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Excipients data sharing initiative: A step forward 3-R principle implementation

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The choice of excipients in pharmaceutical formulations is crucial for manufacturing processes and optimisation of drug pharmacodynamic and pharmacokinetic properties. While most side effects are related to the active ingredient (AI) of the medication, excipients defined as inactive components are not necessarily inert. The guideline on "Excipients in the Label and Package Leaflet of Medicinal Products for Human Use" (CPMP/463/00) is currently under revision in order to encompass safety concerns previously unidentified/addressed.

Toxicological data from excipients safety studies (which are low throughput, expensive and time consuming) are rarely accessible especially as most pharmaceutical formulations will not reach the marketing authorisation stage. The Excipients Data Sharing Initiative is gathering proprietary and literature data in a central repository under a searchable format. Currently involving 11 pharmaceutical companies, the Excipients Database was first released in 2008 and its coverage has been expanded in terms of the types of vehicles, dosages, routes of administration, animal models and endpoints.

After giving a brief overview of the type of information captured within the database, some examples of its potential use in the early stages of new drugs development will be presented. Emphasis will also be placed on how such *in silico* tools provide suitable answers within the context of reach, which requires data sharing between companies in order to avoid duplication of animal experiments.

Biography

Anne-Laure Werner is a toxicology database scientist at Lhasa Limited, a not-for-profit organisation, developing expert knowledge base and database systems to predict toxicity, metabolic fate and chemical degradation. She holds an M.Sc. in Toxicology (University Paris V, 2001) and an M.Sc. in Environmental Toxicology (University Metz, 2002). After working on different ecotoxicological projects investigating micropollutant effects on aquatic systems, she joined Lhasa Limited in 2010. She first worked on expanding the coverage of various endpoints within the Vitic database (genotoxicity, carcinogenicity, skin sensitisation, repeat dose and developmental toxicity) and is currently involved in Excipients, Intermediates and MIP-DILI data sharing projects.

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