

Ten-year impact of the Access to Medicine Index: **Changes in industry pricing and intellectual property policies in Low- and Middle-Income Countries from 2008-2018**

Hans V Hogerzeil, Daniel J Edwards, Jayasree K Iyer

23-24 October 2019, Vienna

Acknowledgements

- This study was made possible with financial support from UK Aid, the Bill & Melinda Gates Foundation and the Dutch Ministry of Foreign Affairs
- Researchers were independent in their analysis and in the presentation of the results; they have no potential conflict of interest to report
- The study was performed by Alex Kong, Margo Warren, Danny Edwards, Karrar Karrar and Jayasree K. Iyer; and was edited by Anna V. Massey
- The full report is available on: accesstomedicinefoundation.org/publications



BILL & MELINDA
GATES *foundation*



Ministry of Foreign Affairs
of the Netherlands

The Access to Medicine Foundation

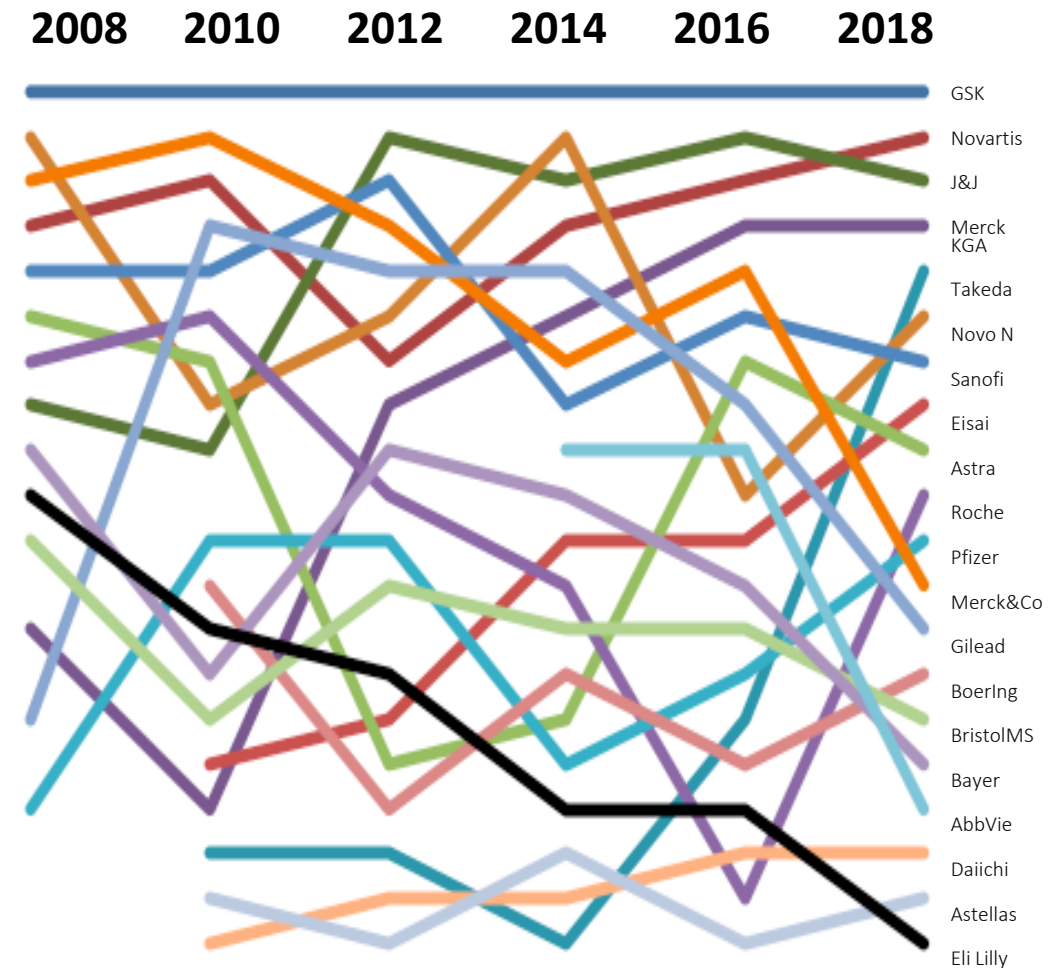
- The Access to Medicine Foundation is an independent non-profit organisation, based in the Netherlands.
- It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding the pharmaceutical industry to play a greater role in improving access to medicine.
- It has published the Access to Medicine Index every two years since 2008.
- 106 Low- and Middle-Income Countries are covered by the ATM Index; covering 83% of the world population.
- In 2017 it published its first Access to Vaccines Index, and in 2018 the first Antimicrobial Resistance Benchmark.

Since 2008, multiple companies have pioneered good practice

- Merck & Co began a donation programme for onchocerciasis in 1987, which is ongoing today.
- Novartis was the first to publicly commit to establishing access plans for all innovative new medicines. Access plans can cover pricing, registration and supply.
- Merck KGaA was the first company to voluntarily disclose the status of patents, in 2014.
- GSK was an early adopter of tiered pricing, notably for vaccines, and has operated a tiered pricing approach for more than 20 years.

