Regulatory Environment in MENA

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Topics to be covered

- Definition
- Background
- Issues
  - Heterogeneity
  - Protectionism
  - Price reduction
  - Pharmacovigilance
  - Intellectual Property
Background

With the growth in populations across the MENA region, the demand for drugs increased to an estimated US$8.5 billion in 2012 compared to US$7.7 billion in 2011. Around 80% of the pharmaceuticals consumed in the Middle East are imported from foreign countries.
What is a regulatory environment?

Regulatory environment consists of laws and regulations that has been developed by local governments in order to exert control over business practices.

The regulatory environment can not be separate from the political and economic system or even law making. Due process needs to be followed in a transparent and participative manner.
Heterogeneity

MENA regulatory environment is characterized by

- Multitude of regulatory authorities, ➔ 16 Authorities
- Some are quite developed and independent of Ministry of Health e.g:
  - Jordan Food and Drug Administration since 2003
  - Saudi Food and Drug Administration since 2006
- The remaining are still part of Ministries of Health and a good number are thinking of establishing independent bodies including Egypt, Algeria, and Sudan
Heterogeneity

- Even though the pharmaceutical industry is a global one, yet the process of approval to have the drug reach the market remains nationally-based.

- Basically, the growing international nature of the pharmaceutical industry’s activities did not bring into being a third party approval process that transcends geographical borders.

- The end result is that the regulatory process is being repeated in each of the markets, which leads to delays in launching products that would
  - serve an unmet medical need
  - unnecessary expense and use of resources in satisfying each regulatory agency’s requirements
  - Lack of competition due to delayed entry
Heterogeneity

- Within the foreseeable future, different countries will continue to have different regulatory requirements

- What can be done?
  - keeping up to date by being proactive and have effective regulatory intelligence
  - Make sure that the work we do will comply with the myriad of MENA regulators.
Heterogeneity

Keeping up with the requirements for such a huge product portfolio clearly shows it is not to be managed by anything short of a Regulatory Information Management System RIMS.
Protectionism

- Protectionism is an economic policy which is meant to benefit domestic producers of goods and services.

- In a country with protectionist policies, domestic producers are insulated from competition against foreign firms by a series of barriers to import.
Trade protectionism is used by countries when they think their industries are being damaged by unfair competition by other countries. It is a defensive measure, and it is usually politically motivated. It can often work, in the short run. However, in the long run it usually does the opposite of its intentions. It can make the country, and the industries it is trying to protect, less competitive on the global marketplace.
What Exactly Is Trade Protectionism?

Countries use a variety of ways to protect their trade. One way is to enact tariffs, which tax imports. This immediately raises the price of the imported goods, and therefore less competitive when compared to locally produced goods.
A second way of protecting trade is when the government subsidizes local industries with tax credits or even direct payments. This again lowers the price of locally produced goods and services. It works even better than tariffs because now the goods are cheaper even when shipped overseas.

http://useconomy.about.com/od/glossary/g/Trade-Protectionism.htm
A third method is by imposing quotas on imported goods. This can be one of the most effective methods for protecting trade, since the foreign country cannot ship more goods no matter how low it sets the price through subsidies.
There is a fourth type of trade protectionism that is not usually mentioned in textbooks, because it is subtle. That is a deliberate attempt by a country to lower its currency value, thereby making its exports cheaper and more competitive. However, this can ultimately result in retaliation, and start up a currency war.
Protectionism

- The logic behind protectionism is that domestic industries may suffer when confronted with foreign imports which are available at cheaper prices due to
  - lower cost of labor,
  - more readily available natural resources,
  - foreign government subsidies which help the producers keep their costs low

• Sometimes, protectionism is practiced out of national pride.
Protectionism

- closing the market to foreign producers.

