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Operational preparedness for Brexit and re-allocation of UK product portfolio in the centralised procedure

Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human medicinal products

Presented by Monica Dias and Tony Humphreys on 23 March 2018
European Medicines Agency

EMA preparedness following the UK referendum

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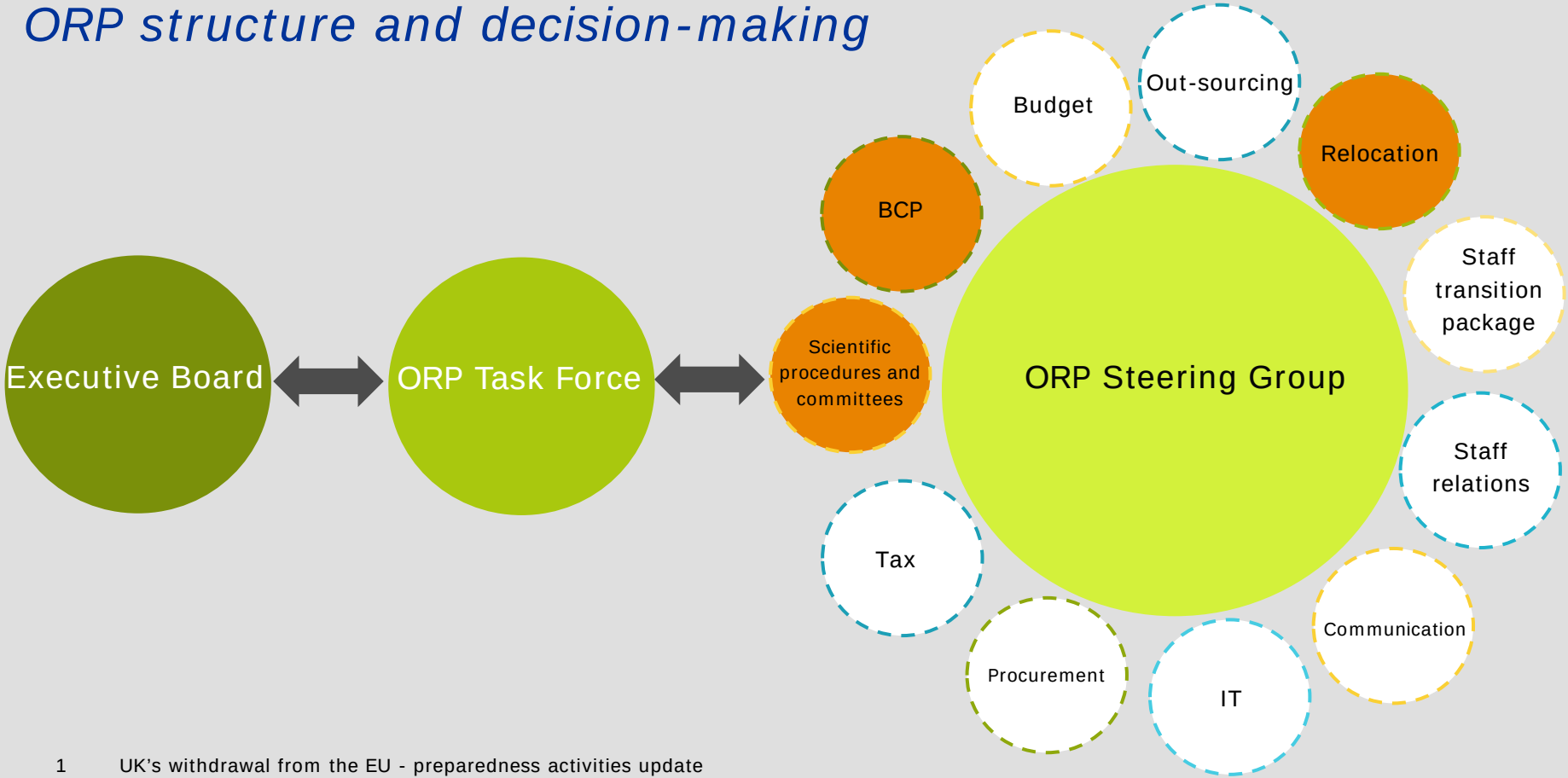
ORP structure and decision-making



Context: EMA and EU Network preparedness

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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 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 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.

