EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Working Groups on Committees' Operational Preparedness

Mandate and objectives

Industry Stakeholder Meeting on Brexit

Presented by Monica Dias and Anthony Humphreys

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.

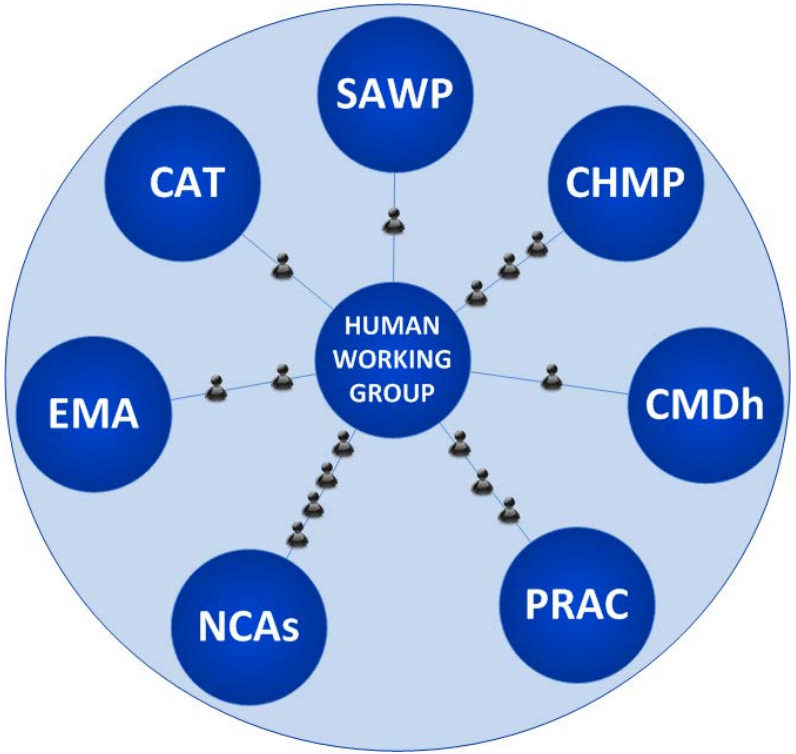
As an outcome of the meeting on 27 April, general principles for the redistribution of the workload and a working methodology to implement the general principles were agreed.

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

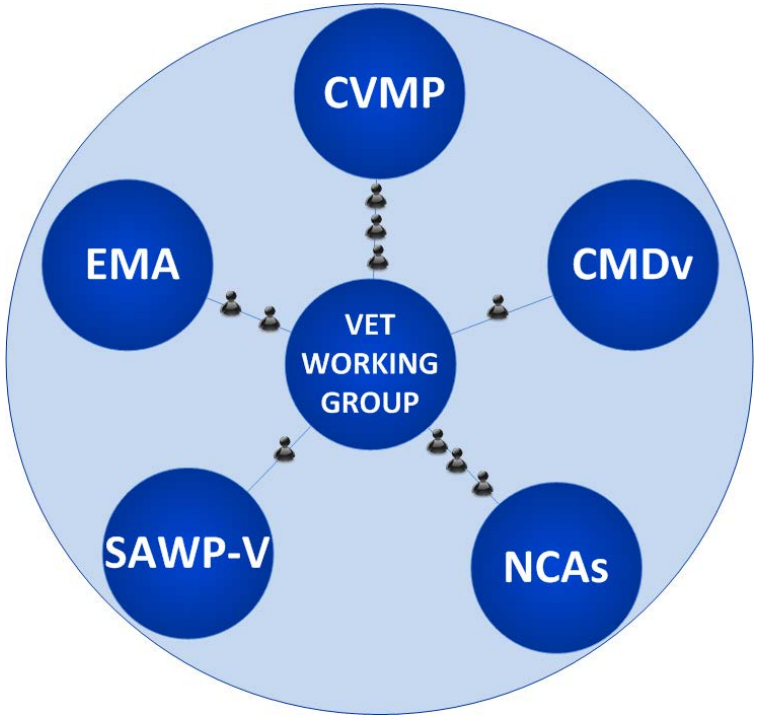
- 4 members from NCAs (HoA)
- CHMP Chair + 2 CHMP members
- PRAC Vice-Chair + 2 PRAC members
- CAT Chair
- SAWP Vice-Chair
- CMDh Chair
- EMA DED (Chair) + 2 EMA staff members



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
- 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?

- *Kick off meeting on 5th July 2017 / 2nd meeting on 4th September 2017 / 3rd meeting today*
- *Survey of NCAs' capacities*
- *Communication exchange with MHRA/VMD on 24th July 2017 / 2nd meeting held on 19th September 2017*
- *Communication to CxMPs / WPs and Industry*

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

Any questions?

Further information

Monica.Dias@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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