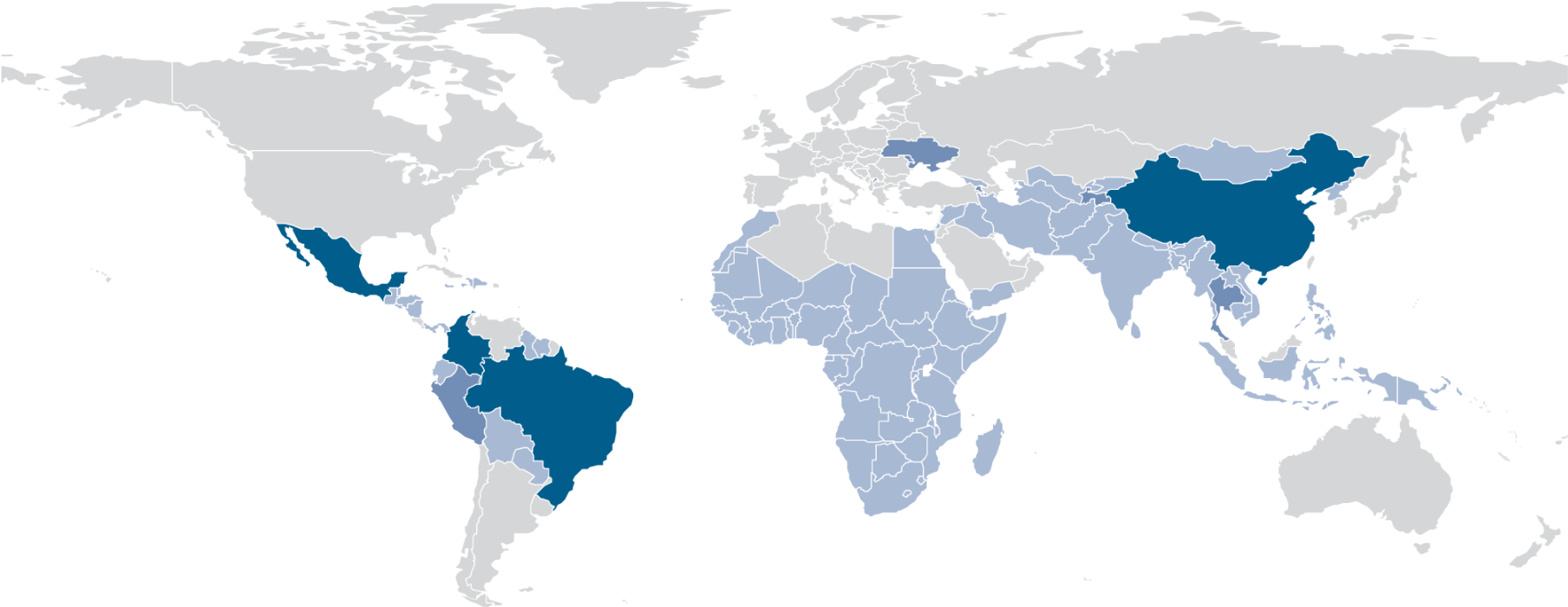
% of equitable pricing strategies* that consider socio-economic factors, per factor.



