



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CMDh Brexit update

Laura Oliveira / Hugo Hurts
November 2018



Brexit preparedness: Impact on National workload

Planned increased involvement in MRP/DCP per MS (capability of MS to take on both new and old procedures) HMA/EMA Survey

PSUSA lead MS re-allocation due to Brexit completed in October 2018– 85 procedures

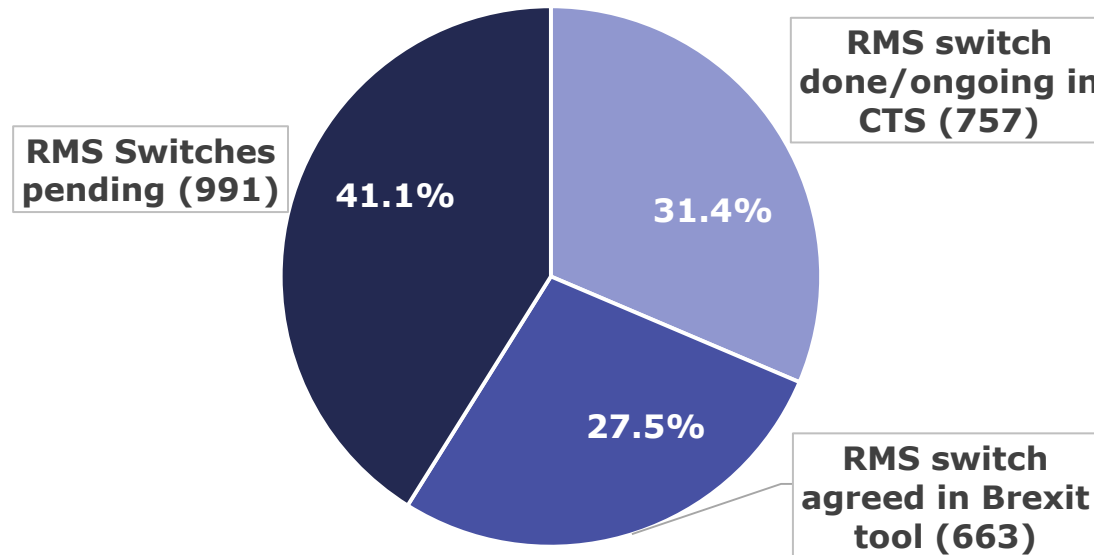
UK procedures having only one CMS - 29,1%. Automatic RMS switch- New RMS have to provide the new number of EU procedure proactively.

2411 procedures =4267 products to be redistributed within EU27

Approximately 60% UK procedures have a new RMS or the agreement of a CMS to become the new RMS

For still 40% of these procedures not yet known who will be the new RMS.

