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SCIENCE MEDICINES HEALTH

Update on EMA Brexit preparedness

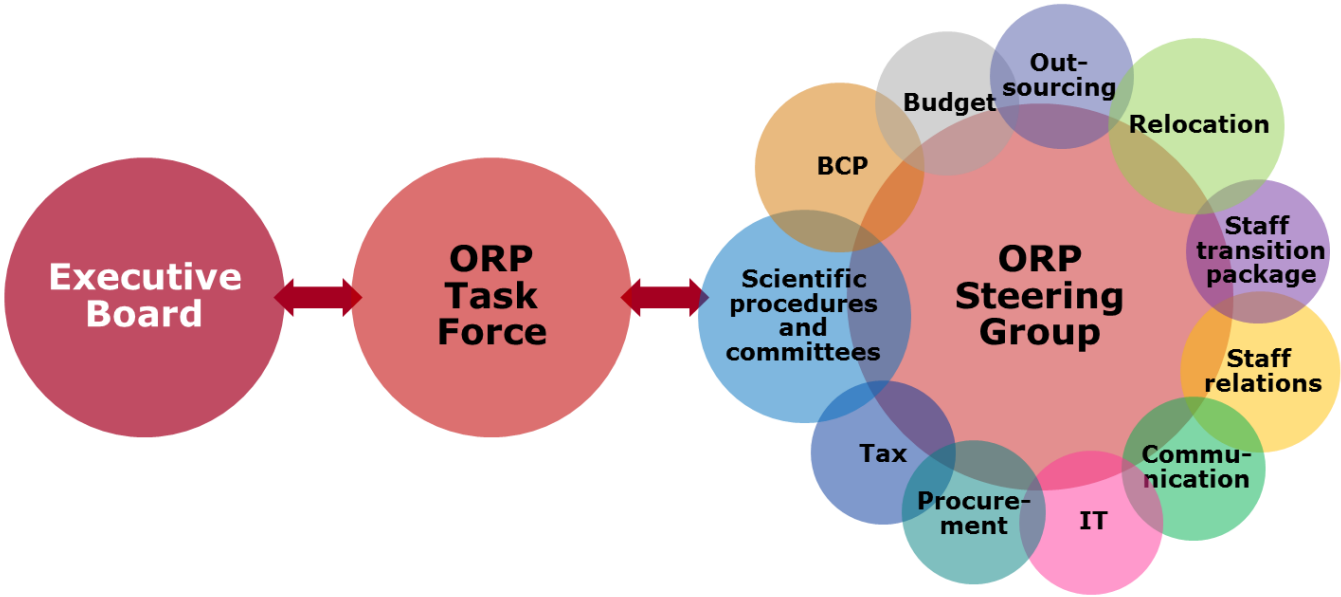
SME Office Info Day on "Supporting innovative medicines' development and early access"
17 November 2017

Presented by Anthony Humphreys

EMA preparedness following the outcome of 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
- 4 Workstreams:
  - Relocation preparedness
  - Operational and financial preparedness
  - HR related matters
  - Communication actions

ORP structure and decision-making



Status report on EMA preparedness

- Important progress over past months in several areas:
  - Finalisation of 1st draft of impact assessment
  - Development of dedicated EMA Brexit Preparedness BCP and launch of phase 1
  - EMA technical input into EC assessment of the MSs' bids for relocating EMA
  - Linking EMA Brexit Preparedness BCP with outcome of EMA staff survey and the staff retention scenarios, including anticipated impact on the operation of EMA and the wider impact on public and animal health in the EU
  - Addressing the loss of UK expertise to be covered by the 27 MSs
  - Developing EMA staff retention support measures
  - Developing guidance for pharmaceutical industry

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EMA Working Groups on Committees' Operational Preparedness

Mandate and objectives

Presented by Monica Dias

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.

