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TITLE

BIOSIMILARS AND EU CHMP SCIENTIFIC ADVICE

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At any stage of development, and irrespective of eligibility to use the centralised procedure for marketing authorisation, sponsors can request scientific advice from the EMEA. This helps the sponsor to ensure that the appropriate tests and studies are performed, so that no major objections regarding the design of the tests are likely to be raised during evaluation of the marketing authorisation application. Such major objections can significantly delay the marketing of a product, and, in certain cases, may result in refusal of the marketing authorisation. Following the Agency's advice, therefore, increases the probability of a positive outcome. For human medicinal products, scientific advice is given by the EMEA's Committee for Medicinal Products for Human Use (CHMP) on the recommendation of the Scientific Advice Working Party (SAWP-H).

Biosimilars are an integral part of the scientific advice agenda and the number if applications is increasing continuously. The SAWP evaluates requests regarding the quality, preclinical and clinical development to support biosimilarity using a network of EU experts but also input from BWP, BMWP and CHMP. The assessment of the requests is based on the regulatory framework for EU biosimilars, the relevant guidelines but also new scientific knowledge and input from the applicant. Therefore the interaction between SAWP/CHMP and sponsors is bilateral. In this talk we will outline the scientific advice process for biosimilar products and we will elaborate on frequent issues encountered by the SAWP in this context.