EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

UK's withdrawal from the EU - preparedness activities update

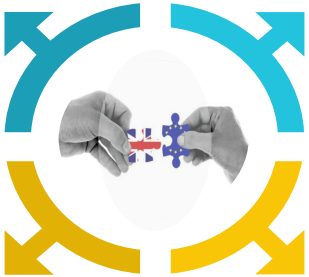
14th industry stakeholder platform – operation of EU pharmacovigilance - 28 September 2018

Presented by
Marie-Helene Pinheiro, EMA Industry Liaison
Claudia Galeazzo , Head of Service – Products and Applications Business Support
European Medicines Agency

Agenda

Relocation preparedness

Operational preparedness



Human resource preparedness

Communication preparedness

EMA Operational preparedness

- EMA Business Continuity Planning Phase 3
- UK Portfolio re-distribution implementation status update
- EMAA Industry CAPs Brexit Survey Analysis and Follow-up
- PhV Fees invoicing update

EMA Brexit Preparedness BCP in a nutshell

- The aim of the EMA Brexit Preparedness BCP is to address a situation where a “business as usual” scenario is no longer possible
  - Either because EMA has to ensure that the necessary human resources are available to work on EMA Brexit preparedness
  - Or because EMA can no longer compensate staff loss through the recruitment of replacement resource
- Both situations can exist in parallel and may persist for a longer period
- To operate the EMA Brexit Preparedness BCP, EMA activities have been grouped in 3 categories which can broadly be described as follows:

Category	Activities covered
Category 1 (highest priority) activities	Core scientific activities and supporting IT applications, corporate/communication/other IT activities necessary for EMA’s operation, legal obligations put on EMA
Category 2 (medium priority) activities	Either strategic activities or other core activities, sub-classified into 2A and 2B
Category 3 (lowest priority) activities	Non-strategic activities such as governance and support activities

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Brexit preparedness: EMA to further temporarily scale back and suspend activities

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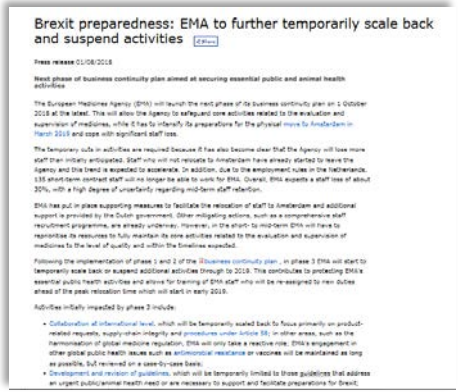

Brexit preparedness: EMA to further temporarily scale back and suspend activities

Press release 01/08/2018

Next phase of business continuity plan aimed at securing essential public and animal health activities

The European Medicines Agency (EMA) will launch the next phase of its business continuity plan on 1 October 2018 at the latest. This will allow the Agency to safeguard core activities related to the evaluation and supervision of medicines, while it has to intensify its preparations for the physical move to Amsterdam in March 2019 and cope with significant staff loss.

The temporary cuts in activities are required because it has also become clear that the Agency will lose more staff than initially anticipated. Staff who will not relocate to Amsterdam have already started to leave the Agency and this trend is expected to accelerate. In addition, due to the employment rules in the Netherlands, 135 short-term contract staff will no longer be able to work for EMA. Overall, EMA expects a staff loss of about 30%, with a high degree of uncertainty regarding mid-term staff retention.

EMA has put in place supporting measures to facilitate the relocation of staff to Amsterdam and additional support is provided by the Dutch government. Other mitigating actions, such as a comprehensive staff recruitment programme, are already underway. However, in the short- to mid-term EMA will have to reprioritise its resources to fully maintain its core activities related to the evaluation and supervision of medicines to the level of quality and within the timelines expected.

Following the implementation of phase 1 and 2 of the Business continuity plan , in phase 3 EMA will start to temporarily scale back or suspend additional activities through by 2019. This contributes to protecting EMA's essential public health activities and allows for training of EMA staff who will be re-assigned to new duties ahead of the peak relocation time which will start in early 2019.

