16 December 2016
EMA/756854/2016
Human Medicines Research and Development Support Division

Tailored scientific advice to support step-by-step development of new biosimilars

Pilot project to commence in February 2017

Questions and Answer

This page lists questions that biosimilar developers may have on the tailored scientific advice procedure.

1. I would like to take part in the pilot. Who should I contact?

For any information regarding the pilot please contact ScientificAdvice@ema.europa.eu.

2. Who can apply?

The Pilot is open to all Companies seeking Scientific Advice for the development of a biosimilar. However, the data package to be reviewed should be mature in order to fully benefit from the pilot.

3. What should be included in the briefing package?

It is expected that the Applicant will provide an overview of the full development plan and include questions not only related to the quality development but also in relation to the proposed non-clinical and/or clinical development, thus allowing the CHMP to provide appropriate advice on the next steps of the development (quality, non-clinical, clinical) based on the quality data available.

The analytical and functional data included in the briefing package (physico-chemical, biological, in-vitro testing etc.) should be mature and appropriate in view of the specific question(s) put forward by the Applicant. In view of the expected diversity of products, developments and questions it is not possible to further pre-define detailed data requirements. The data submitted should be directly related to the comparability exercise between the biosimilar and the reference medicinal product (i.e. data that is intended to be included in module 3.2.R of the future Marketing Authorisation Application). The statistical methods/analysis used for the comparison of quality data should be presented, if applicable.

Advice on the questions regarding the biosimilar development will be given under the assumption that the manufacturing process is well controlled, methods suitably validated/qualified etc., but any data

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

intended for other parts of module 3 than 3.2R will not be reviewed as part of the scientific advice procedure.

4. What should not be included in the briefing package?

Questions on quality issues unrelated to the comparability between the biosimilar and reference medicinal product are outside the scope of the pilot and can be submitted separately using the normal scientific advice procedure.

5. How will the procedure be handled?

Applicants need to submit a Letter of Intent and a briefing package following the time line for a Scientific Advice procedure with pre-submission meeting.

A pre-submission meeting will always be organized in order to define whether the briefing document contains the appropriate data for the scope of the pilot. The pre-submission meeting will be managed by EMA Scientific Officers from Scientific Advice, Quality, Statistics and from specific therapeutic areas as needed. The Quality Assessors appointed for the procedure are also expected to take part in the pre-submission meeting.

The timelines will be modified compared to a normal SA procedure. To allow sufficient time for the review of the quality data **an extra month** will be added between SAWP 0 and SAWP 1.

A final Advice letter will be issue at day 70 or 100.

6. Will the review of data conducted by the SAWP have an impact on the assessment at the time of MAA?

The Scientific Advice will be based on the data presented at the time of the advice and will be non-binding, like all Scientific Advice. It will not pre-empt the decision of the CHMP on the MAA, which will ultimately depend on the totality of data presented at the time of the MAA submission.

7. For how long will the pilot run?

It is foreseen that the pilot will run until the completion of 6 Scientific Advices. A maximum of one Scientific Advice per month can be accepted.

8. What fee will be applied?

The fee will be the standard fee for a SA procedure including Quality, Non Clinical and Clinical questions.