The need for a longitudinal study

- The six ATM rankings in 2008-2018 are each a relative comparison amongst companies over a two-year period
- Published ATM scores and ranking are not comparable over time, as
 - Indicators are deleted and added
 - Disease and country scopes are changed
 - Scoring guidelines are tightened to reflect changes in global priorities



- The Foundation published a ten-year report on pharmaceutical company policies and practices in absolute terms
- Focus of this presentation:
 - progress in pricing and intellectual property policies in LMICs
 - information on R&D trends

Methodology

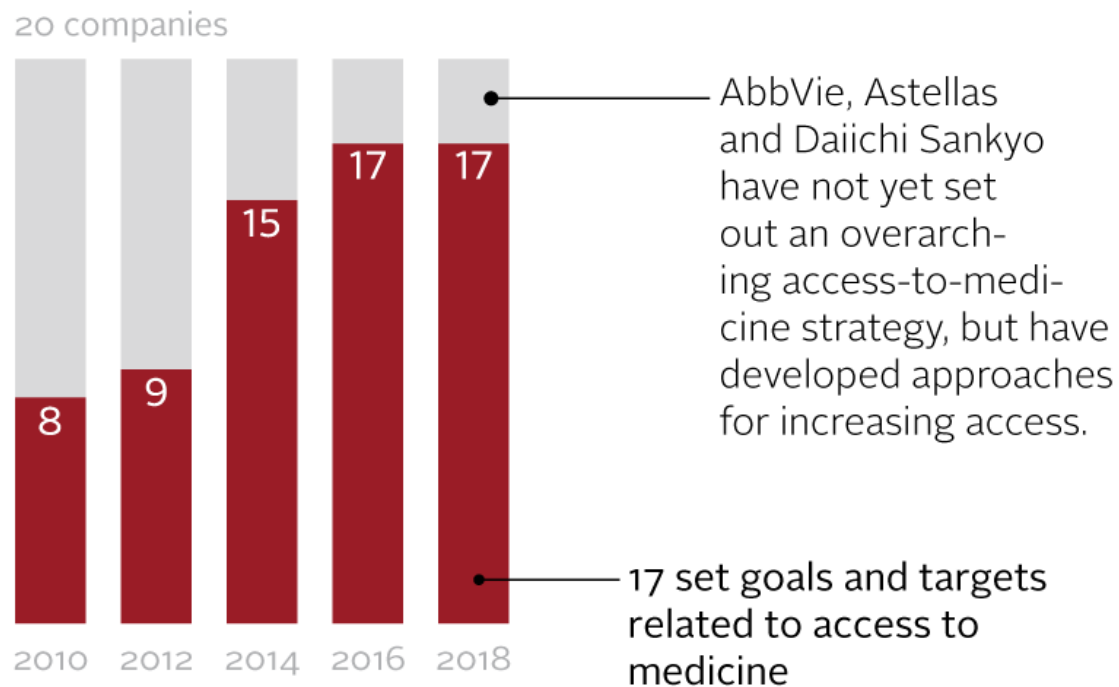
- Public information and original data provided by the 20 companies for six ATM Indexes (2008-2018) were re-analysed in a systematic approach to allow for longitudinal comparisons
- This was achieved by comparing fixed data points which had not changed over the lifetime of the Index (e.g, number of licences agreed).
- NB: Not all areas could be compared uniformly across all indices in this period.

Results

Have companies changed?

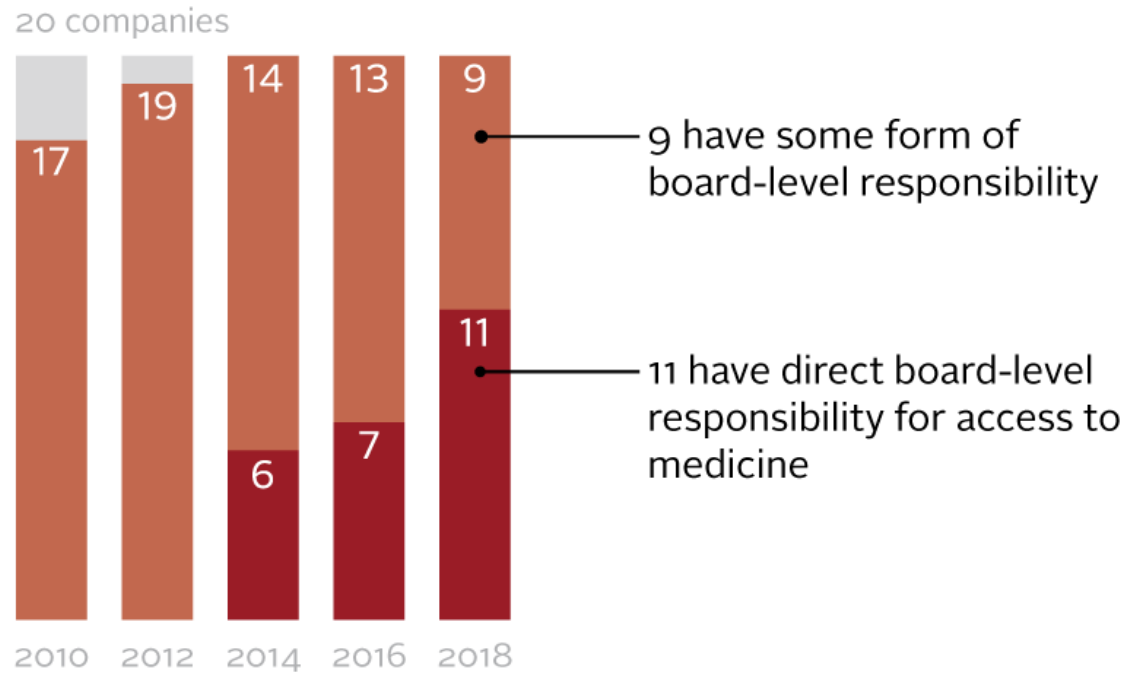
Governance and strategy

Figure 1. Compared to 2010, 17 companies now set goals and targets related to access to medicine



