EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

UK’s withdrawal from the EU - preparedness activities update

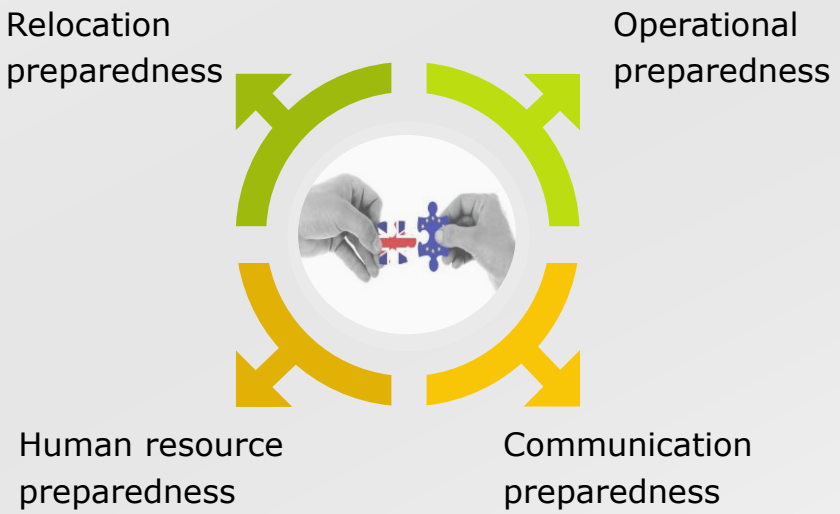
13th industry stakeholder platform – operation of EU pharmacovigilance

Presented by Tony Humphreys on 20 March 2018
European Medicines Agency

EMA preparedness following the UK referendum

Initial steps taken

- Internal task force (Operation and Relocation Preparedness (ORP) Task Force) established on 24 June 2016
- Mandate: to deal with the Agency's preparedness for any possible scenario following the UK referendum on EU membership and the UK's exit from the EU



EMA preparedness following the UK referendum

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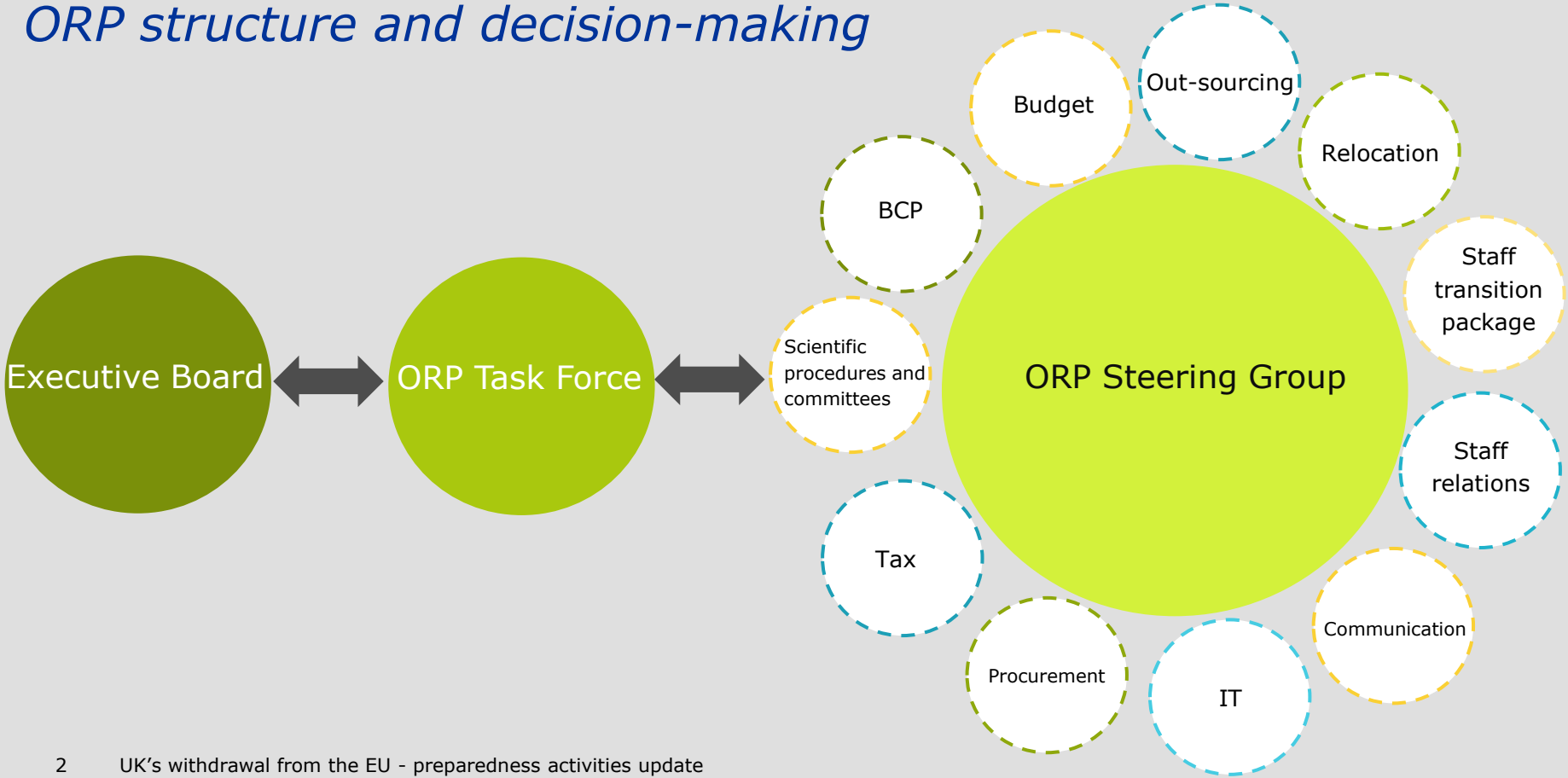
ORP structure and decision-making



