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Access to Medicine: Reach more patients through a deeper understanding of access issues

Introduction

The leading pharmaceutical companies have intensified efforts to broaden Access to Medicine in Low- and Middle-Income Countries (LMICs) over the past few years, (cf. *Pharmaceutical companies intensify their social impact reporting on Access-to-medicine,* Deloitte, January 2023). Nevertheless, efforts to improve Access to Medicine sometimes fail to address the true barriers to access, which vary across therapeutic areas, geographies, and patient populations. As a result, if not well designed, access initiatives may not have the intended impact, and potentially have a negative impact on the broader commercial business. In this paper, we break down the types of access barriers at the system and individual level, as well as provide examples of targeted strategies to address these challenges. Contrary to common belief, most of these strategies do not require lowering drug prices and jeopardizing commercial and financial value. Here, we show that there are many strategies – some traditional and well known, others quite innovative – that allow broader **Access to Medicine in a way that reinforces the overall value of the product for pharmaceutical companies and their shareholders.**

Breaking down the complexity: Five types of barriers

Access barriers in healthcare refer to any factor that impedes an individual's ability to obtain appropriate and timely care services and products. These barriers can arise from various sources, including the patient's personal circumstances, socioeconomic conditions, cultural or language differences, or the healthcare system itself.

Five distinct types of access barriers exist, ranging from countrywide healthcare delivery system and institutional barriers (e.g., lack of health system funding or lack of IP protection for pharmaceutical companies), to patient-level barriers (e.g., lack of trust, lack of interaction with the health system). When developing an access strategy, it is important to identify the specific barriers that are relevant to the therapeutic area or indication as well as the contextual challenges of the populations or geographies that can benefit most from the treatment. The five types of barriers to access include:

1. **Affordability and funding barriers**
   Insufficient or incomplete health system funding for medicines, as well as individuals' inability to pay for direct (out-of-pocket) or indirect costs (e.g., lost work time to travel to doctors' visits)
2. **Healthcare delivery system barriers**
   Lack of basic or advanced healthcare infrastructure, insufficient number of skilled or trained healthcare practitioners, long distances to facilities, and complex system navigation
3. **Patient-level barriers**
   Lack of understanding or awareness of disease and care practices, lack of trust in the healthcare system, and unhealthy behaviors preventing proper disease management
4. **Drug and treatment design**
   Narrow indications, complexity and burden of treatment protocols
5. **Health system institutional barriers**
   Lack of regulatory framework to facilitate marketing approval, absence of patent protection policies, lack of robust pharmacovigilance laws to ensure drug safety and integrity, and protectionist laws favoring local manufacturers.

We now break down each barrier in more detail and describe specific strategies and tactics to overcome them.

1. Affordability and funding barriers

Affordability is one of the key barriers to access. However, there are many root causes behind this challenge, depending on where the inability to pay comes from (i.e., at the system or at individual level) and what aspect of care is unaffordable (i.e., the product itself, health insurance, etc.).

High out-of-pocket costs – In some countries, particularly LMICs, national payer institutions may not have enough resources to cover the full cost of healthcare services, leaving patients with the burden of paying for their treatment themselves. In private-based markets, insurance may be strongly exclusive, making it even more difficult for low socioeconomic-status groups, who may not benefit from broad coverage and have limited or no coverage for some healthcare services, such as specialized treatments or procedures.

Prohibitive cost of diagnosis – High costs of diagnosis can raise barriers for patients to access the treatments they need. For example, precision medicine may require genomic testing, a complex and specialized type of diagnostic testing that analyzes a patient's genetic material to identify potential disease risk, genetic mutations, or other factors that may impact their response to treatment. These tests can be costly, ranging from hundreds to thousands of dollars per test.

Prohibitive indirect costs – Receiving healthcare services often involves additional costs, such as transportation, childcare, time off work, and other related expenses. For example, the cost of transportation to a medical appointment or taking time off work can be prohibitive (especially in cases where treatment requires multiple appointments or procedures), leading to missed appointments and delayed care. This particularly impacts low socioeconomic-status groups, for whom the relative financial and logistical burden might be greater, as well as people living in remote areas, for whom the time and cost to physically access services are more important.

Strategies to overcome barriers

A wide range of strategies can be leveraged by pharmaceutical companies to address affordability-related access barriers, from basic levers to more advanced strategies:

Donations – Donations from pharmaceutical companies to non-governmental organizations (NGOs) are a direct and impactful lever to improve affordability, although they may not be sustainable in the long term (financially for pharmaceutical companies, but also for healthcare systems that in this case rely on the ability and willingness of the company to provide their product for free).