Activities initially impacted by phase 3 include:

- Collaboration at international level, which will be temporarily scaled back to focus primarily on product-related requests, supply-chain integrity and procedures under Article 58; in other areas, such as the harmonisation of global medicine regulation, EMA will only take a reactive role; EMA's engagement in other global public health issues such as antimicrobial resistance or vaccines will be maintained as long as possible, but reviewed on a case-by-case basis;
- Development and revision of guidelines, which will be temporarily limited to those guidelines that address an urgent public/animal health need or are necessary to support and facilitate preparations for Brexit;

Activities initially impacted by phase 3 include:

- Collaboration at international level, which will be temporarily scaled back to focus primarily on product-related requests, supply-chain integrity and procedures under Article 58; in other areas, such as the harmonisation of global medicine regulation, EMA will only take a reactive role; EMA's engagement in other global public health issues such as antimicrobial resistance or vaccines will be maintained as long as possible, but reviewed on a case-by-case basis;
- Development and revision of guidelines, which will be temporarily limited to those guidelines that address an urgent public/animal health need or are necessary to support and facilitate preparations for Brexit;
- Holding of non-product-related working parties, which will be temporarily reduced as a consequence of the scaling back of guideline development or revision;
- Programmes and projects, where activities in relation to project governance will be reduced in line with the reduction/suspension of projects;
- Organisation and attendance at stakeholder meetings, which will be limited to Brexit-related interactions;
- Clinical data publication, for which the launch of new procedures will be temporarily suspended as of 1 August 2018; data packages submitted for medicines until the end of July 2018 will be processed and finalised.

The implementation date for phase 3 of EMA's business continuity plan is 1 October at the latest. Detailed

2 – EMA Preparedness context

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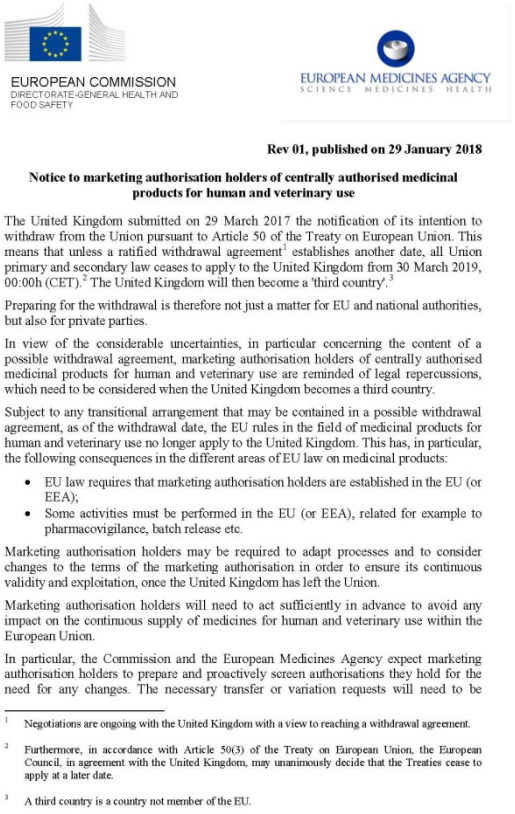
EC and EMA published a **Notice to MAHs** of centrally authorised medicines products for human and veterinary use 2nd May 2017

Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use

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 a ratified withdrawal agreement[1] establishes another date, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET).[2] The United Kingdom will then become a 'third country'.[3]



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Rev 01, published on 29 January 2018

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Preparing for the withdrawal is therefore not just a matter for EU and national authorities, but also for private parties.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, marketing authorisation holders of centrally authorised medicinal products for human and veterinary use are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of medicinal products for human and veterinary use no longer apply to the United Kingdom. This has, in particular, the following consequences in the different areas of EU law on medicinal products:

- EU law requires that marketing authorisation holders are established in the EU (or EEA);
- Some activities must be performed in the EU (or EEA), related for example to pharmacovigilance, batch release etc.

Marketing authorisation holders may be required to adapt processes and to consider changes to the terms of the marketing authorisation in order to ensure its continuous validity and exploitation, once the United Kingdom has left the Union.

