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SCIENCE MEDICINES HEALTH

EMA update on Brexit preparedness activities & EMA working group on committees operational preparedness for veterinary medicines

Update on Brexit regulatory preparedness activities for veterinary companies

Presented by Isaura Duarte & Tony Humphreys on 20 April 2018
European Medicines Agency

EMA preparedness following the UK referendum

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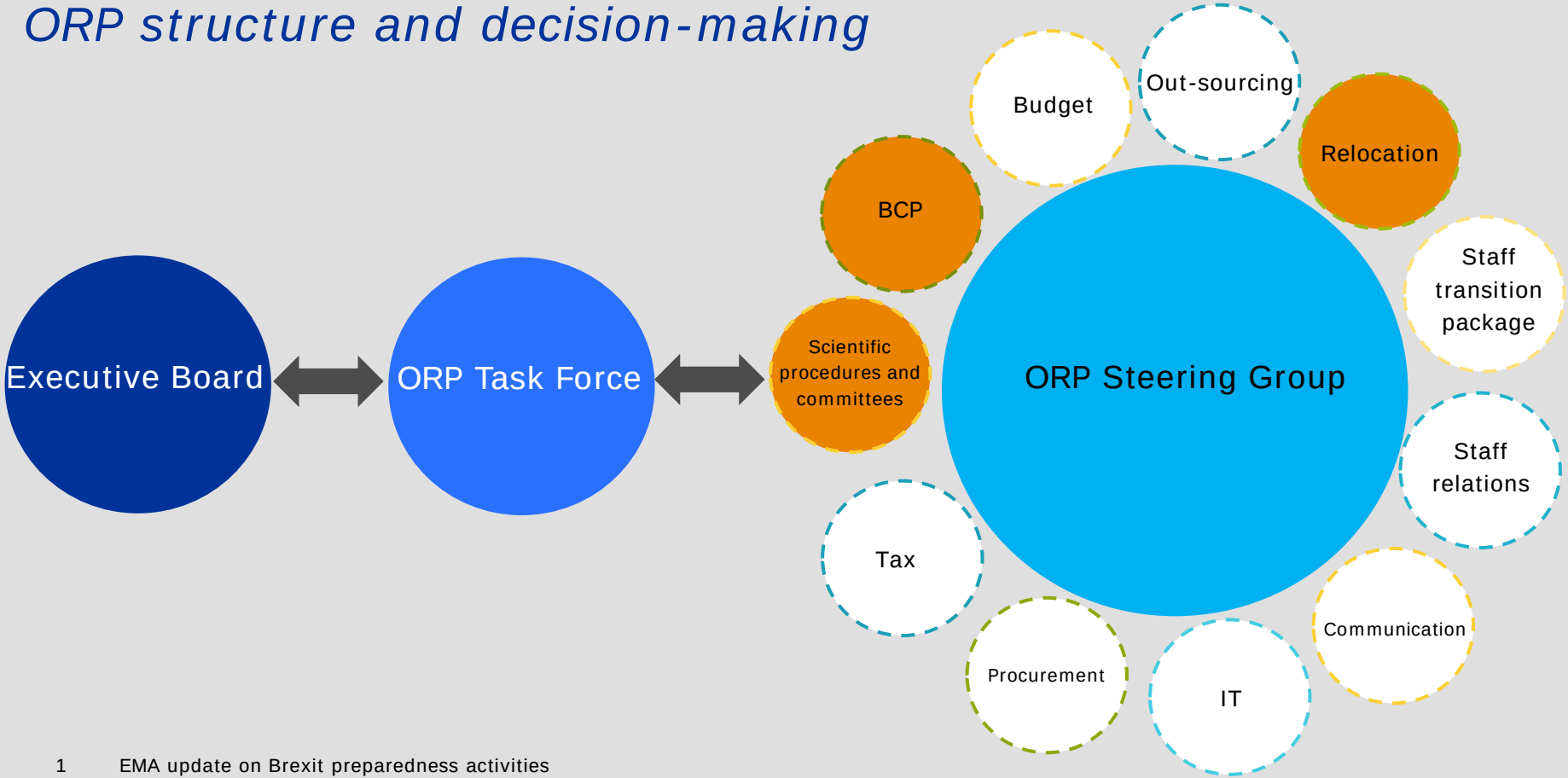
ORP structure and decision-making