Differentiated or 'tiered' pricing – Companies can differentiate prices based on country or patient profile. This can be achieved through direct price adjustments or through indirect mechanisms like patient access programs (e.g., coupons or loan-based schemes). Second brands also allow pharmaceutical companies to differentiate prices by selling the same drug under different brand names. Price levels can therefore be adapted depending on the country's ability to pay (i.e., market at a lower price under the second brand in countries with lower income levels or less developed healthcare systems, and maintain a higher price for the original brand in more affluent markets).

Licensing – Pharmaceutical companies can grant rights to a company, often local, to manufacture and/or sell its products, increasing the likelihood that the product will be launched and commercialized in a LMICs. Non-exclusive licenses can potentially create competition and lower prices further.

Dedicated standalone business unit – A standalone business unit that is not subject to the same profitability thresholds as the rest of the company and isolated from the rest of the firm's business lines can more effectively target and commercialize products in LMICs.

2. Healthcare delivery system barriers

Insufficient healthcare delivery systems and infrastructure create barriers to access, even if the drug is registered and reimbursed in a given country. For this reason, it is critical to ensure that the underlying challenges related to the healthcare system itself are understood and addressed to ensure patients are prescribed and can access treatment. Barriers include:

Lack of or insufficient healthcare infrastructure – The lack of appropriate facilities and trained clinicians or specialists needed to deliver treatment is a systemic challenge in low-resource settings, which creates inequity across countries, but also within countries, as rural populations are often far from hospitals or specialized centers of care.

Lack of advanced capabilities and competencies – Healthcare systems may not be equipped with advanced technologies to be able to treat patients using the latest advances in medical innovation. For example, the expansion of precision medicine in LMICs has been limited because these countries often lack advanced diagnostic capabilities (e.g., genomic testing).

Complex and uncoordinated healthcare systems – Healthcare systems are often challenging and time-consuming for patients to navigate (i.e., obtaining an appointment, finding the right clinician, ensuring communication between practitioners, etc.). This is often due to the fragmented nature of health system organization and lack of data sharing between facilities, but can result in patients not seeing the right specialist, the specialist not having the correct information to make a proper diagnosis, or patients giving up altogether, reducing the benefits patients can derive from care.

Strategies to overcome barriers

To secure access despite suboptimal conditions, pharmaceutical companies can help to bridge capability gaps.

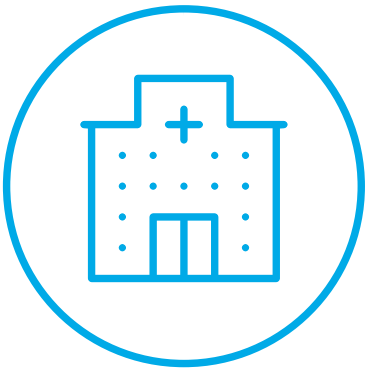
Maximizing ease of administration – Pursuing simpler, patient-friendly administration modes in the drug clinical development phase can ensure treatment access is not dependent on skilled clinician administration. For example, a self-administered mode of administration, where patients can take or administer the treatment themselves without needing a healthcare professional (HCP), is often more suitable for LMICs. Typically, self-administered products are prioritized by governments and are increasingly covered by access strategies compared to HCP-administered drugs in Low-Income Countries (LICs) – 38% vs. 29% in 2022 – according to the Access to Medicine Index[1].

Reducing infrastructure requirements in the treatment protocol – Reducing requirements in the treatment protocol can help mitigate delivery risks. For instance, insulin products are governed by strict regulatory supply chain guidance, where they must be kept cool from manufacturing until patient use. Yet in LMICs, where ~75% of adults with diabetes live, refrigerated storage and supply chain refrigeration are often unavailable, resulting in restricted access to treatment. Real-world conditions stability testing can help anticipate infrastructural gaps and ensure products are adapted for use in restrictive delivery settings.

Alternatively, pharmaceutical companies can proactivity work on filling capability gaps, especially through capacity-building programs that aim at:

Improving HCPs' knowledge and skills – Capacity-building programs may focus on disease-specific initiatives, such as training healthcare workers on the diagnosis and treatment of specific diseases or providing support for disease prevention programs. For instance, Rwanda's Ministry of Health has collaborated with the pharmaceutical industry to provide HCPs with enhanced education and training to support care delivery for cancers and infectious diseases.

