



Five challenges to improving access to cancer treatments

Market access and pricing
in emerging markets

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Following decades of public health investments that have reduced the burden of communicable diseases, non-communicable diseases are becoming a bigger threat to the health of populations in emerging markets. The rise in per capita GDP and purchasing power in these markets has been accompanied by an increased prevalence of diabetes, cardiovascular disease, and cancer. Cancer is now the leading cause of death in China and the second leading cause of death in Latin America (Chen, et al., 2016) (Kielstra, 2017).

Healthcare infrastructure in emerging markets, however, has not kept pace with the rise in non-communicable diseases, especially cancer. Historical health priorities such as childhood and communicable diseases remain priorities, ahead of cancer, chronic diseases, and other diseases of aging. Given limited resources and fixed government healthcare budgets, public health systems face considerable challenges in delivering timely diagnosis and treatment to cancer patients. **We have identified five major challenges to accessing innovative cancer treatments in emerging markets:**

1. Delayed regulatory approval and marketing authorization
2. Limited availability of health insurance and insurance coverage
3. Lagging disease awareness and screening
4. Restricted reimbursement and access
5. Low affordability for patients and their families

Despite these challenges, increased demand for cancer prevention, screening, early detection, diagnosis, and treatments in emerging markets presents significant opportunities for pharmaceutical and biotechnology manufacturers. We describe the five challenges and how manufacturers might improve access to cancer treatment.

Delayed regulatory approval and marketing authorization

Government healthcare systems may have multiple mechanisms to deny or delay access to innovative and expensive cancer drugs. Regulatory delays are common and frequently result in rejections.

- In China, the drug regulatory agency, **the China Food and Drug Administration (CFDA), had only 345 employees in 2016, compared to 9,300 employees at the US Food and Drug Administration (FDA)**. This contributed to approval delays, with the review period for some new medicines taking 14 to 28 months (Yu, 2016). In contrast, the FDA sets a goal of 10 months for standard review and six months for priority review (US Food and Drug Administration, 2017). The CFDA also has significantly fewer approved innovative new drugs – 100 in the years 2012–2017, compared with about three times that in developed markets (Taylor P., 2017).
- In Turkey, the Good Manufacturing Practice (GMP) inspection alone can **add one to three years to the marketing authorization process**, despite the official regulation stating that it should take no more than 210 days (Karakulak, 2018).

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To counteract these challenges, there needs to be effective cooperation and pressure from multiple stakeholders – patients, advocacy groups, providers, government affairs, and industry – in order to expedite approval.

- In 2017–2018, **China saw significant regulatory reforms to encourage innovation and reduce regulatory burden** (Saleh, 2018). The reforms included restructuring the CFDA to streamline approvals and relaxing the requirement for in-country clinical trials in order to consider applications (Liu, March 20, 2018) (Liu, March 13, 2018).

Limited availability of health insurance and insurance coverage

Even when government-provided universal healthcare exists, it may be limited to basic needs, leaving critical coverage gaps for cancer patients.

- **Mexico established Seguro Popular to cover uninsured people in 2004, but there are gaps in the accessibility and quality of care.** Seguro Popular covers some of the most prevalent adult tumors (e.g., breast, cervix, testicle, prostate), but not all tumor types (e.g., lung) (OECD, 2016) (Moye-Holz, Saucedo, van Dijk, Reineveld, & Hogerzeil, 2018).

Private insurance can be uncommon or unavailable in emerging markets, and limited reimbursement from public healthcare systems can lead to high out-of-pocket health expenditures for patients on low incomes. Health outcome inequalities and vast disparities in access are systemic problems in emerging markets.

In South Africa, just 16% of the population has private insurance but this relatively small segment accounts for about half of the country's health expenditure. This has resulted in low-quality care in South Africa's public sector (Rispel, 2018).

Some patients with the physical and financial means travel internationally for care to overcome barriers to access. Patients may use medical tourism to access treatments or specialists unavailable in their home country, higher quality of medical care, or comparable procedures or treatments at a fraction of the price they would pay at home. However, this option remains out of the economic reach of the vast majority of the population.

- **Hong Kong is a popular location for medical tourism in the Asia-Pacific region, particularly for mainland Chinese patients due to cost, proximity, and a lower language barrier.** The cost of certain treatments, such as 1L targeted therapy for breast cancer, is more expensive in mainland China than in Hong Kong, even when factoring in the travel and accommodation costs. The expedited regulatory approval process in Hong Kong also allows Chinese patients earlier access to the latest drugs (Chen & Sunderland, 2015).
- **In Thailand, 9% of the country's 2013 visitors were medical tourists,** with over half traveling from the Middle East (Netherlands Embassy in Bangkok, n.d.).