Marketing authorisation holders will need to act sufficiently in advance to avoid any impact on the continuous supply of medicines for human and veterinary use within the European Union.

In particular, the Commission and the European Medicines Agency expect marketing authorisation holders to prepare and proactively screen authorisations they hold for the need for any changes. The necessary transfer or variation requests will need to be

[1] Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

[2] Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

[3] A third country is a country not member of the EU.

Companies reminded to **plan in advance in order to avoid any impact on the continuous supply of medicines** for human and veterinary use within the Union (EEA).

4 Further details can be seen in the European Commission presentation from the 24/9/18 – See EMA webpage events

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Implementation of the redistribution of the UK centrally authorised products portfolio (1/3)

- The **redistribution of the UK product portfolio*** was finalised on 4 April 2018 and the **new (Co)-Rapporteurships were communicated to the MAHs** on **30 April 2018**
- The **new (Co)-Rapporteurs** will only take **full responsibility** for the re-allocated medicinal products as of **30 March 2019 when the UK withdraws from the Union** and becomes a third country. The MHRA/VMD will be accountable for the medicinal products for which they are (Co)-Rapporteurs until 29 March 2019
- However, the new (Co)-Rapporteurs may be required to handle, **from Q4 2018 onwards**, **post-authorisation procedures** when it is envisaged that the procedures may be still **under evaluation after the 30 of March 2019**
- The decision is taken at procedure level and depending on the average length of the procedure

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Implementation of the redistribution of the UK centrally authorised products portfolio (2/3)

- For **lines extensions** and **extensions of indication** the cut-off dates have already surpassed and therefore all procedures starting after **1 October 2018** will be allocated to the new (Co)-Rapporteurs.
- **Quality, safety and efficacy type II variations** will be allocated to the new (Co)-Rapporteurs if submitted after **26 October 2018** and **renewals** submitted after **24 October 2018** will also be allocated to the new (Co)-Rapporteurs
- **PSURs (CAPS only)** submitted after **6 November 2018** will already be handled by the new (Co)-Rapporteurs
- **Type IB variations** submitted after **16 January 2019** will be allocated to the new (Co)-Rapporteurs

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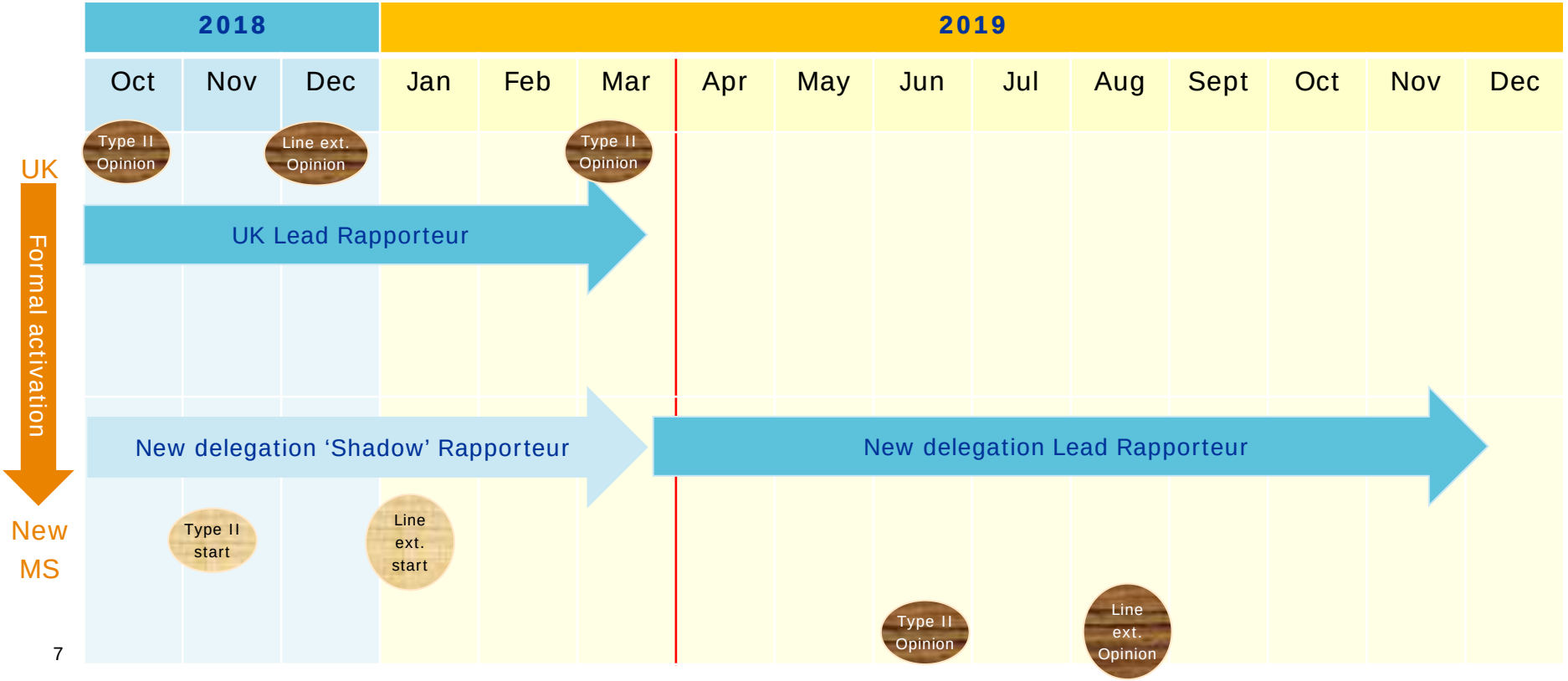
Implementation of the redistribution of the UK centrally authorised products portfolio (3/3)



