INTRINSIC ACTIVITY

CONSENSUS STATEMENT

Biosimilars:
Aktueller Stellenwert in der Onkologie und Hämatologie

Hellmut SAMONIGG, Günther GASTL, Richard GREIL, Hildegard GREINIX, Ulrich JÄGER, Philipp STABER, Günther STEGER & Ewald WÖLL

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SUPPLEMENTARY MATERIAL

ENGLISH ABSTRACT*

[Biosimilars: current status in oncology and haematology]

The introduction of biopharmaceutical drugs, so-called biologics, has revolutionised pharmacological therapy in many areas of medicine. In many cases, a targeted treatment, *i.e.* a therapy directed to a particular molecular target (*e.g.* blockade of HER2/neu), has become possible. Biologics are used today in almost all medical specialties.

The expiration of the related patents has allowed companies other than the manufacturers of the respective original biological (hereinafter referred to as "originator") to produce follow-on products called "biosimilars" (BS). The number of BS coming onto the market will increase significantly in the coming years and decades.

However, as the name implies, BSs are not identical copies of the originator, as is the case with generics. Since the exact manufacturing process of the originator product partly remains a company secret even after expiry of the patent protection, each BS manufacturer must define its own production process, which inevitably results in deviations from the originator product.

Thus, a completely new situation has arisen here, which poses regulatory, organisational and practical challenges for regulatory authorities, hospital operators, pharmacies and social insurance institutions, and above all for the physicians treating the patients. The European Medicines Agency (EMA) has taken a leading role worldwide in the definition of regulatory routes for the approval of BS.

In Austria, a first Austrian consensus statement on BS, which was supported by six specialist societies, already in 2014 took account of the current problem. On this basis, the Austrian Society for Haematology and Medical Oncology (OeGHO) wants to present for the first time some key points on BS on the basis of specific hematological and oncological indications. This applies above all to switching and medication beginning, interchangeability and extrapolation. These points are presented based on some haematological indications (CLL, NHL) and breast cancer. Before that, regulatory and organizational aspects are dealt with in separate sections.

*Translation of summarising section(s) of the original paper created by the editorial board of *Intrinsic Activity*.