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An update on the registration of biosimilars in Malaysia

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Biotherapeutics are medicinal products made by or derived from living organisms and may be produced by biotechnology. Due to its structure and complex manufacturing process, every biotherapeutic product (BTP) is considered 'high risk' and must therefore adhere to stringent quality assurance and control requirements. Similarly, copy products of original biotherapeutics (termed as 'biosimilars') are subjected to equally strict regulatory control. BTPs have been registered in Malaysia since 1990's. Registration of biosimilars started only in 2008. This research aims to compare evaluation practice on biosimilar and novel BTPs at the Biological Product Registration Section in Malaysia. Evaluation activities were studied in terms of evaluation questions, evaluation timeline, nonclinical and clinical requirements, and local requirements on product label (including package insert). Six biosimilar product dossiers and six novel BTP dossiers evaluated in 2013-2015 were sampled. Parameters for comparison were determined and analysed using data collection forms. Specific to the biosimilar products, the evaluation practice on labels and package inserts were dissected and described in a qualitative arm of this research. The analysis on findings revealed some similarities and differences in current evaluation practice (timeline and requirements) for biosimilar vs. novel BTPs. The findings of this research also provide an insight on current evaluation practice on biosimilar product labelling.

Biography

Tien Yew TANG completed his B. Pharm (Hons.) degree at the UCSI University in 2013. He has been a biotherapeutic product evaluator at the Biologics Section, Centre for Product Registration, National Pharmaceutical Control Bureau, Ministry of Health Malaysia since February 2015. Prior to his present position, he completed pharmacy training at Hospital Pakar Sultanah Fatimah, Muar.

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