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Redistribution of the UK centrally authorised product portfolio

EMA working groups on committees' operational preparedness

1. Executive Summary

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'. As a consequence, the MHRA and VMD will no longer be able to engage in centralised regulatory procedures, as (Co)-Rapporteurs, which are expected to finalise after 30 March 2019.

The redistribution of the UK centrally authorised product (CAP) portfolio involves the reallocation of UK rapporteurs and co-rapporteurs from EMA's Committee for Medicinal Products for Human Use (CHMP), Pharmacovigilance Risk Assessment Committee (PRAC), Committee for Advanced Therapies (CAT) and Committee for Medicinal Products for Veterinary Use (CVMP).

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. It allows Member States to participate in EMA activities according to their individual capacity, as indicated in the feedback received from the capacity-building surveys distributed to the network. The methodology is flexible, easy to implement, and can be applied equally to human and veterinary medicines.

The methodology involves redistribution based on current expertise with a class of medicines. It also foresees building on existing knowledge, for example, by allocating medicines to the current co-rapporteur for a particular product, or to the peer reviewer involved in the initial marketing authorisation application.

It takes into account the legal basis of the product, for example, generic medicines will be allocated to 'newer' National Competent Authorities (NCAs) who have indicated in the survey that they would like to increase their involvement with such medicines.

Clusters of products with the same international non-proprietary name (INN) and/or belonging to the same marketing authorisation holder (MAH) will be allocated to a single rapporteur in order to facilitate review of post-authorisation procedures and ultimately improve efficiency within the Network.

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The redistribution of the UK centrally authorised product portfolio started before 30 March 2019 to ensure timely preparedness of the European medicines regulatory Network. In addition, EMA will facilitate the transfer of knowledge from the UK to the new (Co)-Rapporteurs once marketing authorisation holders have been informed of the changes. The new (Co)-Rapporteurs will only take full responsibility for the re-allocated products as of 30 March 2019, when the UK withdraws from the European Union and becomes a third country.

2. Background

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'. As a consequence, the MHRA and VMD will no longer be able to engage in centralised regulatory procedures, as (Co)-Rapporteurs, which are expected to finalise after 30 March 2019.

The EMA working groups on Committees Operational Preparedness for human and veterinary medicines were given a mandate to explore options for a robust allocation of the workload across the European medicines regulatory network. At the December 2017 Management Board meeting, the methodology for the redistribution of the work currently carried out post authorisation for CAPs by the MHRA and the VMD was endorsed.

3. General principles

The general principles, adopted by the EMA Management Board, which should guide the redistribution of the UK product portfolio were to:

- ensure business continuity;
- ensure knowledge retention, either building on existing knowledge, or through knowledge transfer;
- allow compliance with the legally required timelines and to maintain the quality of the output;
- be as easy as possible to implement and, in addition, to be sustainable;
- 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;

The proposal for redistribution of the workload should also take into consideration the outcome of the surveys on capacity building in the Network.

4. Methodology - Human Medicines

The redistribution of the UK centrally authorised product portfolio of human medicines comprises the reallocation of UK rapporteurs and co-rapporteurs from CHMP, PRAC and CAT.

It follows a multifaceted approach and takes into consideration the results from the surveys on capacity. The methodology also takes into account the scientific expertise and knowledge within the Network and the workload associated with each medicine.

A maximum number of products (ceiling) is allocated per NCA to ensure that all NCAs are allowed to participate in EMA activities as per each NCAs' capacity. The ceiling is adjusted for each role (CHMP Rap, CHMP Co-Rap or PRAC Rap) based on the number of products to be allocated.

UK CHMP Rapporteur

The UK CHMP Rapporteurships to be allocated also include the role of PRAC Rapporteur for medicinal products that were authorised before 2012 and the PRAC Co-Rapporteurships for newer products (see figure 1).

CHMP Rapporteur	CHMP Co-Rapporteur	PRAC Rapporteur	PRAC Co-Rapporteur	
UK	Delegation X	UK	Delegation X	Redistribution of both roles (CHMP Rap and PRAC Rap)
UK	Delegation Y	Delegation Z	UK	Redistribution of both roles (CHMP Rap and PRAC Co-Rap)
UK	Delegation X	Delegation Y	-	Redistribution of CHMP Rap only

Figure 1. UK CHMP and PRAC roles to be redistributed.