By imposing stiff import tariffs and quotas, theoretically increase the market for domestic goods, benefit the domestic economy.
Protectionism

It theoretically protects domestic employment, by encouraging companies to hire domestically, and it can be used to promote living wages and better benefits for employees.
However, this is not always the case. Lack of competition leads to:

- Less interest in developing innovative new products
- Sticking with old inventions and technologies
Protectionism face export barriers, because foreign countries often respond to protectionism with protectionist policies of their own.
Price reduction

- Even though pricing of drugs is not a regulatory function in the sense it is far away from the mandate of many authorities, yet it’s the practice.

- Companies face price reduction in three different ways:
  1. Price of generics is linked to the originator and thus will go down automatically whenever the originator drug goes down
  2. Pricing schemes directly hitting generics including the automatic 10-15% reduction based on the number of alternatives in the market
  3. Whenever an imported drug goes into local production such as in Algeria
Rapidly changing pharmacovigilance regulatory requirements

- PV requirements were almost none existent in MENA 3 years ago
- Have considerably evolved since the publication of EU guidelines in 2009 and 2012
- Increasing requirements in registration applications for:
  - Detailed description of PV system (DDPS)
  - Periodic safety update reports (PSURs)
  - Risk management plans (RMPs)

- Anticipated future developments
  - Electronic reporting and use of standard terminology
  - PV inspections of pharmaceutical companies
  - Post-authorization safety studies (PASS)
Pharmacovigilance requirements in MENA
Patent Linkage

“Patent Linkage refers to the communication between the national regulatory authorities and the Patent Office to prevent marketing approval of generic drugs until after the expiration of patents covering the drug product or approved use.

This practice requires that “second applicants” usually generic companies seeking marketing approval demonstrate that the pharmaceutical product for which they are applying is not protected by a valid patent.

Under this kind of regulation, national regulatory authorities have an obligation to prevent registration and marketing of generic pharmaceuticals when patent covers the product.”*

*http://www.sinapseblog.com/2011/03/patent-linkage-overview.html, last accessed May 2013
TRIPS and Linkage

- No reference to any obligation to link patents to marketing approval of generics

**On the contrary**

- Preamble recognizes that IP rights are “private rights”
- i.e. it is up to patent holders to enforce their rights, NOT Regulatory Authorities
Issues with Patent Linkage

- Regulatory issues do not fall within the scope of definition of infringement.
- Patent law requires patentees to actively enforce their rights, but linkage uses government regulatory authority to inhibit infringement. (Regulatory Authority becomes patent police)
- The task of the regulatory bodies is to verify whether a medicinal product is safe, effective and of good quality. Their main function is to ensure that the pharmaceutical products reaching market are not harmful to public health. Other factors, such as the patent status of product, should therefore not be taken into account when assessing risk/benefit balance of medicine.
Issues with Patent Linkage (2)

- Patent linkage creates problems if national patent office grants low quality patents.

- Regulatory agencies may not be competent enough to determine validity and relevance of patents. This adds burden on them. Legally, only a court or tribunal, depending on a country’s law, can decide whether there is a patent for that particular medicine.

- A generic medicine manufactured under a compulsory license may not get registered until the patent has expired defeating the purpose of compulsory license.
No patent linkage in EU

There is no patent linkage in Europe. Even when linkage was tried under different legal umbrellas, it was considered not only anti-competitive but also unlawful under European laws.

During its pharmaceutical sector inquiry for anti-competitive practice, the European Competition Commission said:

“Moreover, they point to the fact that some regulatory bodies consider whether the generic product may infringe the originator company's patents (so called "patent linkage“ is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No 2001/83).” The directives related to drug registration as those do not mention patents.
Often times the MENA regulatory environment is examined from a harmonization perspective. The problem is efforts to do that are hampered by addition of exit texts that allow countries to add additional requirements. The latter defeats the purpose.
The legal brick wall

- Harmonization of regulations efforts often times are faced with the legal brick wall. Efforts to change it means entry into a labyrinth of bureaucracy
What needs to be done

- Harmonization of the format such CTD
- Changes of regulations should allow for a grace period so that the industry can adjust