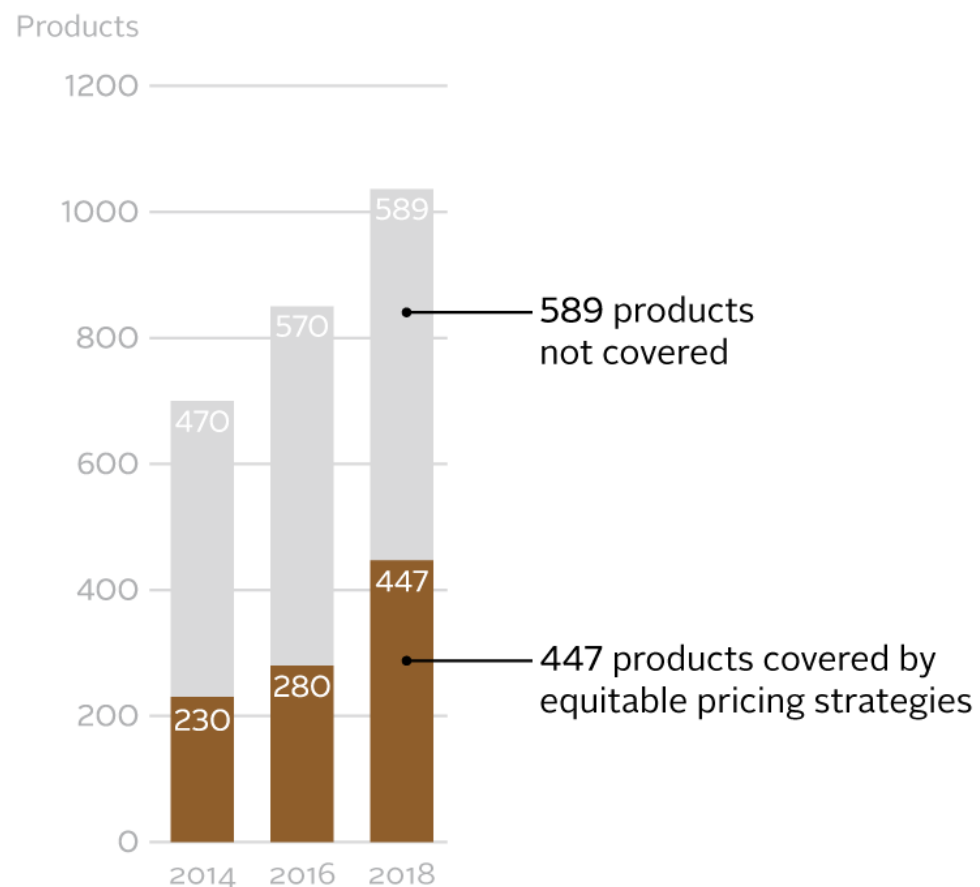
Governance and strategy

Figure 2. Since 2010, more company Boards now take direct responsibility for access to medicine



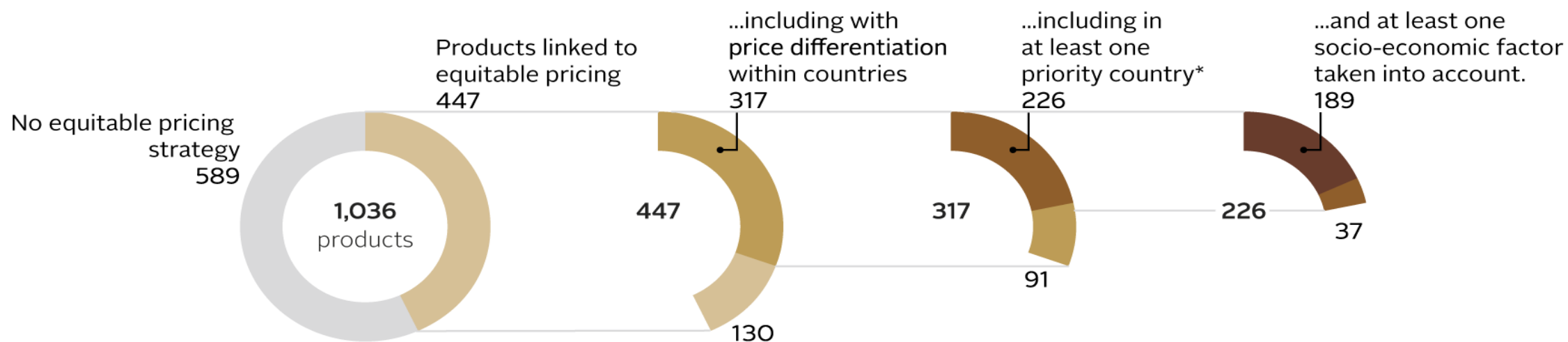
Access to specific products

Figure 31. Compared to 2014, equitable pricing strategies are applied to more products



Needs-based pricing strategies remain low

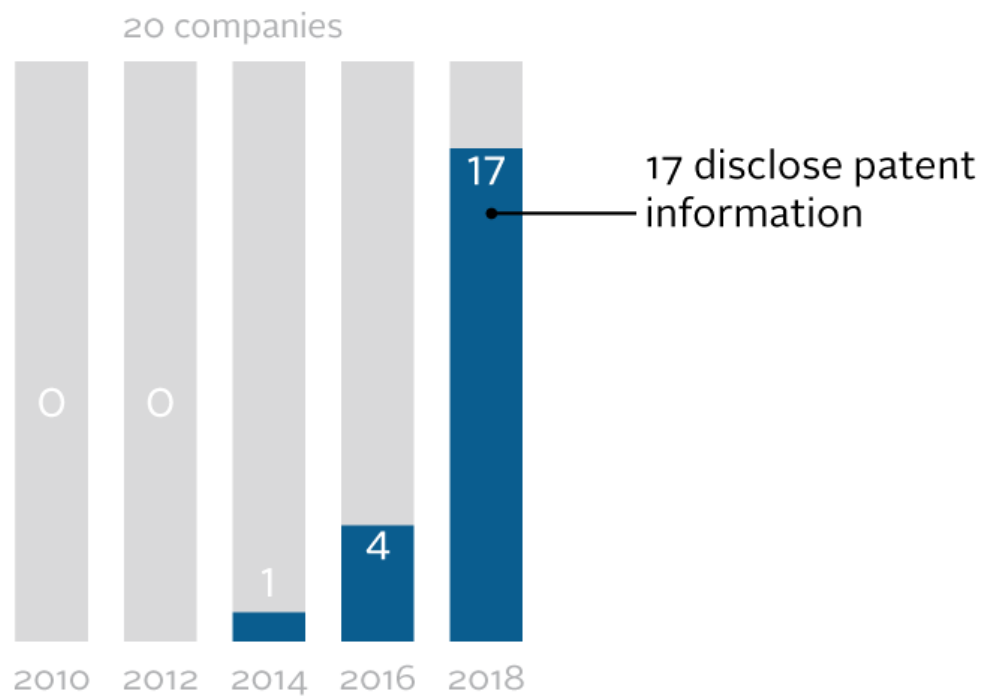
Figure 42. Do companies use people's ability to pay to shape pricing strategies?