UK CHMP Rapporteurships for generic and hybrid medicinal products are allocated to "newer" MSs who have indicated in the surveys the wish to increase their involvement in these types of products. In addition, generic medicinal products are associated with a low workload in the post authorisation phase, therefore not requiring a substantial increase in resources for these NCAs.

UK CHMP Rapporteurships for all other products (i.e. full applications and biosimilars) are allocated to the current Co-Rapporteur to a maximum of 10 medicinal products per NCA. The ceiling of 10 products per NCA ensures an optimised and robust allocation of the workload across the Network.

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 and ultimately improve efficiency within the network.

The remaining medicinal products are allocated based on the current expertise in the Network (current expertise in the Network as CHMP Rapporteur, based on ATC code distribution) and the workload associated to each medicine in post authorisation, as CHMP Rapporteur.

The methodology for the redistribution of UK CHMP Rapporteurships will ensure business continuity since it provides continuity in the lifecycle of the medicinal product, with the NCA involved in initial review also being involved in the post authorisation phase, hence facilitating knowledge transfer. In situations where the new NCA was not previously involved in the lifecycle of the product, the quality of

the output can be maintained due to the NCA's previous involvement in the lifecycle of similar products (i.e. same INN or same ATC code).

UK CHMP Co-Rapporteur

UK CHMP Co-Rapporteurships are allocated to the Peer Reviewer involved in the initial application for marketing authorisation to a maximum of 15 medicinal products per NCA. The redistribution to the Peer Reviewer will facilitate knowledge transfer.

When a Peer Reviewer has not been appointed, medicinal products are allocated based on the current expertise within the network (current expertise in the Network as CHMP Co-Rapporteur, based on ATC code distribution) and the workload associated with each medicine in post authorisation (for procedures that require Co-Rapporteur's involvement).

For products redistributed based on expertise, knowledge transfer will be facilitated, even if the new Co-Rapporteur was not previously involved in the lifecycle of the product, due to previous involvement with similar products (same therapeutic indication) in post authorisation as Co-Rapporteur, thus maintaining the quality of the output.

Redistribution of products based on workload will lead to an increased number of CHMP Co-Rapporteurships being allocated to "newer" NCAs, providing them with an opportunity to build capacity.

The CHMP Co-Rapporteurships that become available due to the allocation of UK CHMP Rapporteurships to the current Co-Rapporteur (i.e. vacant CHMP Co-Rapporteurships) will be allocated following the same methodology.

UK PRAC Rapporteur

The UK PRAC Rapporteurships to be allocated following the methodology described below comprise only medicinal products which have been approved after 2012 and for which the UK is PRAC Rapporteur only, i.e. the UK does not hold any other roles within the assessment team for a given medicinal product (see figure 2).

Figure 2. UK PRAC Rapporteur roles to be redistributed.

The UK PRAC Rapporteurships for generic medicinal products are automatically allocated to the PRAC Rapporteur of the reference medicinal product.

For all other types of medicinal products allocation is based on clusters of products with the same INN, current expertise in the Network (current expertise in the Network at the level of the PRAC, based on ATC code distribution) and the workload associated to each medicine in post authorisation, as PRAC Rapporteur. The Peer Reviewer of the initial application for marketing authorisation was also taken into consideration when the delegation of the Peer Reviewer also had expertise (at the level of the PRAC) in the ATC of the product to be redistributed.

Each NCA is allocated a maximum of 5 medicinal products as PRAC Rapporteur.

The methodology for the redistribution of UK PRAC Rapporteurships will facilitate the review of periodic safety update report single assessments (PSUSAs) and improves efficiency within the Network since clusters of products with the same INN are redistributed to the same PRAC Rapporteur. The redistribution of medicinal products based on the expertise in the Network (i.e. ATC code distribution) facilitates knowledge transfer due to current experience in the evaluation of similar products at the PRAC, thus maintaining the quality of the output. Inclusivity and sustainability of the Network was addressed by spreading allocation of UK PRAC Rapporteurships to NCAs which currently have the lowest number of products within a given ATC code.

