EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/151751/2010 Rev. 4
Committee for Medicinal Products for Human Use (CHMP)

Procedural advice on CHMP/CAT/PRAC rapporteur/co-rapporteur appointment principles, objective criteria and methodology in accordance with Article 62(1) of Regulation (EC) No 726/2004

Adoption by CHMP		September 2006
Adoption by CAT/CHMP	Revision 1	September 2009
Adoption by CHMP	Revision 2	March 2010
Adoption by CAT/CHMP/PRAC	Revision 3	November 2014
Adoption by CAT/CHMP/PRAC	Revision 4	February 2025

This document has been revised in order to provide more clarity with regard to (co-)rapporteurship appointments taking into account case law and a European Ombudsman recommendation[1]. The key elements of this revision are the requirement to consider the prior role of the (co-)rapporteur as coordinator for scientific advice for initial applications and changes in Rapporteurship, as well as the requirement to take into account if the National Competent Authority of the nominated Committee member adopted a decision or was involved in court proceedings related to the same subject matter identified in referral procedures. This document is also revised to reflect the change in process to no longer appoint a CHMP Pharmacovigilance Rapporteur for generics/hybrids.

[1] Decision in the strategic inquiry OI/7/2017/KR on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU.

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1. Introduction

The **Committee for Medicinal Products for Human Use (CHMP)** is responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for human use. Specifically, the CHMP is responsible for the assessment of applications for marketing authorisation submitted under the centralised procedure as well as the assessment of referrals on human medicines (in the case of referrals related to pharmacovigilance issues, on the basis of the recommendation prepared by the PRAC).

The **Committee for Advanced Therapies (CAT)** is responsible for preparing the opinion of the Agency on any question relating to the assessment of advanced therapy medicinal products (ATMPs). Specifically, the CAT is responsible for the assessment and preparation of draft opinions on ATMP applications submitted under the centralised procedure.

The **Pharmacovigilance Risk Assessment Committee (PRAC)** is responsible for assessing all aspects of the risk management of medicines for human use. The main responsibility of the PRAC is to prepare recommendations on any questions relating to pharmacovigilance activities in respect of medicines for human use and on risk-management systems, including the monitoring of the effectiveness of those risk-management systems.

For any scientific evaluation in respect of a procedure submitted under the centralised procedure, a rapporteur and, if relevant, a co-rapporteur shall be appointed from amongst the members and alternates of the CHMP. For ATMPs, a rapporteur and, if relevant, a co-rapporteur shall be appointed from amongst the members and alternates of the CAT; in addition, two CHMP co-ordinators will be appointed (one supporting the CAT rapporteur assessment team and another supporting the CAT co-rapporteur assessment team). In addition, for activities covering all aspects of the risk management of the use of human medicinal products, a rapporteur and, if relevant, a co-rapporteur shall be appointed from amongst the members and alternates of the PRAC.

For the evaluation of safety related referrals resulting from the evaluation of data relating to pharmacovigilance, a rapporteur and, if relevant, a co-rapporteur shall be appointed from amongst the members and alternates of the PRAC.

For the evaluation of all other referrals, a rapporteur and, if relevant, a co-rapporteur shall be appointed from amongst the members and alternates of the CHMP.

The appointment of rapporteur/co-rapporteur is made on the basis of objective criteria, which will ensure the provision of objective scientific opinions and will allow the use of the best available expertise in the European Economic Area (EEA) on the relevant scientific area.

This paper outlines the principles, objective criteria and the procedure on the rapporteur/co-rapporteur appointment procedure.

2. Legal basis

Regulation (EC) No 726/2004 provides the legal framework for the rapporteur/co-rapporteur appointment.

Article 62(1) states "*Where, in accordance with this Regulation, any of the Committees referred to in Article 56(1) is required to evaluate a medicinal product for human use, it shall appoint one of its members to act as rapporteur, taking into account existing expertise in the Member State. The Committee concerned may appoint a second member to act as co-rapporteur.*"

Article 61(1) states: "*…The **alternates** shall represent and vote for the members in their absence and may be appointed to act as rapporteurs in accordance with Article 62.*"

Note: For PRAC, in accordance with Article 61a(1), only those alternates appointed by the Member States may be appointed to act as rapporteurs.