4 - EMA Brexit Industry Survey for CAPs update

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Timelines and Response rate

- **22 January 2018** – The Industry survey was launched and sent to contact points for 694 CAPs corresponding to 176 MAHs.
- Industry survey was circulated to additional contact points for 4 CAPs (medicinal products that were authorised after cut-off date of October 2017) with a deadline for responses by 19 March 2018.
- The Industry survey received a **91% response rate** with a grand total of 662 CAPs responses (both H and V).

Total sent		
UK involvement	**CAPs**	**MAHs**
Human	**661**	**167**
Veterinary	**33**	**13**
Total	**694**	**180**

Industry survey results - PSMF and QPPV response analysis (Human CAPs)

PSMF Human CAPs

- **360 CAPs** have Pharmacovigilance System Master File (PSMF) located in the UK and will change.
- Only 1 CAP has a PSMF located in the UK and did not response to the question.
- For 208 out of 360 CAPs, the new location is “Not known yet”.

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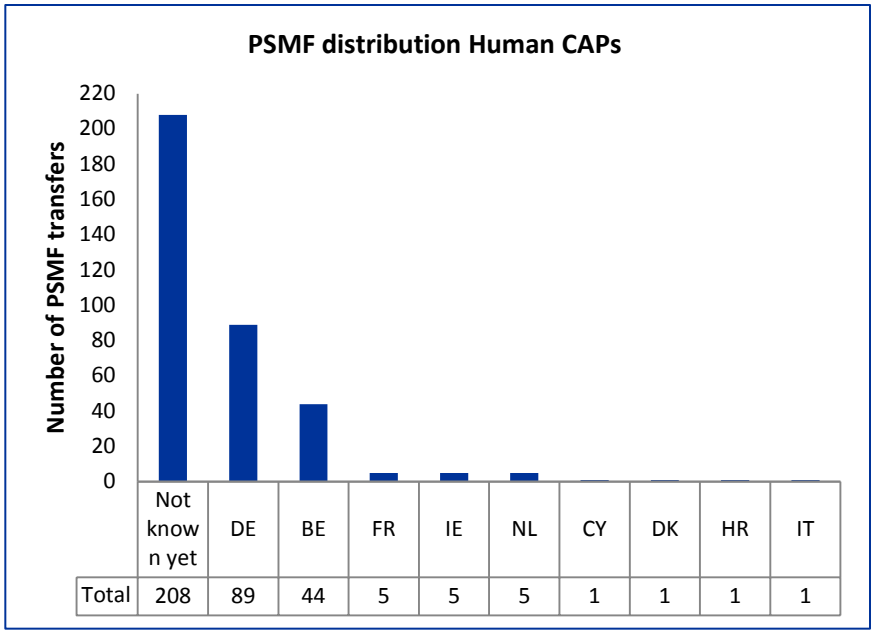
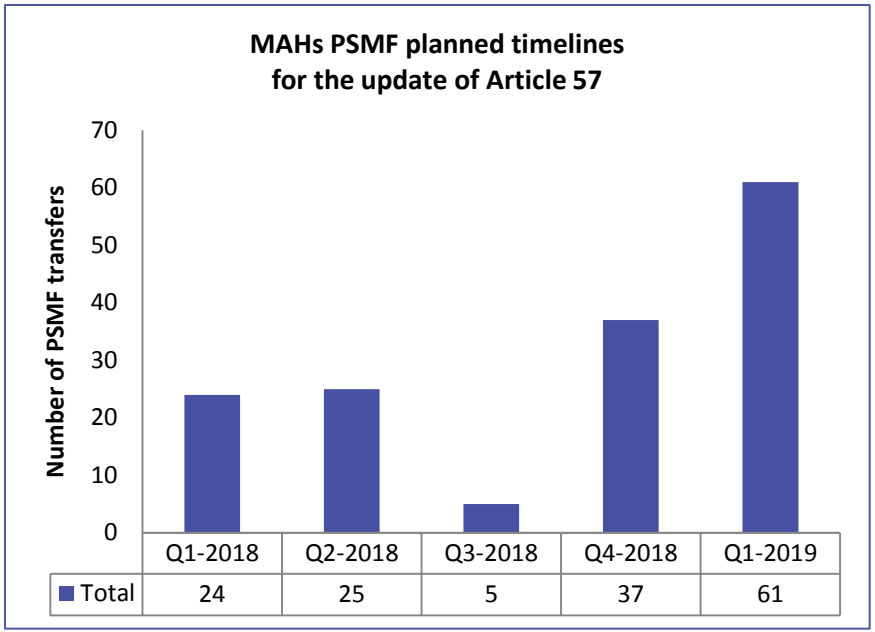
Industry survey results - PSMF (Human CAPs)





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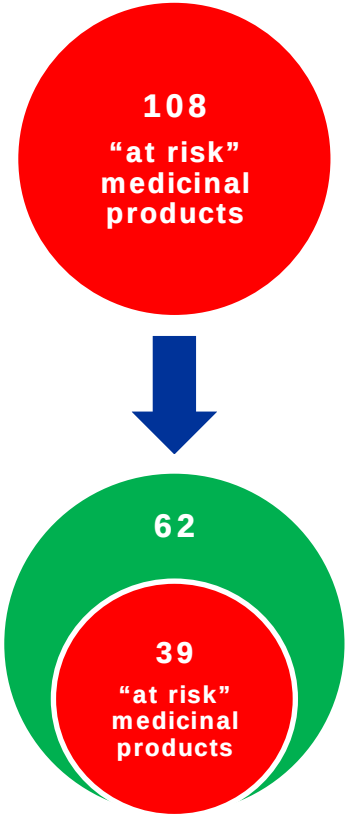
Follow up with MAHs on “at risk” products

- Follow up meetings for **108 centralised medicinal products** were organised with **54 MAHs** (45 Human and 9 Veterinary)
- A total of 51 teleconferences took place (43 Human and 8 Veterinary). A small number of MAHs provided information by email.
- As seen from the feedback provided by MAHs, **plans are changing** for a number of companies since the launch of the survey and **many companies will make the necessary changes before 30 March 2019**.
- **39 centralised medicinal products** (25 Human and 14 Veterinary) are **currently considered “at risk”** and may have **potential supply issues**.
- 6 Human products have been already withdrawn or will be withdrawn before 30 March 2019. 1 Veterinary product will not renew its Marketing Authorisation.



