10 December 2020
EMA/654054/2020
Public and Stakeholders Engagement Department

Report of Industry Stakeholders webinar on the UK withdrawal from the European Union – End of Transition period

30 November 2020, 14:00 -16:00

Disclaimer

These minutes reflect the situation as laid down in legal provisions in force on the date of their drafting, and is 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 that are historically dependent on medicines supply from or through Great Britain, notably Northern Ireland.

Welcome and introduction

- The Co-Chairs, Agnes Mathieu-Mendes from the European Commission and Marie-Helene Pinheiro from EMA, welcomed the participants to this virtual meeting to discuss the United Kingdom's withdrawal from the European Union ("Brexit") end of transition period and to provide updates on the practical implementation of the Ireland and Northern Ireland Protocol. This meeting was also attended by Member states representatives from CMDh, CMDv and HMA.
- This meeting is part of the continuous stakeholder dialogue established with industry since 2017 when the United Kingdom notified its intention to withdraw from the Union, to prepare for an orderly withdrawal of the UK in the pharmaceutical sector and optimise dialogue and exchanges with impacted stakeholders. The ultimate objective is to avoid any human and veterinary medicines' shortages and supply disruptions in Europe.
- Ms Agnes Mathieu-Mendes opened the meeting and recalled the following points:
  - Since the United Kingdom notified the Union of its intention to withdrew from the Union on 31st March 2017, the United Kingdom has left the European Union as of the 1st February 2020. The Withdrawal Agreement (OJ L 29, 31.1.2020) between the UK and the Union provides for a transition period, which lasts until the 31st December 2020 and includes also provisions and rules applicable to and in the United Kingdom in respect of Northern Ireland and also after the

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transition period as part of the Ireland and Northern Ireland (IE/NI) Protocol. Publication of guidance explaining the implications of the Withdrawal Agreement including IE/NI protocol in the area of medicinal products was included in the European Commission and EMA Notice published on 13th March 2020, Parts B and C in particular.

- Industry was informed during the meeting that as discussions on the EU-UK future relationship were ongoing, it could not be confirmed whether these would be completed in time for additional arrangements to be in place from 1 January 2021. It was clarified, however, that any potential relationship would in any case be very different from those with EU/EEA countries and also different from Canada, US and Japan under established specific MRAs.
- In relation to the end of the transition period and implementation of the IE/NI protocol, any additional measures to support supplying small markets, in particular Northern Ireland, are still being considered and will be communicated, if and when agreed, to all stakeholders.
- It was acknowledged that a lot of preparedness activities have been undertaken since March 2017 by Industry to prepare for the end of the transition period. However, there are still some remaining regulatory changes to be made by certain companies to avoid potential medicine shortages in the EU/EEA. It was emphasised that it is **therefore important for Industry to finalise the implementation of their preparedness plans before the end of the year as it is part of industry's responsibilities to ensure continuous supply of medicines for patients.**

Operational preparedness for Brexit and practical implications of the implementation of Protocol on Ireland/ Northern Ireland

- Alberto Ganan Gimenez updated the audience on EMA's preparedness activities, the status of implementation of Brexit related changes to Marketing Authorisations of centrally authorised medicinal products in preparation for the end of transition period and also the impact on parallel distribution notices.
- In term of operational preparedness, the Agency is continuing to closely monitor Brexit-affected centrally authorised medicinal products, completing its preparation of IT databases' and systems' changes, updating regulatory guidance and adjusting EMA internal processes in view of the end of transition period and implementation of the IE/NI Protocol by the end of 2020.
- All MAHs for centrally authorised medicinal products have confirmed that they will be compliant with EU legal requirements to place their medicinal product on the EU/EEA market by 31st December 2020, while for a very small number of centrally authorised medicinal products for veterinary use this is not yet confirmed.
- Further to the very high level of preparedness, only a few CAPs (23 Human and Vet CAPs) still need to transfer manufacturing activities and/or need to change QPPV/PSMF by the end of 2020.
- A large number of CAPs still need **to remove UK(GB) sites/activities from MA dossier by submitting Type IA (A.7 scope) variation** by **28 February 2021** It was stressed that **replacement of UK by UK(NI) local representatives** located in EEA or Northern Ireland should be done in the MA Annexes **during 2021 in the first regulatory procedure affecting Annexes**. For centrally authorised medicinal products for human use Article 61(3) procedure should **only** be considered if no other amendments to the Annexes will take place by the end of 2021.

