BREXIT

Zuzana Baťová

SARAP, Bratislava

FAKTY

Jún 2016	Referendum 53% za Brexit
29. Marec 2017	Aktivácia článku 50 Lisabonskej zmluvy
29. Marec 2019	UK nebude súčasťou EU
30. marec 2019 00:00 h CET	UK bude „tretia krajina“

Zhodnotenie dopadov pre ŠÚKL

- Registrácia liekov
- Farmakovigilancia
- Inšpekcie
- Workload/prerozdelenie práce medzi zostávajúce ČS
- Personálne posilnenie ŠÚKL

Zhodnotenie dopadov pre Vás

	Počet procedúr/aktivít
DCP/MRP	+ 30 už zaregistrovaných liekov; schvaľovanie a posúdenie zmien v kvalite, bezpečnosti, účinnosti
Centralizované procedúry	2 procedúry - nové registrácie/rok
PRAC	12 liekov
GMP inšpekcie	+ 5 inšpekcií/rok
GCP inšpekcie	+ 1 inšpekcia/rok
GPhV inšpekcie	+ 1 inšpekcia/rok

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Regulatory guidance for industry to prepare for the UK's withdrawal from the EU

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31/05/2017

Regulatory guidance for industry to prepare for the UK's withdrawal from the EU

EMA and the European Commission publish first in a series of Q&As for companies

The European Medicines Agency (EMA) and the European Commission have published guidance to help pharmaceutical companies to prepare for the United Kingdom's withdrawal from the European Union. The guidance relates to both human and veterinary medicines.

The questions-and-answers document concerns information related to the location of establishment of a company in the context of centralised procedures and certain activities, including the location of orphan designation holders, qualified persons for pharmacovigilance (QPPVs) and companies' manufacturing and batch release sites.

EMA is preparing a series of further guidance documents which will be published on its website in due course. Companies are advised to regularly check EMA's dedicated webpage on the consequences of Brexit.

This first questions-and-answers document follows the publication of the European Commission/EMA notice to marketing authorisation holders of centrally authorised medicines for human and veterinary use on 2 May 2017.

Related content

- United Kingdom's withdrawal from the European Union

Related documents

- Questions and answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the centralised procedure (31/05/2017)

External links

- European Commission


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• Notice to marketing authorisation holders of national authorised medicinal products for human use (May 2017)
• Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to national authorised medicinal products for human use (May 2017)

- MAH musí mať sídlo v EU/EEA; prevod registrácie
- QPPV musí sídlo a vykonávať svoje povinnosti v EU/EEA; oznámenie zmena sídla
- PSMF musí byť umiestnený v EU/EEA
- Výrobné miesto účinnej látky
- Výrobné miesto lieku
- Prepúšťanie šarže

Odporúčanie pre MAH

- overiť stav jednotlivých registrácií
  (všetkých! – NÁR, MRP/DCP, EU)
- proaktívne, v primeranom čase naplánovať podanie prípadných zmien

Ďakujem za pozornosť!