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Human Medicines Research and Development Support Division

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

## Update on Pilot project started in February 2017

**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.

### 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. This will allow 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 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 pre-define detailed data requirements. Companies may however contact the Agency in advance to discuss their questions and proposed data package.

Examples of topics that can be presented in the tailored scientific advice are outlined below (non-exhaustive list):

(a) Confirmation on whether the available data package indicates that the biosimilar pathway is suitable

(b) Differences identified at the quality level and their impact on the overall development programme

(c) Suitability of the intended clinical development programme based on the quality data available, including but not limited to cases where the clinical development programme deviates from the available guidance (e.g. waiver of clinical efficacy/safety trial).

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The data submitted should be directly related to the comparability exercise between the biosimilar and the reference medicinal product. The statistical methods/analysis intended or used for the comparison of quality data should be presented and justified, 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 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 only be included on an exceptional basis.

### 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 or without pre-submission meeting. While the applicant is encouraged to request a pre-submission meeting this is not mandatory.

If a pre-submission meeting is requested by the company a team composed of EMA scientific officers from Scientific Advice, Quality, Statistics and from the relevant therapeutic areas as needed will take part in the meeting. The Quality Assessors appointed for the procedure are also invited to take part in the pre-submission meeting.

Whether or not the questions and data package are suitable for the Pilot will be determined at the phase of validation as for a normal SA procedure.

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 Advices. 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.

### 8. What fee will be applied?

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

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