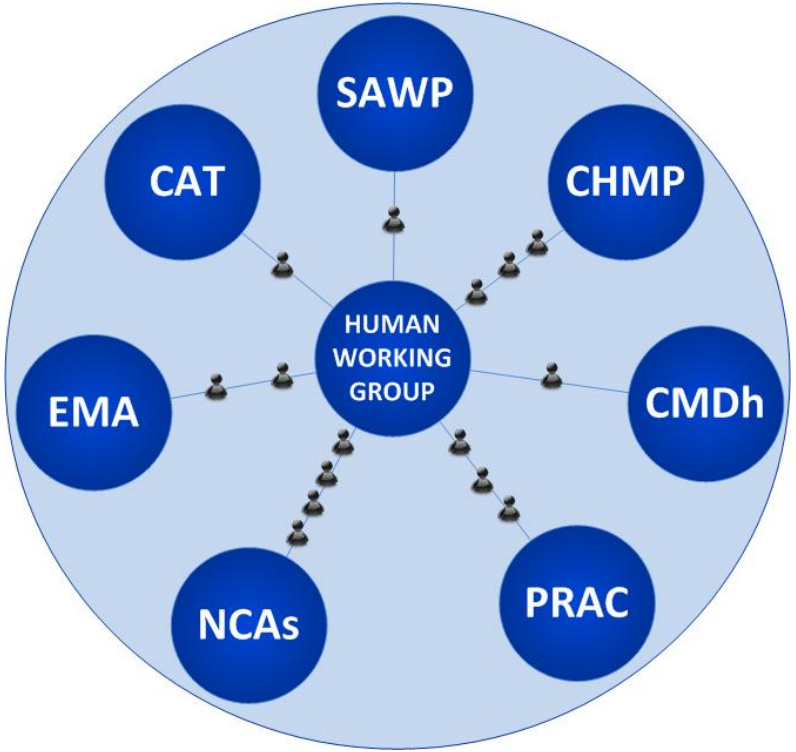
As an outcome of the meeting on 27 April, general principles for the redistribution of the workload and a working methodology to implement the general principles were agreed.

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 groups (1/2)

Human Medicines

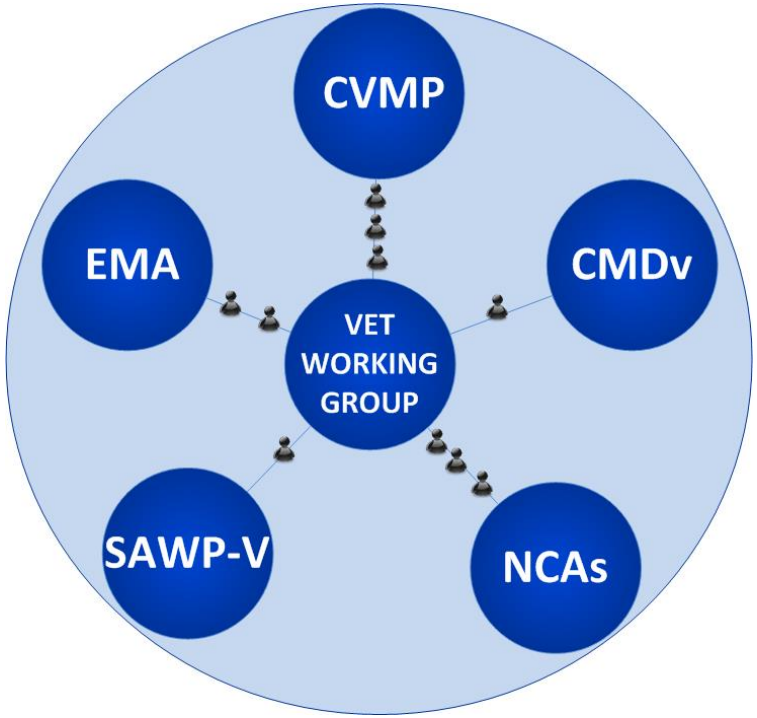
- 4 members from NCAs (HoA)
- CHMP Chair + 2 CHMP members
- PRAC Vice-Chair + 2 PRAC members
- CAT Chair
- SAWP Vice-Chair
- CMDh Chair
- EMA DED (Chair) + 2 EMA staff members



Composition of the working groups (2/2)

Veterinary Medicines

- 3 members from NCAs (HoA)
- CVMP Chair + 2 CVMP members
- SAWP-V Chair
- CMDv Chair
- EMA Head of SciRS (Chair) + 2 EMA staff members



