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Consequences of Brexit on biosimilars

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The European Union introduced the first regulatory pathway to biosimilars more than a decade ago, making a centralized authorization valid throughout the European Union available for biosimilars. The validity of these authorizations in the UK post Brexit is called into question. What is more, marketing authorization holders have to reside in the European Union and close to 40% of all central marketing authorizations (not only biosimilars) are held by companies residing in the UK. Thus, access to the UK market is thrown into question, and existing corporate structures for marketing authorization holders have to be revisited. Also distribution contracts may have to be renegotiated, where it comes to the territory of the UK. Adding uncertainty for the industry is the expected move by the European Medicines Agency from London.

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