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# WHO to begin pilot prequalification of biosimilars for cancer treatment

News release

4 MAY 2017 | GENEVA - This year WHO will launch a pilot project for prequalifying biosimilar medicines, a step towards making some of the most expensive treatments for cancer more widely available in low- and middle-income countries.

In September, WHO will invite manufacturers to submit applications for prequalification of biosimilar versions of two products in the WHO Essential Medicines List: rituximab (used principally to treat non-Hodgkin's lymphoma and chronic lymphocytic leukemia), and trastuzumab (used to treat breast cancer). The decision comes after a two-day meeting in Geneva between WHO, national regulators, pharmaceutical industry groups, patient and civil society groups, payers and policymakers to discuss ways to increase access to biotherapeutic medicines. WHO also plans to explore options for prequalifying insulin.

Biotherapeutic medicines, which are produced from biological sources such as cells rather than synthesised chemicals, are important treatments for some cancers and other non-communicable diseases. Like generic medicines, biosimilars can be much less expensive versions of innovator biotherapeutics. They are usually manufactured by other companies once the patent on the original product has expired. As the patents of some biotherapeutics have expired, more biosimilars are being produced. Like generic medicines, biosimilars could help to increase access to treatment in lower-resourced countries and provide a solution to escalating health costs in high-income countries.

“Innovator biotherapeutic products are often too expensive for many countries, so biosimilars are a good opportunity to expand access and support countries to regulate and use these medicines,” said Dr Marie-Paule Kieny, WHO Assistant Director General for Health Systems and Innovation.

If WHO finds that the biosimilars submitted for prequalification are comparable to originator products in terms of quality, safety and efficacy, the medicines will be listed by WHO and become eligible for procurement by United Nations agencies. Many low- and middle-income countries also rely on WHO prequalification before buying medicines. An additional benefit of WHO prequalification could be to increase competition and further reduce the price of medicines.

WHO will also review its 2009 Guidelines on the evaluation of similar biotherapeutic products to ensure that WHO's guidance to national regulatory authorities reflects recent evidence and experience.

"Biosimilars could be game-changers for access to medicines for certain complex conditions," said Dr Suzanne Hill, WHO's Director of Essential Medicines and Health Products. "But they need to be regulated appropriately to ensure therapeutic value and patient safety."

Increased use of biosimilars will also require patients and their physicians to understand and trust that the benefits of this type of medicine substantially outweigh any risks. WHO will be looking to countries with positive experience of biosimilars and partners for support in educating prescribers and patients on the benefits of these medicines and in advocating for greater awareness of biosimilars.

In addition, WHO will advocate for fairer prices for all biotherapeutics to ensure that these treatments can truly benefit public health. This will include support to countries to develop price-setting strategies that foster sustainable markets to deliver treatments to patients, savings to payers and incentives to producers to keep manufacturing the medicines needed.

**Note to editors**

Biotherapeutics are pharmaceutical products derived from biological and living sources. They include therapeutic vaccines, blood, blood components, cells, gene therapies, tissues and other materials.

Several biologic medicines are 'specialty drugs', highly priced and effective in treating medical conditions for which no other treatments are available. Gene- and cell-based therapies are among these pharmaceuticals.

Some biotherapeutics are effective treatments for certain forms of cancer, chronic diseases such as diabetes, Crohn's disease and other autoimmune conditions, including lupus , and various forms of rheumatoid arthritis.

Appropriate regulation of biosimilars is of paramount importance for the quality, safety and efficacy of the treatment. As their source is biological, or living, the product may change during manufacture and no biotherapeutic product of the same category is exactly the same as another. It is therefore more difficult to make a comparison between a biosimilar and its original, than it is between chemically identical active ingredients in a fully synthesised medicine. For that reason, WHO must accompany global policies on expanding access to biosimilars with rigorous guidance on the way these medicines are quality-assured before they enter markets.

Every year, billions of dollars' worth of medicines and other health products are purchased by international procurement agencies for distribution in low-income countries. Prequalification is a service provided by WHO to assess the quality, safety and efficacy of those products that address global public health priorities. If the products meet international

standards, they are listed on the WHO web site as eligible for procurement, giving purchasing agencies a range of quality-assured diagnostics, medicines and vaccines from which to choose. Many low-income countries also use WHO's lists of prequalified products to guide their selection of medicines, vaccines and technologies for national procurement.

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