WORKSHOP REPORT

Ramping up access to medicine toward 2030

18 July, 2019

The Amsterdam Session took place on Tuesday 18 June, 2019 in Amsterdam, the Netherlands
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On 18 June, 2019, the Access to Medicine Foundation convened a dedicated workshop to identify which factors are key for ensuring new products reach more patients and are widely accessible and affordable. The springboard for discussions was the Foundation's recent 10-Year Analysis of pharmaceutical companies' activities to improve access to medicine for people living in 103 low- and middle-income countries, home to 83% of all people alive today.

This 10-Year Analysis identifies clear evidence of progress. Yet to achieve SDG 3 by 2030, efforts must be ramped up. Access to safe, affordable and effective medicines is a core pillar for achieving universal health coverage, and a critical enabler of sustainable development.

The one-day Amsterdam Session aimed to facilitate open discussions between strategic leaders working within the pharmaceutical industry as well as independent experts working to improve access to medicine. The workshop was open to senior market access and pricing leads as well as access and global health directors from companies evaluated in the Access to Medicine Index and Antimicrobial Resistance Benchmark. The independent experts brought investor and global health perspectives, and direct experience of implementing access programmes.

This report summarises the day's discussions, organised by theme:
1. What does the next decade look like for access to medicine?
2. Access planning during R&D: what are the key factors?
3. Affordability and commercial sustainability: a path to effective strategies

The workshop was held under the Chatham House Rule. For more information or to discuss the contents of this report, please get in touch via mverhoef@accesstomedicinefoundation.org.

1. What does the next decade look like for access to medicine?

The workshop was chaired by Jayasree K. Iyer, Executive Director of the Access to Medicine Foundation, who opened with a recap of the Foundation's most recent research; it found evidence of progress since 2008 in how pharmaceutical companies approach access to medicine, most notably in R&D.

Today, the pharmaceutical industry acknowledges it has a role to play in improving access to medicine, and is shifting toward managing access-to-medicine goals alongside commercial goals. Investors are comparing pharmaceutical companies on their access strategies, prioritising these above other ESG factors. Product development partnerships (PDPs) are increasingly prevalent and are now a main driver of pharmaceutical R&D for communicable and neglected tropical diseases. Modern healthcare is moving towards specialised medicines that require complex care and supporting technologies. The costs of innovative new drugs have risen sharply; price pressures are increasingly felt in mature markets. Yet, the scale of the challenge remains vast, with many millions of people living without access to robust healthcare systems.

Against this backdrop, workshop participants identified the main challenges facing pharmaceutical companies in the next decade in improving access to medicine and how companies can prepare.

Main challenges in the next decade

- Providing access to chronic and specialty care that requires a suite of products and services in such a way that can reach mass populations. A particular challenge will be ensuring adherence where there is a lack of robust health infrastructure and people may live long distances from health services.
- Meeting demand from the emerging middle-classes, which is forecast to grow in multiple countries and in all regions, as low-income countries become middle-income countries.
- Building capacity of healthcare infrastructure to make modern medicine accessible at scale. Technology, such as telehealth and drones, can support efforts to reconfigure healthcare systems, retrain and deploy last-mile healthcare workers, connecting them with hospitals, logistics centres and other hubs.
- Bringing attention to NCDs without diverting resources away from delivery agenda. Non-communicable diseases (NCDs) will become a bigger focus for donors, particularly in the context of providing universal healthcare (UHC), and as the NCD disease burden continues to increase.

What does this mean for pharmaceutical companies?

