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Tunisian guidelines on biosimilars registration: Main requirements and issues

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This work deals with the tunisian experience in the redaction of guidelines on biosimilars registration and the main encountered problems. Our project started in April 2015 and we aim to accomplish the first draft before 2016. For this purpose, we established a working group composed of representatives of the competent authorities (responsibles of drug registration, quality assessment, clinical trials and pharmacovigilance) and experts in pharmacology, in analytical chemistry and in biotechnology. Delegates of the syndicate of local manufacturers (CNIP) and the Tunisian syndicate of research and developement laboratories, clinical investigators and representatives of CRO biosimilar development were also involved in order to take their perspectives into account. Guidelines from other countries were also benchmarked. The working group was then splitted into 3 taskforces working on the quality, preclinical and clinical guidelines. In some sections, most of the guidelines are in a complete concordance. In others, many disparities were highlighted; especially regarding interchangeability and clinical trials for some biosimilar classes. Even though the decision was made to refer to the existing guidelines in each part, many questions remained unanswered like the specific case of biosimilars manufactured in Tunisia after a technology transfer. Many other issues we were confronted to, such as the choice of the reference product when it is not registered in Tunisia and there is no access to its pharmaceutical data to assess its quality comparability.

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Regulatory market exclusivity issues for biologics and biosimilars

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This presentation will describe the market exclusivity provisions that apply to biosimilars in the United States and the associated commercial implications of those provisions. The presentation will include a brief review of the market exclusivity provisions for small molecules (the Hatch-0Waxman Act) and a comparison between the legal and regulatory structure for generic drugs and biosimilars.

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