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Rev 01, published on 29 January 2018

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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.

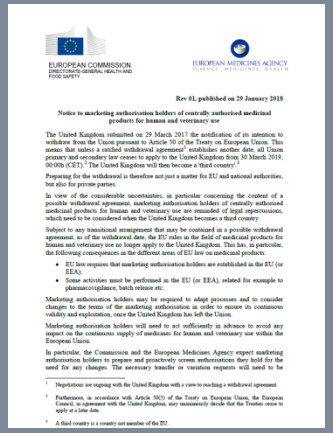
2 Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

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

Context: EMA-Industry Preparedness Activities

EC-EMA Notice publication 2nd May 2017 followed by EMA-EC Notice publication 31st May 2017

EC-EMA Q&A publication 27 November 2017



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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.

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Background

- At the information meeting on 27 April 2017 members of the Management Board and Heads of NCAs discussed the challenges and a way forward in an EU-27 setting.
- As an outcome of the meeting on 27 April, general principles for the redistribution of the workload and a working methodology to implement the general principles were agreed.
- It was also agreed to establish EMA Working Groups on committees' operational preparedness for human and veterinary medicines, which will explore options for a reasonable and robust allocation of the workload related to human and veterinary medicines across the network.

Composition of the working group on human medicines

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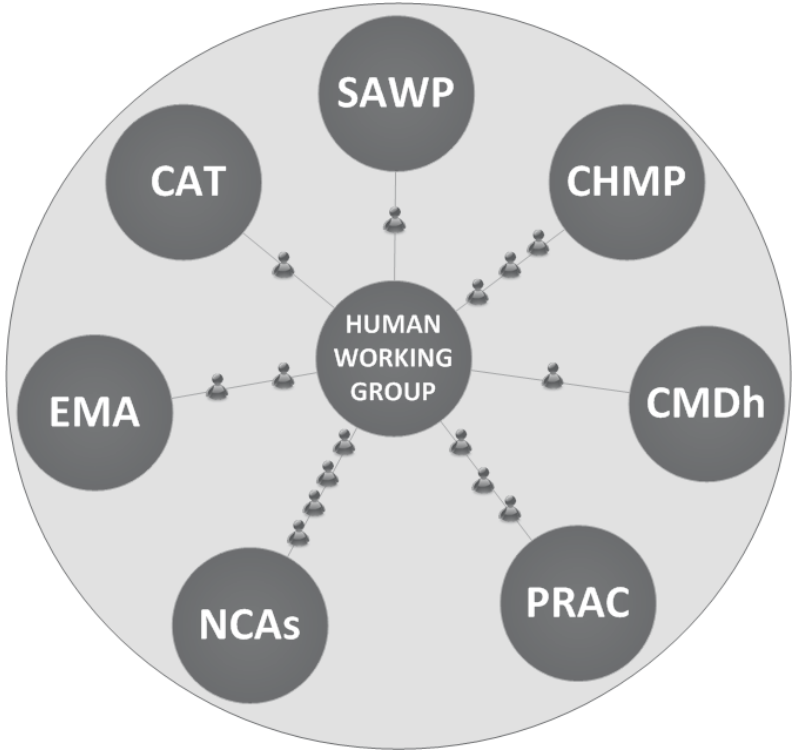
Human Medicines

- 4 members from NCAs (HoA)
- CHMP Chair + 2 CHMP members
- PRAC Vice-Chair + 2 PRAC members
- CAT Chair
- SAWP Vice-Chair
- CMDh Chair
- EMA DED (Chair) + 2 EMA staff members