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.
- General principles for the redistribution of the workload and a working methodology to implement the general principles were agreed.
- EMA Working Groups on committees' operational preparedness for human and veterinary medicines were established to explore options for a reasonable and robust allocation of the workload related to human and veterinary medicines across the network.
- A survey on the capacity within the EU27 Network system was initiated to assess potential preparedness

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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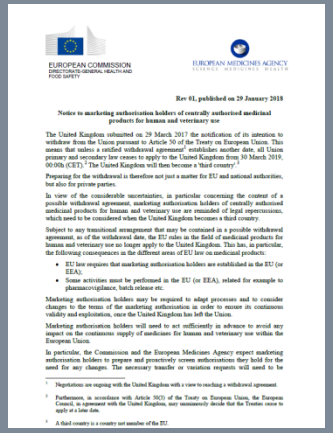
Rev 01, published on 29 January 2018

Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use

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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- 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.

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.


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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 establishes another date, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET). The United Kingdom will then become a 'third country'."*

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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Overview of capacity surveys

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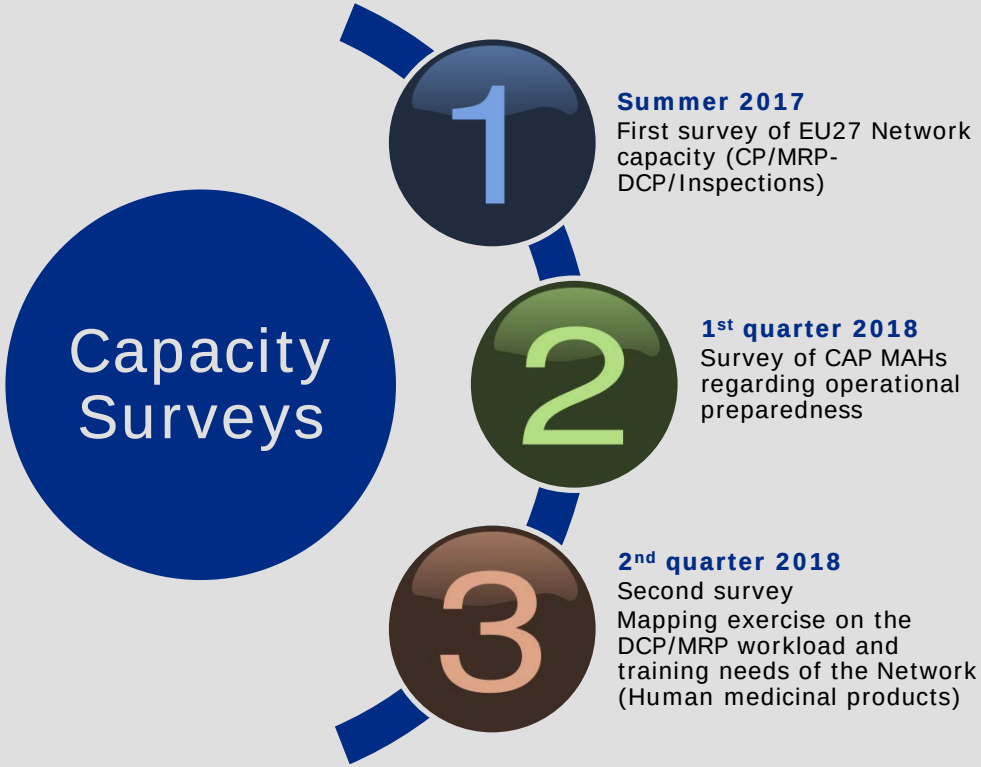

Summer 2017
First survey of EU27 Network capacity (CP/MRP-DCP/Inspections)

1st quarter 2018
Survey of CAP MAHs regarding operational preparedness

2nd quarter 2018
Second survey
Mapping exercise on the DCP/MRP workload and training needs of the Network (Human medicinal products)