The majority (53%) of the most robust pricing strategies (high disease burden countries, segmented within country, multiple factors to determine affordability) are concentrated in only three companies: Boehringer Ingelheim, Gilead, and Novartis.

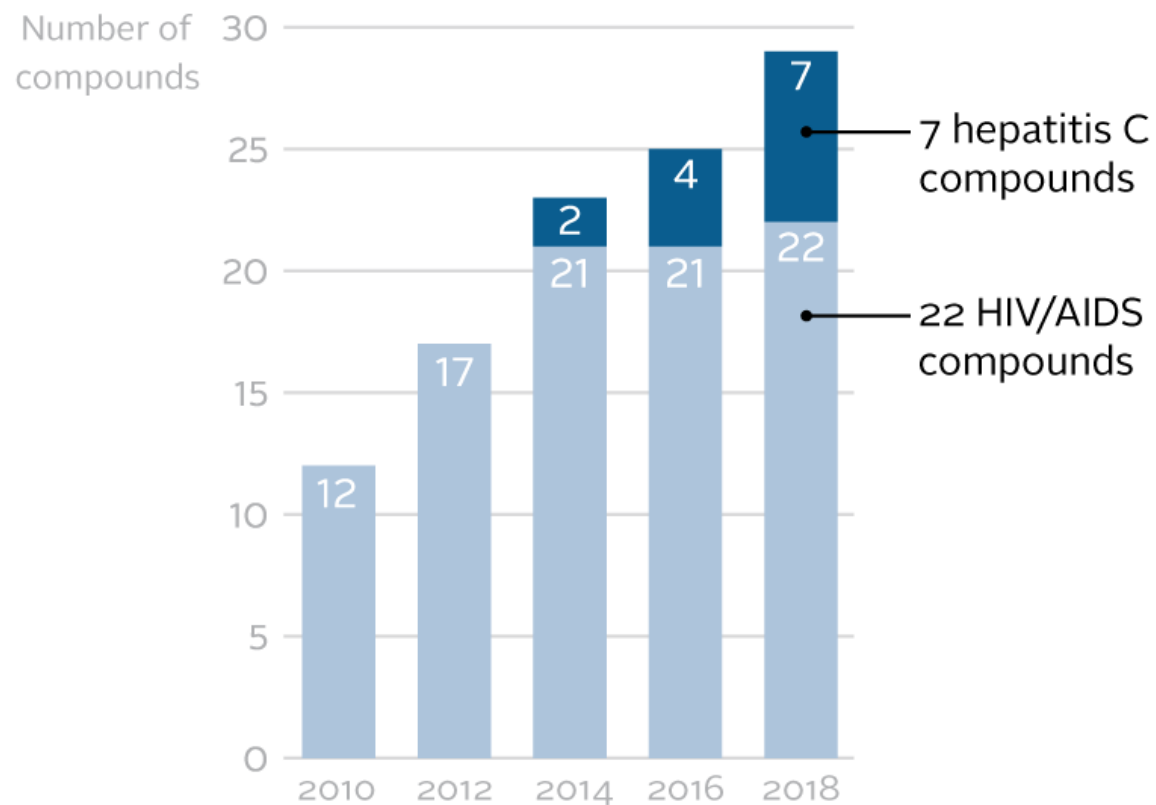
Improved disclosure of patent status

Figure 28. Since 2010, publicly disclosing patent information has become new industry standard



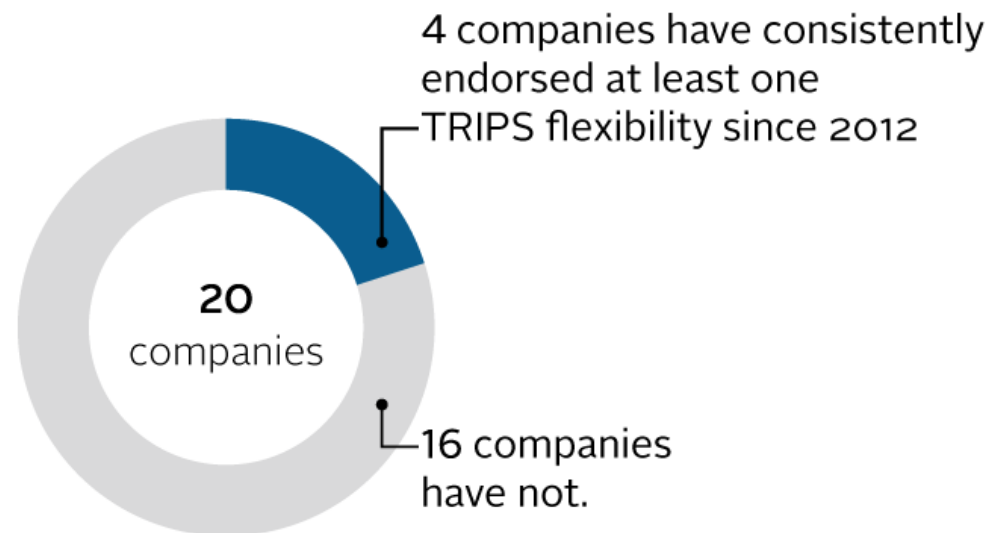
Improved practice in voluntary licensing