Objectives of the working groups

Human Medicines

- Redistribution of UK product portfolio
- Distribution of workload for initial marketing authorisation applications, including reassignment of procedures not yet started but currently assigned to the UK
- Distribution of workload for scientific advices
- Distribution of workload for PRAC procedures, for which the contribution of the CMDh is required concerning the national authorised medicinal products

✓ Operational adjustments

Veterinary Medicines

- Redistribution of UK product portfolio
- Distribution of workload for initial marketing authorisation applications and maximum residue limits (MRLs), including reassignment of procedures not yet started but currently assigned to the UK
- Distribution of workload for scientific advices
- Distribution of workload for Pharmacovigilance procedures for centrally authorised products

✓ Operational adjustments

Taking into consideration the outcome of mapping exercise (human and veterinary medicines)

General principles: Redistribution of workload (1/2)

- Since each area of activities (i.e. human medicines, veterinary medicines, inspections) has its own characteristics and complexity, the approach to workload redistribution in each area can be different
- Even within the same area of activities the approach can be different for each Scientific Committee, unless there is a significant level of interaction between these Committees, such as for instance between the CHMP and the PRAC

General principles: Redistribution of workload (2/2)

- Whatever the approach to the workload redistribution, it should
  - ensure business continuity
  - allow to ensure knowledge retention, either building on existing knowledge, or through knowledge transfer (if the latter applies, this should be accommodated)
  - allow to comply with the legally required timelines and to maintain the quality of the output
  - be as easy as possible to implement and, in addition, should be sustainable (both short/medium term to address the more immediate Brexit consequences, as well as longer term)
  - strive to allow all NCAs to participate in EMA activities, as per the capacity and capability of each NCA, so as to ensure an optimised and robust allocation of the workload across the Network
- Since each situation not only brings challenges but also opportunities, current distribution principles should be reviewed and operational adjustments in a resource constrained environment should be explored, although always with the understanding that the robustness of the scientific review should not be compromised

Working methodology: Aspects covered

- Mapping of capacity and expertise
- Implementation of the general principles/criteria for redistribution of workload
- Decision-making process
- Communication to stakeholders

Working methodology: Implementation of the general principles (1/2)

- In order to implement the aforementioned general principles a differentiated approach is favoured so that due account can be taken of the characteristics and complexity of each area. This means that:
  - For Committees who are interacting in a significant way and for which the complexity is such that various scenarios can be designed to implement the aforementioned general principles, the best possible scenario is proposed following a SWOT analysis of the different options
  - In order to address the characteristics of the medicinal product lifespan a more holistic view is taken

Working methodology: Implementation of the general principles(2/2)

- In order to implement the aforementioned general principles a differentiated approach is favoured so that due account can be taken of the characteristics and complexity of each area. This means that (cont'd):
  - For other Scientific Committees not falling within the previous category they could make proposals on the most optimal solution taking into account the aforementioned general principles themselves, in close collaboration with EMA
  - For activities such as inspections, the workload redistribution will be driven by legislative requirements, but these need to be mapped with the available resources first and in case such mapping indicates that resource constraints will hinder the implementation, a further reflection across the Network will be needed before the ultimate scenario can be designed; this can be undertaken by EMA and the respective working group

Working methodology: Decision-making and communication

- Decision-making: proposals put forward by the working group and agreed by the Executive Director will be submitted by the Executive Director to the Management Board for endorsement
- Communication: communication will ensure coherent and targeted communication to the Scientific Committees, to the Network and to stakeholders

Timeline: what happened when?

Next steps

- Proceed with planning the redistribution of the legacy products
- Address ongoing and yet-to-start initial MA procedures
- Proceed with planning the redistribution of PSUSAs / CMDh involvement

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2017-2018 EMA-Industry Stakeholder interactions planning related to the preparation of the United Kingdom's withdrawal from the European Union: Regulatory preparedness

SME info day „Supporting innovative medicines' development and early access"
17 November 2017

Presented by Dr Marie-Helene Pinheiro

Report of Industry Stakeholder meeting on "Brexit" and operation of the centralised procedure for human medicinal products 1/2

1st Industry Stakeholder meeting on "Brexit" and operation of the centralised procedure for human medicinal products of 4th October 2017 [report]

- From Industry Stakeholders **priority topics** identified:
  - MAHs Transfers
  - Manufacturing and supply chain
  - Pharmacovigilance
  - Cross projects activities i.e. telematics etc.