Working methodology: Mapping exercise

- To better understand capacity and expertise gaps and to match with NCAs' willingness and possibilities to invest, the following is undertaken:
  - Mapping of capacity and expertise across the Network
  - To achieve this a questionnaire is sent to each individual NCA to obtain feedback (launch is envisaged in June)
  - Subsequent mapping by EMA taking into account feedback received

On 23 January 2018, EMA launched a survey to **gather information from marketing authorisation holders** of centrally authorised medicines who are located in the UK or who have quality control, batch release and/or import manufacturing sites or a QPPV or pharmacovigilance system master file (PSMF) in the UK, on their plans to submit transfers, notifications or variations to their marketing authorisations in preparation for Brexit.

The aim is to:

- identify companies where there is a need for concerted action to address **medicines supply concerns** due to Brexit in order to protect human and animal health;
- help EMA and the Commission **plan resources** in the areas where these submissions will be processed.

The survey also serves to stimulate those companies who have not yet taken any action to **start planning** for any regulatory steps required for their centrally authorised products to remain on the EU market post-Brexit in order to minimise disruption to medicines supply and **avoid shortages**.

Second survey to NCAs on increased workload for DCP/MRP procedures and EU Network's training needs (1/3)

- Joint EMA/HMA survey was launched on 27 March 2018
- The aim of the survey:
  - to help fill in any gaps of information identified from the first survey
  - to identify training needs in the Network in the context of Brexit.
- The main focus of the second survey is on the increased capacity for MRP/DCP and training needs for both centralised and decentralised assessments and inspections.

Working group on veterinary medicines

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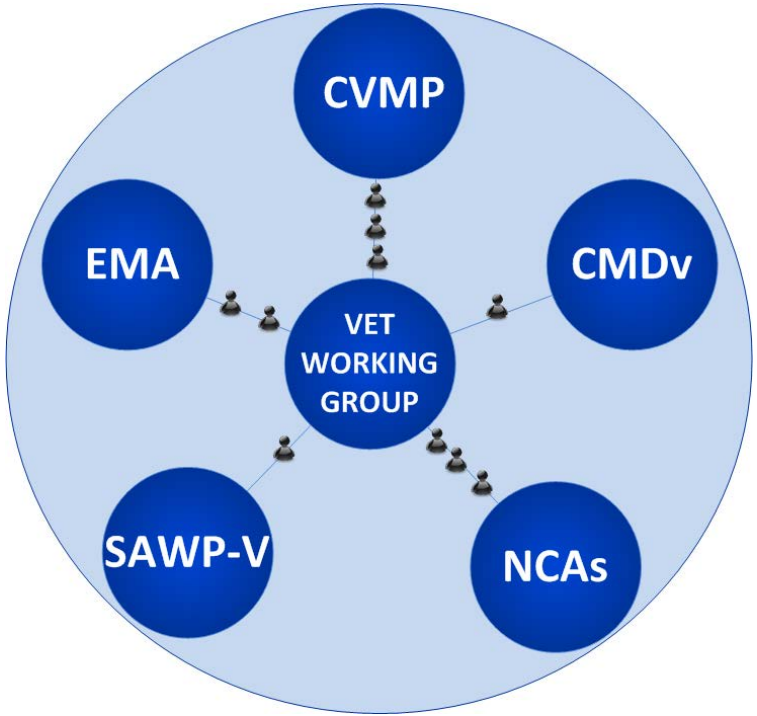
Composition

- 3 members from NCAs (HoA)
  - Jean-Piere Orand (FR)
  - Lorraine Nolan (IE)
  - Hugo Hurts (NL)
- CVMP Chair + 2 CVMP members
- SAWP-V Chair
- CMDv Chair
- EMA Head of SciRS (Chair) + 2 EMA staff members



Objectives of the EMA working group on veterinary medicines

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1. • Redistribution of UK product portfolio
2. • Distribution of workload for initial marketing authorisation applications and maximum residue limits (MRLs), including reassignment of procedures not yet started but initially assigned to the UK
3. • Distribution of workload for scientific advices
4. • Operational adjustments

