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The possible effect of Brexit on the pharmaceutical industry: Pharmacovigilance

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The European Union (EU) has led the way in pharmacovigilance legislation, processes and understanding for many years and are the global leader in the review and approval of biosimilar medicines, orphan drugs and paediatric medicines 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 medicines. The United Kingdom is due 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 centralised registered 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 innovative medicines and the maintenance of the current pharmacovigilance reporting mechanisms.

Biography

Aaron Damien Barzey was the Global Labelling lead for the orphan drug 'ofatumumab'. He was responsible for the company core datasheets, labelling strategy, EU labelling negotiations and oversaw the product launch in emerging markets. The major accomplishment was leading the launch of Arzerra for the treatment of chronic lymphatic leukaemia across the EU, Australia and other countries. In 2015 Aaron started his own regulatory consultancy, ADB Medical, providing ad-hoc support or project specific guidance to various companies. In 2016 Aaron 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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