EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA-Industry Stakeholder pharmacovigilance Q&A session on "Brexit Regulatory preparedness"

Presented by: Marie-Helene Pinheiro,
Industry Stakeholder Liaison

BACKGROUND

- ***EMA-EC Notice publication 2nd May 2016*** *followed by* ***EMA-EC Notice publication 31st May 2016***

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

On 2 May 2017, the European Commission and EMA published a **Notice to marketing authorisation holders of centrally authorised medicines products for human and veterinary use**, stating: *"The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that unless the withdrawal agreement establishes another date or the period is extended by the European Council in accordance with Article 50(3) of the Treaty on European Union, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET). The United Kingdom will then become a 'third country'."*

In this regard, marketing authorisation holders of centrally authorised medicinal products for human and veterinary use are reminded of certain legal consequences that need to be considered in a timely manner. Preparing for the consequences of the UK's withdrawal from the Union is not just a matter for European and national administrations, but also for private parties.

This first list of Questions and Answers (Q&As) has been drafted jointly by the European Commission and EMA and concerns information related to **establishment requirements** within the Union (EEA). The Q&As will be further updated and complemented in the near future.

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

4. **What if my Qualified Person for Pharmacovigilance (QPPV) resides and carries out his/her tasks in the UK?**

According to Article 8 of Directive 2001/83/EC and Article 74 of Directive 2001/82/EC, the qualified person responsible for pharmacovigilance must reside and carry out his/her tasks in the Member State of the Union (EEA). The QPPV will therefore need to change his/her place of residence and carry out his/her tasks in the Union (EEA) or a new QPPV residing and carrying out his/her tasks in the Union (EEA) will need to be appointed. Changes in the QPPV, including contact details (telephone, and fax numbers, postal address and email address) may, for medicinal products for human use, be updated through the Article 57 database only (without the need for a variation) (see Variation Guideline C.I.8). Regarding medicinal products for veterinary use the changes should be updated through a variation (see Variation Guideline C.I.9).

5. **What if my Pharmacovigilance System Master File is located in the UK (PSMF)? (*for medicines for human use*)**

According to Commission Implementing Regulation (EU) No 520/2012, the PSMF must be located within the Union (EEA). The supervisory authority for pharmacovigilance is the competent authority of the Member State in which the pharmacovigilance system master file is located .The marketing authorisation holder will therefore need to change the location of the PSMF to a Member State within the Union (EEA). Changes to the location of the PSMF (street, city, postcode, country) may be updated through the Article 57 database only (without the need for a variation) (see Variation Guideline C.I.8).

Next Steps

Report of Industry Stakeholder meeting on "Brexit" and operation of the centralised procedure for human medicinal products

1st Industry Stakeholder meeting on “Brexit” and operation of the centralised procedure for human medicinal products of 4th October 2017 [report] and for Veterinary product of 13th October 2017 [report]

- From Industry Stakeholders **priority topics** identified:
  - MAHs Transfers
  - Manufacturing and supply chain
  - Pharmacovigilance
  - Cross projects activities i.e. telematics etc.
- Need for **continued and frequent dialogue** with Industry Stakeholders to exchange information in the months to come
- Need for **regular Q&A updates and EMA procedural guidance** to be released. For the latter, with *(short period)* industry consultation, where and as appropriate
- **Centralised MAHs Survey** to be launched 4Q, 2017-1Q, 2018:
  - To obtain companies specific “Brexit” preparedness activities” information for EMA submission “workload” 2018 forecast for 2018 planning.

2017-2018 EMA-Industry Stakeholders interactions on “Brexit” related topics

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2017 calendar

- Industry Brexit meetings & webinars
- SME Info Day
- Platform meetings
- Publication of EC Q&A update – EMA procedural guidance – EMA Survey
- # EMA holidays

September

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

October

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1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

November

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			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

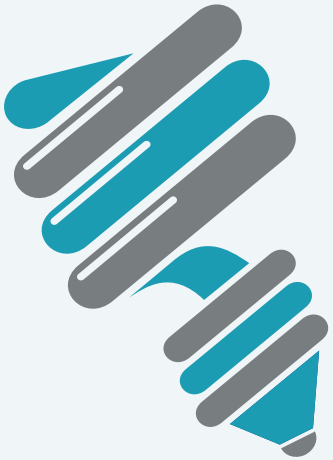
December

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

2017 – 2018 planned meetings with industry stakeholders

	2017 EMA Industry Stakeholder ‘Brexit’ Meetings & Webinars
04.10.17	Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human medicinal products (H)
13.10.17	Industry Stakeholder TC on Brexit and operation of the centralised procedure for veterinary medicinal products (V)
23.11.17	Industry Brexit webinar on Transfers (H&V)
24.11.17	Industry Brexit Q&A session on Pharmacovigilance in the context of Industry Stakeholder platform meeting on Pharmacovigilance (H)
12.12.17	Industry Brexit webinar on Manufacturing and Supply (H&V)

	2018 EMA Industry Stakeholder ‘Brexit’ Meetings & Webinars
26.01.18	Industry stakeholder meeting or webinar (H&V) tbc
23.03.18	Industry stakeholder meeting or webinar (H&V) tbc
14.06.18	Industry stakeholder meeting or webinar (H&V) tbc
28.09.18	Industry stakeholder meeting or webinar (H&V) tbc
22.11.18	Industry stakeholder meeting or webinar (H&V) tbc



RECOMMENDATIONS to INDUSTRY

- ***Consult regularly EMA website*** *on the* "United Kingdom's withdrawal from the European Union ('Brexit')" [Link] *for update on EMA "Brexit" related information;*
  - *Publication EMA procedural guidance*
  - *EMA-EC Q&A document(s)*
- *For any* ***questions*** *that you may have further to the Q&As publication, EMA procedural guidance, you are advised to liaise with your EMA following contacts :*
  - **Product specific** - **EMA Project Manager** as primary Brexit related matters contact: **"nameEMA PM"@ema.europa.eu**
  - **SME office** – for queries from small and medium sized enterprises – **SME@ema.europa.eu**
  - Company portfolio discussions – EMA pipeline meeting discussions: **businesspipeline@ema.europa.eu**
  - **Industry stakeholders liaison** – for industry EU trade questions particularly *via* trade associations: **industry@ema.europa.eu**
  - **Ask-EMA** – for **general Brexit-related questions**: Complete form in enclosed **link**.
- ***Inform EMA of any changes in intended submissions*** *at centralised level across pre- and post- activities*

Any Questions ?

Thank you

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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