Strengthening local infrastructures – In LMICs, pharmaceutical companies can work on strengthening diagnostic infrastructures, which are fundamental for access to treatment. This can also be done in partnership with NGOs. For example, the World Federation of Hemophilia (WFH) is a partnership between pharmaceutical companies and not-for-profit organizations founded with the goal of furthering access to treatment for hemophilia. Calls to action include improving diagnosis capabilities in LMICs and helping emerging hemophilia treatment centers develop partnerships with well-established centers.



1 Access to Medicine Foundation. (2022). *Access to Medicine Index*.

3. Patient-level barriers

Patients' backgrounds and behaviors can raise major barriers to access, potentially influencing patients' willingness and/or ability to connect to the healthcare system and receive the care they need.

Lack of trust – Mistrust and distrust of the healthcare system and medical professionals can drive patients to delay or avoid seeking care. Persistent stigma related to race and ethnicity, gender, sexual orientation, or socioeconomic background results in unwillingness from concerned patient groups to engage with the health system. For example, the stereotype that Black people have a higher pain tolerance leads to racial biases in pain assessment and negatively affects pain management for Black patients[2].

Lack of understanding and awareness – Poor health literacy, referring to a patient's ability to understand common healthcare communications (such as prescription instructions or test results)[3], leads in most cases to delayed treatment, suboptimal outcomes, or missed care opportunities, and is persistently associated with low socioeconomic status (SES). In fact, once people become ill, chronic conditions are more likely to persist and progress in people with low SES backgrounds[4]. Another challenge is lack of treatment adherence. Glaucoma, for instance, requires rigorous treatment practices (i.e., daily eye drops), with nonadherence leading to disease progression and blindness in the long term, without triggering any short-term symptoms.

Limited autonomy – Certain pathologies can diminish a person's autonomy (e.g., cause cognitive and/or physical difficulties) or affect populations with already limited autonomy (e.g., children or the elderly), creating challenges for patients to reach healthcare facilities or adhere to treatment regimens. The lack of available caregivers to accompany patients to visits and support them with treatment compliance may be an aggravating factor. For example, Parkinson's disease, which highly affects elderly people, causes motor difficulties and a loss of autonomy in daily life, leading to a strong dependency and high burden on caregivers[5].

Strategies to overcome barriers

Pharmaceutical companies may employ different levers to address patients' limited health literacy and to prompt them to seek care, such as:

Raising patient education and awareness – Pharmaceutical companies can engage with patient associations or NGOs to improve patient education, which is particularly important to unlock patient access to cutting-edge therapies. For example, the National Organization for Rare Disorders (NORD) provides educational support for people with rare diseases and their caregivers, to enable a better understanding of how to navigate the healthcare system and obtain proper care. Companies can also conduct targeted awareness campaigns alongside their product launches to maximize patients' access to the treatment. In the case of glaucoma, some pharmaceutical companies have led awareness campaigns targeted at people of African descent, who represent ~30% of glaucoma cases.

Fostering treatment adherence – Companies may also consider leveraging Patient Support Programs (PSPs) to drive treatment compliance behaviors. Providing appropriate patient support can help patients during treatment onboarding, which improves long-term adherence, reduces discontinuation rates, and ultimately delivers a better health outcome. Patient Support Programs are common for chronic illnesses such as diabetes. Additionally, the adoption of digitally-enabled programs creates new opportunities to improve adherence and offer better outreach, especially in remote locations (e.g., smartphone apps to monitor symptoms and deliver treatment reminders, telehealth advice platforms).

2 Hoffman et al. (2016). Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. *Proceedings of the National Academy of Sciences of the United States of America.* (link)

3 Lagay F. (2003). Reducing the effects of low health literacy. *Virtual mentor.* (link)

4 Jansen et al. (2018). The role of health literacy in explaining the association between educational attainment and the use of out-of-hours primary care services in chronically ill people: a survey study. *BMC Health Serv Res.* (link)

5 Mosley et al. (2017). Caregiver Burden in Parkinson Disease: A Critical Review of Recent Literature. Journal of geriatric psychiatry and neurology. (link)

4. Drug and treatment design barriers

The treatment design itself can present significant access hurdles.

Narrow indications – When developing a medication, pharmaceutical companies study a limited set of conditions and diseases. Consequently, indications for which treatments are approved may not cover all patients who could potentially benefit from them. Additionally, indications might remain understudied among certain patient groups, resulting in safety and efficacy evidence gaps, and ultimately to HCPs' reluctance in prescribing the treatment. For instance, comorbidity exclusion criteria in clinical trial participation makes it challenging for clinicians to determine how to interpret trial findings in people with multimorbidity.