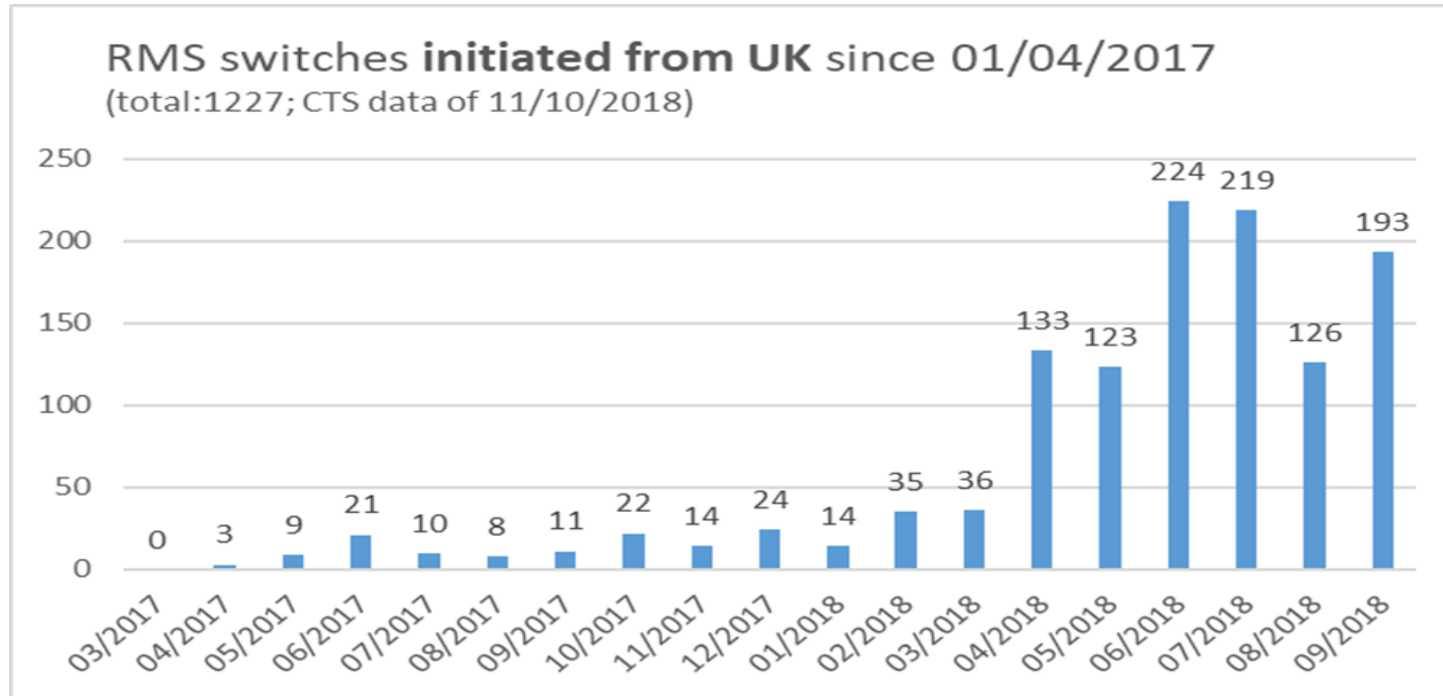
UK Procedures to be redistributed within the EU27 (TOTAL: 2411)



CMDh Preparedness: RMS Switches – Case Studies

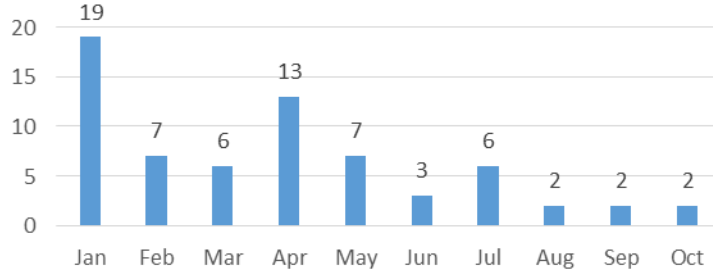
- **CASE 1:** MAH has approached all the CMSs and all have declined to become the RMS
***CMDh Position:** MAH has to contact CMDh. CMDh commits to provide RMS in case all CMS refuse to become the new RMS (methodology already in place)*
- **CASE 2:** MAH has not initiated any contact with CMS to find a new RMS before the Brexit date. Validity of the authorizations in question
***CMDh position:** The MA remain valid but no regulatory action can be started until a new RMS is identified. No proactive action is expected from CMDh in this case*

Tracking on Brexit related RMS changes (online tool)



Monitoring of ongoing procedures

Number of UK RMS DCP started 2018,
procedures
(status: 11/10/2018)



CMDh press release October 2018

Applicants of procedures with UK as RMS that are currently in clock stop are reminder to submit responses asap to allow the finalization of the procedure before March 2019



17 October 2018
EMA/CMDh/708655/2018

Report from the CMDh meeting held on 15-17 October 2018

Brexit preparedness

In preparation for the possibility of no agreement in the Brexit negotiations between UK and EU, the CMDh reminds applicants that on-going MAA procedures with UK as RMS should be closed by 29th March 2019 (i.e. agreement of the concerned Member States in accordance with Article 28(4) or Article 29(3) or decision of the Commission in accordance with Article 34(1) of Directive 2001/83/EC). If the procedure is not completed by 29th March 2019, the procedure will be stopped and the applicant will need to submit a new application to a new Reference Member State (see Q&A No. 1b of the [Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to national authorised medicinal products for human use](#)). Applicants of procedures with UK as RMS that are currently in clock-stop are reminded to submit their responses to the outstanding issues as soon as possible to allow sufficient time for a restart and finalisation of the procedure before 30th March 2019.

