EMA pilot project on tailored scientific advice to support new biosimilars

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Focus on Regulation

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To obtain a marketing authorisation for a biosimilar, applicants need to submit evidence substantiating similarity with the reference biological medicinal product, in terms of quality characteristics, biological activity, safety and efficacy.

The existing EMA scientific advice procedure can advise developers of biosimilars on the appropriate comparability tests and studies they need to conduct to support their marketing authorisation application. The procedure does not, however, allow for a formal assessment of data already available to developers.

As part of the pilot project, the EMA's Scientific Advice Working Party (SAWP) will provide an in-depth review of the data already available to developers that are related to the comparability between the biosimilar and the reference biological medicinal product. Depending on the data already available, developers will receive tailored advice concerning the studies and tests that should be carried out in the next steps of the biosimilar development.

Like the existing EMA scientific advice, the tailored scientific advice will not constitute a formal pre-assessment of the data that will be submitted with the marketing authorisation application for the biosimilar.

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