Biosimilars create opportunities for sustainable cancer care

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Biosimilars create opportunities for sustainable cancer care, says the European Society for Medical Oncology (ESMO) in a position paper published in ESMO Open.1 The document outlines approval standards for biosimilars, how to safely introduce them into the clinic, and the potential benefits for patients and healthcare systems.

"Biosimilars are an excellent opportunity to have good, valid drug options that improve the sustainability and affordability of cancer treatment in various countries," said Professor Josep Tabernero, Chair of the ESMO Cancer Medicines Working Group, from the Vall d'Hebron University Hospital and Institute of Oncology (VHIO), Universitat Autònoma de Barcelona, Spain. "To do that we have to be sure that biosimilars follow appropriate manufacturing procedures, are clinically tested, and adhere to regulations from the European Medicines Agency (EMA)."

Optimal safety and efficacy is, critically, the shared responsibility of both the manufacturers and the regulatory bodies, states the paper.

Biosimilars are medicinal products derived from living organisms that contain a similar version of the active substance as the original biologic. They differ from generics, which are chemically synthesised and are identical copies of the original drug. Unlike generics, biosimilars require clinical studies to ensure that the manufacturing process is sound and does not differ from that of the originator biologic.

In Europe, price reductions for biosimilars are expected to range from 20% to 40%, and potential savings of €50–100 billion by 2020 have been forecast. The majority of monoclonal antibodies are set to come off patent by 2020, which will open the door for biosimilars and could dramatically change the oncology landscape.

"Biosimilars are must-have weaponry in financially sustaining healthcare systems on a global scale as well as significantly improving outcomes for an increasing number of patients throughout Europe and the rest of the world," said ESMO President Professor Fortunato Ciardiello, Università degli Studi della Campania Luigi Vanvitelli in Naples, Italy.

In this position paper, ESMO tackles current issues surrounding definition, labelling, extrapolation, interchangeability, switching and substitution of biosimilars.

"ESMO calls for strict adherence to approval standards of biosimilars as well as their accelerated introduction into the clinic," said Tabernero. "Aligned with ESMO´s mission to facilitate equal access to optimal cancer care for all cancer patients, and as clearly set out in its 2020 Vision, this paper provides a timely overview on where we are and the 'where to next' for biosimilar products and their respective regulatory approval processes."

He continued: "The paper highlights a number of areas that should be carefully considered by all stakeholders including prescribers, pharmacists, nurses, patients, reimbursement bodies, and manufacturers. Importantly, it also outlines a number of directions that will need to be collectively followed to guarantee the highest safety and efficacy standards of these medicines and ensure that all patients, irrespective of geographical borders, can access the very best evidence based treatments."

"Biosimilars give us the chance to make treatment options for cancer more affordable everywhere," the ESMO President said. "This ESMO position paper sets out a series of principles that should be fulfilled to ensure that the biosimilars that reach the market are of good quality, safe and effective. Clinicians are starting to ask questions about how to incorporate biosimilars into their daily practice and until now they did not have an authoritative source of information. This paper serves to educate practising physicians on this complex topic."

ESMO is the leading European professional organisation for medical oncology. With more than 15,000 oncology professionals from over 130 countries, it is the society of reference for oncology education and information. ESMO's online open access journal, ESMO Open, is a key avenue for disseminating valuable information to the entire oncology community.

More information: Josep Tabernero et al. Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers, *ESMO Open* (2017). DOI: 10.1136/esmoopen-2016-000142