ACCESS TO AFFORDABLE BIOLOGICS: BIOSIMILARS OR BIOMIMICS?

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Background

Biologics constitute an essential part of targeted therapy in the management of cancer. However, the costs of biologics remain high which limits access to patients especially in the low- and middle-income countries. With the patent expiry of originator products, the use of biosimilars is growing significantly. This promises a cost reduction of up to 30% for these products.

Biosimilars are biologics that are highly similar in terms of quality, safety and efficacy to a licensed originator product.Their difference from the originator product is not clinically meaningful. Unlike small-molecule generics, they have differences in molecular structure and inactive compounds.

Selection of safe and effective biosimilars however, still remains a challenge with the availability of biomimics in most markets in the region. A biomimic is an intended replica of biotherapeutic products that do not meet regulatory requirements of bio similarity to the originator products.

An African survey on implementation of biosimilars showed one of the biggest barriers to implementation is lack of availability of licensed biosimilar products with 25% of respondents indicating the availability of biomimics in their markets.

In a bid to harmonize the registration of biosimilars, the Pharmacy and Poisons Board of Kenya (PPB)has developed guidelines in line with other stringent regulatory authorities. However, some of the registered biologics do not meet the regulatory requirements as per the PPB guidelines as well as the stringent regulatory authorities.

The International Society of Oncology Pharmacists Practitioners (ISOPP) global position on the use of biosimilars in cancer treatment and supportive care discourages the use of biomimics.

Methodology

A review of 9 bio-therapeutics registered by PPB was done to check for harmonization with selected stringent regulatory authorities; US Food and Drug Administration, European Medicines Agency and South Africa Health Products Regulatory Authority.

Findings

Only two of the nine bio-therapeutics were registered by a stringent body and PPB an indication that some of the products in the market could be biomimics.This poses a challenge when selecting biosimilars for use in an institution.

Conclusion

Selection of safe and effective biologics remains a challenge for institutions this calls for vigilance by practitioners in collaboration with their pharmacists that their biologics in use are biosimilars.