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## EU biosimilar regulation and the possible effect of Brexit on biosimilar medicines

The European Union (EU) has led the way for the global expansion of the biosimilar market for 15 years and is the global leader in the review and approval of biosimilar medicines and biosimilar regulation via the London based European Medicines Agency (EMA). Other countries, such as Australia, work side by side with the regulations and guidance produced from the EMA, and institutions, such as the World Health Organisation, have periodic meetings in London to discuss biosimilar medicines. Because, the United Kingdom is about to leave the EU on 29th March 2019 and the EMA and all its staff will have to relocate to remain in the EU as a result. All biosimilar products will need to be re-registered to one of the remaining 27 countries and there is the very real risk that this relocation will see losses in talented staff as well as hinder the approval and maintenance of biosimilar medicines.

### Speaker Biography

Aaron Damien Barzey has been working in the Pharmaceutical Industry, covering Medical Affairs, Pharmacovigilance, Regulatory Affairs and Compliance, in multiple countries and multiple companies. At GSK, he was the Global Labelling Lead for the orphan drug 'ofatumumab'. He was responsible for the company core datasheets, labelling strategy, EU labelling negations and oversaw the product launch in emerging markets. His major accomplishment was leading the launch of Arzerra for the treatment of chronic lymphatic leukaemia across the EU, Australia and other countries. In 2015, he started his own regulatory consultancy, ADB Medical, providing ad-hoc support or project specific guidance to various companies. In 2016, he was chosen as the Pharmaceutical Industry SME to discuss the possible impact of Brexit on the pharmaceutical industry, which included debating with Nigel Farage live on national television and to discuss further on live on UK TV with Piers Morgan and Susanna Reid.

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