Choices and Challenges in developing biosimilars in the MENA region

Marcel Bassil, Ph.D., C.C.R.P.
Associate Director Biotech

- Advances in diagnosis, aging, fast growing populations, advances in technologies and treatment and increasing in chronic and lifestyle diseases.

- Biosimilars represent an opportunity for emerging economies such Lebanon to build domestic biologics and biotechnology capabilities which, in turn, would allow them to penetrate and more efficiently compete for a share of the global Biopharmaceutical market.

Biosimilars/Biologics production

- Process important for biosimilars production
- Production process for biologics has more steps and is more complex than process for conventional drugs
- Requires significant capital investment

The rising popularity of biosimilar products in emerging markets such the MENA region especially Lebanon can be explained by a number of factors:

- High cost of branded biologics is placing enormous financial pressure on the national healthcare system.
- Fill in for lower-cost biosimilars for branded biologics would help to reduce government healthcare costs and minimize the financial burden of insuranc companies and third-party payers.
- Lebanon and other from the MENA region are extremely dependent on foreign biologic manufacturers and suppliers for many biologic products.
- Problems of oncopathies, rising drug prices and reductions of patient access to potentially life-saving drugs.

“A 2013 report from the European Commission looking at Europe’s strong regulatory and commercial foundation for biosimilars found that biosimilars are helping improve competition and are thus increasing access to biologic medicines for patients”

- "Panion proteins and monoclonal antibodies used in cancer and autoimmune diseases are expected to form a substantial portion of the new line of biosimilars.

Impact of Regulatory Agencies

The approach for market authorization for generics cannot be extrapolated to biosimilars

- Generics
- Biosimilars

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Conclusion

A learning period is important in all new activities; biosimilars are no exception

"The only source of knowledge is experience."