General principles: Redistribution of the UK workload

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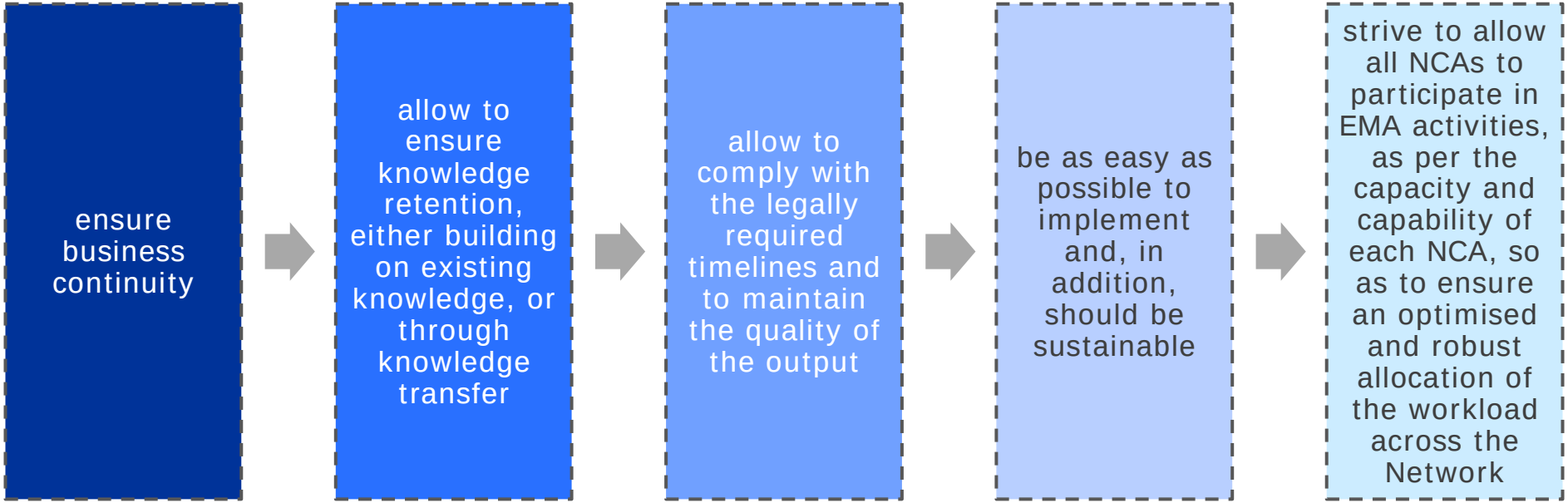
As per the mandate of the EMA Working Groups adopted by the EMA Management Board, the general principles guiding the redistribution proposal are:



All the proposals for redistribution took 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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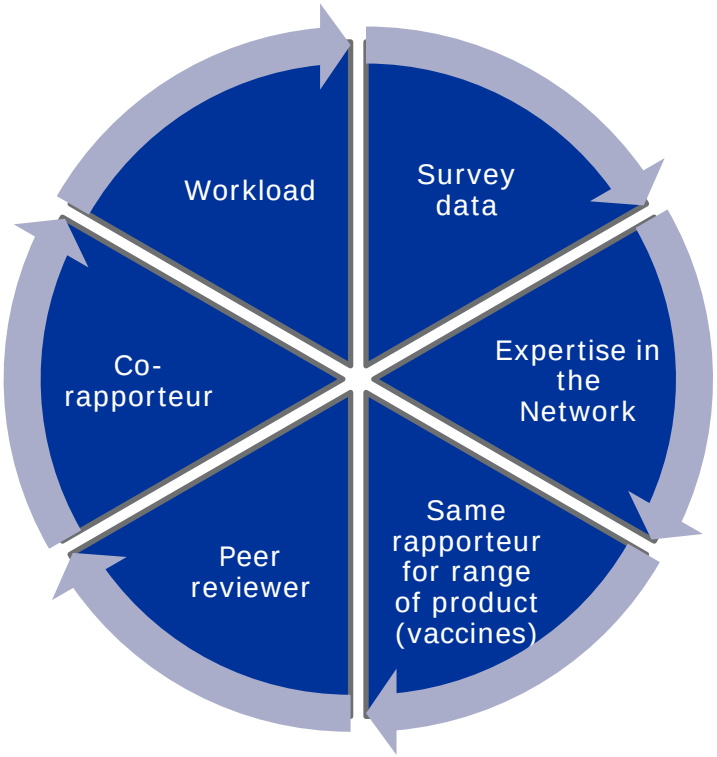
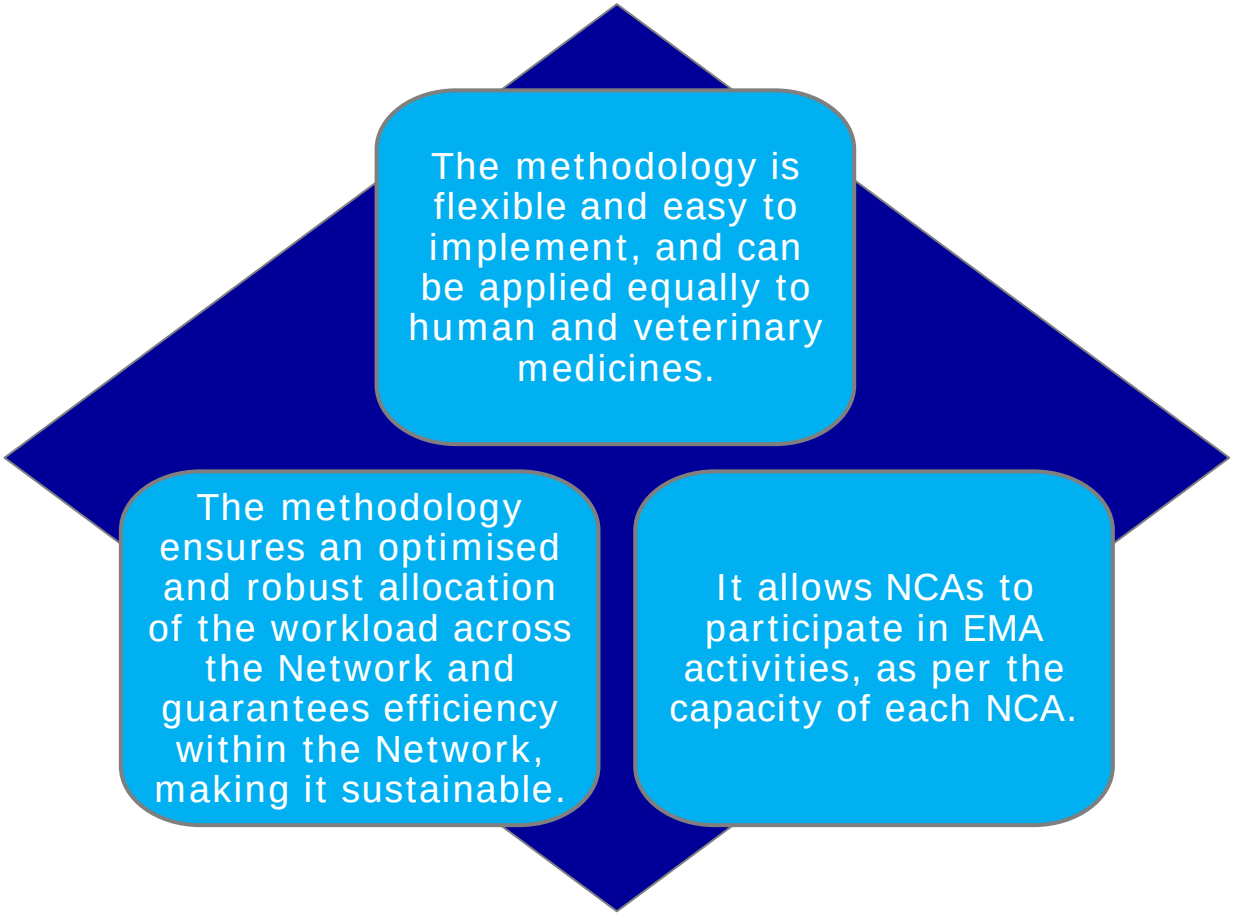
- The redistribution follows a multifaceted approach and takes into account the diverse expertise in the European medicines regulatory network and the workload associated with each medicine
- Building on existing knowledge, medicines are allocated to the current co-rapporteur or to the peer reviewer involved in the initial marketing authorisation application