Industry Brexit related Pharmacovigilance questions

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- UK (PRAC) Rapporteurship — Principles explained
- EMA Databases (EudraVigilance) access — Future EC-EMA Q&A update
- Deputy QPPV location — Future EC-EMA Q&A update
- Pharmacovigilance Annual Fees — EMA information in March 2018
- Continuous Industry Stakeholders Communication — Update

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[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]

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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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

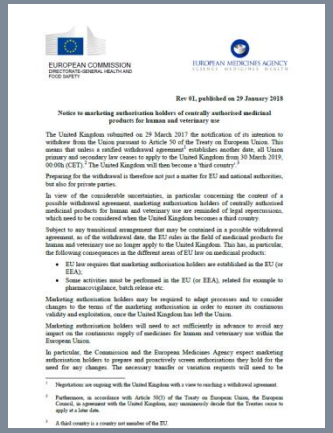
Rev 01, published on 29 January 2018

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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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.

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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EUROPEAN MEDICINES AGENCY

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.

[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.

UK participation in EMA activities

The scenario that is considered is the one by which the UK membership will cease to exist as of 30 March 2019. As of that date, the UK will be a "third country" and, as a consequence, will no longer be able to engage in centralised procedures which are expected to finalise after 30 March 2019.

Therefore, cut off dates for EMA procedures (pre and post authorisation) for human and veterinary medicines were established.

The cut-off dates were extrapolated by averaging the length of each procedure from submission to outcome and by taking into consideration the deadline of 30 March 2019.

The calculations are based on the analysis of data from the past 5 years for the different procedures.

Timelines: Redistribution of the UK portfolio

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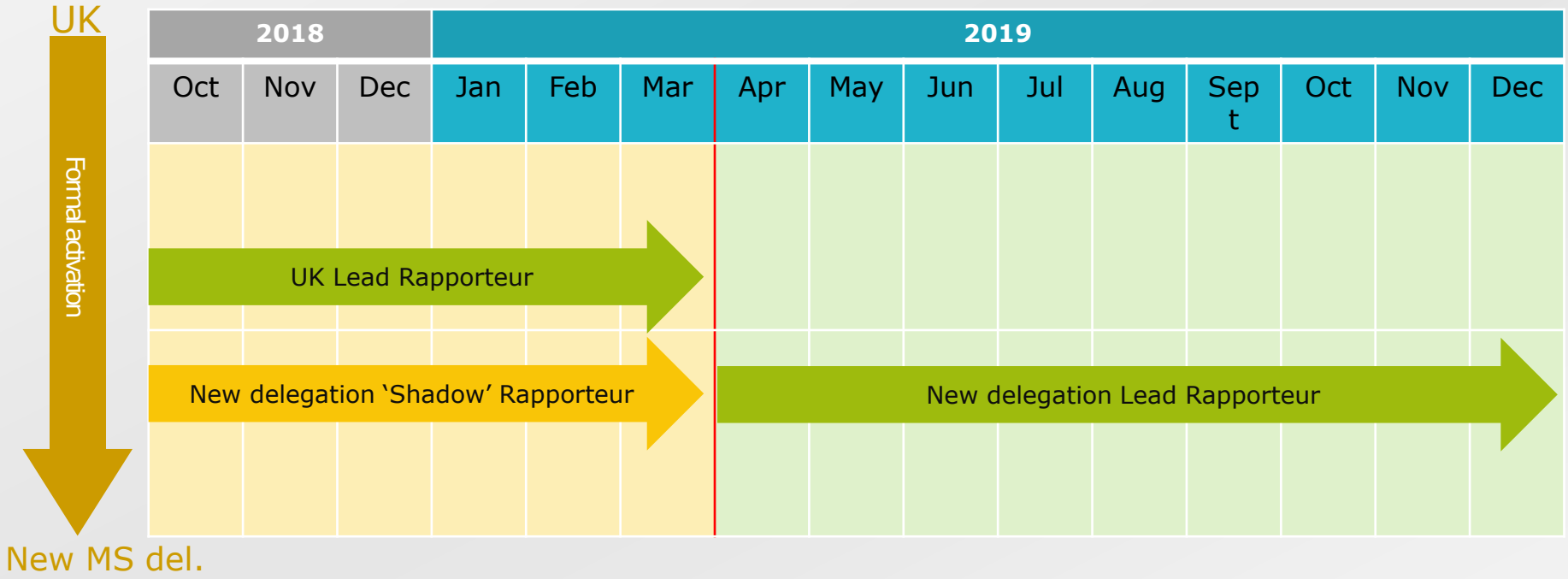
Workload sharing timeline 2018-2019