- Finally, for Parallel Distribution Notifications with UK as destination/sourcing country, from the perspective of the pharmaceutical law these will remain valid with regards to the territory of Northern Ireland, however, the applicable restrictions based on the intellectual property laws must also be considered. In addition, it was clarified that Parallel Distribution Notices where the parallel distributor or all repackaging site(s) are located in Great Britain will become invalid after 31st December 2020.
  See further details in presentation (see link).

- Zigmars Sebris, gave a presentation on the practical aspects of the implementation of the IE/NI protocol of the Withdrawal Agreement with respect to EMA operations and centrally authorised medicinal products. The audience was informed of the consequential changes to Article 57 database, fee calculation, Eudravigilance, other IT tools and systems, GMP and manufacturing, orphan incentives and SME status, marketing status reporting and dossier submission. Detailed additional practical guidance as "Questions and answers to stakeholders on the implementation of the Protocol on Ireland / Northern Ireland" is also published by EMA in the following link.

- Guidance was given for **UK nationally authorised medicinal products** included in **Art. 57 database** and the need for **authorisation country** to be updated to "United Kingdom (Northern Ireland)" with a code "XI", where applicable. It was highlighted that affected MAHs, can **start changing the country code** from **15th December 2020** and be completed preferably by **31st December 2020** but no later than 31st January 2021. See further details in the EMA Q&As on IE/NI Protocol referred above.
  Clarifications on the MAH, QPPV and PSMF location in EU/EEA and NI were also given together with the consequential fee impact calculation.

- In terms of changes to reporting of ICSRs into Eudravigilance, distinction in the post-marketing ICSR reporting occurring in Northern Ireland and the rest of the UK from 1st January 2021 was highlighted; the latter following requirements for 3rd country cases reporting in all situations (for post-marking cases and clinical trials cases), whereas for Northern Ireland cases, post-marketing cases would follow EU reporting requirements and clinical trials ADRs reporting, 3rd country requirements.

- Information on eApplication form, PSURs and OMS changes was also given. See presentation and EMA Q&As on IE/NI Protocol for further details.

- In respect of GMP and manufacturing in NI for centrally authorised medicinal products, clarifications were given on the acceptance or not of finished product importation, batch control testing, batch certification, OMCL (for OCABR/OPBR) site locations in NI and the rest of the UK after 1st January 2021.

- Orphan designation sponsors and SMEs were informed of the possibility to benefit from the EU incentives if established in NI but were reminded of the need for respectively transfer their designation to EU/EEA and obtain the SME status for an EU/EEA entity before submitting the marketing authorisation application to maintain such benefits.

  Finally, it was clarified that Union marketing authorisations continue to be valid in the territory of Northern Ireland after 31st December 2020 and it was highlighted that in this context from 1st January 2021 the dossier for regulatory procedures concerning centrally authorised medicinal products is to be provided by MAHs also to the UK authorities.
  See further details in presentation (see link).

Industry update on Brexit preparedness activities

- Craig Johnson provided a joint update on Industry "Brexit" preparedness on behalf of EFPIA/Vaccines Europe/EuropaBio, Medicines for Europe, AESGP, Eucope and Europharm SMC.
- He highlighted the need to avoid as a priority any disruption to the supply of medicines and medical devices to patients, consumers and citizens and called for a comprehensive trade agreement between the EU and the UK to be established starting from a joint EU-UK phased implementation process of the Ireland and Northern Ireland Protocol.
- Industry mentioned the preference for a medicines specific EU-UK Mutual Recognition Agreement (MRA) on GMP, inspections, conformity assessment to cover medical devices, batch and import testing by manufacturers and OMCLs to:
  - ensure continuity of supply of medicines, including in Northern Ireland,
  - minimise negative economic consequences of Brexit i.e. competitiveness of both the EU and the UK vis a vis US, Japan and China.
  - continue the EU's best practice and strengthening existing regulatory cooperation and simplifications of procedures via ICMRA, PIC/S and ICH for instance.

  See further details in presentation (see link).

