Title

Regulatory Challenges of Biopharmaceuticals

PhD
Ebbers, Hans C.

Start of research: 2008
Status: Finished
End of research: Doctorate 2012

Background
The safety profile of biopharmaceuticals may be affected by seemingly minor changes in the production process. This makes them prone for immunological reactions. The unpredictability of safety concerns of biopharmaceuticals has triggered increased regulatory interest in the safety of this class of molecules.

Objective
To study the challenges that biopharmaceuticals present to the regulatory system with regard to safety. This is achieved through the analysis of safety concerns associated with biopharmaceuticals and the ability of existing regulatory instruments to deal with these issues.

Regulatory impact
Overall, regulators and industry have gained more experience with biopharmaceutical-related Adverse Drug Reactions. The research by Ebbers has advanced understanding of safety concerns associated with biopharmaceuticals. This knowledge may facilitate the translation of regulator and industry experience into appropriate risk schemes and tools that can be applied to biopharmaceuticals, both innovative and biosimilar.

Quote
A closer collaboration between the organised medical community and regulators is needed.

Academic collaboration
Copernicus Institute
Institute of Pharmaceutical Sciences
Utrecht University

Research track
Consumer use & safety
Research group
Leufkens, Hubert GM
Mantel-Teeuwisse, Aukje K
Moors, Ellen HM
Schellekens, Huub

Keywords
biopharmaceutical, immunogenicity, pharmacovigilance, regulation, drug safety, risk management

Achievements
5. Ebbers HC, Mantel-Teeuwisse