PSUSA Lead Member State re-allocation due to Brexit

With a view to the United Kingdom's withdrawal from the European Union, the CMDh has conducted an exercise to re-allocate PSUSAs that previously had the UK as Lead Member State to new Lead Member States within the EU-27 (including IS and NO). The newly appointed Lead Member States will be reflected in the next update of the EURD list.

Availability issues related to the BREXIT

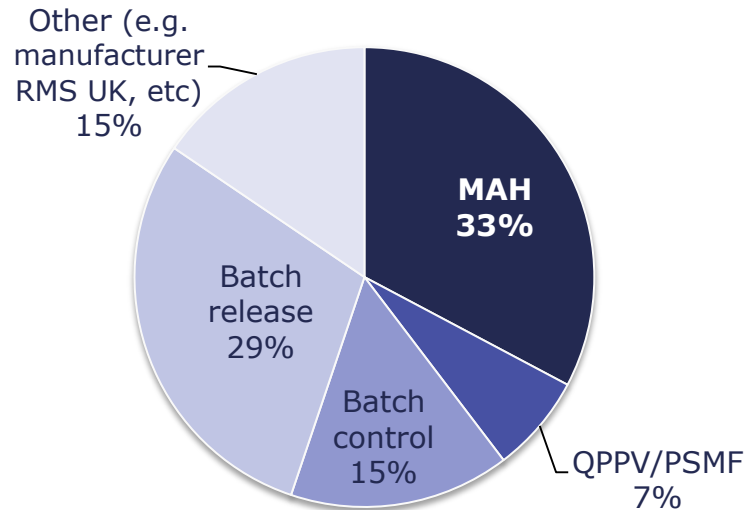
The CMDh agreed not to prepare a common list of essential products in April 2018 due to difficulties in carrying out a common criticality assessment.

However, this analysis has been carried out nationally by many MSs according to the results of the **CMDh survey on availability issues related to Brexit- Nov 2018 (21/27 responses)**

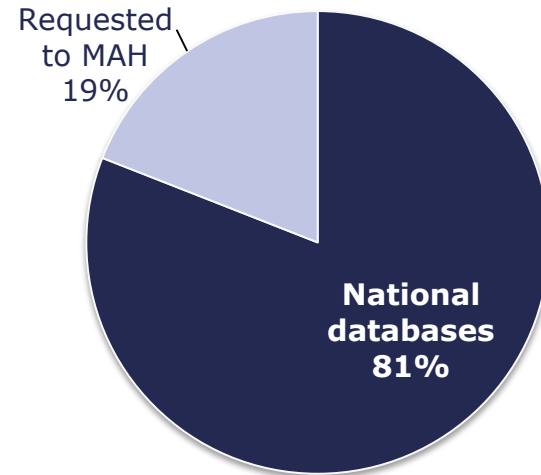
95% of the responders identified medicinal products with authorized entities located in the UK or conducted any other analysis to identify medicines that could be at potential risk of shortage due to Brexit

CMDh survey on availability issues related to Brexit-Nov 2018: Identification of NAPs with entities located in the UK

Entities analysed by MSs to identify UK location

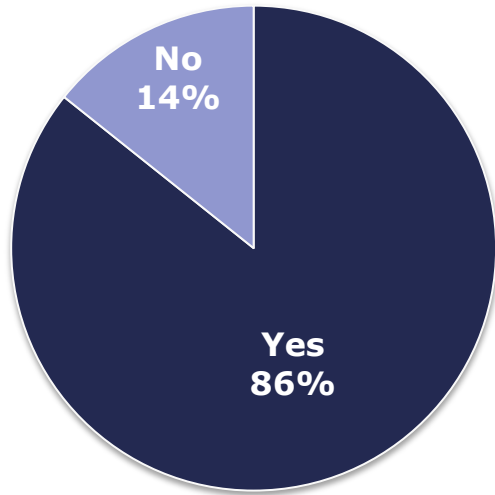


Source of information



CMDh survey on availability issues related to Brexit-Nov 2018: Review for criticality