Lagging disease awareness and screening

Many cancer cases in emerging markets are diagnosed at later stages of disease due to limited disease awareness and/or access to screening procedures. Once diagnosed, the patients are often beyond the point of treatment. To address these challenges, manufacturers have developed programs to improve earlier screening and to support earlier diagnosis of cancer patients.

- **In 2011, Sanofi launched a breast cancer awareness campaign and support program in partnership with leading Russian cancer institutes and clinics to improve early detection and treatment of breast cancer** (PharmaBoardroom, 2015). Merck KGaA supports a head and neck cancer awareness initiative to encourage testing and screening (Make Sense campaign, n.d.). Merck KGaA has also supported the RUSSCO program, “Improvement of molecular genetic testing in the Russian Federation” since 2011 to improve molecular genetic testing in patients with metastatic colorectal cancer (mCRC) and to improve physicians’ mCRC treatment decision-making (IFPMA, 2014).
- **In Algeria, China, and Indonesia, Roche has disease awareness campaigns for breast cancer and colorectal cancer** (Roche, n.d., Enhancing access to our current and future cancer solutions).

Another way that manufacturers can help improve awareness and screening infrastructure is to financially support the education of healthcare personnel and to fund scholarships for medical training (e.g., physician exchange programs, preceptorships). In many emerging markets, the demand for healthcare providers far exceeds the supply, and this is especially true in oncology.

Restricted reimbursement of innovative cancer therapies

Even if a drug receives regulatory approval and patients receive the necessary diagnostic care, access is not guaranteed due to lack of effective coverage, exclusion from key public formularies, and drug shortages.

Budgetary restraints in public health insurance markets in many emerging markets have been known to slow or prevent expensive therapies, such as novel oncology drugs, from reaching the market. This just leaves access to the private market, which may only cover a much smaller proportion of the population.

- **For cost-containment reasons, some federal payers such as Brazil’s Sistema Único de Saúde (SUS) do not cover certain targeted cancer therapies, such as Avastin (bevacizumab), Sutent (sunitinib), and Nexavar (sorafenib).** Despite having made their way into the treatment guidelines of most public hospitals in Brazil, these hospitals do not frequently stock angiogenesis inhibitors (Taylor L., 2012).
- **In China, far fewer patients have private health insurance policies which cover cancer treatment than in Mexico (6% of the population as of 2017).** Some pharmaceutical companies have started partnering with private Chinese insurance companies to offer insurance policies that provide cancer-care coverage (Frick & Lim, 2017) (Roche, 2013).

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Exclusion from national medicines lists (NMLs) or essential medicines lists (EMLs) is an additional challenge for drug companies in some markets. Governments may establish these lists in order to prioritize the public procurement of medicines most crucial to public health and to facilitate cost containment. Without inclusion on a country's NML/EML, a drug is essentially excluded from public reimbursement (unless there are several different public payers, as in Mexico). An estimated four out of every five countries has an EML (World Health Organization, n.d.).

- South Africa established an **EML in 1996 to meet a variety of health equity and economic objectives**. In mandating that essential drugs should “be available at all times, in adequate amounts and in proper dosage forms,” South Africa is one example which demonstrates the level of priority given to procuring drugs selected for the list (The Department of Health, n.d.) (Perumal-Pillay & Suleman, 2017).
- In Brazil, the **SUS provides essential medicines to patients free of charge, circumventing out-of-pocket affordability issues** which might otherwise pose a significant barrier to care (Bertoldi, Helfer, Camargo, Tavares, & Kanavos, 2012).

Faced with insufficient funding, payers may purchase only limited supplies of some approved and reimbursed therapies.

- The governments of Belarus and Kazakhstan **only purchase and reimburse a certain quantity of oncology drugs each year**, and patients only have access to these treatments while the supplies last (Vrdoljak, et al., 2016).
- In Hungary in 2012, the National Health Insurance Fund Administration reported that it required significant cash infusions, as it had **spent 80% of its budget by the beginning of August**. This coincided with the onset of a shortage of generic oncology drugs. Hungary has since introduced several measures to improve the financial sustainability of its health delivery system (Bochenek, 2012).
- Brazil had **major shortages in both essential and specialty medicines during the summer of 2016**, which analysts attributed to a heavy reliance on imported medicine and an unsustainably financed SUS, Brazil's primary public payer (Moura, 2016).

