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Comment on the article:

Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers

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The progress in research on molecular basis of oncogenesis has led to the unprecedented development of new anticancer treatment methods. Traditional cytotoxic drugs are increasingly being replaced by targeted therapies, that affect molecular or immunologic mechanisms in cancer. Many of these drugs are of biological origin, and their active substances include polypeptides, glycoproteins, proteins, or nucleic acids, produced by living organisms or derived with the use of genetic manipulations. These agents often require the use of advanced, specific diagnostic methods (companion diagnostics). Naturally, these highly specialised and "new-quality" therapies are very expensive (some prices at the time of marketing authorisation can reach hundreds of thousands of euros per year), that limits their availability. One of the ways to significantly reduce high costs is to replace the original biological drugs with their cheaper counterparts — biosimilars. In recent years, more than 20 biopharmaceuticals have been authorised in the European Union, including erythropoiesis or leukopenia stimulants, growth factors, ovulation stimulants, antibodies used in rheumatoid arthritis, and insulins. Up to now, among these newly registered biosimilars there were virtually no biological anticancer agents because their original prototypes were launched slightly later and are still covered by patent protection. However, in the coming years patent protection for the entire group of biological anticancer drugs expires (mainly monoclonal antibodies), that will undoubtedly result in their broad replacement with biosimilar drugs.

Introduction of biosimilars raises hopes, but also some fears; these concern primarily the potential differences between original and reproductive biological drugs and the related questions regarding their effectiveness and safety. Indeed, while reproductive synthetic drugs are the same chemical molecules, a biosimilar, due to the complex biotechnological process of its production, cannot be considered to be an identical copy of its prototype. This situation is noticed by drug registration agencies; unlike synthetic reproductive medicine, registration of a reproductive biological drug is subject to a number of additional requirements, including a clinical trial that confirms its reproducibility with the original, or prolonged period of safety monitoring (pharmacovigilance). Nevertheless, even meeting all these additional requirements does not allow unambiguous settlement of the aforementioned doubts. Examples of such dilemmas include exchange of original and biosimilar medicines, replacement of one biological drug for another during therapy, and the right to dispense by pharmacy a biosimilar instead of the original drug. In the European Union countries regulations in this field are not the competence of the European Medicines Agency (EMA), but rather of member states' institutions. In some countries, it is regulated on a legal basis, but in the majority, there is still space for different interpretations. Practitioners and pharmacists should not be faced with a situation in which they will have to resolve these problems themselves in their daily practice. Experts from the European Society for Clinical Oncology (ESMO) highlight that the physician should make a decision on the possible replacement of a biological drug due to his/her responsibility regarding monitoring a course of treatment.

Recognising the importance of oncological biosimilars the ESMO decided to publish a position statement in this matter. It is worthy to note that this document was signed by all members of the ESMO Management Board. We tried to objectively and sustainably present the opportunities that biosimilars provide in oncology but also highlight conditions that would enhance the safety of their use. This article is addressed to a wide range of professionals: physicians, pharmacists, drug manufacturers, national payers, and private insurers. To facilitate access to this article, we published it in a web-based journal with open access ESMO Open — Cancer Horizons. The interest exceeded our expectations; within the first two months the number of downloads exceeded 6500. We hope that the publication of this article in Polish version will allow our community to become more familiar with this important topic.

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