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The consequences and possible consequences of brexit on biosimilars medicines

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The European Union (EU) has led the way in biosimilar regulation, processes and understanding for many years and is the global leader in the review and approval of biosimilar medicines1, via the London based European Medicines Agency (EMA). The EMA's Biosimilar Medicinal Products Working Party (BMWP) provides expert advice on authorised and developmental biosimilar medicines. Other countries, such as South Africa2 and Australia3, have adopted the biosimilar regulations and guidance produced by the EU, and institutions, such as the World Health Organisation, have periodic meetings in London to discuss medicines with the EMA. The United Kingdom is due to leave the EU on 29th March 2019 and the EMA and all its staff must relocate to Amsterdam as a result. All centralised 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, hindering the approval and maintenance of biosimilar medicines and, as many non-EU markets will approve a biosimilar that has EU approval, this may also have a knock-on effect on the approval of biosimilar medicines around the world.

Biography

Aaron D Barzey's first taste of scientific research came in 1997, where at the early age of 14 he became the youngest paid intern in Imperial College London's history and contributed to ground breaking research in tyrosine hydroxylase and its regulation of dopamine synthesis. Since graduation Aaron been working in the pharmaceutical industry, covering Medical Affairs, Pharmacovigilance, Regulatory Affairs and Compliance, in multiple countries and multiple companies. At GSK, Aaron 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. 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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