Figure 29. Since 2010, number of licensed compounds has steadily increased



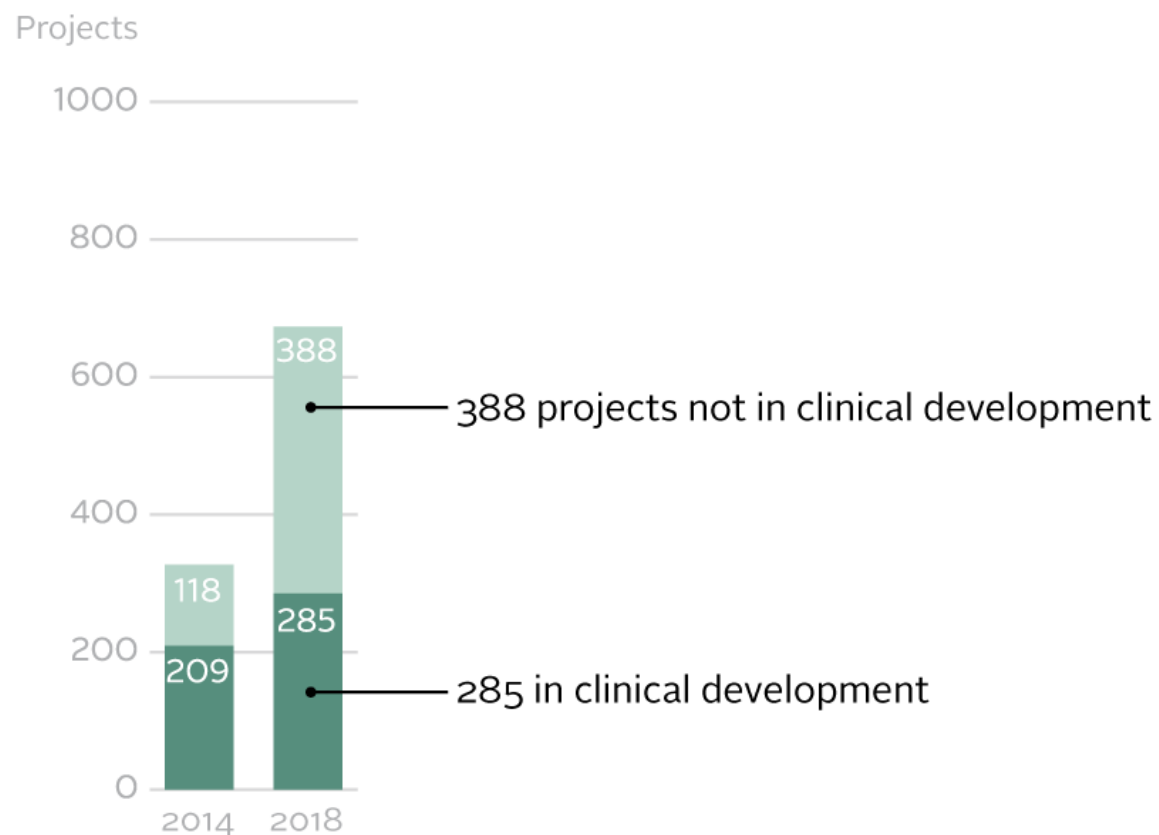
Limited endorsement of the Doha Declaration

Figure 27. Since 2012, four companies have consistently publicly endorsed the Doha Declaration and at least one TRIPS flexibility



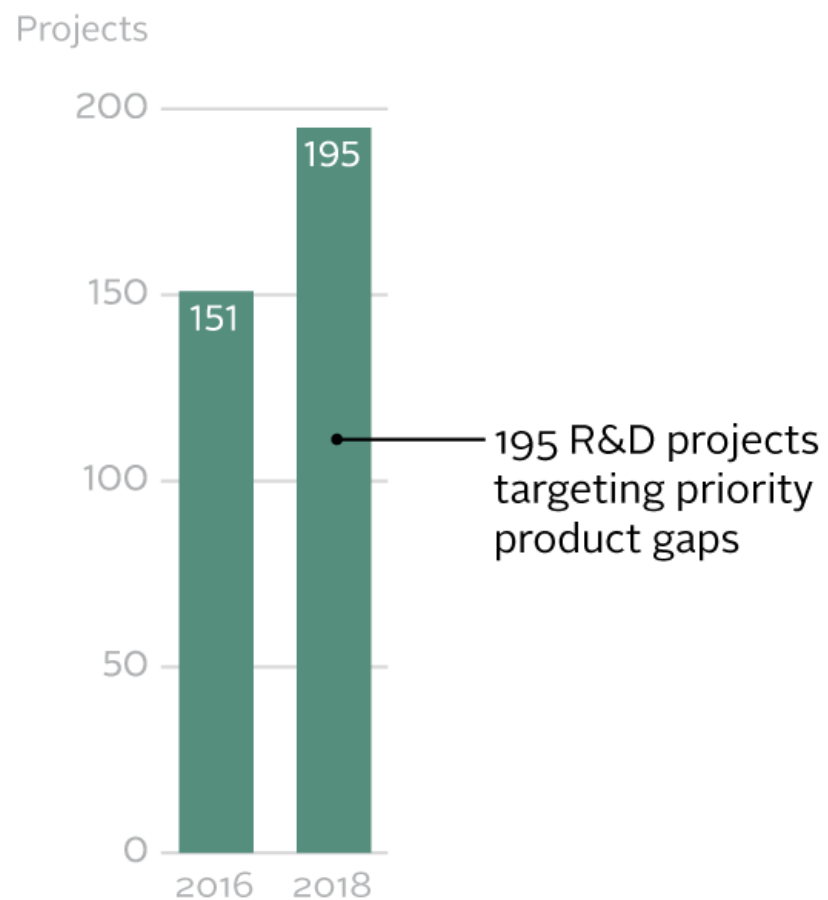
Increase in pipelines for neglected and high-burden diseases