Licensing expands but excludes key middle-income countries



Large emerging markets are often overlooked in voluntary licensing agreements

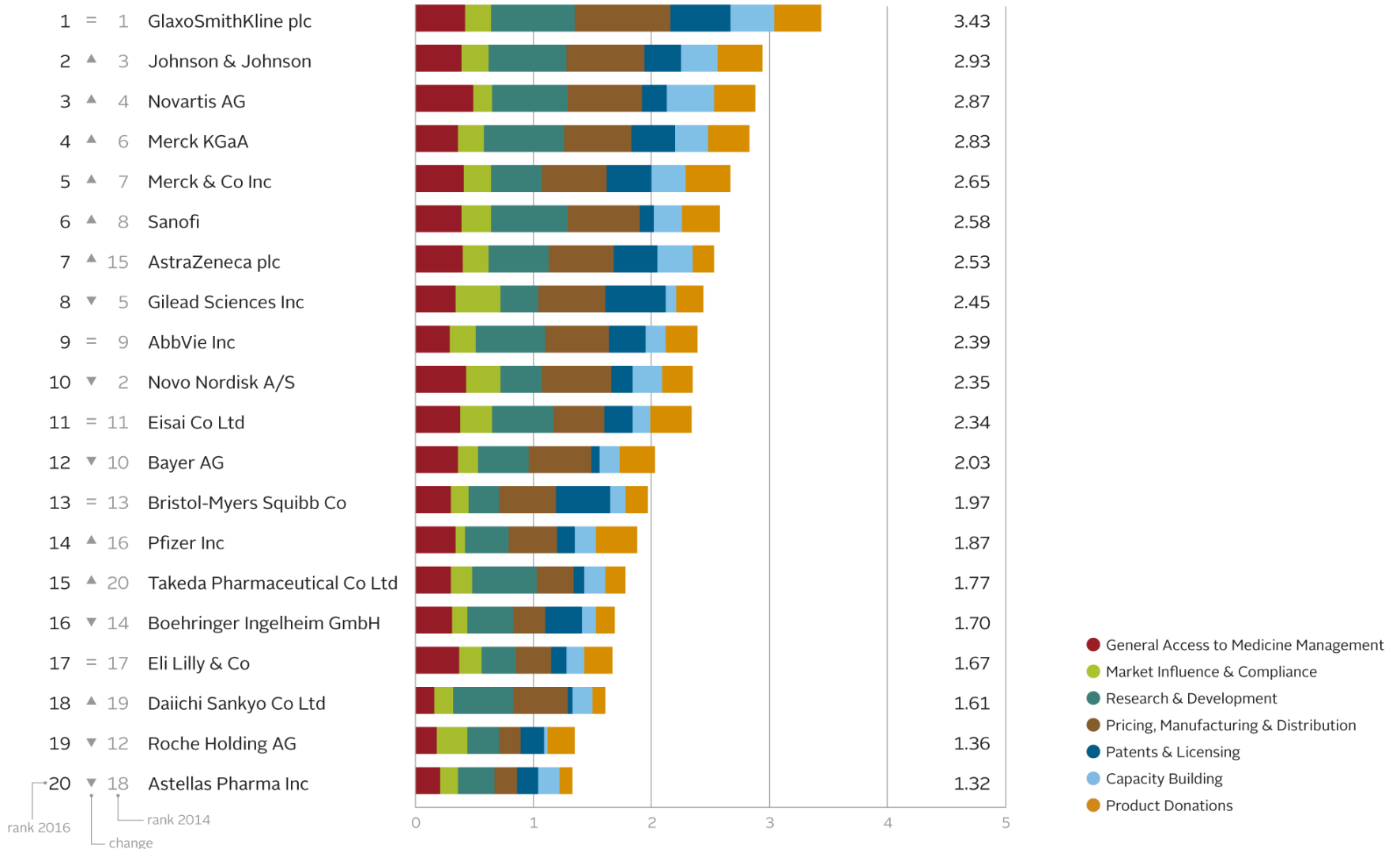


- Covered by licences for at least one HIV/AIDS product AND at least one hepatitis C product
- Covered by at least one licence for an HIV/AIDS product but not for a hepatitis C product
- Not covered by licences for either HIV/AIDS or hepatitis C products
- Not in scope

