

MEETING REPORT

Mumbai high-level meeting: sharing best practices on appropriate access to medicine and AMR

Panel-led event, hosted by the Access to Medicine Foundation, convening executives from India-based pharmaceutical companies.

26 September, 2018

On 5 September 2018, the Access to Medicine Foundation hosted executives from the pharmaceutical industry in India and globally, for a day-long meeting in Mumbai, India, to discuss appropriate access to medicine and antimicrobial resistance (AMR).

India has the third largest pharmaceutical industry in the world, with an annual turnover of over USD 20 billion. The Indian pharmaceutical market is projected to be worth USD 100 billion in revenue by 2025. Many of the world's major producers, especially of generic medicines, are located in India or have operations there. The strategies adopted by these companies will have a significant impact on access to medicine and AMR globally.

Companies covered in the Foundation's three research programmes: the Access to Medicine Index, the Access to Vaccines Index and the Antimicrobial Resistance Benchmark, attended the meeting. Earlier this year, the Foundation published a [briefing paper](#) specifically looking at how the pharmaceutical industry can take action to combat the growing problem of AMR in India.

Discussion themes

The meeting was structured around four panel discussions, with each panel including representatives from leading international pharmaceutical companies. The themes were as follows:

- 1) **The role of the pharmaceutical industry in addressing the access challenge**
- 2) **New approaches to spur anti-infective R&D**
- 3) **Manufacturing responsibly to reduce the risk of antibiotic resistance**
- 4) **Key access issues in India today**

The meeting was held under the Chatham House rule.¹ The following report presents a summary and takeaway messages from the discussions.

¹The Chatham House Rule: participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.

1. The role of the pharmaceutical industry in addressing the access challenge

This panel of four CEOs and board members of prominent pharmaceutical companies shared their personal visions for improving access to medicine in India, including how companies can balance profitability and productivity with having a meaningful impact on the health needs of the population. The panel was followed by two talks from industry associations on how they see these visions being implemented and the challenges and solutions to incentivising access.

Main discussion points:

- Pharmaceutical companies and the generics industry are in a unique position with the opportunity to contribute to a global cause. The government has a central role in addressing the access challenge but the panel agreed that companies also have a responsibility to get involved.
- Historically, affordability of medicines was the main barrier to access in many parts of the world. The panel agreed that affordability remains an important component of access. While the prices of generic medicines in India are currently among the lowest in the world, inappropriate use of medicines is a bigger issue in India today.
- Panelists agreed that opportunities to improve access in India today depend on pharmaceutical companies working in partnership with the government and other actors to help shape the ecosystem. The panellists stressed the importance of considering all stakeholders' objectives and being willing to share expertise within partnerships. All stakeholders should be accountable.
- Examples of where the partnership approach could be applied include: addressing promotional behaviour, looking in to specific R&D needs that Indian manufacturers can co-develop, and sharing data on surveillance information obtained from partnerships with hospitals and other public institutes.
- There was consensus that regulatory harmonisation is key to speeding up access to medicine in low- and middle-income countries. Regulatory authorities and procedures vary widely between countries. Plus, regulatory systems are often inefficient with long product review times. Companies can identify regulatory gaps and work with governments to develop policies and incentives to support the introduction of products to market.

2. New approaches to spur anti-infective R&D

As AMR increases, more antibiotics lose their effectiveness and new ones are required to take their place to treat infectious diseases. One theme of the event was the need for companies to step up their engagement in antibiotic R&D, which led to consideration of the commercial incentives needed to spur antibiotic R&D.

Main discussion points:

- Excessive use of antibiotics is a problem in India. In 2010, Indians consumed 12.9 billion antibiotic pills, up from 8 billion in 2001. Medical practitioners are regularly prescribing

antibiotics as treatment for patients who may not need them. Furthermore, some practitioners regularly prescribe the same antibiotic, rather than selecting the most suitable antibiotic from the wider class. Additionally, antibiotics are widely available without a prescription in India. It is important that correct prescribing practices are taught in medical schools to reduce over-prescription.

