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Post-Brexit world: Biosimilar challenges

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The UK left the European Union on 23rd June 2016 but what are the challenges of biosimilar market in Post-Brexit UK? One of the main challenge is that the approval of biosimilars has been carried out through European Medicines Agency (EMA) and UK does not have a regulatory pathway to approve biosimilars. The key concern is the delay in biosimilar approval due to UK's potential loss of EMA membership and separate regulatory framework. UK is interested in securing close working relationship with EMA on drug regulations to ensure that patients in UK continue to have access to best medicines. However, if negotiations don't result in the desired relationship, UK will have to establish its own regulatory pathway for biosimilar approvals. This could result in delay in biosimilar approvals, cost increase and patient access to biosimilar medicines. If EMA-UK negotiations result in desired outcome, UK will still loose the benefits of hosting EMA's headquarters, which will be relocated to another European city from London. How UK will negotiate regulatory approvals of biosimilars with EMA, is yet to be determined. The challenges of biosimilar market for Post-Brexit UK, will be presented.

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