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Expert Workshop on Key Challenges and New Developments in Ensuring Access to Medicines, Vaccines and Other Health Products

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Your excellencies, distinguished delegates, colleagues,

It is a great pleasure to join you for this workshop on Key Challenges and New Developments in Ensuring Access to Medicines, Vaccines and Other Health Products.

The issue of access to medicine is a fundamental component of the full realisation of the right to health. The right to health in all its forms should be viewed through the lens of appropriateness, availability, and affordability. Ensuring these 3 factors are applied to all people in the world, regardless of where they live or their socioeconomic status is essential to promote the realisation of the right to health and specifically access to medicines, vaccines and other health products, including medical oxygen. Improving global and equitable access takes the long-term willpower and creativity of multiple organisations and people to solve it. While inequities in health access have been highlighted by the COVID-19 pandemic, they are an age old, chronic problem.

While 80% of the world's population live in low-and-middle income countries (LMICs), innovative and essential medicines are still not reaching those who need them the most. This challenges human dignity and the basis of all human rights, including the rights to life, health and development of all persons.

We at the Access to Medicine Foundation have been tracking the actions of the pharmaceutical companies for nearly 20 years, and today also track the actions of selected generic medicine manufacturers, medical oxygen producers and several vaccine manufacturers who still control the world's supply of essential health products. We also have advised on policies retaining to regulation, universal health coverage, financing and engaging with the healthcare industry, and our work is used by companies, states, civil society and over 150 institutional investors who invest directly in healthcare companies.

The Access to Medicine Foundation reports highlight the broad range of strategies available to companies for the purpose of increasing access, including:

- More comprehensive access plans and R&D for products that better meet the needs of those living in resource constrained settings;
- Wider product registration with regulatory health authorities; and
- Stronger and wider access strategies, including voluntary licensing to reach more people with generic variations.

States can play a valuable role in enabling pharmaceutical companies to expand access on a global scale through supporting and enabling these strategies.

I) The development of more comprehensive access plans and R&D for products that better meet the needs of those living in resource constrained settings

Healthcare companies have key roles to play in ensuring their products are appropriate, available and affordable through their R&D, access and delivery efforts. Investing in R&D, whether it be for priorities already well defined by the WHO and others or for unmet medical needs for new diseases that emerge is only the first step. Furthermore, R&D is not only for innovator companies as several generic manufactures have significant R&D units and have been involved in innovative steps to address formulation issues, temperature stability and making products more appropriate to diverse populations. We support early access planning where companies need to ensure that products upon launch are available in, and suitable for, countries affected by the greatest burden of disease, and not only those living in the US and Europe. In several areas, companies can work together with states to ensure that elements of access planning are in place early on.

Over the years, companies have progressed in this area with 6 out of the 20 biggest global R&D-based companies now developing access plans for 100% of their products in phase 2 of the R&D pipeline, when efficacy is known (compared to 0 in 2021). But the scale is still limited to a few LMIC countries and thus a limited reach. On average, an access plan includes only 6/108 LMICs in scope of the Index, and only 15% of projects are covered by an access plan that includes at least one low-income country (LIC). This gap in access is amplified further for non-communicable diseases (NCDs) where only 5.5% of plans include a low-income country. Further collaboration is needed to embed access planning across R&D pipelines to help ensure equitable and timely access as soon as new products are approved.

What can states do?

- States providing funding to support R&D projects, whether through overseas development budgets, academic institutions or government bodies, should embed in their contracts the development of comprehensive access plans tailored to LMICs to improve global access.
- Sates can also help ensure products being developed are suitable for resource deprived areas (e.g., heat stable, easy to administer) through similar research stipulations, along with equity embedded into clinical trial conduct to maintain that innovative products are proven efficacious for all populations.

Opportunities:

The 2022 Index, Antimicrobial Resistance Benchmark and the Generic and Biosimilar Medicine Manufacturers Company Profiles highlight specific and tailored opportunities for respective companies related to ensuring all late-stage R&D projects have comprehensive access plans.

Several companies, including AbbVie, AstraZeneca, BMS and Novartis have opportunities aimed at ensuring all of their late-stage R&D projects have comprehensive access plans.