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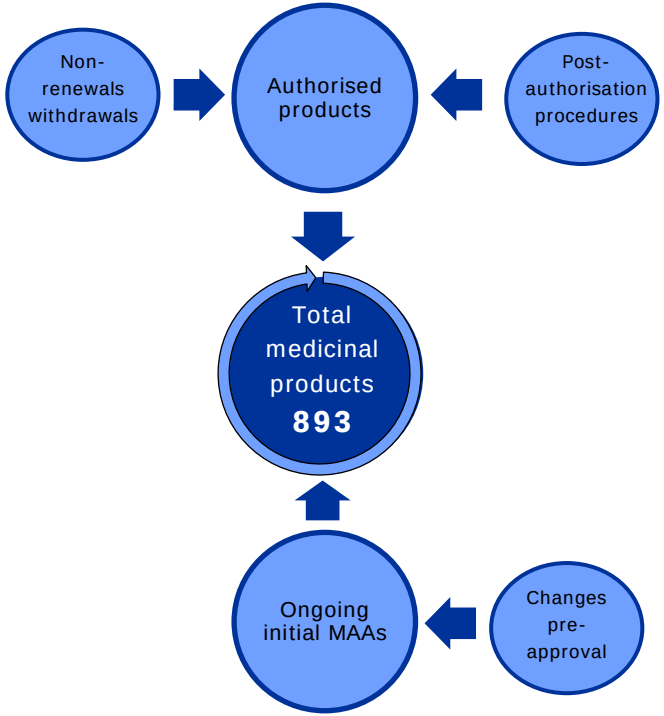
Tracking and monitoring of Brexit related changes

- EMA has been and will continue to monitor and track the submissions of required changes for **all 893 Brexit affected CAPs.**
- Currently **65 products** have completed all the necessary changes in order to comply with the legal requirements.
- **MAHs are reminded of their legal obligations to inform EMA on supply issues and product withdrawals.**
- Furthermore, **MAHs are requested to timely inform EMA on any changes to their current plans**.



5 - EMA-EC Regulatory Guidances update

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Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use

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Preparing for the withdrawal is therefore not just a matter for EU and national authorities, but also for private parties.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, marketing authorisation holders of centrally authorised medicinal products for human and veterinary use are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of medicinal products for human and veterinary use no longer apply to the United Kingdom. This has, in particular, the following consequences in the different areas of EU law on medicinal products:

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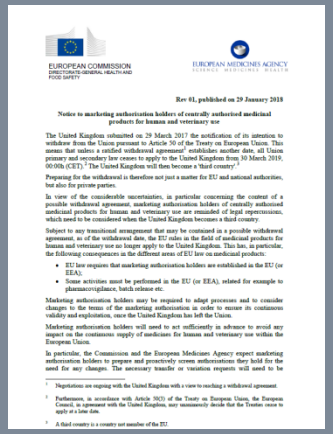
Context: EMA-Industry Preparedness Activities

EC-EMA Notice publication 2nd May 2017 followed by EMA-EC Notice publication 31st May 2017, updated June 2018

EMA Procedral guidance publication2 7 November 2017,, updated June 2018



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In particular, the Commission and the European Medicines Agency expect marketing authorisation holders to prepare and proactively screen authorisations they hold for the need for any changes. The necessary transfer or variation requests will need to be

1 Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

2 Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

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Rev 02, published on 29 January 2018

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, which was updated on 29 January 2018. The Notice states: *"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 a ratified withdrawal agreement[1] establishes another date, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET).[2] The United Kingdom will then become a 'third country'.[3]*

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, 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 EU and national authorities, but also for private parties. Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of medicinal products for human and veterinary use no longer apply to the United Kingdom.

This list of Questions and Answers (Q&As) has been drafted jointly by the European Commission and EMA. This version is an update of the initial list of Q&As published on 31 May 2017 and it replaces that initial list of Q&As. The new text introduced in the version of Q&As "Rev 01" published on 1 December 2017 is indicated by the word "**NEW**". The version "Rev 02" published on 29 January 2018 does not amend the Q&A, but consists of a technical revision of the introductory text on page 1 to introduce standardised wording across all sectorial guidance documents. The Q&As may be further updated and complemented in the future. The advice below applies equally to medicinal products for human or veterinary use, unless otherwise indicated in the heading to the question.