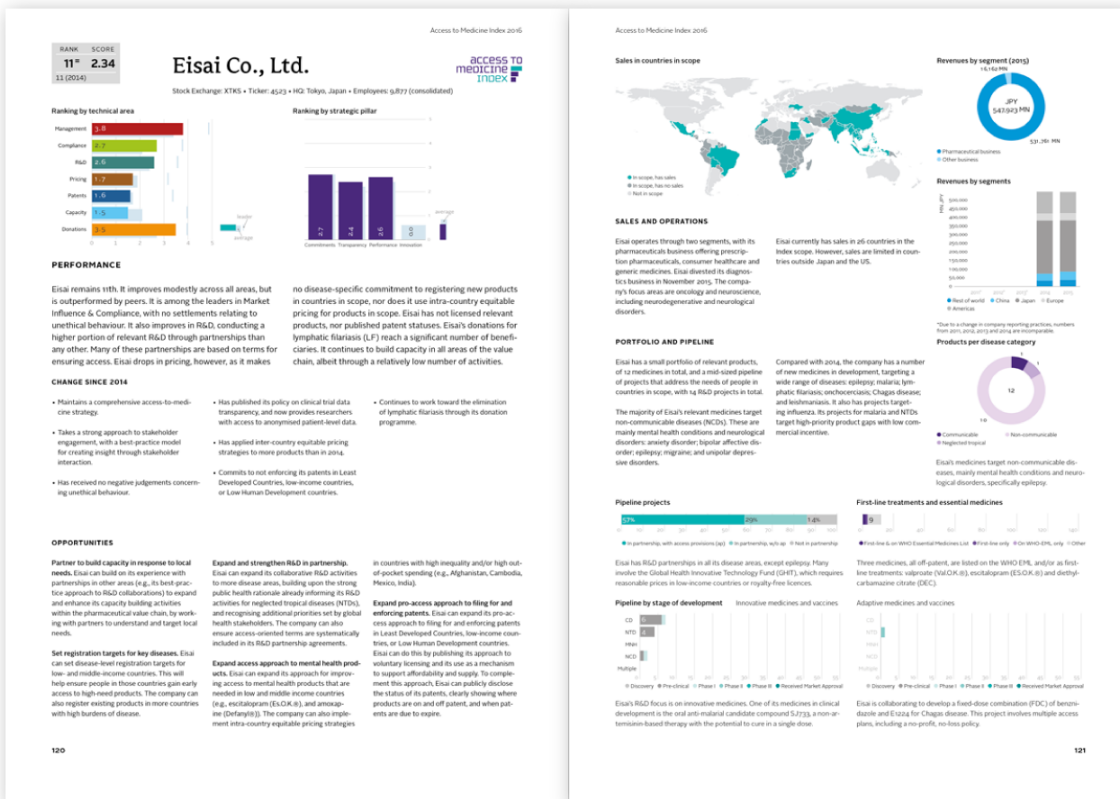
2016 Access to Medicine Index Performance of Japanese Companies

2016 Access to Medicine Index

OVERALL RANKING



Eisai Co., Ltd.



- Strong in Market Influence & Compliance
- Highest proportion of R&D through partnerships, notably NTDs
- Commits to not enforcing patents in certain low-and middle income countries
- Donates to eliminate Lymphatic Filariasis

Takeda Co., Ltd.

RANK SCORE
15* 1.77
20 (2014)

Takeda Pharmaceutical Co., Ltd.
Stock Exchange XTKS • Ticker: 4520 • HQ: Osaka, Japan • Employees: 30,618 (consolidated)

Ranking by technical area

Management	2.0
Compliance	2.8
R&D	2.8
Phising	2.0
Patents	2.0
Capacity	2.8
Operations	2.8

Ranking by strategic pillar

Commercial	2.8
Regulatory	2.8
Manufacturing	2.8
Marketing	2.8

PERFORMANCE

Takeda is one of the biggest risers, moving 5 places to 15th. Its access-to-medicine strategy aligns with its overall business strategy. This is not yet coupled with a solid compliance system, as evidenced by cases of misconduct settled since 2014. Takeda has strong R&D commitments related to access to medicine, and shares IP for leishmaniasis and Chagas disease. It also improves IP pricing, where Takeda has newly

CHANGED SINCE 2014

- Has launched new access strategy supported by a centralized dashboard for tracking progress and performance.
- Has been handed the largest fine following a case of misconduct of all companies in scope during the period of analysis.
- Has improved its measures for ensuring clinical trials are conducted ethically and is more transparent with clinical trial data.
- Implements relevant inter-country equitable pricing strategies for the first time.
- Does not provide price or volume-of-sales information.
- Improves its accountability for its sales agents' pricing practices.
- Newly commits to not filing for patents and to abandoning patents held in sub-Saharan Africa.
- Has improved its auditing processes related to its off-sec product donations, which it applies to a limited selection of partners.
- Has supported local health services in Haiti through Access to Health Project Haiti, in partnership with Partners in Health and other stakeholders.

OPPORTUNITIES

Engage with stakeholders to act on commitment to voluntary licensing. Takeda has a new commitment to considering the use of voluntary licensing as a mechanism for addressing the affordability and supply of on-patent and pipeline products in lower-middle income countries. It can actively seek potential partners (including manufacturers, where relevant) to explore viable opportunities for turning this commitment into action.

Implement access plans as company expands its focus. As Takeda expands its pipeline and the geographic scope of its pharmaceutical business, it can implement detailed plans for ensuring successful new products are accessible upon market approval. This can include registration

targets for products targeting diseases with high burdens in low- and middle-income countries and plans to ensure affordable pricing.