Figure 5. Since 2014, the pipeline for high-burden and neglected diseases and conditions has more than doubled



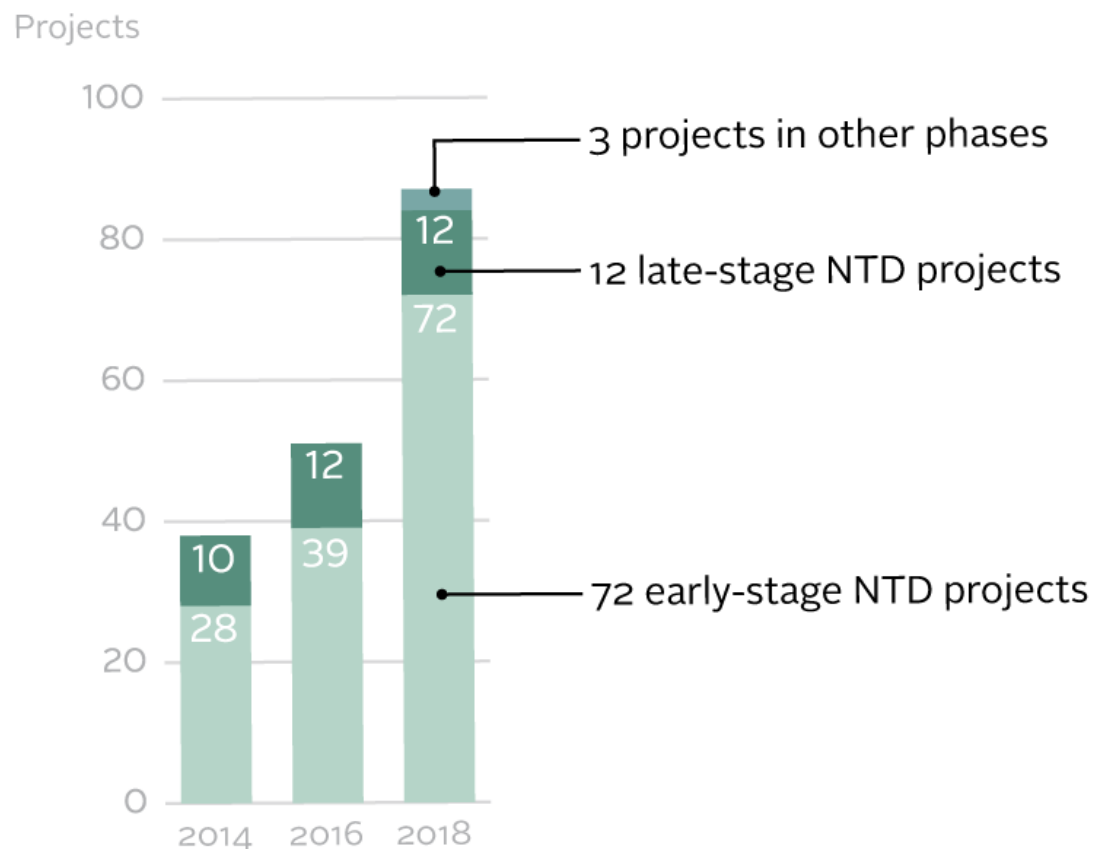
Increases noted in 'priority' R&D

Figure 12. Since 2016, priority R&D has increased



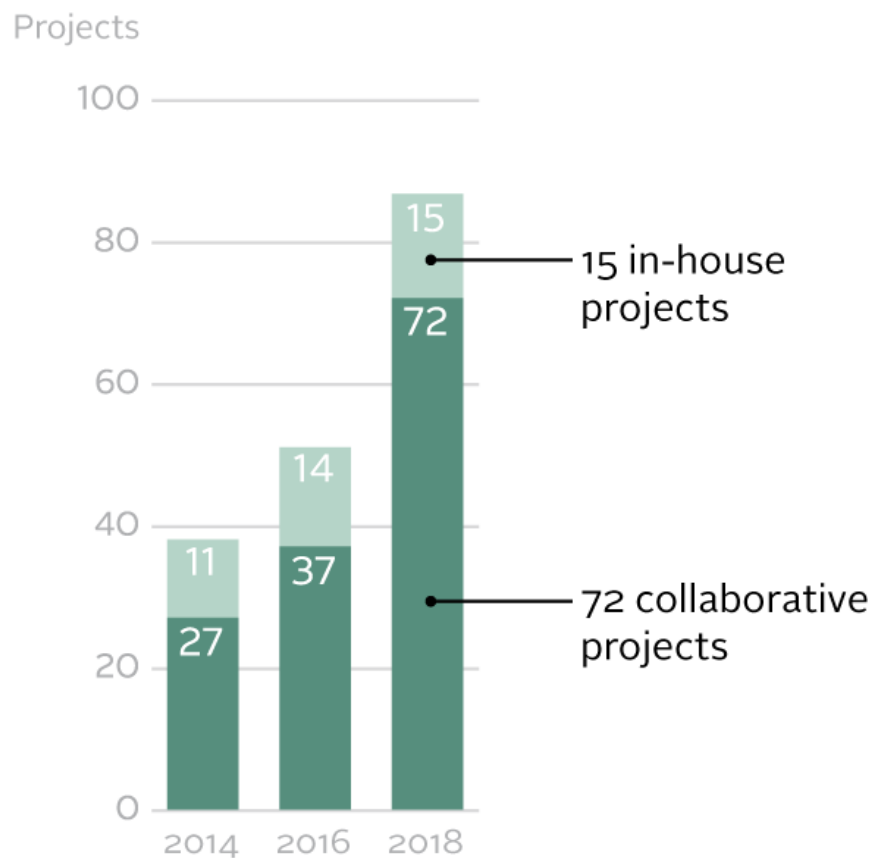
Significant increases in NTD R&D, mainly in early stage