Burdensome protocol of treatment – Treatment burden (e.g., high frequency of administration, lengthy protocol duration, significant adverse effects, etc.) can create substantial hurdles as well. For instance, age-related macular degeneration (AMD) commonly affects older patients with limited autonomy, but the treatment protocol imposes a constraining schedule and frequent injections, therefore intensifying patients' dependency on caregivers. These factors put patients' ability to properly adhere to the treatment at risk, potentially leading to suboptimal outcomes.

Strategies to overcome barriers

Example solutions to tackle drug and treatment-related barriers include:

Broadening the scope of indications and improving representativity in clinical trials – Prior to and throughout clinical trials, pharmaceutical companies should thoughtfully decide which indications should be prioritized and in which sequence (based on criteria such as epidemiology, disease severity, existence of alternative treatments, etc.), and take into consideration all possible indications for the product. Further, enrolling underrepresented populations and ensuring broad

diversity (including based on race and ethnicity, gender, age, medical conditions, etc.) in clinical trials would help fill evidence gaps. Pharmaceutical companies have begun to address the issue of clinical trial diversity, for instance by broadening enrollment eligibility criteria, when scientifically and clinically appropriate, or by identifying sites where diverse patients may be located and where HCPs treat underrepresented populations.

Anticipating protocol burden in treatment design – Key decisions can be anticipated as early as the clinical development stage to achieve streamlined treatment protocols (e.g., finding the optimal dosage to avoid burdensome frequency of administration and extended duration of care, designing drugs with simple modes of administration like oral or self-administered drugs). In the case of AMD for example, reducing the frequency of re-administration and monitoring would make it easier for patients to properly adhere to the treatment protocol. In treating chronic diseases such as diabetes, the use of self-administered pens provides a convenient and easy-to-use method for patients to manage their medication.

5. Health system institutional barriers

The peculiarities of health system institutions may intensify access challenges in LMICs. Institutional barriers can lead to pharmaceutical companies encountering difficulties, delays, or an inability to launch products in LMICs.

Lack of regulatory framework – In LMICs, healthcare systems can have limited regulatory resources and capabilities, resulting in undefined or unclear access guidelines. In addition, launch processes may not be standardized or adapted for innovative therapies. This creates an uncertain and lengthy regulatory environment, which is rendered even more challenging given pharmaceutical companies' often limited resources and capabilities in these countries (e.g., small local subsidiary with limited expertise). This can cause pharmaceutical launches in LMICs to be delayed, postponed, or abandoned.

Absence of patent protection policies – Restrictive patent filing and granting procedures (e.g., limited patent coverage, strict patent application requirements), a lack of patent protection enforcement (e.g., suboptimal judicial system capabilities, no linkage mechanisms), and compulsory licensing (e.g., domestic industry favoring) may create reluctance among pharmaceutical companies to launch innovative medicines, compromising patients' timely access to safe and effective medicines.

Protectionism laws favoring local manufacturers – In certain countries, pharmaceutical launch is conditioned to country requirements regarding manufacturing: local production (i.e., relocation of the manufacturing line locally, with or without tech transfer) can be a mandatory condition. The need to build additional manufacturing capabilities constrains pharmaceutical companies and launches as it requires massive investments.

Strategies to overcome barriers

In order to draw down institutional barriers, pharmaceutical companies can leverage many mechanisms and strategies such as:

Optimizing access sequencing – Some LMICs recognize drug and medical device approvals from foreign regulatory authorities, including the FDA (US Food and Drug Administration) and the EMA (European Medicines Agency). More precisely, these countries would accept submission after US or EU approval, upon presentation of the Certificate of Pharmaceutical Product (CPP) and the Reference Approval, which confirm product marketing authorization status, compliance with good manufacturing practices, and regulatory approval of the drug. Considering these approval mechanisms and the related requirements would help pharmaceutical companies optimize access sequencing and maximize global access to their products.

