

# ACCISS Study Report | Biosimilar Insulin Regulatory Profile

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The Biosimilar Insulin Regulatory Profile discusses the regulatory pathways and challenges faced by companies seeking marketing authorisation for insulin biosimilars, particularly in highly-regulated markets such as the European Union (EU) and the United States (US). It also includes a case study of two manufacturers who sought marketing authorisation from the European Medicines Agency (EMA) for insulin products.

You can download the full report [here](#).