Figure 24. Since 2014, early-stage pipeline for NTDs has more than doubled



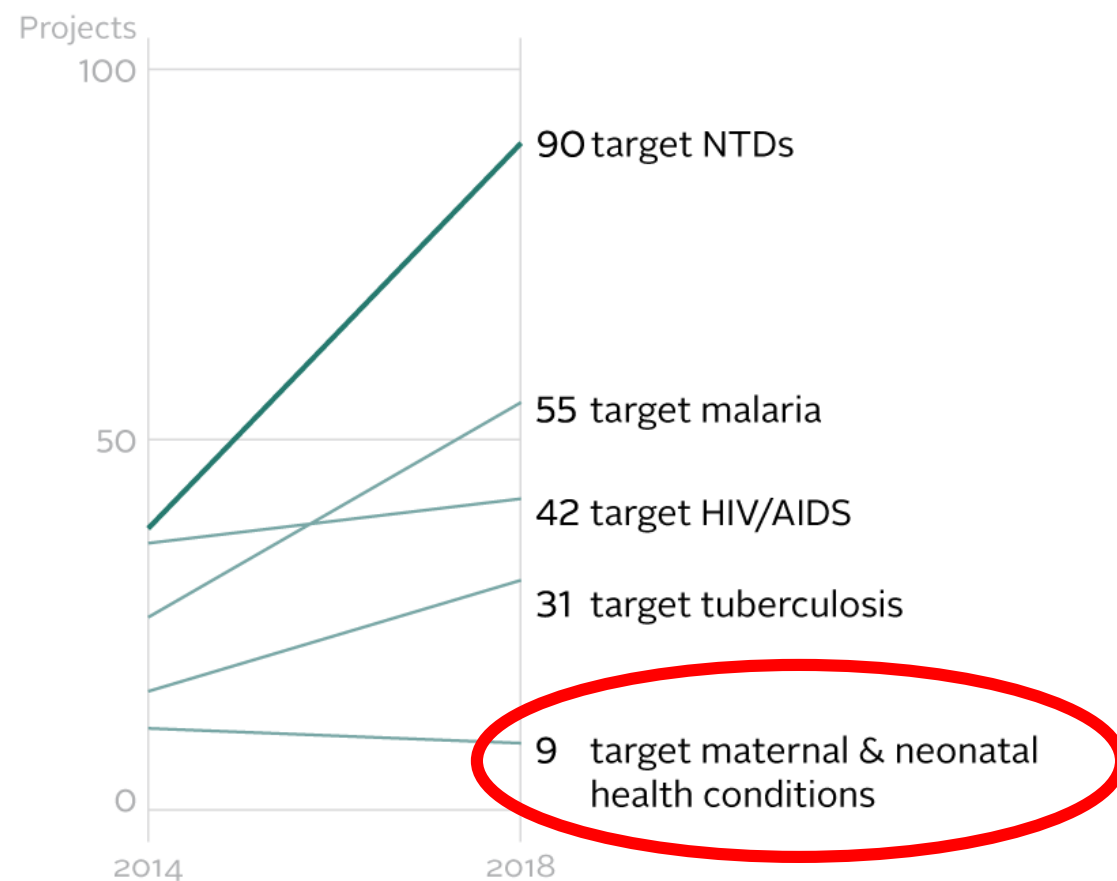
Partnerships a key driver

Figure 25. Since 2014, R&D for NTDs consistently driven by partnerships



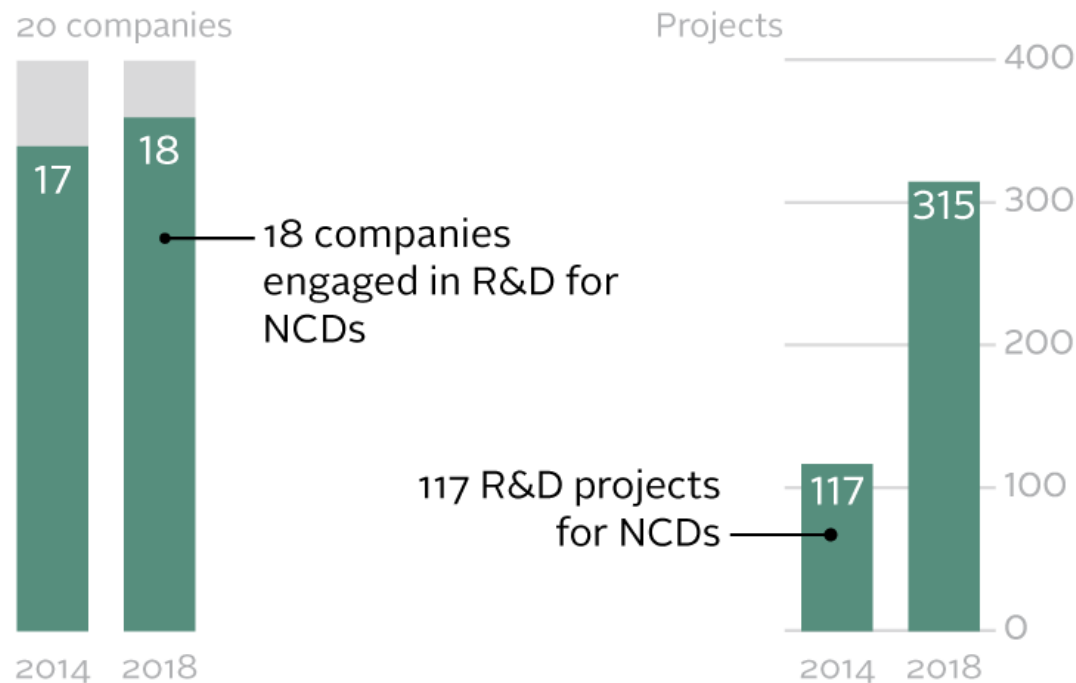
No increase in pipeline size for maternal and neonatal health