- Need for **continued and frequent dialogue** with Industry Stakeholders to exchange information in the months to come

- Need for **regular Q&A updates and EMA procedural guidance** to be released. For the latter, with *(short period)* industry consultation, where and as appropriate

- *Centralised MAHs Survey to be launched 4Q, 2017-1Q, 2018:*
  -To obtain companies specific "Brexit" preparedness activities" information for EMA submission "workload" 2018 forecast for 2018 planning.

2017-2018 EMA-Industry Stakeholders interactions on "Brexit" related topics

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2017 calendar

- Industry Brexit meetings & webinars
- SME Info Day
- Platform meetings
- Publication of EC Q&A update – EMA procedural guidance – EMA Survey
- # EMA holidays

September

S	M	T	W	T	F	S
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December

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31						

2017 – 2018 planned meetings with industry stakeholders

	2017 EMA Industry Stakeholder 'Brexit' Meetings & Webinars
04.10.17	Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human medicinal products (H)
13.10.17	Industry Stakeholder TC on Brexit and operation of the centralised procedure for veterinary medicinal products (V)
23.11.17	Industry Brexit webinar on Transfers (H&V)
24.11.17	Industry Brexit Q&A session on Pharmacovigilance in the context of Industry Stakeholder platform meeting on Pharmacovigilance (H)
12.12.17	Industry Brexit webinar on Manufacturing and Supply (H&V)

	2018 EMA Industry Stakeholder 'Brexit' Meetings & Webinars
26.01.18	Industry stakeholder meeting or webinar (H&V) tbc
23.03.18	Industry stakeholder meeting or webinar (H&V) tbc
14.06.18	Industry stakeholder meeting or webinar (H&V) tbc
28.09.18	Industry stakeholder meeting or webinar (H&V) tbc
22.11.18	Industry stakeholder meeting or webinar (H&V) tbc

2017 publication of EC Q&A update – EMA procedural guidance – EMA survey

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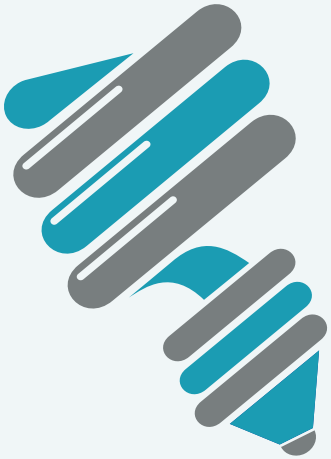
2017 Publication of EC Q&A update - EMA procedural guidance – EMA Survey	
02.05.17	Publication of EC/EMA Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use
31.05.17	Publication of EC/EMA Q&A related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure *
08.11.17	EMA Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure: **release for targeted EU Trade Association consultation**
17.11.17	EMA Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure: **end of targeted EU Trade Association consultation**
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: **publication**
Q4 2017/Q1 2018	**Launch** of EMA Brexit Survey to Centralised MAHs

* Expected publication EC/EMA Q&A updated document 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, by end of 2017. (tbc)

Recommendations to SMEs



- ***Consult regularly EMA website*** *on the* "United Kingdom's withdrawal from the European Union ('Brexit')" [Link] *for update on EMA "Brexit" related information;*
- *For any* ***questions*** *that you may have further to the Q&As publication, EMA procedural guidance, you are advised to liaise with your EMA following contacts :*
  - Product specific - EMA Project Manager as primary Brexit related matters contact
  - SME office – for queries from small and medium sized enterprises
  - Company portfolio discussions – EMA pipeline meeting discussions
  - Industry stakeholders liaison – for requests particularly via trade associations
  - Ask-EMA – for general Brexit-related questions
- ***Inform EMA of any changes in intended submissions*** *at centralised level across pre- and post- activities*
- *Take part of* ***EMA Survey*** *on "Brexit preparedness".*

Any questions?

Further information

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