EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on EMA Committees Operational Preparedness

Agenda item 3.1 – update on EMA Committees' Operational Preparedness

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Agenda

- Redistribution of the UK centrally authorised products' portfolio and implementation from Q4 2018;
- Distribution of workload for initial marketing authorisation applications, including reassignment of procedures not yet started but currently assigned to the UK;
- UK participation in other EMA activities (SA, PIP, ODD).

Redistribution of the UK centrally authorised products portfolio

- EMA published the working methodology agreed by the MB at its December 2017 meeting, including the process for assignment of the (Co)-Rapporteurships

  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/04/WC500247359.pdf

- EMA also published an accompanying “news item” on the EMA homepage

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/04/news_detail_002937.jsp&mid=WC0b01ac058004d5c1

- New (Co)-Rapporteurships were communicated to MAHs on 30 April 2018

Implementation of the redistribution of the UK centrally authorised products portfolio (1/4)

- The redistribution of the UK product portfolio* was finalised on 4 April 2018 and the new (Co)-Rapporteurships were communicated to the MAHs on 30 April 2018
- To support knowledge transfer, a stepwise approach is applied
  - EMA to provide the new (Co)-Rapporteurs with a knowledge transfer package
  - Option for the new (Co)-Rapporteurs to liaise with the MAHs in order to gather further information on the allocated medicinal products, including forecast of post-authorisation procedures
  - If any outstanding issues remain, new (Co)-Rapporteur to liaise with MHRA/VMD

**authorised medicinal products as well as ongoing MAAs*

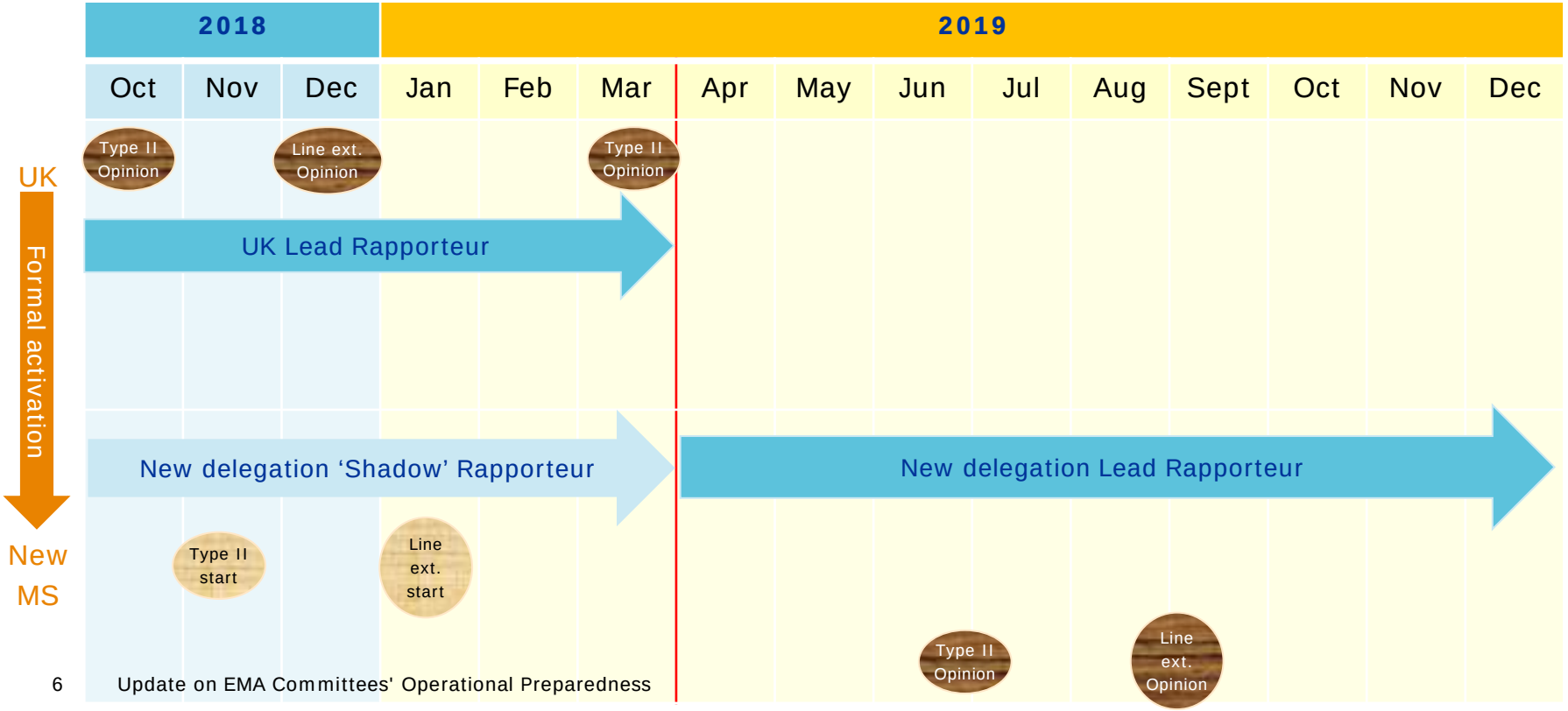
Implementation of the redistribution of the UK centrally authorised products portfolio (2/4)

