Biosimilar Medicines Virtual Summit 2021:

Translating experience into regulation

What do regulatory frameworks for biosimilar medicines look like today?

More than 15 years of experience with biosimilar medicines show us that these medicines can be used to expand access to treatment, as they are just as safe and effective as their originator counterparts and can therefore be considered interchangeable with them. This means that an originator and its corresponding biosimilar(s) are different versions of a given biological medicine.

Improvements in analytical techniques and ever-expanding scientific knowledge continuously deepen our understanding of the structure and function of the active principles of biological medicines.

To determine whether a biological medicine can be considered a biosimilar, regulators have designed specific frameworks that look at whether a candidate biosimilar and its corresponding originator are comparable. These frameworks have evolved significantly since the approval of the first biosimilar medicine, to keep up with accumulated experience and scientific progress. Such continuous adaptation gradually eliminates steps that have become redundant, to focus on the data that can provide meaningful information for the assessment.

How can we keep improving the global regulatory landscape for biosimilar medicines?

Continue to increase the efficiency of the available frameworks based on science and experience

CT tailoring and more flexible sourcing of comparators are key to achieve this.

Develop new and solid frameworks in jurisdictions where they are not yet available

The WHO has a key role in promoting the establishment of new frameworks, including by providing template guidelines.

Inform patients and HCPs on biosimilar medicines

Communicate changes proactively and with early involvement of all stakeholders, focusing on basic principles

Harmonise guidelines internationally

Regulators consortia and clusters provide a platform for alignment.

What changes can deliver the greatest improvement to regulatory frameworks for biosimilar medicines?

Introduction of clinical trials tailoring

In May 2021, the UK regulator MHRA waived the default requirement for one of the clinical trials that was previously considered necessary to demonstrate the biosimilar medicine's comparability with the respective originator, provided there is enough laboratory-based evidence that supports the comparability. It had been shown that this particular type of clinical trial did not help regulators to assess whether there were meaningful differences between versions of a given biological medicine.

This approach is called "CT tailoring" or "streamlined development". More regulators are looking at ways to adopt this strategy and its widespread implementation will be key in improving regulatory efficiency for biosimilar medicines.

Increased flexibility in comparator sourcing requirements

When developing a new biosimilar medicine, sourcing of sufficient amounts of comparator product to run the necessary comparability tests remains a hurdle, due to local regulatory restrictions on product origin as well as other obstacles. To mitigate this problem, more regulators should implement flexible sourcing requirements, allowing developers to obtain comparator products from all jurisdictions with sufficiently stringent guidelines.This approach is supported by current scientific knowledge and experience with biological medicines.

biosimilar medicines

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