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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 implementation: 1Q18

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

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

2017-2018 EMA-Industry Stakeholder interactions on Brexit related topics

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Publication of 23 March meeting ***high level summary report*** *by end of April 2018*

Expected publication of ***EC/EMA Q&A*** *and* ***EMA procedural guidance***

2017-2018	Publication of EC Q&A update - EMA procedural guidance - EMA Survey
02.05.17	Publication of **EC/EMA Notice** to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use
31.05.17	Publication of **EC/EMA Q&A** 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
27.11.17	**EMA Practical guidance** for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure
23.01.18	**Launch** of EMA Brexit Survey to Centralised MAHs
Q2 2018	Publication of **EC/EMA Q&A** 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, **1st update**
Q2 2018	**EMA Practical guidance** for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure, **1st update**

2018 EMA-Industry Stakeholder interactions on Brexit related topics

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2018 calendar

March

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

✓

April

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confirmed

June

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tentative

September

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30						

tentative

October

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14	15	16	17	18	19	20
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28	29	30	31			

tentative

November

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25	26	27	28	29	30	

tentative

Thank you for your attention

Further information

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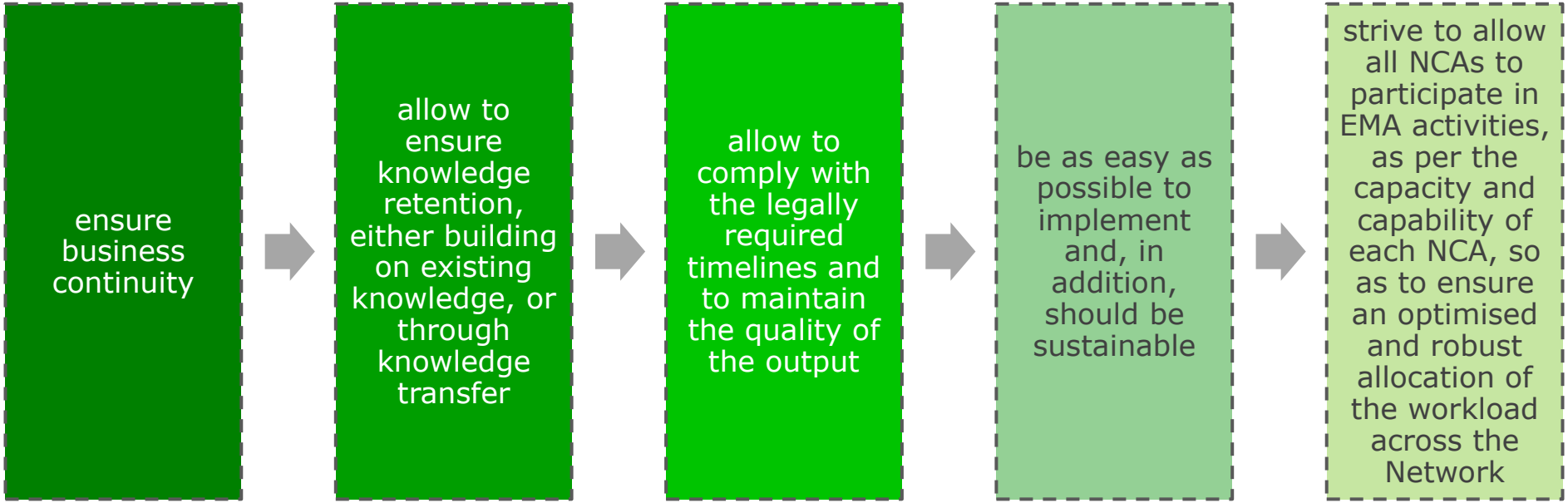
General principles: Redistribution of the UK workload

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)

- 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.

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.