- Integrating access management into the structure of the business, as opposed to running access activities through dedicated departments and foundations in siloes. This will be key to scaling up successful pilots to reach mass populations.
- Discussing access regularly at Board-level, demonstrating to investors and other stakeholders that access is an intrinsic part of doing business for the coming 5-10 years, e.g., by tailoring access strategies to address access needs that the company is best suited to meeting, and using KPIs to track and report on impact beyond delivery (i.e., adherence and outcomes).
- Empowering in-country business units to identify hurdles and develop solutions for improving access to medicine, e.g., ways of delivering new products, while working with NGOs or civil society.
- Systemically integrating access planning into clinical development, to accelerate the speed at which new products become accessible after launch. Current best practice shows access plans (including registration, pricing and supply plans), being developed during Phase II clinical development, continuing throughout the development of commercialisation and stewardship strategies.
- Changing how companies work with partners and governments, particularly for capacity building. New kinds of ambitious partnerships are needed that address countries' specific needs at the health system level, prioritising the availability and affordability of health products. These partnerships will need to be driven and owned by the public sector and be able to engage a diverse group of private sector companies.
- Actively seeking new partnerships, as opposed to waiting for others to lead, while acknowledging that the private sector cannot and should not fill the gap alone. Civil society and local government involvement can ensure local needs are addressed and mitigates the risk of conflicts of interest.

2. Access planning during R&D: what are the key factors?

Pharmaceutical companies are generally either built for scale (e.g., for supplying generics or vaccines); or have deep expertise in developing new products and bringing them to market. Both types are needed to ramp up access to medicine globally at scale, as this requires: (a) innovating new approaches to improving access; and (b) meeting a wide range of access needs. New life-saving products must be made rapidly available to people who need them, wherever they live. This requires detailed access plans to be developed before launch. The Access to Medicine Index has defined the elements of a good access plan, including registration targets and pricing commitments. Here are the main factors for systematically developing effective plans, as identified during the workshop by company representatives and experts from the investor and global health communities, and from a deeper dive into one company's approach to access planning.

What are the factors of successful access planning?

- Access planning blueprint covering all products: Access planning is shifting from a decentralised, *ad hoc* activity to a systematic process governed at the global level. Current best practice shows that companies can commit to systematic access planning for all R&D projects, including for specialty products as well as for high-burden and neglected diseases. This commitment can be enforced at Board level and linked to performance incentives of key personnel, including those working in-country or within commercial teams.
- Regular Board-level engagement: Frequent meetings (e.g, quarterly) enable Boards to engage with the access planning process at the local and per-product level. These meetings also provide an opportunity to discuss products that lack access plans, and how to scale access as a strategic issue.
- Start planning during Phase II: Access plans should be developed during Phase II of clinical development. This ensures access plans for LMICs are part of the global plans reviewed by Boards. One company reports introducing products in LMICs within 7 months of first launch, by preparing registration dossiers alongside FDA filings, setting pricing tiers early and carrying out clinical trials in specific locations with high disease burdens. For recent mergers and acquisitions, access strategies must be part of the discussion early on.
- Set guidelines and expectations for in-country commercial teams: Local teams are ideally placed to identify barriers to access plus potential solutions, regarding, e.g., supply chain issues, formulation requirements, infrastructure development and access to diagnostics. Local teams need clear guidance on how to come up with solutions, supported with incentives. Asking what teams need to make a product more available, apart from lowering cost, is an important conversation starter. E.g., one company established company-wide guidance for introducing and managing local brands for innovative medicines, which has now led to those products reportedly reaching significantly more people from low-income countries.
- Seek diverse partnerships that cut across sectors: Partners such as donors, multilateral agencies and NGOs can help to establish sustainable mechanisms for improving access. Companies must first identify where they can act alone, and where partnerships can maximise the benefit to the patient. Discussions with local partners are key to developing locally appropriate access strategies. Faith-based organisations are seen as having strong, fast-moving supply chains with less risk of corruption. Technology companies can support in repurposing healthcare workers, e.g., through tele-healthcare. Social impact bonds can be developed with investors. For established products, patient organisations can help identify unmet R&D needs, e.g., related to formulation. Partnerships with local governments based on contractual obligations can provide stronger guarantees regarding procurement and the inclusivity of commercial models (In Ghana, one company is now directly managing imports, supporting supply and demand alignment). Discussions around productivity and economic development can be effective at bringing finance ministers on board.
- Private-private partnerships to ramp up access at scale: Originator and generic companies can launch generic versions of new products in lower-income countries at the same time as in high-income countries, e.g., by using voluntary licensing based on pro-access terms, supported by wide registration filings, with each licensee focusing on those countries where they have the networks, capacities and partners to rapidly ramp up access at scale.
- Build in metrics for tracking impact: Impact KPIs must be built into access plans from the start. Investors view impact in four ways: (1) Intentionality: do Boards and managers demonstrate genuine intention to have impact; (2) Materiality: to what extent are impact-related activities also material (influencing the bottom line); (3) Additionality: do the activities deliver an additional impact that would otherwise not be achieved; and (4) Measurability and transparency: are impact measurements transparent and meaningful.