Article 57(1) states that the Agency [and therefore its Scientific committee(s) Members] shall provide the best possible scientific advice: "*The Agency shall provide the Member States and the institutions of the Union with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Union legislation relating to medicinal products.*"

Article 61(6) states with regard to the scientific evaluation and resources: "*Members of the committees and experts responsible for evaluating medicinal products shall rely on the scientific evaluation and resources available to national marketing authorisation bodies. Each competent national authority shall monitor the scientific level and independence of the evaluation carried out and facilitate the activities of nominated committee members and experts. Member States shall refrain from giving committee members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.*"

For re-examinations of opinions under the centralised procedure

Article 62(1) (fifth sub-paragraph) of Regulation (EC) No 726/2004.

3. Scope of this paper

This paper sets the principles, objective criteria and the methodology on the (co-)rapporteurship appointment procedure.

These principles and objective criteria shall apply to several application types (e.g. centralised applications, applications under Article 58 of Regulation (EC) No 726/2004, compassionate use).

Additional principles are added for the (co-)rapporteurship appointment for other types of application procedures; this includes generics, hybrids, similar biologicals, re-examination of an opinion, signals and PSURs.

Similarly, additional principles are added for the (co-)rapporteurship appointment for referrals and re-examinations, when applicable.

4. Role of the rapporteur and co-rapporteur

The rapporteur and co-rapporteur for the CHMP/PRAC/CAT committees will:

- Take responsibility for the scientific assessment/evaluation undertaken by the assessment team within the scope of their committee's involvement with the concerned procedure in accordance with the timeframes laid down in the EU legislation and the EMA regulatory procedures.
- Coordinate input from her/his assessment team.
- Coordinate input from a variety of fora e.g. Working Parties (WPs), Ad Hoc Expert Groups (AHEGs), Scientific Advisory Groups (SAGs).
- Involve additional expertise, as considered necessary.

- Act as a committee representative/spokesperson in liaison with Applicant/Marketing Authorisation Holder (MAH).
- Interact with the EMA product team.
- Ensure that all her/his activities are performed in a transparent manner (informing accordingly the EMA Secretariat).
- Establish contacts with Patient Organisations/Health Care Professional Associations (in accordance with the provisions laid down in Article 78(2) of Regulation (EC) No 726/2004).
- Collaborate with the rapporteur(s) from other relevant EMA committees for the medicinal product for human use and ensure comments are taken on board, as appropriate.
- Take responsibility for the preparation of the required documentation in line with procedural milestones as appropriate (assessment report, draft opinion etc.) and in accordance with procedural timelines.

5. Rapporteurs' appointments

5.1. Principles

5.1.1. General principles for appointment of rapporteurs – centralised procedure

- All members and alternates can act as rapporteur/co-rapporteur. (Note: Alternates of patient and healthcare professionals' representatives cannot be rapporteurs at the PRAC).
- The rapporteur/co-rapporteur shall be supported by a team of assessors/experts (assessment team) during the various phases of the assessment of the application. The resources of the rapporteur/co-rapporteur's assessment team shall be assessors/experts available not only from the rapporteur/co-rapporteur NCAs' level but could be available from across the EEA. The use of multinational assessment teams (with provisions in place at level of EMA for division of fees between participating NCAs) is strongly encouraged, as a means of increasing capacity, competence and collaboration within the EU regulatory network.
- The appointment of the rapporteur/co-rapporteur shall be made on the basis of objective criteria, which will ensure the provision of objective scientific opinions and will allow the use of the best and available expertise in the EEA in the relevant scientific area, over the lifecycle of the medicinal product.
- In principle, the rapporteur(s) to be appointed should be member(s) or alternate(s) who have not acted as Scientific Advice coordinator for the same product. Exceptions to this approach could be justified in case that no other member or alternate with a comparable or equally adequate expertise for that product is available. However, this exception may be applied only in relation to either the rapporteur or to the co-rapporteur of the procedure at issue, to guarantee that at least one of them has not acted in the past as Scientific Advice coordinator for the same product.
- Members and alternates from the concerned committees are invited to indicate their interest in (co-)rapporteurships.
- The committee Chairperson in consultation with the Chairperson of other involved committees will decide on the final rapporteur/co-rapporteur and their assessment team appointment as applicable.

- The (co-)rapporteurs are bound by the EMA Rules on the handling of competing interests.[2]
- For any scientific evaluation in respect of an application submitted under the centralised procedure, the following shall be appointed:

Procedure	CHMP rapporteur	CHMP co-rapporteur	PRAC rapporteur	PRAC co-rapporteur
Full application	Delegation A	Delegation B	Delegation X	Delegation A
Similar biological medicinal product	Delegation A	Delegation B[3]	Delegation of reference product	-
Generics	Delegation A	-	Delegation of reference product[4]	-
Hybrids	Delegation A	On a case-by-case basis	Delegation of reference product	-
Ancillary medicinal substances in medical devices	Delegation A	Delegation B	-	-
Companion diagnostics	Delegation A[5]	-	-	-

- For initial applications for ATMPs, the rapporteur and co-rapporteur are appointed from the CAT, following the same appointment process. In such cases, two CHMP Coordinators are appointed from the same Delegation as the CAT rapporteur and co-rapporteur.