An additional hurdle for manufacturers is that the competitive landscape in many emerging markets is flush with generics and biosimilars, and local companies often receive priority for approval or reimbursement.

- In Saudi Arabia, local companies may win tenders despite submitting offers that are **10% more expensive than the lowest bid** (Kavanos, 2018).
- Malaysian officials also **favor locally manufactured products when evaluating tenders** (Maniadakis, 2018).

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Access barriers due to restricted reimbursement are often systemic and widespread, and finding ways to overcome them, even in part, poses a persistent challenge to entrants in emerging markets. Nonetheless, there are three ways pharmaceutical manufacturers can make progress:

- **Target earlier reimbursement and adoption in the private sector.** While small in some countries, and typically more fragmented than public payer systems, the private segment may be the surest way to gain an initial foothold due to its higher concentration of resources relative to the public system. For example, in Chile, most oncologists work in the private sector, and some believe that outcomes differ “substantially” between patients in the public and private sectors (Goss, 2013). In South Africa, there is a disproportionately large amount of healthcare spend in the small private sector (Rispel, 2018). Generating in-country data via the private sector for a newly introduced product may also prove useful when making an appeal for public sector coverage.
- **Prioritize gaining a place on EMLs.** EMLs are not a complete solution to accessibility and affordability issues but they are more likely to be available than drugs excluded. One study found the median availability of essential medicines to be over 60% globally, while non-essential medicines reached less than half that level (Bazargani, Ewen, Boer, Leufkens, & Mantel-Teeuwisse, 2014).
- **Establish partnerships with local entities.** Local manufacturing or close ties with a local distributor may increase the chance of success in markets where preference is given to in-country suppliers. Due to regulation favoring local production in Saudi Arabia, many manufacturers, such as Boehringer-Ingelheim and AbbVie, have either established production facilities or partnered with local companies for secondary packaging (Stanton, 2017) (Ghazal, Siblini, & Shaqhan, 2018).

Low affordability for patients

For patients who are diagnosed and seek treatment, access to therapies can be challenging and cost prohibitive, often resulting in treatment termination. Due to the price sensitivity of patients and payers in these markets, unique approaches need to be taken to maximize access to therapies.

Manufacturer-led negotiations, volume discounts and rebates, pay-for-performance models, sliding scale discounts, and product donations are effective ways to increase access, as well as build brand recognition and goodwill. Promotions such as “buy X cycles, get Y free” and different size medication packs are other examples of how pharmaceutical companies have helped facilitate access.

Figure 1: Access to therapies based on ability-to-pay model



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- **In China, Roche has implemented a program to donate the last eight cycles of Herceptin (trastuzumab) after the patient has paid for the first six**, allowing them easier access to the full 14-cycle course of treatment (Roche, n.d., Helping people receive cancer treatment in China).
- In the Philippines, **public healthcare funding does not cover biologics and 80% of the population pays out-of-pocket for healthcare**. Roche has also established a program there to increase access to Herceptin. A third party evaluates the patient's ability to pay for treatment and then price discounts are set based on their financial status. This sliding scale discount program has significantly increased treatment and adherence (Roche, 2013).
- In Asia, Zuellig Pharma, a healthcare group that provides services ranging from distribution to patient engagement, **helps address patient affordability issues by providing payment plans, discounts, and redemption offers** (Zuellig Pharma, 2018).
- Novartis established the Glivec International Patient Assistance Program (GIPAP) in partnership with The Max Foundation to offer assistance to patients in emerging nations in Asia, the Middle East, Central and Eastern Europe, Africa, and Latin America. **GIPAP provides Glivec (imatinib) at no cost to eligible patients with chronic myeloid leukemia (CML) or gastrointestinal stromal tumor (GIST). Nearly 50,000 patients from 80 countries benefitted from GIPAP as of 2014** (Garcia-Gonzalez, Boulton, & Epstein, 2015).

Conclusion

Emerging markets present significant opportunities for improvements in cancer treatment and growth for pharmaceutical and biotechnology companies. Unique considerations and approaches must be taken into account to succeed in these countries, given the challenges faced by different stakeholders – patients, healthcare providers, and payers. Market entry and success is not impossible but requires innovative strategies and tactics unique to each market. The tactics and examples outlined here are just a few of the approaches that can increase the potential to improve opportunities for patients to be treated with the latest and most effective oncologic drugs.

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