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Pharmaceutical Market Access in Developed Markets

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Preface

In the good old days, pharmaceutical companies used to develop a new molecule and launch it without any resistance, except those regarding clinical effectiveness, safety, and quality assessment. The main assessment was conducted on the basis of science-driven, evidence-based characteristics. However, in the last decades, market access has become the most important element for the pharmaceutical industry, with a primary focus on pricing and reimbursement, which are political and economic-driven characteristics.

Depending on specific health policies, some medicines are favored over others in the market access process, because the reflexes in the community for politics are different in each country, depending on demographics and the community perceptions. For example, elderly patients are more considered in the developed countries, due to health policies focusing on late-life diseases. But children are more considered in the emerging countries, due to health policies focusing on early-life diseases.

In this political and economic-driven environment, market access is getting harder than ever for all countries, especially the developed ones. After the financial crisis in 2008, developed countries have been under pressure due to a lack of cash and budget deficits. This situation is more important in government-based reimbursement countries, like France and United Kingdom, rather than private-based insurance countries, like the United States and Germany.

The pharmaceutical market access in the emerging markets has been thoroughly reviewed in the book "Pharmaceutical Market Access in Emerging Markets", published in 2016. The perception of readers was amazing. The book had been listed among Amazon's top 100 hot books for nearly three months. After such "literary" success, we decided to start a new project, focusing on the developed countries. This book focuses on the developed markets, with the aim of helping students, academics, industry employees and government decision-makers understand the environment in the developed markets. Hopefully, it will be helpful to all who want to understand market access, which is rock and roll compared to the evidence-based and science-driven decision process.

I would like to extend my thanks to my beloved wife, Dr. Pınar Daylan Kockaya, and my son, Uras Kockaya, of whom I am proud, for enduring my lack of presence in their life; my dearest lecturer and supporter Prof. Dr. Albert I. Wertheimer, for supporting me without any questions in any situation, and the authors and reviewers of the book, for supporting this project.

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1. Introduction to the Market Access

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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 relation between the domestic and the imported products of a country.

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.

Healthcare Market Specifics

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

1. **The price is not determined by supply and demand**. In a traditional market economy context, the price is determined by supply and demand. In the healthcare market, however, the prices are determined by payers through negotiation or are simply notified by the manufacturer. Further, in the traditional market, a single entity assumes the functions of the buyer, the payer, and the consumer. In the healthcare market, however, 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 the value of healthcare goods.
2. **Payers are committed to purchasing health for the society**. The healthcare payers' intent is to provide health for the patient. When payers fund medicine they wish to fund health production. However, 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.
3. **Health is specific to each individual.** Unlike food or technology, health cannot be shared or traded between individuals. The outcome of a treatment procedure also depends on individual characteristics of the patient. The patients' characteristics may be not fully known *a priori* because of the lack of appropriate tools. This repertoire of

medical tools is evolving and changes our understanding of the disease and our approach to therapies.

4. **Externality of health.** Medicines can have a positive impact on the health of people, other than the ones who consume it. This is particularly the case for vaccinations and antibiotics. The treatment and prevention of contagious diseases at the level of an individual can protect the global population from a potential epidemic. Therefore, i) restricting access to health care for a population's subgroup can have dramatic impact on that population health status, ii) poor health care in a population's subgroup will affect the health of the remaining part of the population that has good access to health care. This is one of the main reasons for the creation of national health care systems. Illustratively, it has been iteratively reported that, despite the highest *per capita* healthcare expenditure, the US does not have the best population health status, notably because of the wide disparity in access to health care.

1.2 Healthcare Market Access Definition

The concept of MA is complex to define, depending on whether we are dealing with a private, public or mixed health care system. MA is the process by which a healthcare goods company gets its product available on the market after having obtained a Marketing Authorization (MAu) from a regulatory agency and by which the product becomes available/affordable for all patients for whom it is indicated as per its MAu.

The following definition will be used in this chapter:

MA for pharmaceuticals defines the ability for a drug to achieve through a health insurance system a reimbursed price and a favorable recommendation for medical prescriptions.

It covers a group of activities intended to provide access to the appropriate medicine for the appropriate group of patients and at the appropriate price.

For the manufacturers, the ideal outcome of the MA process is to achieve the optimal price with maximum reimbursement for the approved target population with no limitation on prescription or funding procedures. However, in practice the company needs to strike a trade-off between:

- Price and reimbursement conditions;
- Target patient population selection;
- Prescription and funding procedures.

Therefore, MA can be also seen as activities that support the management of potential barriers, such as non-optimal price and reimbursement level, the restriction of the scope of prescription for a drug or complicated prescription or funding procedures.

The scope of these activities encompasses the management of pricing and reimbursement, Health Technology Assessment (HTA) and formularies. The formularies are the lists of medicines that may be prescribed at the expense of the institutionalized payer.