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Biosimilars in oncology

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Biosimilars will soon become broadly available in the oncology field, raising important questions from both patients and healthcare providers. These questions need to be clarified upfront, in order to increase confidence in using these therapies.

In this podcast, Teresa Amaral (Young Oncologist Committee member) talks to JTosep Tabernero (ESMO President and Director of the Vall d'Hebron Institute of Oncology) in Barcelona about this timely topic—biosimilars in oncology.

'Biosimilars are biological products that contain a similar version of the active substance of their originator or reference product (biologic), derived from living organisms.[1] Minimal differences between biosimilars and their original might exist, but the original compounds themselves can differ slightly in their composition (different oligo- or polysaccharides, for example), depending on the time they were produced. However, the difference between the original compound and the biosimilar is never related to the mechanism of action, since the potential variable polysaccharides are never incorporated in the Fab or distal Fc region of the antibody.

The clinical and preclinical investigation programs for biosimilars are very well established, both by EMA (European Medicines Agency) and FDA (Food and Drug Administration), and include pharmaceutical quality studies, comparative analytical functional studies, comparative non-clinical tests and clinical studies. Moreover, a very comprehensive pharmacovigilance plan is also implemented.

In terms of safety, the potential differences observed between biosimilars and their original are most likely related to immunogenicity. Yet, these small differences can also be perceived with original compounds, as mentioned previously, and here comes into play the central role of the pharmacovigilance plan.

The use of biosimilars can be extrapolated from one clinical indication to another (extrapolation), and a switching process (from original to biosimilar, biosimilar to original and one biosimilar to another biosimilar) can also occur. The *ESMO* position paper[1] emphasizes that physicians are responsible for the prescription and therefore patients must be clearly and thoroughly informed about the switching process, before it takes place. Automatic substitution/switching should be avoided.

A strong collaboration between the different stakeholders in the biosimilars investigation field exists, and should be maintained, since this represents a possibility of easier access to biological drugs in an era where the health systems' sustainability is an everyday issue.'

You can hear more about it in the following link: (link to the audio recording)

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REFERENCE

1. Tabernero J, Vyas M, Giuliani R. Biosimilars: a position paper of the european society for medical oncology, with particular reference to oncology prescribers. *ESMO Open* 2016;1:e000142.