- Similar of products (e.g. range of vaccines) are as far as possible 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 is to be communicated to the MAHs by 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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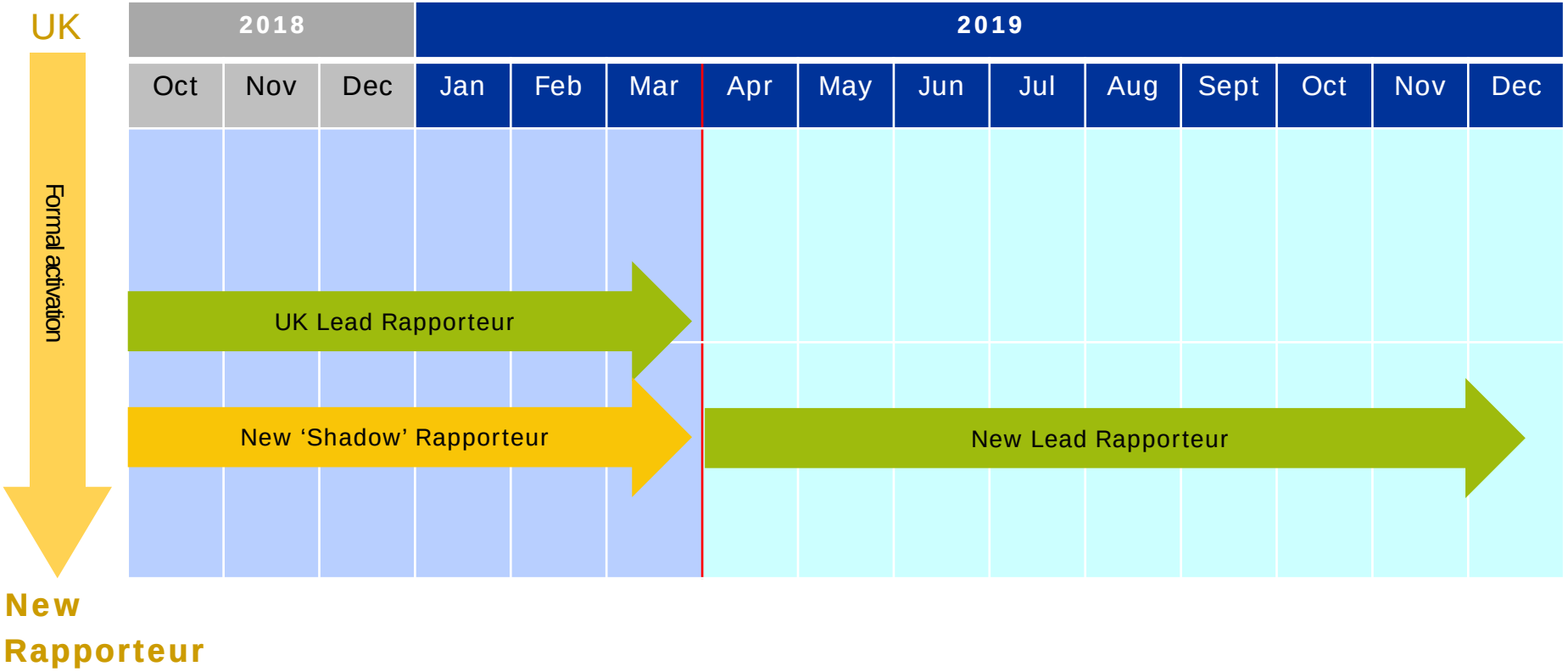
Workload sharing timeline 2018-2019



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Next steps

Publication of Notice 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: 1Q 2018

Questionnaire to centralised MAH on Industry Brexit Preparedness: 1/2Q 2018

Survey on NCAs capacities / training needs: 1/2Q 2018 (Priority on MRP-DCP)

Thank you for your attention

Further information

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