EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Operational and Procedural preparedness update

EMA webinar on UK withdrawal from the EU. 30th November 2020

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Disclaimer

This presentation only reflects the situation as laid down in legal provisions in force on the date of its presentation, and without prejudice to any of the ongoing discussions between the Union and the UK concerning the application of the Union acquis concerning medicinal products in respect of Northern Ireland after the transition period, in light of the particular challenges that small markets historically dependent on medicines supply from or through Great Britain are facing.
In this regard it has to be borne in mind that the EMA is not participating in any of the negotiations between the Union and the UK that aim at solving – before the end of 2020 - the particular challenges that small markets face as that historically are dependent on medicines supply from or through Great Britain, notably Northern Ireland.

Topics covered

- Brexit preparedness activities at EMA
- Status of Brexit changes to MAs of CAPs to implement by 31.12.2020
- Brexit changes to MAs of CAPs to implement after 31.12.2020
- Brexit Impact to Parallel Distribution Notifications

Brexit preparedness activities at EMA

- EMA continues to track and monitor Brexit-affected CAPs
- EMA prepares for required changes to the EMA IT databases and systems at the end of the transition period
- EMA is updating regulatory guidance and introducing the required adjustments to EMA's internal processes in view of the implementation of the IE/NI Protocol and the end of the transition period

Centrally Authorised Products: Status update (I)

- **Most MAHs have made the necessary changes** and are now ready to be regulatory compliant after 31 December 2020
- **All MAH transfers have been submitted** for authorised CAPs and therefore there are no CAPs with a MAH in the UK
- A limited number of CAPs for which changes to the QPPV, PSMF or manufacturing sites (where batch release, batch control testing and/or importation currently are only authorised for UK sites) are still pending, but these changes are only required to be implemented by the end of the transition period

Human CAPs: Status update (II)

- **8 CAPs still need to transfer manufacturing activities by 31.12.2020*,**** (Batch release / Batch control testing / Importation):
  - All MAHs have (re)confirmed that the changes will be implemented by 31.12.2020 and variation(s) will be submitted on time.
  - All pending variations fall under IA or IAIN scopes and should be submitted within 15 days (IAIN) or 2 months (IA) after 31.12.2020.
  - EMA strongly encourages the submission of these pending IA/IAINs early December aiming to issue Acknowledgement of Receipt before 31.12.2020, where possible.
  - For MAHs that have not submitted the variations during December, we appreciate confirmation that the change has been implemented by email to EMABrexitSurveyFU@ema.europa.eu by 04.01.2021.

- **13 CAPs still need to change the QPPV/PSMF***
  - All MAHs have confirmed to be in process of updating Art 57 database or will do it by the end of the year.

**does include a small number of CAPs that will be withdrawn before the end of the transition period.*

***this does not include sites in Northern Ireland and situations where alternative sites are already approved, even if the UK sites are not yet removed from the dossier*

Veterinary CAPs: Status update (III)

- **4 CAPs still need to transfer manufacturing activities by 31.12.2020*,**** (Batch release / Batch control testing / Importation):

  - Most remaining changes fall under IA or IAIN variations to be submitted within 15 days (IAIN) or 2 months (IA) after 31.12.2020.
  - EMA strongly encourages the submission of the pending IA/IAINs early December aiming to issue Acknowledgement of Receipt before 31.12.2020, where possible.
  - For MAHs that have not submitted the variation during December, we appreciate confirmation that the change has been implemented by email to vet.applications@ema.europa.eu (cc EMABrexitSurveyFU@ema.europa.eu) by 04.01.2021.
  - For changes that will not be implemented by 31.12.2020, EMA strongly recommends the submission of any outstanding variations immediately after 31.12.2020.

does include a CAP that will be withdrawn after the end of the transition period.

**this does not include sites in Northern Ireland and situations where alternative sites are already approved, even if the UK sites are not yet removed from the dossier*

Changes to MA of CAPs after 1.1.2021 (I)

~417 CAPs (H+V) will require the removal of obsolete activities / sites located in UK(GB) after 31.12.2020**

- Sites located in UK performing activities of batch release, batch control for release and importation will become non-applicable in the EU/EEA marketing authorisation (MA) and should be removed from the MAH's internal Quality systems after 31.12.2020.

- The removal of these sites/activities from the MA dossier of affected CAPs should submitted as a Type IA (A.7 scope) within 2 months.