- The new (Co)-Rapporteurs will only take full responsibility for the re-allocated medicinal products as of 30 March 2019 when the UK withdraws from the Union and becomes a third country. The MHRA/VMD will be accountable for the medicinal products for which they are (Co)-Rapporteurs until 29 March 2019
- However, the new (Co)-Rapporteurs may be required to handle, from Q4 2018 onwards, post-authorisation procedures when it is envisaged that the procedures may be still under evaluation after the 30 of March 2019
- The decision is taken at procedure level and depending on the average length of the procedure
- Cut-off dates for each procedure in post authorisation, e.g. line-extension, type II quality variation were extrapolated by averaging the length of each procedure from submission to outcome, and by taking into consideration the deadline of 30 March 2019

Implementation of the redistribution of the UK centrally authorised products portfolio (3/4)

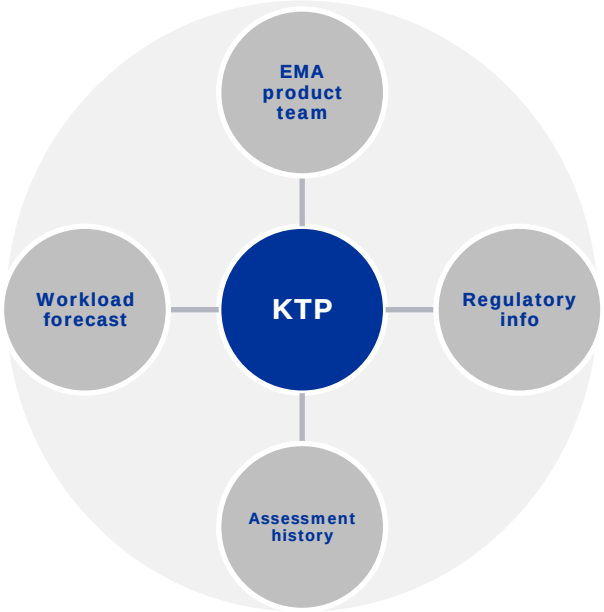
- For lines extensions and extensions of indication the cut-off dates have already surpassed and therefore all procedures starting after **1 October 2018** will be allocated to the new (Co)-Rapporteurs.
- Quality, safety and efficacy type II variations will be allocated to the new (Co)-Rapporteurs if submitted after **26 October 2018** and renewals submitted after **24 October 2018** will also be allocated to the new (Co)-Rapporteurs
- PSURs (CAPS only) submitted after **6 November 2018** will already be handled by the new (Co)-Rapporteurs
- Type IB variations submitted after **16 January 2019** will be allocated to the new (Co)-Rapporteurs
- For veterinary medicines the above cut-off dates apply with the exception of renewals (November 2018) and PSURs (December 2018)

Implementation of the redistribution of the UK centrally authorised products portfolio (4/4)



Knowledge Transfer Package (KTP)

- Aims to provide background knowledge on the regulatory and evaluation history of each product, to help identifying complex medicinal products in the portfolio of each NCA and to forecast upcoming workload to better support planning of resources
- ***Quick start guide*** - safety concerns, product overview and most recent benefit /risk assessment
- ***Elements of the KTP*** - EMA product team, regulatory information, assessment history and workload forecast



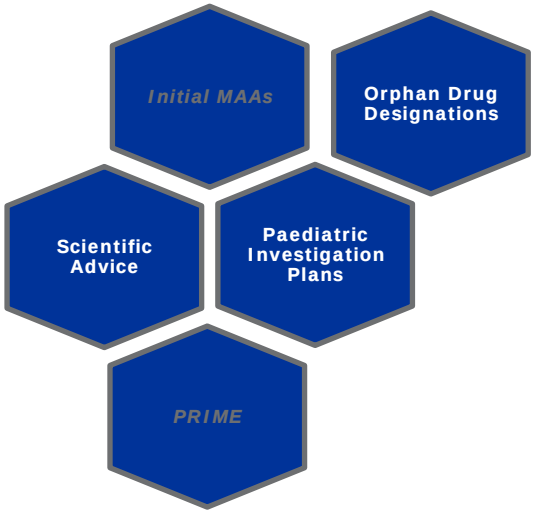
MAHs of affected products may be invited to support the knowledge transfer by providing information on upcoming planned regulatory applications to help each NCAs to forecast upcoming workload.

Distribution of workload for initial marketing authorisation applications

- For some initial MAAs for which the UK had been appointed as (Co)-Rapporteur, Applicants informed EMA of the delayed in the submission of their applications;
- If these procedures were to be submitted in the coming months, they would not be finalised before 30 March 2019;
- Therefore, these MAAs were be subject to a new bidding process and new (Co)-Rapporteurs were allocated;
- Applicants were informed of their new (Co)-Rapporteurs in August 2018.

UK participation in other EMA activities

Rapporteurships in pre-authorisation



- Cut-off dates for procedures in pre-authorisation have also been established to ensure that they are finalised before 29 March 2019;
- The same methodology was used, i.e. cut-off dates were extrapolated by averaging the length of each procedure from submission to outcome and by taking into consideration the deadline of 29 March 2019;
- Therefore, UK's involvement in PIP/SA/ODD will gradually be phased out with no UK Rapporteurs/Coordinators being appointed for these procedures after the cut-off dates.

Further information

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