Leveraging alternative/accelerated regulatory pathways – Pharmaceutical companies can also apply for the World Health Organization (WHO) prequalification program (PQ), whereby the WHO handles assessment of the product's quality, safety, and efficacy. Additionally, the WHO Model List of Essential Medicines (EML) serves as a guideline for countries in developing their own National List of Essential Medicines (NLEM), which gives priority status to medicines that are deemed necessary to satisfy fundamental healthcare needs. The NLEM serves as a reference for national drug regulatory agencies and can influence the registration of new medicines. Donated drugs may also be subject to less rigorous regulatory requirements and benefit from accelerated access pathways in LMICs. Initiatives to accelerate access may target specific indications. For instance, the Orbis Project aims to accelerate access to cancer medicines globally: its members, regulatory authorities from the US (coordinator), Australia, Canada, the UK, Singapore, Switzerland, and Brazil, work together on the review of submissions for cancer drugs.

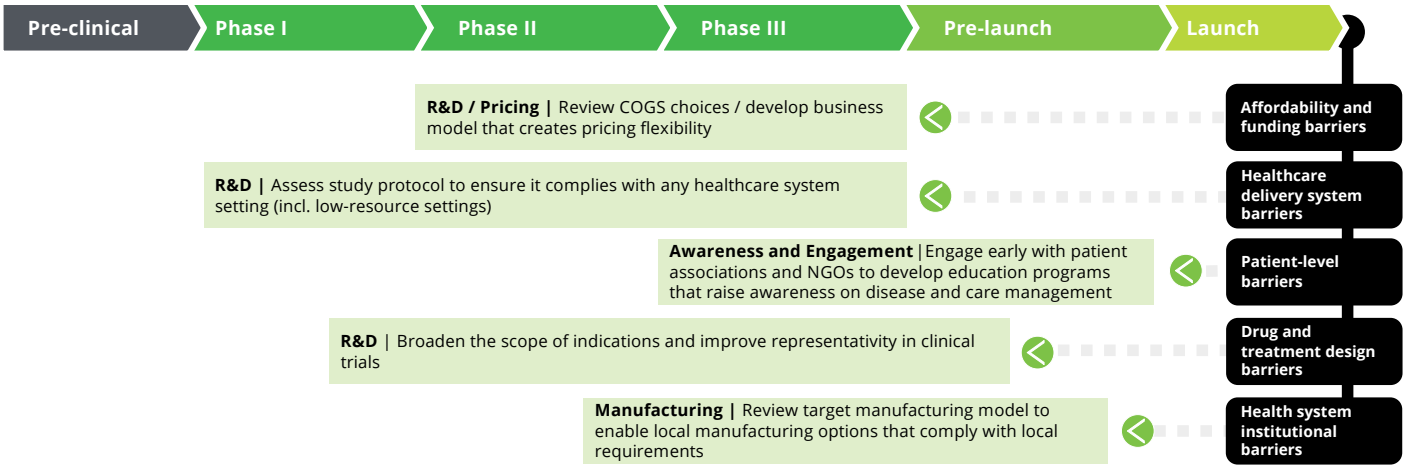
Responding to government calls for local manufacturing through capacity building – Building local manufacturing capabilities can help secure launches in LMICs and ensure sustainable access to high-quality medicines locally. This strategy involves significant investments and must be planned adequately. This may involve, for instance, identifying a local partner, preparing for technology transfer, and/or adapting an initial target manufacturing model that, for innovative products, tends to be based on global specialized facilities serving all markets.

Conclusion

For the Life Sciences industry to transition successfully to a more sustainable and inclusive model, it is essential for pharmaceutical companies to deeply and comprehensively understand the barriers that prevent patients from accessing their products in a timely, safe, and efficient manner. This is a fundamental first step that will enable companies to grasp the root causes of access challenges and deploy tailored efforts when promoting greater access.

By gaining a thorough understanding of access barriers and incorporating them into their access planning process, pharmaceutical companies can take a proactive approach to identify and address challenges to patient access. There are a multitude of choices that can be made from the pre-clinical to pre-launch stages, including decision-making related to R&D (e.g., ensuring patient diversity in clinical trials), manufacturing and supply chain (e.g., demand forecasting), and pricing (e.g., COGS optimization). By prioritizing access at every stage of the drug development process, pharmaceutical companies can help ensure that their products reach the patients who need them the most.

Access barriers can be anticipated throughout the drug development process (Illustrative - Not exhaustive)



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At Deloitte, we support large pharmaceutical companies and biotechs to design and broaden their Social Impact strategy globally, leveraging our dedicated Access to Medicine team and our leading expertise at the intersection of Life Sciences and Sustainability. We help companies expand access to their products to underserved populations and geographies, and we accompany their organizational transformation and the development of the necessary capabilities to improve access.

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