- Within one single A.7 scope, MAHs can remove multiple sites/activities for one CAP.

Changes to MAs after 1.1.2021 (II)

- **All CAPs** will require the **replacement of the local representative for the UK by** a local representative for **Northern Ireland (NI)** (i.e. a representative for UK (NI)). Such representative has to be located in the EU/EEA or NI.

  - The MAH should **update the PI within 12 months** from 31 December 2020 **in any upcoming regulatory procedure that affects the Annexes of the MA**, as a change to align with the revised QRD PI template to be published in December 2020.
  - For human CAPs that will have no regulatory procedure affecting the MA annexes by end of 2021, the marketing authorisation holder should submit a dedicated notification under Article 61(3) of Directive 2001/83/EC at the end of 2021.
  - To update the local representatives, **Art 61(3) should ONLY be submitted towards the end of 2021**.

Impact of Brexit on EMA Parallel Distribution notices

- Parallel trade of medicines sourced in the UK (Great Britain) is in practice no longer possible as of the end of the transition period.

  After 31.12.2020, the rules for exhaustion of trade mark rights in the EU no longer apply in respect of products placed on the UK market. Moreover, the terms of the marketing authorisation will over time differ.

- The EU Pharmaceutical Law applies in UK (Northern Ireland) after 31.12.2020. Parallel distribution notices with the UK as destination/source country will remain valid only with respect to the territory of NI.

  However, the distributors should also note the restrictions based on the intellectual property laws, which also need to be considered. For further guidance please refer to EC notice to stakeholders on exhaustion of intellectual property rights.

Brexit impact on EMA Notices for Parallel Distribution (PD)

PD Notices issued to a PD located in UK(GB) will become invalid after 31.12.2020 and removed from the EMA PD register.

PD notices with:	Validity after 31.12.2020	Actions for Parallel Distributor
Parallel distributor located in UK (NI)	Yes	None. PD EMA register will be updated after 31.12.2020
Parallel distributor located in UK (GB)	No	None. PD notices will be removed from EMA register after 31.12.2020 unless the PD has submitted a bulk change to report a change to a UK(NI) address
Site(s) for repackaging located in UK (NI)	Yes	None
ONLY site(s) for repackaging located in UK (GB)	Yes*	*Replacement of the repackaging site by a site located in EU/EEA or UK(NI) should be implemented by 31.12.20 and reported in due time (e.g. at the time of Annual Update). PD notifications will be removed from EMA register when confirmed that no replacement site has been added and at latest by end of 2021.
Multiple site(s) for repackaging located in UK (GB) + at least one EU/EEA MS or UK (NI)	Yes	The site(s) located in UK(GB) should be removed from the PD notification at next Annual Update

Brexit impact on EMA Notices for Parallel Distribution (PD)

- The update of the product information/package leaflets of CAPs to replace the UK local representatives by the UK/NI local representative located in an EU/EEA MS or NI will happen with the earliest procedure affecting Annexes finalised throughout 2021.

- The update of the annexes will be published on the EPAR for the product, and on the EC website if the procedure triggers immediate EC decision.

- Parallel distributors should continue to monitor the updates of the EPARs / EC website to identify the updated Annexes and to ensure the latest version of the Package leaflet is used.

Conclusions

- **All human centrally authorised products have confirmed compliance with legal requirements** to place the medicinal product in the EU/EEA market after 31.12.2020.

- **Only 3 (2 not marketed) veterinary centrally authorised products have confirmed non-compliance** with legal requirements to place the medicinal product in the EU/EEA market after 31.12.2020.

- **High level of preparedness** of human and veterinary CAPs for Brexit. Only a limited number of CAPs (>25) still require implementation of manufacturing changes or QPPV and confirmed implementation by 31.12.20. EMA recommends MAHs to submit the IA variations early Dec 20, if possible.

- **Variations for removal of UK sites/activities to be submitted by 28.02.2021**. Replacement of UK by UK(NI) local representative located in EEA or NI should be done during 2021 in the first regulatory procedure affecting Annexes. Art 61.3 procedure ONLY to be considered if no Annexes have been amended by the end of 2021.

- **Parallel Distribution Notifications** with UK as destiny/source remain valid with regards to the territory of NI. PDs should note the restrictions based on the intellectual property laws. Parallel Distribution Notices where the parallel distributor or the only repackaging site is located in UK(GB) become invalid after 31.12.2020.

Any questions?

Further information

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