Objectives of the EMA working group on human medicines

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1. • Redistribution of UK product portfolio
2. • Distribution of workload for initial marketing authorisation applications, including reassignment of procedures not yet started but currently assigned to the UK
3. • Distribution of workload for scientific advices
4. • Distribution of workload for PRAC procedures, for which the contribution of the CMDh is required concerning the national authorised medicinal products
5. • Operational adjustments

General principles: Redistribution of the UK workload

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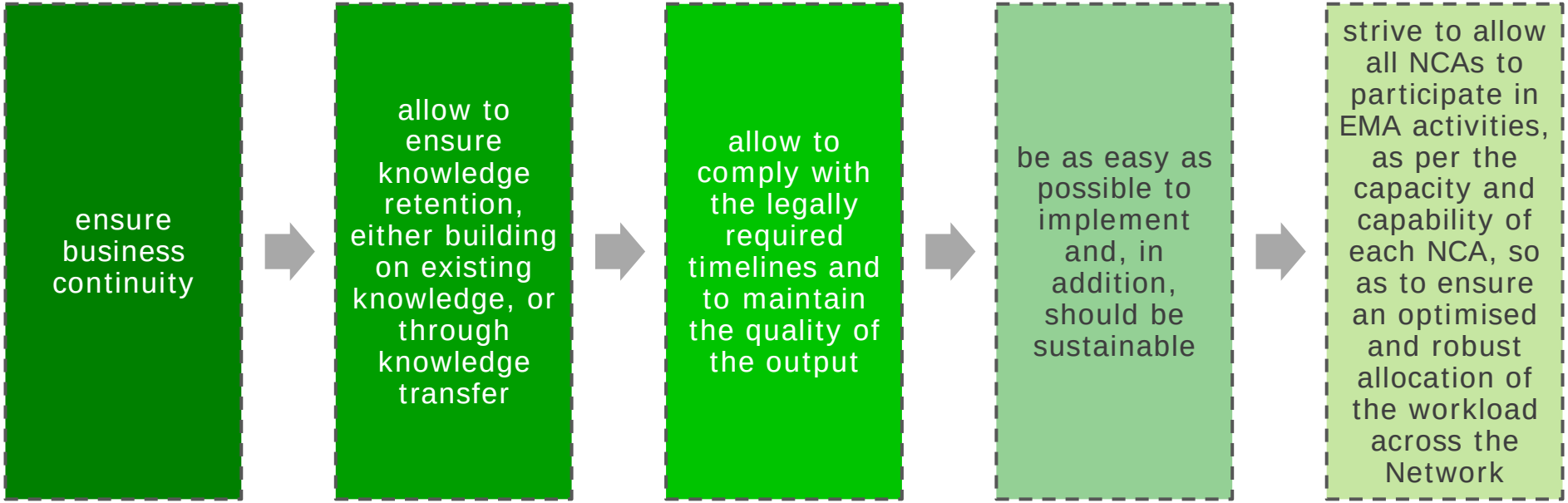
As per the mandate of the EMA Working Groups adopted by the EMA Management Board, the general principles that should guide any redistribution proposal are:



All the proposals for redistribution will take into consideration the outcome of the surveys on capacity building in the Network.

