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# Pharmaceutical Market Access in Emerging Markets

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# Summary

# Preface

The definition of Market Access was first reported by the World Trade Organization as "to open markets for trade and improve transparency, reciprocity and non-discrimination in international trade". But Market Access in pharmaceuticals is different than regular products like television, clothing, or cars. For these, the definition of market access for pharmaceuticals could be achieving the optimal price for a product or service and/or maximum reimbursement for the approved target population with no restrictions on funding for the medical technology.

By the way, market access is not only market authorization. It covers market authorization also, but more than market authorization including overlapping activities like pricing, health technology assessment, formulary and reimbursement. Especially pricing and reimbursement are the key factors of market access. Market access is one of most important activities for pharmaceutical companies nowadays.

Lets make examples;

- Think of a company that markets the most innovative products in the market. However, none of the products are secured through market access. Will anyone buy the shares? Possibly not.
- Think a patient where there is a current treatment available. However, her/his country`s MA process for the pharmaceutical is not finished yet. Can she/he reach the treatment? Possibly not and the suffering continues.
- Think a physician who wants to prescribe a pharmaceutical. However, the pharmaceutical is not covered under reimbursement. Can she/he prescribe it easily, especially an innovative high priced drug? Possibly not and again the treatment may not be available.

Depending on all these, market access is the key for pharmaceutical companies. We think these definitions are important and different enough to justify this book about market access. Emerging countries are important for the multinational pharmaceutical companies. It was reported that CAGR was 6.0 percent in the period from 2011-2017, and expected sales exceeding USD 1.1 trillion by 2017. In additional, CAGR 2008-2012 for recent launched pharmaceuticals were 9,8% for Emerging Countries and 1.5% for the top 8 developed countries. Depending on all of this knowledge, emerging countries can`t be ignored by multinational pharmaceutical companies for launching new products. So the market access process in emerging countries will be important in the near future also.

The market access processes in the most important countries in the selected regions are defined in this book and we hope it may help the local experts who are in the beginning or in middle of their careers, the government officers who are lookin for new implementations and examples from other countries, the headquarters managements who want to learn more about emerging markets.

*Güvenç Koçkaya, Albert I. Wertheimer*

# 1. Introduction to the Market Access

**Mondher Toumi, Szymon Jarosławski**

## 1.1 Origin of the Market Access term

### Market Access for goods

The Market Access (MA) term was first introduced by the World Trade Organization (WTO) to define the competing relationship between the domestic and the imported products of a country [1].

The WTO defines MA as a set of conditions, tariff and non-tariff measures, agreed by WTO members for the entry of specific goods into their markets, that is to say the government policies regarding trade-barriers in general, and specifically the issues of import substitution (to promote local production) and free competition.

There are two types of trade barriers established by countries [1]:

- Tariff measures are taxes on imports of commodities into a country or region. Tariff commitments for goods are set out in each member's schedules of concessions on goods;
- Non-Tariff Barriers/Measures are any measure other than import duties (tariffs) used to restrict imports.

Whereas tariff barriers have steadily declined over the past few years, non-tariff barriers, such as technical regulations, safety or sanitary measures, have been increasing. Other non-tariff barriers are import prohibitions, requirement of a distribution network or effective means of marketing or of homologation for a product in a given country.

### Application of the Market Access concept to healthcare: similarities with market economy

The concept of MA can easily be adopted for pharmaceuticals. For example, certification or homologation in the case of machinery is equivalent to the Marketing Authorization that is necessary in the pharmaceutical field in order to access a new market. Remaining trade barriers mentioned above also apply to the pharmaceutical market.

- Tariff Barriers on pharmaceuticals: As most countries import pharmaceutical products, they charge import tariffs, value-added tax (VAT), and other domestic taxes on these products to generate revenue and protect the local manufacturers from competition. E.g. Nigeria, Pakistan, India and China all have significant local pharmaceutical industries and are among countries with the highest import duties. The global trend has however been to reduce or eliminate tariffs and taxes on medicines in order to stimulate trade, competition, and the scaling down of prices [2].

- Non-Tariff Barriers on pharmaceuticals: Non-tariff measures have dramatically increased in the pharmaceutical field. The pharmaceutical industry is one of the most regulated. Complex measures range from marketing authorization, efficacy and safety controls, quality standards, pricing and reimbursement of pharmaceutical products, to import and distribution regulations, etc. Most governments have mandatory procedures to ensure the safety and efficacy of the medicines distributed on their market. Requirements for registration may involve specific local clinical studies that are not necessarily justified clinically. An increasing number of countries require clinical trials of a new product to be conducted or repeated on their territory. E.g. in China and Russia early clinical tests, as well as pivotal trials need to be repeated locally, which may take up to five years [3].

Finally, achieving positive reimbursement recommendation in countries with significant health insurance population coverage has become the most complex obstacle pharmaceutical companies need to face.

## 1.2 Healthcare market specifics

In spite of many similarities between healthcare products and other goods in a free market economy, the former is a unique field that challenges the traditional economic paradigm. There are four features that clearly differentiate the healthcare market from other markets.

- **The price is not determined by supply and demand**. In a traditional market economy context, the price is determined by supply and demand. A single entity assumes the functions of the buyer, the payer, and the consumer. In the healthcare market however, the prices are determined by payers through negotiation or are simply notified by the manufacturer. The buyer is the physician who prescribes the treatment, the payer is the health insurance provider, and the consumer is the patient. The three parties do not necessarily have convergent views on how healthcare should be delivered and what are the priorities.
- **Payers are committed to purchase health for the society**. The payer's intent is to provide health for the patient. When payers fund medicine they fund health production. They can only buy a proxy of health through the purchase of medicine and healthcare services. The actual outcome in terms of health improvement remains uncertain.
- **Health is specific to each individual**. Unlike food, real estate or technology, health cannot be shared or traded between individuals. The outcome of a treatment or a procedure also depends on individual characteristics of the patient [4]. The patients' characteristics may be not fully known *a priori* because of the lack of appropriate tools. This repertoire of scientific tools is evolving fast and changes regularly our understanding and approach to disease and therapies.
- **Externality of health**. Medicines can have a positive impact on the health of people, other than those who consume it. This is particularly the case for vaccinations