Questions & Answers session

- Further to the receipt of questions from across the 21 Industry EU Trade Associations and organisations for human medicines and veterinary medicines invited, the topics discussed included:
  - EMA-CMDh/v and MHRA-VMD interactions, UK members participation, roles (Rapporteurs/RMS and CMS) in the context of NI discussions,
  - MRAs, extension of transition period and phased approached of IE/NI protocol implementation,
  - Regulatory requirements related to MAHs, Local representatives and QPPV locations, validity of the centralised procedure marketing authorisations in NI, variations, on-going referrals, product information and Blue box requirements, sunset clause, PASS, PSURs,
  - Access, changes and reporting to EMA databases (Art. 57, EudraVigilance, EudraCT),
  - Manufacturing and supply,
  - Clinical trials.

The questions received on parallel distribution were not answered verbally but considered addressed in the first EMA presentation (see slides 8-9 of the presentation)

- Clarifications were provided by EMA, the European Commission and CMDh/v Chairs where applicable.
- In particular it was reminded that in relation to the UK participation to EMA Committees that since 1st February 2020, when the UK left the European Union, UK authorities do not participate anymore in the EU decision making or decision shaping and this also applies to EMA committee meetings under any role (e.g. observer or otherwise).
- In respect of negotiations on future relationship between EU and UK, it was clarified that for the EU this is exclusively conducted by the EC and there are no negotiations on this at the EMA level. As stated at the beginning of the meeting, in relation to the end of transition period and

implementation of the Ireland and Northern Ireland protocol, any additional measures to support supplying small markets, in particular Northern Ireland, are still being considered and will be communicated, if and when agreed, to all stakeholders.

- Industry highlighted the need for timely clarifications on the UK participation in CMDh/v meetings and MRP/DCP procedures, the local representative location for UK nationally authorised products with respect to Northern Ireland and voiced concerns with the tight timelines for Art. 57 database updates.
- It was reminded that the European Commission, EMA, national competent authorities along with the MAH have a collective responsibility to ensure preparedness of the system so that the expectations and needs of patients can be met. Industry's responsibilities for continuous supply of medicines were flagged.
- Industry was advised to consult the following European Commission and EMA Notice to Stakeholders on the withdrawal of the UK and EU Rules for human and veterinary medicinal products, published on 13th March 2020 and the EMA "Questions and answers to stakeholders on the implementation of the Protocol on Ireland / Northern Ireland" published on EMA webpage containing Brexit-related guidance, where most of the "procedural, technical and practical" answers provided at the meeting can be found.

Close of meeting: next steps

- Agnes Mathieu-Mendes closed the meeting by thanking all attendees for their participation and for the fruitful feedback and exchange and Marie-Helene Pinheiro informed the audience that a short report of the meeting will be published shortly, together with EMA's presentations.

List of Participants

European Commission

Name	Role
Agnes Mathieu-Mendes	Directorate-General for Health and Food Safety, Unit B4 Health systems, medical products and innovation - Deputy Head of Unit
Marilena-Silvia Lungu	Directorate-General for Health and Food Safety, Unit B4 Health systems, medical products and innovation
Agnieszka-Maria Kasperek	Directorate-General for Health and Food Safety, Unit E5, Food and feed safety, innovation, Animal nutrition, veterinary medicines
Fabrizio Sacchetti	Economic Affairs I Task Force for Relations with the United Kingdom European Commission

EU Network

Name	Role
Thomas Heberer (BVL, Germany)	HMA Brexit TF Co-Chair
Michiel Hendrix	HMA Brexit TF
Daniel Freudl	HMA Brexit TF
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Christin Oloffson	CMDh SE member
Nicole Kavanagh	CMDh IE member
Helen Vella	CMDh MT member
Emilia Mavrokordatou	CMDh CY member
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Paula Kajaste	CMDv vice-chair, FI
Rhona McHugh	CMDv IE member
Juliane Schäffer	CMDv DE-BVL member

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Name	Role
Marie-Helene Pinheiro	Industry Stakeholder Liaison
Veronika Baker	Master Data Manager
Caroline Blanc	Procedure Manager – Procedures Department
Fabrizio Boccacci	Legal Department
Christelle Bouygues	Head of Regulatory Affairs Office
Ivo Claassen	Head of Veterinary Division
Brendan Cuddy	Clinical Studies and Manufacturing Task Force
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