Methodology: Redistribution of the UK portfolio (1/2)

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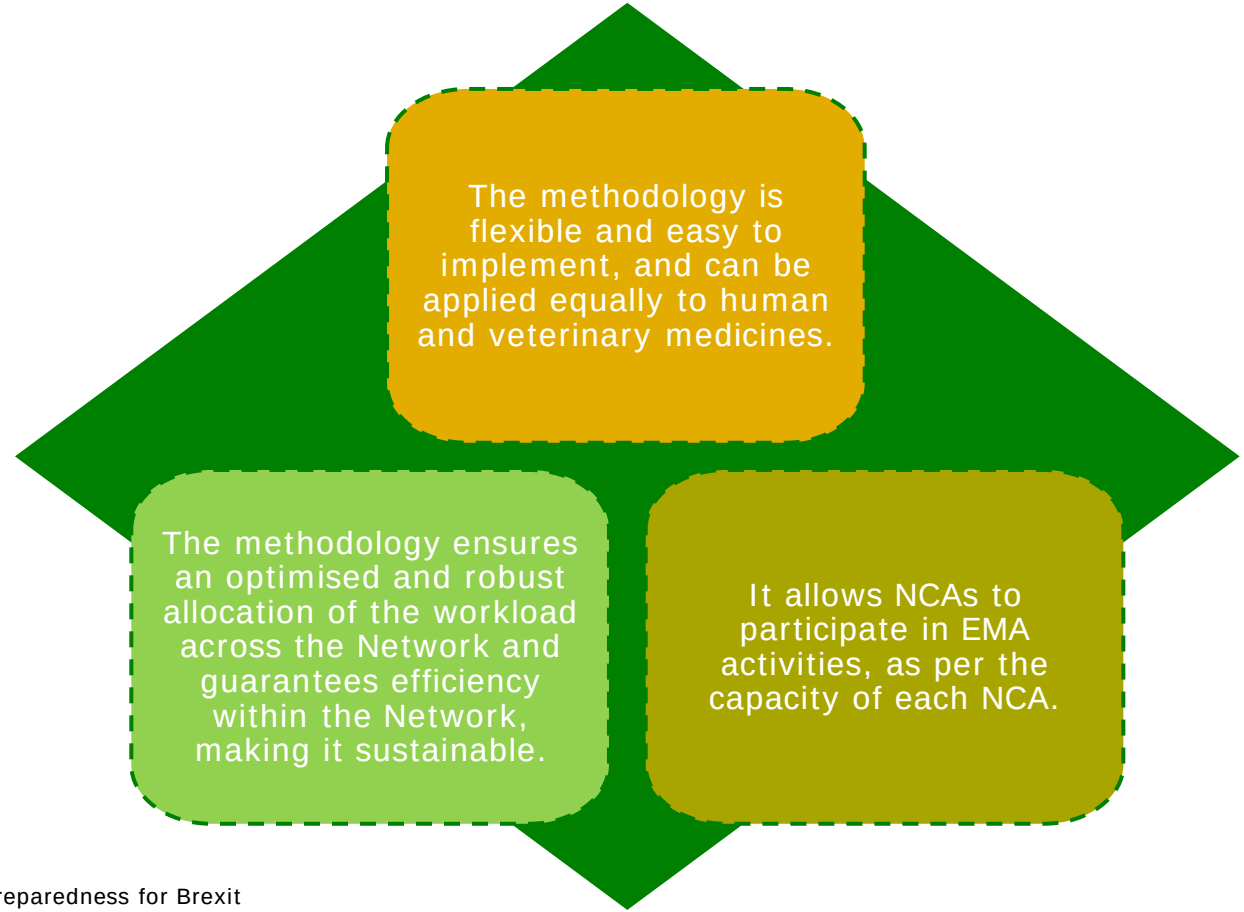
- The redistribution follows a multifaceted approach and takes into account the diverse expertise in the European medicines regulatory network and the workload associated with each medicine
- Building on existing knowledge, medicines are allocated to the current co-rapporteur or to the peer reviewer involved in the initial marketing authorisation application;
- Allocation is also based on current expertise with a class of medicines (ATC code);
- Clusters of products with the same INN and belonging to the same MAH are allocated to a single rapporteur in order to facilitate review of post-authorisation procedures.

