23 June 2019 ICMRA Plenary San Diego Agenda Item 6 b
Statement on biosimilars cover paper

ICMRA WHO joint statement on biosimilars

A request was initially received from WHO for ICMRA to provide a supportive statement to provide reassurance that biosimilars are appropriately authorised biological medicines and to support wider global adoption. This statement will confirm that we are confident in our robust regulatory licensing process for biosimilars. Once a biosimilar is demonstrated to be highly similar to the originator with no clinically meaningful differences, it can be approved for the same indications as the originator on the basis of the established efficacy and safety of the originator in each indication.

This statement is also intended to dispel some of the myths suggesting that biosimilars are inferior to originator products and are not tested properly. This was a problem years ago when biosimilars were first introduced in Europe, but now it appears to be happening in other countries. This statement aims to provide clarity on the robustness of the regulatory system for the approval of biosimilars to minimise attempts to delay or block the introduction of biosimilars by undermining Healthcare Professional (HCP) and patient confidence.

Competition between different biological medicines, including biosimilar medicines, creates increased choice for patients and clinicians. When biosimilar medicines have entered the market, the increasing competition enables significant savings to be realised, which has enabled increased access of these biologics to a larger number of patients.

Following an ICMRA executive committee discussion on 23 January 2019, an initial draft statement was proposed at the ICMRA all members teleconference on 13 March 2019 (Annex B: DRAFT ICRMA/WHO statement about confidence in biosimilar products). It was agreed that two separate documents should be developed: one for clinicians (HCP) and one for patients and public.

ICMRA sub-group on statement on Biosimilars

UK (MHRA) agreed to lead a sub-group to develop and deliver a joint statement on biosimilars. The work involved experts from WHO, Europe (EMA), USA (FDA), Health Canada, Japan (PDMA and MHLW), Germany (PEI), Australia (TGA), India (CDSCO), Ireland (HPRA), South Korea (MFDS) and Singapore (HSA).

<u>Statement on biosimilars for healthcare professionals (HCP)</u>

An initial teleconference (14 May 2019) was held to discuss the draft HCP statement and comments received from several experts. The statement was subsequently reorganised, with improved wording, but most of the key points were maintained. In the discussion, it was agreed to use the term ‘highly similar’, rather than similar. Some clear messages from the teleconference included emphasising the scientific rigour of the biosimilar approval process and the pharmaceutical quality of biosimilar products. A list of the biosimilar products (not exhaustive) approved in several countries was included to illustrate the range of biosimilars available.

There was agreement for not using the term ‘extrapolation’ as this can be confusing to stakeholders. Instead, a more narrative explanation was drafted. Terms such as ‘interchangeability’ and ‘substitution’ have not been used as these have different meanings in various jurisdictions. Reference to risk management plans was removed as this is not required in all jurisdictions, but a comment about monitoring (pharmacovigilance) was retained.

After 4 rounds of drafting for the HCP statement (by email) and a teleconference on 12 June 2019, the final statement was agreed.

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Statement on biosimilars for patients and public

Patients and public may have similar concerns about biosimilars, but the explanations have been made simpler, with minimum technical terminology to enable easier understanding for this audience. There was some discussion about the level of detail required and which terms to use, but consistency throughout the statement was agreed. The format was changed to one of questions and answers, to make this easier to read.

Three drafts were circulated before discussion at the teleconference on 12 June, where the final statement was agreed.

Recommendation

The two statements for HCP and patients/public on biosimilars have been developed and agreed by the ICMRA sub-group (see annexes). It is recommended that ICMRA consider the output statements of the sub-group, endorse and adopt these for publication.