86% have established any criticality criteria to identify essential/critical products

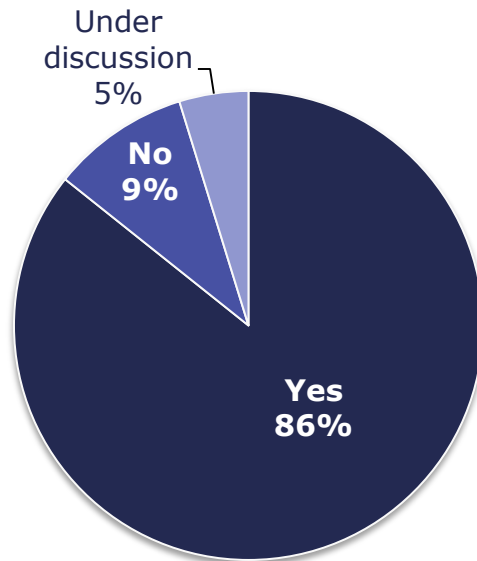


Examples of methodology for establishing criticality (non exhaustive):

- ✓ Availability of adequate therapeutic alternatives.
- ✓ Principles as defined in "Criteria for classification of critical medicinal products for human and veterinary use" (EMA/24304/2016).
- ✓ Seriousness of the illness, chronic diseases, life threatening conditions
- ✓ Specialist societies and the WHO list

CMDh survey on availability issues related to Brexit-Nov 2018: Contact with the affected MAHs

86% of the responders have already made (or intend to make) a contact with the affected MAHs



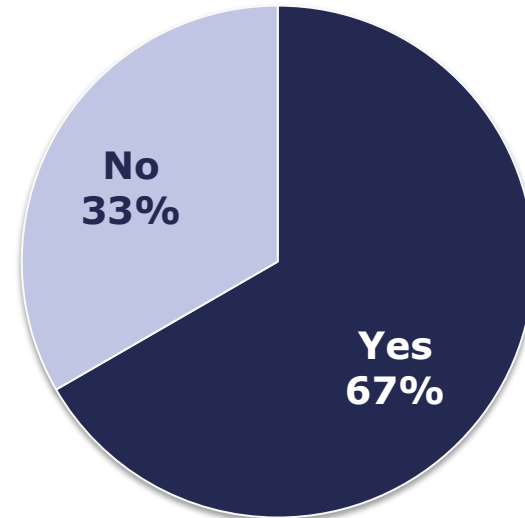
Purpose of the communication (non exhaustive)

- ✓ Availability of adequate therapeutic alternatives.
- ✓ Principles as defined in "Criteria for classification of critical medicinal products for human and veterinary use" (EMA/24304/2016).
- ✓ Seriousness of the illness, chronic diseases, life threatening conditions
- ✓ Specialist societies and the WHO list

CMDh survey on availability issues related to Brexit-Nov 2018: Contact with the affected MAHs

67% of responders have established (or plan to establish) at national level any measure for those products that are essential and that are at risk of shortages

The measures will be shared and commented in the CMDh



Availability Issues due to Brexit: Conclusions

Despite the difficulties in identifying NAPs at potential shortage risk due to Brexit at EU level, most authorities have carried out the identification of the affected national products and are considering measures to minimize the impact.

The CMDh is the discussion forum where information is shared about the products and the measures that should or can be taken.

Oral hearing with Companies are being organized at CMDh to discuss specific Brexit contingency planning

The CMDh is willing to contribute to day 0 MRP/RUPs for those MSs affected by the art 126 MA

The contribution of the MAH is essential to ensure the preparation of the network

Any questions?

Further information

AAMTFSecretariat@ema.europa.eu

See websites for contact details

European Medicines Agency www.ema.europa.eu

Heads of Medicines Agencies www.hma.eu

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