Methodology: Redistribution of the UK portfolio (2/2)



Implementation: Redistribution of the UK portfolio

EMA Working Group has developed a methodology for the redistribution of the work currently carried out by the UK,

The methodology was endorsed by the EMA Management Board at its December 2017 meeting,

The **first step** of the implementation started in Q1 2018 and will be finalised in April 2018,

The new (Co)-Rapporteurships will be communicated to the MAHs on 30 April 2018,

To support knowledge transfer, EMA will provide a knowledge transfer package to the new (Co)-Rapporteurs.

Timelines: Redistribution of the UK portfolio

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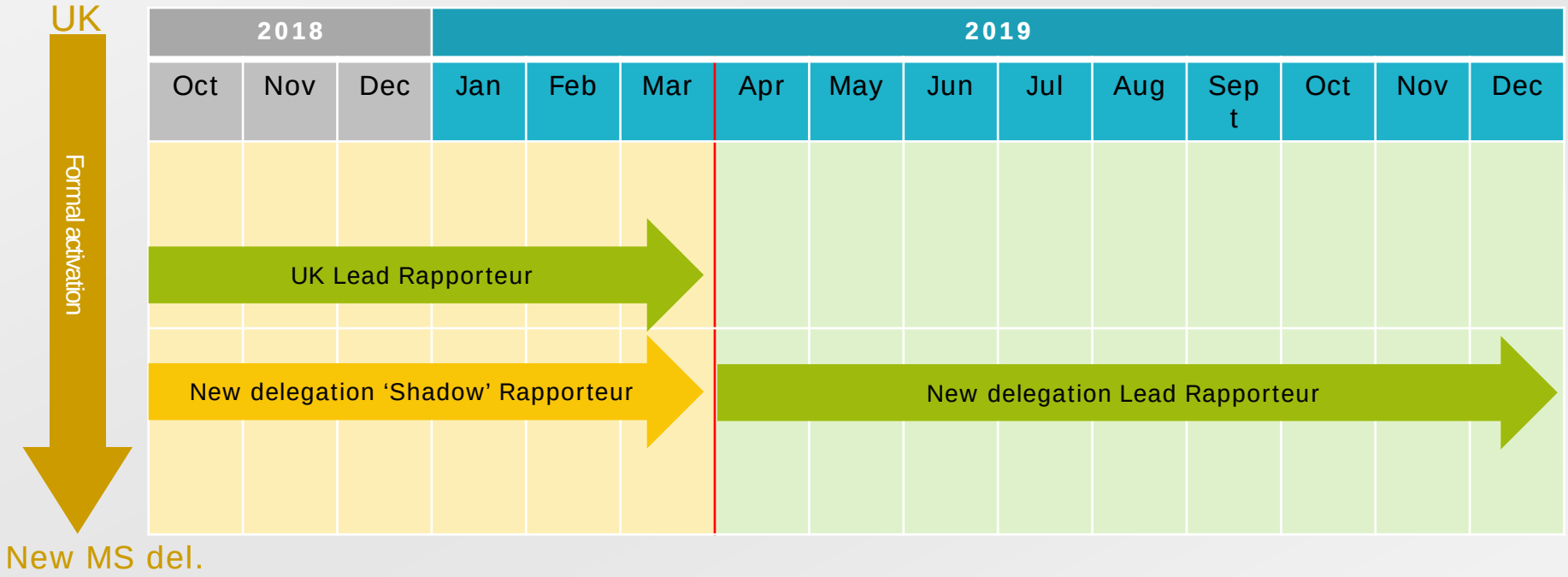
Workload sharing timeline 2018-2019



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Next steps

Publication of Notices to MAHs about establishment issues and other aspects: Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure (27/11/2017 & revised 29/01/2018); 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 (29/01/2018)

Legacy methodology - first step of implementation: 1Q18

Questionnaire to centralised MAH on Industry Brexit Preparedness: 1/2Q18

Survey of EMRN capacities / training needs: 1-2Q18 (Priority on MRP-DCP)

Thank you for your attention

Further information

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