3. Affordability and commercial sustainability: a path to effective strategies

Affordability was one of the workshop's main themes. Participants discussed hurdles and solutions for taking account of people's ability to pay, depending on where they live and what they earn. Affordability depends on who is paying and the constraints they face. In low- and middle-income countries (LMICs), up to 70% of spending on medicines is made out of pocket. During the workshop, two participants presented their company's approaches to maximising affordability in different health systems.

Factors for developing robust affordability strategies

Participants generally agreed that affordability strategies need to be tailored on a case-by-case basis, for example, depending on whether products are established or innovative. To enable this to take place, participants discussed the benefit of defining a company-wide framework or set of principles that market access colleagues and in-country business teams can use to develop their own affordability toolkits. A range of factors for this approach were identified during the workshop:

- **Linking KPIs to affordability:** Market access leads traditionally focus on mature markets when planning product launches. Linking Key Performance Indicators (KPIs) to affordability in LMICs can reset priorities so that they start new conversations with colleagues working in-country or on registration dossiers.
- **Company-wide pricing frameworks:** Such frameworks set out the pricing range, based on defined criteria, that in-country commercial teams can use to modulate prices per product per population segment. Frameworks can be anchored to multiple socioeconomic factors, such as Gross Domestic Product, Human Development Index status, and/or public health expenditure per capita, among other factors, including metrics that take the informal economy into account (e.g., using utility bills to assess standard of living). Company-wide frameworks must be supported by governance structures to ensure rich-market prices are not lower than for less wealthy markets, and to ensure prices do not converge on the lowest price points.
- **Window of affordability/commercial potential:** To achieve access at scale, pricing frameworks must pinpoint the overlap between affordability and commercial potential for the product and the country in question. For companies with established products, identifying this window is a core competency.
- **Segmenting by payer type:** In-country price segmentation can be done by payer type, starting with: (1) the public sector/government-funded reimbursement, and (2) people who pay out of pocket. More sensitive strategies are tailored to the ability to pay of populations paying out of pocket. For some segments, governments might reimburse part of the cost with the remainder being contributed by the company.
- **Working with partners**: Third parties can help to establish the socioeconomic models that are needed for determining people's ability to pay or to develop insurance vehicles to mitigate against financial catastrophe, e.g., where UHC is not covering the minimum standard of care. They also offer independent expertise for collecting and analysing the patient-level data needed to decide which patients qualify for which level of rebate. Companies cannot legally control mark-ups across the supply chain. Civil society, particularly faith-based organisations, acting without a price control are considered more likely to act ethically when it comes to mark-ups (in some countries, governments control mark-ups).
- **Reinvesting revenue generated through setting reasonable margins:** Matching the list price to the cost price will not necessarily improve access at scale; cost price can be too high for some populations while other populations continue to face access hurdles related to supply. It can also lead to the commodification of treatments and increase the fragility of the market. Setting prices with a small margin (i.e., which can be managed in terms of reimbursement) can build in sufficient room to: (a) invest in capacity building to improve supply chain management or in health system strengthening before public investment increases; and (b) discount prices further for those people for whom cost price remains unaffordable. Market segmentation that includes the growing middle class is a key route for generating such margins.