Figure 6. Since 2014, pipelines for key diseases have grown, but not for maternal and neonatal health conditions



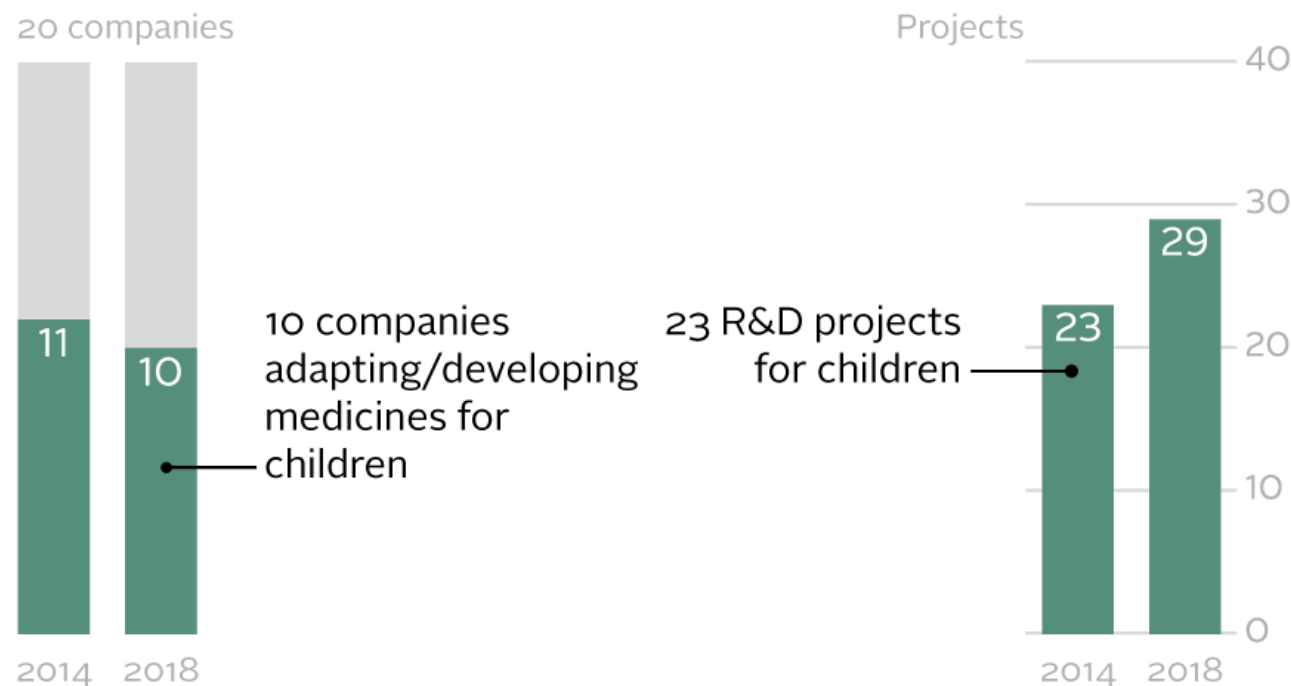
Overwhelming engagement in NCD research

Figure 10. Since 2014, most companies have engaged in NCD research; R&D projects for NCDs have nearly tripled



Limited engagement in paediatric RD

Figure 11. Since 2014, the number of medicines being developed or adapted for children remains low



Discussion: What does this mean?

- Company policies and practices are a surrogate endpoint for access to medicine for one actor in the system. This analysis covers (a) areas where pharmaceutical companies have a clear role and responsibility to act; and (b) where action by pharmaceutical companies is critical for improving access
- Between 2008-2018 there is absolute progress in company policies and practices; however, progress has been concentrated in a few companies only, and in a few key areas and diseases. This makes progress vulnerable to company changes
- Marked progress in company policies and company board representation, patent disclosure, access plans, R&D pipeline, and R&D in NTDs on the basis of partnerships
- Limited progress in endorsement of Doha Declaration, and in R&D for maternal and neonatal health; main R&D focus remains on NCDs

Future of the Access To Medicine Index

- The permanently updated ATM Index is a valuable reflection of current public health demands and expectations of the role of the pharmaceutical industry; it is a “wish-list” of desired behaviour.
- It is not easy to prove the causal link between the ATM Index and the changes in company policies and practices; but the data show progress in several areas identified and promoted by the ATM Index.
- The 2020 ATM Index will focus on future needs, with emphasis shifting:
 - from company policies towards company performance;
 - from company-provided data towards publicly available information.

Hans V Hogerzeil, Daniel J Edwards, Jayasree K Iyer
dedwards@accesstomedicinefoundation.org
www.accesstomedicinefoundation.org