Ensure the long-term sustainability of its new access strategy. Takeda can strengthen the link between access and its corporate strategies to go beyond a philanthropic approach to improving access to medicines. This would ensure the long-term sustainability of its strategy, as the company moves ahead with an increased focus on access.

Expand use of equitable pricing strategies. Takeda can expand its commitment to equitable pricing, as well as its use, to more products, e.g., atazanavir (Aztivan), as first-line treatment

for hypertensive heart disease. The company can also implement intra-country equitable pricing strategies in countries with high levels of inequality and/or high out-of-pocket spending.

Join efforts to combat antimicrobial resistance. Takeda has seven antibiotics that are on the WHO Model Essential Medicines List (EML), are used in clinical practice and are important for low-resource settings. The company can take actions to increase access to these medicines, while ensuring their responsible use. Takeda can join global efforts to address antimicrobial resistance, for example by signing the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

SALES IN COUNTRIES IN SCOPE

SALES AND OPERATIONS

Takeda's core therapeutic areas are gastrointestinal diseases, oncology, central nervous system diseases and cardiovascular and metabolic diseases. The company's Ethical Drug Division accounts for its largest share of sales, derived from its small presence in the consumer health-care market. In April 2016, Takeda announced the establishment of Teva Takeda Yakuhin Ltd., a joint venture between Takeda and Teva

PHARMACEUTICAL INDUSTRIES. This step is intended to allow Takeda to focus on developing innovative medicines, as the separate entity will market the company's off-patent medicines and focus on the generic medicine market. Takeda has sales in 29 countries within the scope of the index.

PHARMACEUTICAL INDUSTRIES. This step is intended to allow Takeda to focus on developing innovative medicines, as the separate entity will market the company's off-patent medicines and focus on the generic medicine market. Takeda has sales in 29 countries within the scope of the index.

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Revenues by segment (2015)

1,802,318 MYR

Revenues by segments

50

Products per disease category

50

Pipeline projects

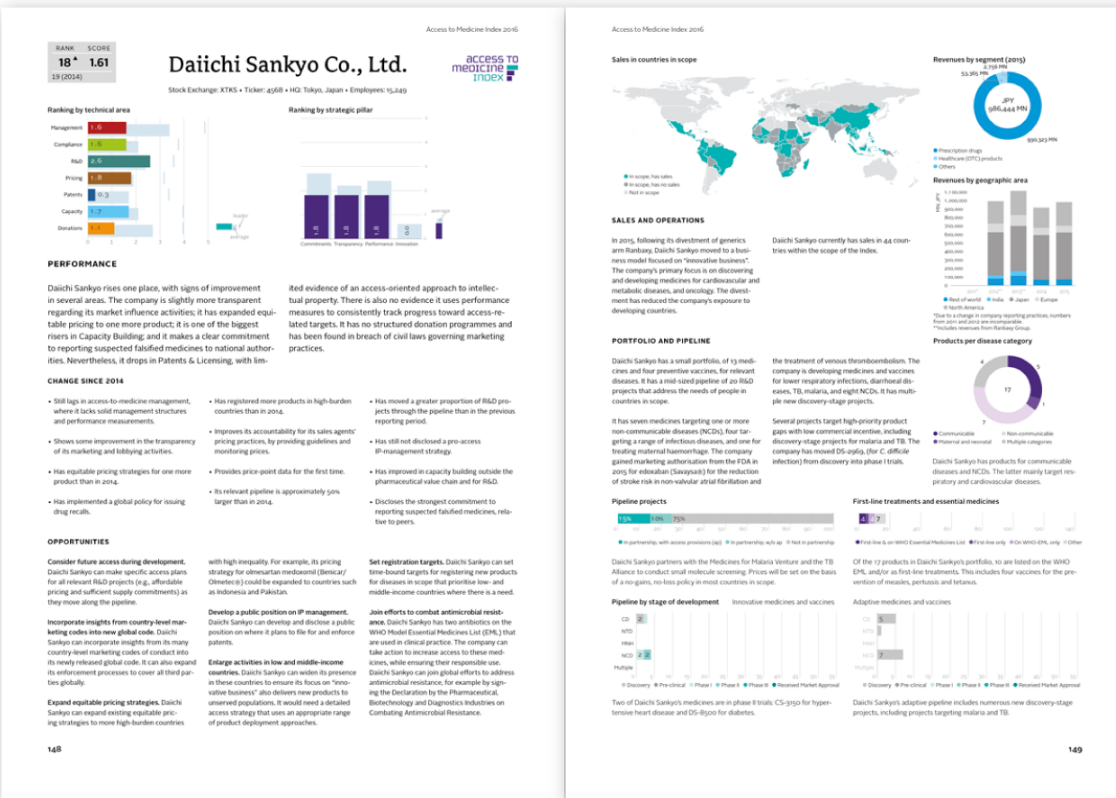
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First-line treatments and essential medicines

