Biosimilars: Impact of Brexit

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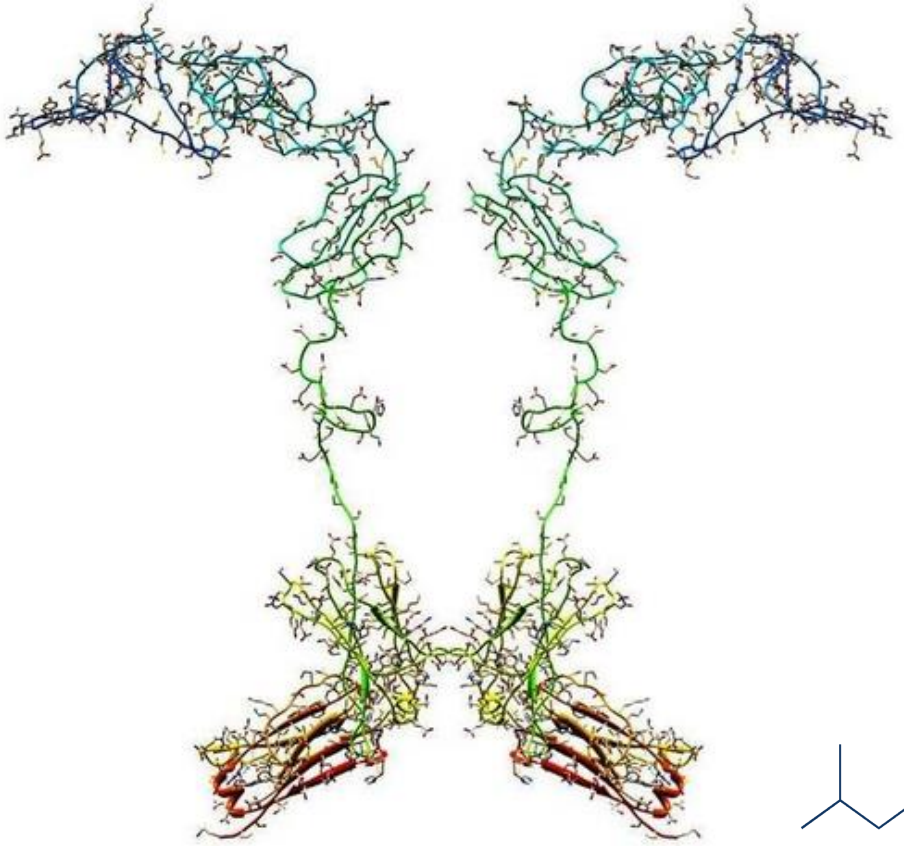
Agenda

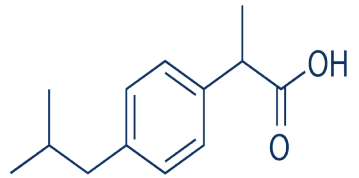
- Biosimilar
- What is Brexit
- Impact of Brexit on Biosimilar Market
- Conclusions

Biosimilars

Biosimilars are a less expensive copy of Biological Products.

Biosimilars are complex heterogeneous molecules manufactured using living cells.





Biosimilar Market

Emerging Biosimilar Market is Fast Growing Market

Biosimilar Market

- EMA has approved 22 Biosimilar, 2 approvals have been withdrawn leaving 20 Biosimilar in Europe.

- FDA approved 4 Biosimilars so far in USA.

- Several approved in ROW (Japan, Korea, India, Canada, Australia Etc.).

Brexit

Will Brexit affect Biosimilar Market?

What is Brexit

- The United Kingdom intends to withdraw from the European Union, as a result of a June 2016 referendum in which 51.9% voted to leave the EU.
- The separation process is complex, causing political, economic and Regulatory changes for the UK and other countries.
- As of September 2016, neither the timetable nor the terms for withdrawal have been established and in the meantime, the UK remains a full member European Union.

Brexit and Biosimilars

UK may lag behind in Biosimilar Sphere.

UK is already trailing in adoption of Biosimilars.

There is no Regulatory Pathway in place in UK for approval of Biosimilars.

Brexit's potential area of impact on UK Biosimilar Market

- Regulatory Uncertainty
- Patient Access to Medicine
- New Drug Development and Launch
- Financial Impact
- Impact of Brexit on EU

Regulatory Uncertainty

- UK does not have regulatory pathway to approve Biosimilars.
- Impact on previously approved Products by EMA.
- Impact on Products in approval process by EMA.
- What is the new regulatory Pathway?
- Will UK follow the same pathways as EMA?
- Regulatory uncertainty may result in Delay in approval and launch of new Biosimilars in UK.
- Regulatory uncertainty may result in temporary drug shortage, if not managed effectively.

Patient Access to Medicine

- There are 7 Biosimilars available in UK and none of them are produced locally.
- Importing may require additional testing, re-certification etc., which will create significant additional work, thus increasing the cost of Biosimilars in UK.
- Importing requirements has potential to cause delay in product release.
- Complex and costly importing process will affect patient access to Biosimilars.
- Delay in approval of new medicines due to lack of approval pathway may affect patient access to medicines.
- Companies may delay launch of Biosimilars in UK due to relatively smaller market than EU.

New Drug Development & Launch

- May impact companies willingness to conduct research in UK.
- Residency status of EU Biosimilar staff.
- UK researchers may loose access to facilities and EU innovative medicine initiatives.
- Loss of EU projects designed for patient access to innovation.

Financial Impact

- Potential impact on UK as clinical trial center.
- Potential impact on loss of EU research funding.
- Complex and costly importation process may make UK less attractive market for Biosimilar launch.
- Cost savings from Biosimilars for National Health Service (NHS) may be impacted.
- Companies may loose the benefit of single Market Authorization granted by EMA and will need separate approval for UK.
- May increase the price of Biosimilars due to UK's ability to obtain global discounted price.

Impact of Brexit on EU

- UK (MHRA) has strong presence and voice in EU, which ensures that balanced and pro business approach.
- Loss of all of the successful work for harmonization.
- Would other members of EU will follow UK?
- Threat to collaborative scientific research between EMA members and UK.
- Affect on 28 nation system of drug regulation.
- Change in interaction of UK system with rest of the Europe.
- Relocation of EMA from London may delay approval of Biosimilar due to disruption.

Brexit Impact

- EMA is headquartered in London and relocation of that headquarters to another EU country will take some time.
- UK may not want drug makers to follow 2 separate and costly regulatory processes to launch their products.
- Adopting existing EMA Biosimilar approval process is beneficial for UK And EU.

Conclusions

- Brexit may significantly impact UK Biosimilar market due to increased cost of existing Biosimilar importation.
- Brexit may impact UK Biosimilar market due to delays in new Biosimilar approval and launch.
- Brexit may impact patient access to medicine due to delay in approval and launch of new medicines.
- Brexit may cause drug shortage due to regulatory uncertainty.