II) Wider product registration with regulatory health authorities

When a product is ready to be launched, the first step the company can take towards making it available in any given country is filing it for registration with regulatory health authorities. Once the product is registered, it can then be marketed and sold. Registering products in a wide range of countries, including LMICs, is vital for ensuring access to those products globally. Among the 108 countries in scope of the Index research, there are particular countries – mainly upper-middle income countries – where products are far more likely to be registered. While products for non-communicable diseases (NCDs) such as diabetes and cancer are at least filed in some low-income countries, more so than products for communicable diseases, there are low-income countries in which no products have been filed at all, rendering them unavailable.

What can states do?

- Regulatory bodies can harmonise and simplify registration procedures, by utilising collaborative registration procedures and other regional mechanisms.
- Challenge companies' pre-conceived notions about the functioning of specific regulatory health authorities in LMICs and make clear where other access pathways are possible.

Opportunities:

The 2022 Index specifically encourages companies in their respective report cards, such as Eli Lilly and Pfizer, to file to register new products in more countries where registration filings for these specific products are low. Beyond the Index, Otsuka, Teva and Viatris, among others, have opportunities in their report cards aimed at improving registration efforts for generic products in countries with the highest burden of disease.

III) Stronger and wider access strategies, including voluntary licensing to reach more people with generic variations

Engaging in voluntary licensing is one way that research-based pharmaceutical companies can ensure that key healthcare products reach more people who need them – particularly those living in LMICs. When companies offer a licence, this can facilitate the entrance of generic manufacturers to market, making medicines more affordable and available.

The 2022 Index finds companies are increasingly engaging in voluntary licensing, enabling generic medicine manufacturers to develop and manufacture generic versions of their on-patent medicines. During the period of analysis (1 June 2020 – 31 May 2022), six companies entered into new voluntary licensing agreements, three of them for the first time: AstraZeneca, Eli Lilly and Novartis. Such agreements can increase regional availability, supply and affordability of new and innovative medicines that would otherwise not reach people living in many LMICs.

While much of this trend is driven by companies engaging in voluntary licensing for COVID-19 products, it opens the door for more companies to consider entering licences for a wider range of medicines, including novel therapies and products for non-communicable diseases (NCDs). Novartis's non-exclusive voluntary licence for a leukemia medicine with the Medicines Patent Pool – the first such agreement covering an NCD – is significant.

What can states do?

Member states can create enabling environments for licensing, including provision in research agreements to enable generic production once a product is approved. Licences can lead to greater access and/or reductions in the cost of essential medicines via increased generic competition. Such strategies can be hugely instrumental in improving primary healthcare capacity and maximising health budgets.

Opportunities:

Several companies have tailored opportunities for voluntary licensing highlighted in their company report cards in the 2022 Index for a selection of their products. For instance, these opportunities target oncology products for Astellas, AstraZeneca, Boehringer Ingelheim, BMS, Eli Lilly, Johnson & Johnson, Merck KGaA, Novartis and Roche; HIV products for Gilead and MSD; and diabetes products for Astellas, AstraZeneca, Boehringer Ingelheim and Johnson & Johnson.

Conclusion

When clarifying the key challenges and solutions pertaining to improving access to medicines, vaccines and other products, we cannot ignore the conflict between commercial profitability on one hand and accessibility in LMICs on the other hand. The research of the Access to Medicine Foundation has demonstrated over the past two decades, there is much more innovative pharmaceutical companies can and must do. The same is true for generic medicine manufacturers, that must, in turn, demonstrate access to all countries within the scope of a given licence. For states, it is important to have a strong understanding of the operating model of companies and to identify the best opportunities for access provisions and for catalysing any efforts by companies. Provisions to increase access in LMICs can be put in place when government bodies sponsor R&D efforts and provide public funding either directly or indirectly to pharmaceutical companies.

The COVID-19 pandemic, clearly articulated the need for stronger and more structured collaboration with the healthcare industry, yet it should not take a pandemic to focus attention on equitable access to the right to health. There is a need for states to build constructive engagement and stronger partnerships with relevant stakeholders, including healthcare industries, in accordance with the local contexts. A key factor in ensuring sustainable access is alignment between the health needs of states and company activities. States have a responsibility to articulate their needs and accept partnerships strategically, encouraging action from companies that benefit the communities and regions most in need. As member states engage in this issue and with the industry, note that there is no silver bullet, but solutions lie in fostering early and long-term partnerships, and embedding actionable stipulations for access into such partnerships.

A rights-based approach towards access requires simultaneous attention to both innovative projects in the pipeline and products reaching the market as well as to existing generic health

products. Improved appropriateness, availability and affordability provides equal opportunity for everyone to enjoy the highest attainable standard of physical and mental health.