THE
NATIONAL LAW REVIEW

# A Report from the “Biosimilars and Biotech: MENA Conference” in Istanbul, Turkey: Part 1

Thursday, November 20, 2014

This is part 1 in a series reporting on the conference entitled, “Biosimilars and Biotech:  MENA Conference” sponsored by Informa in Istanbul, Turkey on November 18-19th. I found the conference to contain a number of really exciting, interesting and useful presentations. In the next few posts, I will provide a summary of some of the presentations that I believe readers of the BRIC Wall Blog will find insightful, and hopefully useful.


Article By Michael Best & Friedrich LLP
Lisa L. MuellerBRIC Wall

Biotech, Food, Drug
Intellectual Property
Turkey
All International

## Biosimilar Development in the Middle East – A Report

A very interesting presentation was given by Dr. Claudia Palmer (Partner and Managing Director of 55east FZ LLC) on the development of biosimilars in the Middle East. Dr. Palmer started her presentation by discussing the exchange she frequently has when asking various stakeholders in the Middle East for their view on the biosimilar marketplace. The response she typically receives is: “Biosimilars? Do you have them?” Ms. Palmer stated that currently, because there are so few companies in the area dealing in biopharmaceuticals, very few biosimilars are actually available.

Despite the limited number of biosimilars presently available, Ms. Palmer stated that the region holds substantial potential for the growth of these products. Specifically, she noted: (1) the population in the Middle East is more than 200 million and is among the fastest growing in the world; (2) there is now political and fiscal stability in the region; (3) the economies of many countries in the area are booming; (4) there is a growing middle class; (5) life styles are changing and life expectancy is increasing; (6) the incidences of serious disease is increasing; and (7) the quality healthcare is improving and the sophistication of treatment increasing.

With respect to biologics, Ms. Palmer stated that the price tag that typically accompanies biologics (such as seen in the U.S.) simply is not viable for many of the smaller Middle Eastern countries. In fact, in her view, as the incidences of cancer grow in this area, biosimilars will be the only affordable treatments for these diseases in many of these countries. Interestingly, Ms. Palmer commented that no one is really sure the exact amount that can be saved by treating a patient with a biosimilar instead of with an innovator biologic.

In Ms. Palmer’s view, there is an opportunity for early entry of three biosimilar products in the region. These products would be erythropoietin (EPO), somatotropin and filgrastim. Ms. Palmer believes that the market opportunity for these three drugs in the Middle East, Turkey and Africa (META) region would be around $160-$190 million dollars, about 3% of the total biosimilar market. She indicated that this number was small because the path to market for any biosimilars in the region was going to be challenging.  First, she noted that it generally takes about two to three years once a biologic is approved in the U.S. or Europe for that biologic to become accessible in the Middle East. Once the biologic becomes available in the region, adoption tends to be slower than in the rest of the world due to a lack of infrastructure and the lack of insurance coverage for these products. Additionally, further complicating matters is that a number of countries in the Middle East have not yet established biosimilar frameworks. As Ms. Palmer noted, a biosimilar is only a biosimilar if it has gone through a biosimilar pathway.

Ms. Palmer also stated there will likely be issues with pricing and reimbursement for biosimilars in these countries. Specifically, she noted that tenders comprise a majority of the market (likely over 80%) and the systems are not

always transparent. Moreover, in many instances, preference for tenders is given to local biopharmaceutical companies.

With respect to potential customers, Ms. Palmer stated that the typical buying entities for speciality drugs in this region will likely include: Ministries of Health, central pharmacies, army/military, hospitals, non-governmental organizations (NGOs) and dialysis centers. Ms. Palmer noted that biologics treatment is normally provided in the region by hospitals and dialysis centers. For nationals receiving these treatments, the treatment is generally paid for by the national healthcare system or by insurance.

Ms. Palmer noted that so far, competition for biosimilars in the region has been limited. Multinational generic companies such as Hospira and Sandoz seem to have the best regional footprint so far. She also noted that currently there are really no local manufacturers in the area to speak of. The lack of such local manufacturers presents a number of positives and negatives. In terms of positives, no local manufacturers means that there will be a longer lead time for local companies to enter the market. Moreover, the lack of local manufacturing might make it hard for authorities to insist on a preference for a local product (particularly if there is none). Finally, the lack local manufacturers might facilitate the slowing of price erosion. With respect to the negatives, the lack of competition will likely mean that there will be few to no companies to partner with for the purposes of contract manufacturing. This lack of manufacturers might cause a cojoining of manufacturers and distributors which might result in a skills gap that could create challenges in distribution. Additionally, the lack of local manufacturers might also impact the ultimate acceptance of these biosimilar products and might instead increase tolerance for products imported from India or China.

Near the end of her presentation, Ms. Palmer stated that companies interested in entering the biosimilar market in the Middle East will need to enhance their capabilities across their organizations and value chains. Ms. Palmer stated that any such companies will want to first make sure they have obtained either a U.S. or European registration for their biosimilars. Next, companies will want to invest in stakeholder management. Specifically, companies will want to: (1) build a network of regional stakeholders; (2) create awareness among these stakeholders; and (3) educate and train these stakeholders. Moreover, when dealing with local regulatory organizations, companies will want to drive rapid marketing authorizations. Businesses will also need to adapt their value chain by: (1) building a tender infrastructure; (2) enhancing supply chain capability; (3) enabling distributors; and (4) engaging with local players. Finally, businesses will want to align the commercial organization by: (1) establishing a speciality marketing approach; (2) developing key account skills; (3) clarifying conflicts of interest; (4) customizing medical education; and (5) leveraging existing footprints.

At the end of her presentation, Ms. Palmer concluded with the following:

1. In general, the Middle East and Africa are the final frontier in pharma: In Ms. Palmer’s view, this is the last sizable area of untapped growth having limited competition.

2. Biosimilars hold a big promise for the Middle East: Biosimilars will provide modern treatments for large populations with limited purchasing power.

3. The biosimilars market will have to be built: Companies will need to work heard to create awareness, education and a safe supply of drugs.

4. This will be a marathon, not a sprint: As discussed previously, the current META commercial opportunity is around $160-$190 million for EPO, filgrastim and somatotropin.

5. Regulatory capability, market access and process management will drive success: The complexity of the challenge will be an opportunity for the right company.

6. The government will become your partner: According to Ms. Palmer, with tenders comprising 80% and more of the biosimilars market, stakeholder management and key account skills will be essential.

7. Build a biosimilars ecosystem:  Ms. Palmer noted that like a highly developed machine, biosimilar treatment can only thrive in a sophisticated, supportive environment.



**Source URL:** https://www.natlawreview.com/article/report-biosimilars-and-biotech-mena-conference-istanbul-turkey-part-1