1 Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

2 Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

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5 - EMA-EC Regulatory Guidances update – PhV Specific

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Rev 03, published on 19 June 2018

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

This list of Questions and Answers (Q&As) complements the Notice **to marketing authorisation holders of centrally authorised medicines products for human and veterinary use**, which was updated on 23 January 2018.

The Notice states: *"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 a ratified withdrawal agreement[1] establishes another date, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET).[2] The United Kingdom will then become a 'third country'.[3]*

Preparing for the withdrawal is therefore not just a matter for EU and national authorities, but also for parties.

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21. How does UK's withdrawal from the Union affect the status of inspection outcomes by the UK competent authority? (NEW)

It is expected that findings of inspections, in particular to determine compliance with good manufacturing practice, good clinical practice and pharmacovigilance obligations, conducted by the UK competent authority before 30 March 2019 are implemented by the inspected entities in accordance with the applicable legislation, in particular Directive 2003/94/EC, Commission Delegated Regulation (EU) No 1252/2014 and Directive 91/412/EEC with regard to good manufacturing practice, Directive 2001/20/EC and Commission Directive 2005/28/EC with regard to good clinical practice and Regulation (EC) No 726/2004, Directive 2001/83/EC and Commission Implementing Regulation (EU) 520/2012 with regard to pharmacovigilance obligations.

25. What if Qualified Person's for Pharmacovigilance (QPPV) back-up arrangements are in the UK? (NEW)

According to Article 2 of Commission Implementing Regulation (EU) No 520/2012 back-up arrangements shall apply in the absence of the QPPV. As the tasks of QPPV need to be carried in a Member State of the Union (EEA), the back-up arrangements for cases of absence of the QPPV, which replace such tasks, also need to be performed in the Union (EEA).

Where a MAH relies on the services of a deputy QPPV as part of its back-up arrangements in the absence of the QPPV, those arrangements should ensure that the deputy QPPV is established and performs his/her tasks in the Union (EEA).

For veterinary medicines, reference is made to the EMA Brexit practical guidance.

6 – Brexit related Pharmacovigilance fees update

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Impact and implementation of fees processing for:

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2019 Pharmacovigilance Annual fee implementation

- Advice note will be sent in April 2019 (instead of March) to all EU based QPPVs for EU NAPs products registered in Art.57
- Exclusion of UK MA products and exclusion of UK QPPVs and UK MAHs (also for EU products)
- Invoice in July 2019 based on data as of 30/06/2019 covering the year, excluding UK MA products and UK MAHs (also for EU products)

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2019 PSUR fee: implementation after 30 March 2019

- UK Rapporteurship re-assigned by PRAC and CMDh/PRAC in September 2018 in EURD list
- At DLP, Advice note **will not be** sent to **UK QPPVs** for PSURs EU and UK products in Art.57
- UK MA products, UK QPPV and UK MAHs (*also for EU products*) **will be excluded** from PSUR repository submission
- UK MA products and UK MAHs (*also for EU products*) will be excluded from Art 57 for the calculation of CUs at start date

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2019 PhV referral fee: implementation for referrals to start after 30 March 2019

- Advice note to **EU QPPVs** for products in Art.57 excluding UK MA or UK MAHs (also for EU products)
- Advice note **will not be** sent to **UK QPPVs** for EU products in Art.57
- UK MA products and UK MAHs (also for EU products) will be excluded from Art 57 for the calculation of CUs at start date

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2019 PASS fee: implementation for PASS (protocol or final results) after 30 March

- No chargeable units. Fee shared by the number of MAHs included in the submission.
- Fee calculated excluding UK MA products and UK MAHs (also for EU products) at start date

7 - 2019 EMA-Industry Stakeholder interactions on Brexit related topics

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2019 calendar - Tentative

January

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		

Human Medicines

planned

June

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						

Human Medicines

planned

Thank you – Questions ?

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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