5. Process for assignment of new CHMP/CAT/PRAC (Co)-Rapporteurs - Human Medicines

The process for assignment of new CHMP/PRAC/CAT (Co)-Rapporteurs is based on the aforementioned general principles, using a multifaceted approach for allocation of the UK product portfolio within the Network following the agreed criteria, taking into consideration the survey results and applying a ceiling per NCA, as described above. Any medicinal products which ultimately were not retained by NCAs using this process of assignment were subject to an open bidding.

6. Methodology - Veterinary Medicines

The redistribution of the UK centrally authorised product portfolio of veterinary medicines comprises the reallocation of UK Rapporteurs and Co-Rapporteurs from CVMP.

It follows a multifaceted approach and takes into consideration the results from the survey on capacity. By establishing NCAs' planned increased involvement in the centralised procedure it is possible to allow all NCAs to participate in EMA activities, as per the capacity of each NCA.

The methodology also takes into account the scientific expertise and knowledge within the Network and balanced workload distribution.

UK CVMP Rapporteur

The UK CVMP Rapporteurships are primarily allocated to the current CVMP Co-Rapporteur ensuring a balanced workload distribution. Although the principle of re-allocating the UK Rapporteurship to the Co-Rapporteur is a straight forward concept, in a small number of cases additional considerations were taken into account such as the surveys' results indicating no capacity of the concerned NCA to undertake new Rapporteurships and maintaining, whenever possible, the same Rapporteur for similar products (e.g. range of vaccines with same MAH).

Similarly to the approach taken for human medicines, the methodology for the redistribution of the UK portfolio for veterinary medicines ensures continuity in the lifecycle approach since the NCA involved in the initial review will also be involved in post-authorisation, and therefore knowledge transfer will be facilitated.

Similar products (e.g. range of vaccines) are, as far as possible, redistributed to the same Rapporteur which facilitates review of post-authorisation procedures and improves efficiency within the Network.

UK CVMP Co-Rapporteur

UK CVMP Co-Rapporteurships are allocated to the Peer Reviewer involved in the initial application for marketing authorisation. The redistribution to the Peer Reviewer will facilitate knowledge transfer.

In the absence of peer reviewers, redistribution of products is based on workload which allows less involved NCAs to participate in EMA activities as Co-Rapporteur, which will provide an opportunity to build capacity.

The methodology also aims at maintaining the same Co-Rapporteur for similar products (e.g. vaccines range) which are allocated to the same Co-Rapporteur. However, knowledge transfer will be facilitated even if the new Co-Rapporteur was not previously involved in the lifecycle of the product due to previous involvement with similar products (e.g. same active substance) in post-authorisation, thus maintaining the quality of the output.

The CVMP Co-Rapporteurships that become available due to the allocation of UK CVMP Rapporteurships to the current Co-Rapporteur (i.e. vacant CVMP Co-Rapporteurships) will be allocated following the same methodology.

7. Process for assignment of new CVMP (Co)-Rapporteurs - Veterinary Medicines

The process for assignment of new CVMP (Co)-Rapporteurs is based on the aforementioned general principles, using a multifaceted approach for allocation of the UK product portfolio within the Network following the agreed criteria, taking into consideration the survey results and applying a ceiling per NCA, as described above. Any medicinal products which ultimately were not retained by NCAs using this process of assignment were subject to an open bidding.

8. Conclusions

The methodology for the redistribution of the UK product portfolio for CHMP/CVMP/CAT/PRAC (Co)-Rapporteurships for human and veterinary products was endorsed by the Management Board at its December 2017 meeting. The methodology is flexible, easy to explain and implement, and can be applied equally to human and veterinary medicines. It involves a multifaceted approach for allocation of the UK product portfolio within the Network, which takes into consideration the results of the surveys, the expertise within the Network and workload for each medicinal product. The proposal ensures an optimised and robust allocation of the workload across the Network and guarantees efficiency within the Network, making it sustainable. In addition, it allows NCAs to participate in EMA activities, as per the capacity of each NCA.