14

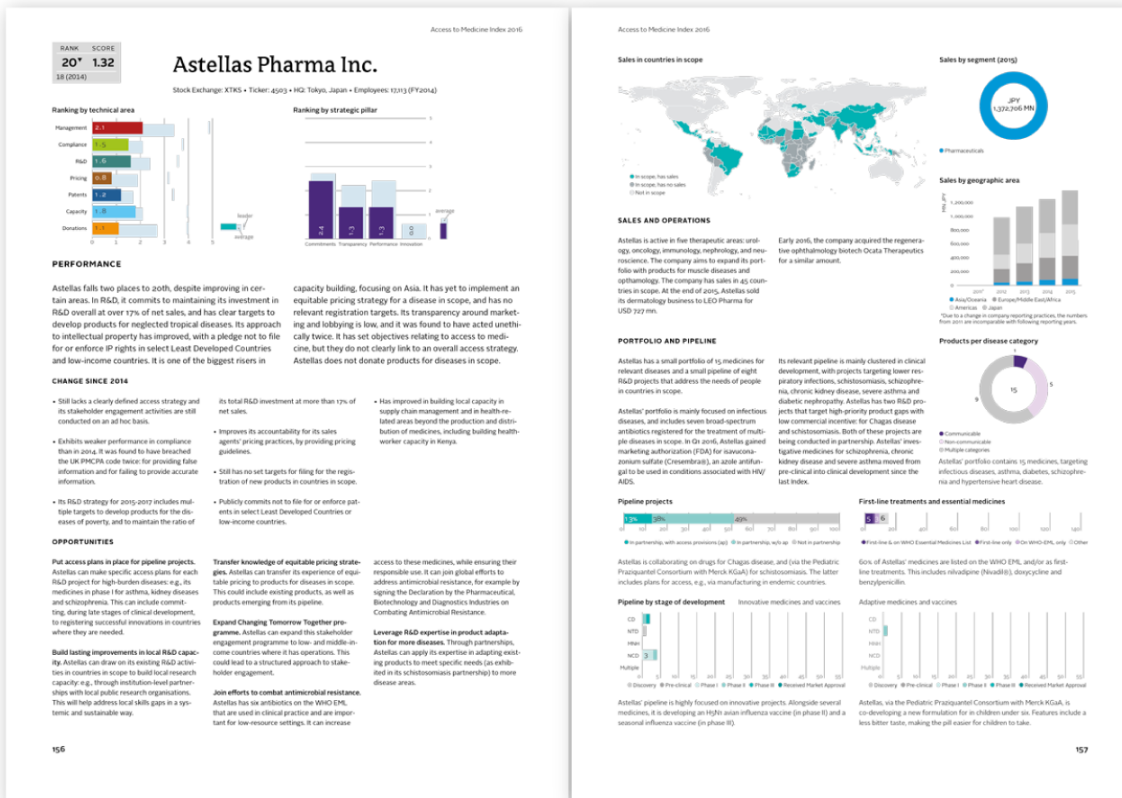
- New access strategy launched
- R&D in NTDs (leishmaniasis, Chagas), dengue and norovirus
- Commits to not enforcing patents in Sub-Saharan Africa

Daiichi Sankyo Co., Ltd.



- Pipeline increased 50% for multiple discovery projects
- Commits to reporting falsified medicine to national authorities
- Supports mobile health clinics, access to medical services
- Technology transfer of vaccines in India, Cameroon and Tanzania

Astellas Pharma Inc.



- R&D in neglected diseases such as schistosomiasis and Chagas disease
- Strengthens supply chain management in China and South East Asia
- Commits to building manufacturing capacity in Brazil and Iran

Q & A

Thank you

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