- Misuse and overuse of antibiotics is also accelerating resistance, which will ultimately make it more difficult to treat common infections, lead to higher medical costs, longer hospital stays and higher mortality. It was agreed by the panel that this has to stop if we are to safeguard the effectiveness of existing antibiotics.
- The panel agreed that new commercial models are needed that incentivise antibiotic development rather than the sale of the antibiotic at volume. Incentivising high sales volumes can lead to antibiotic overuse and irrational prescribing practices, which in turn drive resistance.
- The panel stressed the importance of partnerships for antibiotic R&D: reaching out to those with expertise, interacting and being willing to share knowledge.
- Adapting existing medicines for new populations, environmental conditions or indications is an important type of pharmaceutical R&D. There are opportunities for companies to act. For example, they can take an older antibiotic that has fallen out of use, but not yet developed resistance, and improve its safety and efficacy before bringing it back to the market. Dosing and formulations can be changed to make them safer, more effective or more suitable for specific populations or conditions. The panel agreed that adaptive R&D is being neglected. Financial awards can be used to incentivise companies to act in this area.
- It was suggested that the funding approach taken to fight HIV/AIDS by the Global Fund to Fight AIDS, Tuberculosis and Malaria and PEPFAR could be applied to bolster antibiotic R&D.
- The [Antimicrobial Resistance Benchmark](#), published by the Access to Medicine Foundation, identifies the priority actions and policies that pharmaceutical companies can take to ensure antimicrobials are available and being used wisely.

3. Manufacturing responsibly to reduce the risk of antibiotic resistance

This session discussed the importance of responsible manufacturing practices to limit the concentration of active ingredients in factory wastewaters.

- Significantly curtailing the release of antibiotics into the environment is seen as an important measure for slowing AMR. Consensus around safe limits for antibiotic discharge has yet to emerge. On this issue, the Foundation's Antimicrobial Resistance Benchmark questioned 18 pharmaceutical companies with significant antibiotic manufacturing presence. Of these, 15 reported having some form of an environmental risk-management strategy in place. Eight also reported that they have set factory discharge limits for antibiotics.

- There is a lack of clarity regarding exactly how much active ingredient is being released through industrial wastewaters and there are currently no accepted standards for safe discharge limits. However, research is being undertaken to identify limits for each antibiotic.
- The panel agreed that internal company investment in environmental risk management is currently low. Despite this, panellists and the audience agreed that some company Environment, Health and Safety departments are looking into this area.

4. Key access issues in India today

This theme focused on important access-related challenges that India is facing today, including affordability, the approach taken to fixed-dose combinations and the responsibilities of different stakeholders in improving access.

Main discussion points:

- India's rural populations often travel long distances to reach a health facility. Once there they need access to a doctor who is qualified to diagnose and prescribe correctly. People may spend 200% of their income on a single inpatient episode. This contrasts with India's urban populations, who have much greater access to health facilities and treatment. The Government is taking action to counter this through the Ayushman Bharat health insurance scheme.
- Fixed-dose combinations – products that contain two or more active pharmaceutical ingredients in a fixed-dose ratio – are useful for minimising pill burdens and reducing costs. However, lack of regulations, guidelines and over-the-counter availability, have led to a deluge of questionable fixed-dose combinations and irrational prescription of them in India.
- Governments play a key role in ensuring access to medicine. At the time of the meeting, the Indian government has banned 344 fixed-dose combinations, including products from both Indian companies and multinational companies.
- The panel agreed that rational prescribing of medicines is an important issue and prescribers are not always consulting standard guidelines.
- Physician education is key to overcoming irrational prescription and patient misuse of drugs/antibiotics. This does not have to be the responsibility of an individual pharmaceutical company; the industry can come together to educate physicians, for example, by forming company partnerships. This approach is also more cost-effective in terms of financial sustainability – a key element in company considerations on access to medicine.
- Companies can use not-for-profit models as part of their self-sustaining business models on access to medicine.

Looking ahead

Discussions generated several ideas for how companies can strengthen their own internal practices, as well as areas where companies can work together and pool resources to improve access to medicine and combat AMR in India.

In November 2018, the Access to Medicine Foundation will publish the next Access to Medicine Index, which will identify best practices and innovations from 20 of the world's largest pharmaceutical companies for improving access to medicine. The first Antimicrobial Resistance Benchmark, published in January 2018, reports on how 30 companies with significant presence in antimicrobial markets are addressing issues related to AMR. Companies can use these tools to further their commitments to improving access to medicine and addressing AMR.

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About 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. The Foundation is funded by the Bill & Melinda Gates Foundation, the Dutch Ministry of Foreign Affairs, the Dutch Ministry of Health, Welfare and Sport, and the UK Department for International Development.