EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

SUMMARY RECORD
TECHNICAL EXPERT SEMINAR ON PHARMACEUTICALS RELATED MATTERS, FOLLOWING UK WITHDRAWAL, 8TH MARCH 2018

On 29 March 2017, the United Kingdom (UK) notified the European Council of its intention to leave the European Union. Unless a ratified withdrawal agreement establishes another date or the European Council unanimously decides that the Treaties cease to apply at a later date, all Union law will cease to apply to the United Kingdom from 30 March 2019 ('the withdrawal date'). The UK will then become a third country.

BREXIT preparedness is a key objective to ensuring business continuity and to safeguard continuous supply of medicines to patients after the withdrawal date. Preparing for the consequences of Brexit is therefore a matter for all actors concerned, from EU and national authorities to private parties, individual companies and trade associations.

The European Commission DG SANTE convened a technical expert seminar on pharmaceuticals related matters in order to discuss matters related to preparedness of the UK withdrawal.

The seminar gathered some 80 experts from EU27/ EEA Member States. This seminar complements a series of technical meetings and activities within the European medicines regulatory network (composed of the national competent authorities-NCAs, the European Medicines Agency-EMA and the European Commission-EC) taking place since March 2017 with the aim to ensure regulatory preparedness and business continuity.

The aim of this meeting was to:

1. Inform experts about the overall state of play
2. Inform experts about preparedness measures taken so far by the Network
3. Collect experts' perspectives on preparedness
4. Discuss and identify gaps in preparedness and actions to be taken before the withdrawal date

Representatives of the Commission TF50 and the Brexit Preparedness Group within the Secretariat-General provided information on the draft withdrawal agreement published by the Commission on 28 February 2018. Given all uncertainties on the outcome of the negotiations, and the time for concluding and ratifying a withdrawal agreement, all actors concerned need to get prepared timely, bearing in mind that the UK will no longer be an EU Member State on 30 March 2019.

DG SANTE provided some information on the key requirements of the EU legislation applicable to pharmaceutical products and actions that companies need to take with regard to their marketing authorisations. Representatives of NCAs, and the EMA

presented the measures put in place respectively for Nationally Authorised Products (NAPs) and Centrally Authorised Products (CAPs).

The main conclusions of the meeting can be summarised as follows:

1. Since March 2017, the Network has been performing well in terms of raising awareness internally and with industry. Overall the network has considered carefully how to redistribute the work currently carried out by the UK's both for NAPs and CAPs for human and veterinary medicines.

2. Despite the awareness activities and targeted communication measures (information notices on legal issues, procedural guidance to Marketing Authorisation Holders, meeting with trade associations both at HMA/ EMA and EC levels [1] [2] [3]), many Marketing Authorisation Holders have not yet taken the necessary regulatory actions, e.g. marketing authorisations transfers, relocation of QPPV etc. While recognising the complexity of some of these procedures for companies to put in motion, there seems to be also a "wait and see" approach by the MAHs. Communication with companies needs therefore to be continued and enhanced reminding them of their responsibility to act swiftly, considering as baseline for preparedness the withdrawal date of 30 March 2019, in order to avoid disruption in the supply of medicines.

3. For CAPs, the EMA is undertaking an analysis, including a survey to pharmaceutical companies, to identify centrally authorised products particularly affected by the regulatory consequences of the withdrawal of the UK. EMA and the Commission will communicate with MAHs. The EU 27 Member States and EMA have also developed a methodology for the redistribution of the work currently carried out by the UK, related to the evaluation and monitoring of medicines.

4. For NAPs, the situation is more complex, given the volume of procedures and the complexity inherent to the MRP/ DCP system. Additional and possibly more targeted communication by HMA/CMDh/v with MHAs is already under way. Therefore and to compile all necessary information for decision-making, the HMA has formed an own BREXIT Task Force which became operational at the HMA II meeting in Tallinn in November 2017. HMA/CMDh/v are also working on solutions for the redistribution of the work to new reference Member States, taking into account capacity considerations and the response of industry to take the necessary actions as regards their marketing authorisations. Companies need to act timely given the regulatory consequences of the UK withdrawal.

5. In terms of capacity building for handling CAPs and NAPs procedures, some national agencies have already started investing in extra resources to absorb the UK work load: change of reference Member State, rapporteurships, inspections etc. Member States are reflecting on best ways to support this investment timely, considering that some activities will be eventually fee-financed. The commitment of Member States to this end is valuable and essential.

[1] https://ec.europa.eu/health/sites/health/files/files/documents/qa_on_brexit.pdf

[2] http://www.hma.eu/535.html

[3] http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/11/WC500239369.pdf

6. Laboratory capacity and specific needs of some Member States that rely on UK marketing authorisations, including the use of Article 126a of Directive 2001/83, need further investigating.

Conclusion

The seminar was useful in informing Member States about the state of play and mapping the progress made so far. The discussions highlighted the need to further encourage preparedness activities within companies and competent authorities. Marketing Authorisation Holders need to act swiftly, considering as baseline for preparedness the withdrawal date of 30 March 2019 in order to ensure business continuity and uninterrupted supply of medicines to patients. National competent authorities need to continue their preparedness activities to take up the work currently carried out by the UK. The Commission remains available to support Member States in their communication with MAHs and other preparedness plans, as necessary.

Another technical seminar may be convened in Q2 2018.

Glossary of abbreviations

CAP:	Centrally Authorised Products
CMDhv:	Co-ordination group for Mutual recognition and Decentralised procedures (Human and Veterinary)
DCP:	Decentralised Procedure
EC:	European Commission
EMA:	European Medicines Agency
HMA:	Heads of Medicines Agencies
MAH:	Marketing Authorisation Holder
MRP:	Mutual Recognition Procedure
NAP:	Nationally Authorised Products
NCA:	National Competent Authorities
QPPV:	Qualified Person for Pharmacovigilance
TF50:	European Commission Task Force Article 50