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Human Medicines Division

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

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

### **1. I am considering submitting a tailored biosimilar scientific advice request. Who should I contact?**

For any information regarding tailored scientific advice for biosimilars please contact [ScientificAdvice@ema.europa.eu](mailto:ScientificAdvice@ema.europa.eu).

### **2. Who can apply?**

The tailored scientific advice is open to all applicants 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 include:

- (a) Confirmation on whether the available data package indicates that the biosimilar pathway is suitable if significant difference were observed between the biosimilar candidate and the reference medicinal product in terms of physicochemical characterisation, biological activity, purity and quality attributes



- (b) Suitability of a scaled down clinical development programme based on the quality data available, namely cases where the clinical development programme would deviate from the available guidance (e.g. omission of dedicated clinical efficacy and/or safety studies).

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 no data intended for parts of eCTD module 3 other than 3.2R will be reviewed as part of the scientific advice procedure.

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

Tailored biosimilar advice requests to pre-assess quality, analytical, and functional data without further justification why such request is made will not be accepted. Questions on quality issues unrelated to the comparability between the biosimilar and reference medicinal product are outside the scope of the tailored biosimilar scientific advice and can only be included on an exceptional basis.

#### **5. How will the procedure be handled?**

Applicants need to submit an application through the [IRIS platform](#) following the timeline for a Scientific Advice procedure with or without pre-submission meeting. While applicants are encouraged to request a pre-submission meeting, this is not mandatory.

Whether or not the questions and data package are suitable for tailored scientific advice 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 issued at day 70 or 100.

#### **6. Can I submit a follow-up tailored scientific advice?**

Yes, follow-up tailored scientific advice requests are acceptable and will follow the same principles as explained in questions 3, 4 and 5 above.

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 any Scientific Advice. It will not pre-empt the opinion of the CHMP on the MAA, which will ultimately depend on the totality of data presented at the time of the MAA submission.

#### **7. What fee will be applied?**

The fee will be the initial scientific advice fee for a request including Quality, Non-Clinical and Clinical questions, as applicable. Follow-up tailored scientific advice will be charged a follow-up request fee.