



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Experience from the pilot for tailored scientific advice on biosimilars

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# Background on the pilot for tailored scientific advice on biosimilars

- In-depth advice for biosimilar developments based on a review of available quality, analytical and functional data:
  - pilot open to all types of biosimilars
  - extra month in addition to normal scientific advice (SA) timelines to review applications
- Pilot until 6 scientific advice procedures were completed (02/2017 to 04/2020)
- Analysis of experience including feedback from applicants and assessors is ongoing, conclusions to be communicated in Q1 2021
  - Pending the outcome of the analysis, submissions can still be accepted

## Biosimilar pilot analysis – data collection

- Feedback sought from applicants participating to the pilot on:
  - guidance provided about the pilot
  - reason for choosing this type of SA
  - expectations
  - level of satisfaction
- ➔ Responses from applicants for 4 developments (covering 5 SA procedures)
- Feedback sought from the assessment teams participating to the pilot on:
  - expectations
  - learnings / sustainability
- ➔ Responses from all 9 assessment teams

## Biosimilar pilot analysis – preliminary analysis

- General positive feedback from applicants on the possibility to present interim quality data during the biosimilar development
  - Asked whether the expectations for the tailored scientific advice were met (scale from 1 = not at all, to 5 = absolutely), the average rating was 3.7
- All responding developers recommended that this approach of tailored scientific advice for biosimilars should be continued to be offered
  - Wish for more flexibility in term of maturity of the quality data package and possibility of follow-up
- The concept of a stepwise biosimilar approach is often not followed, as generation of quality comparability data takes place in parallel with clinical development
- Extent of the scientific advice limited by the fact that the data packages presented were fairly immature (e.g. data from pilot scale manufacturing process)