WMA STATEMENT ON BIOSIMILAR MEDICINAL PRODUCTS

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PREAMBLE

1. The expiry of patents for original biotherapeutics has led to the development and approval of copies, called 'similar biological medicinal products' or 'biosimilars' that are highly similar to a previously approved biological product, known as the originator or reference product.

2. In light of the fact that biosimilars are made in living organisms, there may be some minor differences from the reference medicine, as minor variability is a characteristic attribute of all biological medicines. The manufacture of biosimilars is generally more complex than the manufacture of chemically derived molecules. Therefore, the active substance in the final biosimilar can have an inherent degree of minor variability. Innovator biologics also have inherent batch-to-batch variability, and for that reason biosimilars are not always interchangeable with the reference products, even after regulatory approval.

3. Biosimilars are not the same as generics. A generic drug is an identical copy of a currently licenced pharmaceutical product that has an expired patent protection and must contain the 'same active ingredients as the original formulation'. A biosimilar is a different product with a similar, but not identical, structure that elicits a similar clinical response. As a result, biosimilar medicines have the potential to cause an unwanted immune response. Whereas generics are interchangeable, biosimilars are not always interchangeable.

4. Biosimilars have been available in Europe for almost a decade following their approval by the European Medicines Agency (EMA) in 2005. The first biosimilar was approved by the Food and Drug Administration (FDA) for use in the United States in 2015.

5. Biosimilar medicines have transformed the outlook for patients with chronic and debilitating conditions, as it is possible to obtain similar efficacy as that of the reference product at a lower cost.

6. Biosimilars will also increase availability for patients without access to the bio-originator. Greater global access to effective biopharmaceuticals can reduce disability, morbidity, and mortality associated with various chronic diseases.

7. Nonetheless, the potentially lower cost of biosimilars raises the risk that insurers and health care providers may favor them over the originator product, even when they may not be appropriate for an individual patient or in situations when they have not demonstrated adequate clinical equivalence to an original biological product. The decision to prescribe biosimilars or to switch patients from reference medicine to a biosimilar must be made by the attending physicians, not by health insurance companies.

RECOMMENDATIONS

1. National medical associations should work with their governments to develop national guidance on safety of biosimilars.

2. National medical associations should advocate for delivering biosimilar therapies that are as safe and effective as their reference products.

3. National medical associations should strive to ensure that physician autonomy is preserved in directing

which biologic product is dispensed.

4. Where appropriate, national medical associations should lobby against allowing insurers and health funds to require biosimilar and originator product's interchangeability, and for safe regulations of interchanging biosimilar medicines where this is allowed.

5. Physicians must ensure that patient medical records accurately reflect the biosimilar medicine that is being prescribed and taken.

6. Physicians shouldn't prescribe a biosimilar to patients already showing success with the originator product, unless clinical equivalence has been clearly demonstrated and established and patients are adequately informed and have given consent. There should be no substitution between biosimilars and other drugs without the attending physcian's permission.

7. Physicians should seek to improve their understanding of the distinctions between biosimilar products that are highly similar to or are interchangeable with an originator product; raise awareness of the issues surrounding biosimilars and interchangeability; and promote clearly delineated labelling of biosimilar products.

8. Physicians should remain vigilant and report to the manufacturer, as well as through the designated regulatory pathways, any adverse events suffered by patients using originator biological products or biosimilars.