5.1.2. Additional principles for generics/hybrids

The following additional principles are considered for the appointment of rapporteurs/co-rapporteurs and their assessment teams:

Appointment of CHMP rapporteur/co-rapporteur

- The scope of these rapporteurships shall relate to the pre-authorisation phase and the introduction of quality changes in the post-authorisation maintenance.
- In order to ensure and facilitate consistency in the scientific evaluation/post authorisation maintenance of the medicinal products concerned, in the event that more than one application is received for a generic product with the same active substance, priority should be given to the appointment of the CHMP rapporteur in accordance with the following principles:
    - The same rapporteur for applications based on the same dossier.

[2] European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (Policy 44).
[3] As of March 2025, the Agency is piloting the appointment of a single rapporteur for certain biosimilar applications (see EMA pre-authorisation procedural advice for user of the centralised procedure, Q 2.4.2.3).
[4] Depending on the regulatory route of authorisation of the reference medicinal product – see table in section 5.1.2.
[5] Prioritisation of the CHMP/CAT rapporteur(s) of the concerned medicinal product(s) followed by the co-rapporteur(s). In case none is available, the rapporteurship is opened to all NCAs.

    - The same rapporteur for another generic with the same active substance.
- For several different generic applications with the same active substance, a group of rapporteurs shall be identified following the principles outlined above. Ideally, this group shall consist of three to four CHMP members, depending on the number of applications received.
- In case information about the same bioequivalence study used in several generic applications becomes available after the appointment of different rapporteurs, the appointment of rapporteurs should be reconsidered. The first appointed rapporteur for the concerned generic products will be considered for rapporteurship for all generic products with the same bioequivalence study.

Appointment of PRAC rapporteur

- For pharmacovigilance surveillance activities of generic/hybrid medicinal products, a PRAC rapporteur shall be appointed.
- Where the reference medicinal product is a centrally authorised product, the PRAC rapporteur shall be the same as the one previously appointed for the reference medicinal product.
- Where the reference medicinal product is not centrally authorised, the appointment of the PRAC rapporteur will depend on the regulatory route of authorisation of the reference medicinal product (see table below).

Reference medicinal product	PRAC rapporteur
Centrally authorised medicinal product	Shall be the same as the previously appointed rapporteur for the reference medicinal product.
Product authorised through a Mutual Recognition/ Decentralised procedure (MRP/DCP)/National procedure	Shall be the PRAC member who has the lead of the active substance assessment in the EURD list or the 'list of substances and products subject to worksharing for signal management'.

- In order to enable/facilitate consistency in the pharmacovigilance monitoring/processing and follow-up of the medicinal product(s) concerned, in the event that more than one application is received for a generic product with the same active substance, the same PRAC rapporteur shall normally be appointed for the same active substance(s).

5.2. Objective criteria

The appointment of rapporteurs/co-rapporteurs and their assessment teams shall be made on the basis of objective criteria, which will ensure the provision of objective scientific opinions and will allow the use of the best and available expertise in the EEA in the relevant scientific area.

The objective criteria outlined in this paper are identified as:

- **Ability of rapporteur/co- rapporteur to fulfil their role**, which refers mainly to their ability to take responsibility for the scientific assessment/evaluation undertaken by the assessment team, coordination input etc.
- **Assessment team objective criteria** which refer to the scientific competence, regulatory experience, complementary cross-team scientific expertise and competence of the assessment team(s).

- **Individual objective criteria**[6] which refer to the academic expertise, practical working experience and competence of the:
  - Individual assessor(s)/expert(s).
  - Rapporteur/co-rapporteur (when acting as assessor/expert in the scientific assessment of the application).

5.2.1. Assessment team objective criteria

The following assessment team objective criteria shall be taken into consideration on the appointment of the rapporteur/co-rapporteur assessment team(s):

- **Scientific competence** of the team(s) in the handling of particular aspects of the MAA, in addition to the scientific competence aspects considered in the quality, safety and efficacy, such as:
  - Methodological/statistical aspects.
  - Risk management/pharmacovigilance aspects.
  - Environmental risk toxicity.
- **Regulatory experience** such as:
  - Experience in the review of dossiers, preparation and provision of assessment reports for central and/or national applications in the relevant scientific area.
  - Ability to deliver assessment reports on time and in accordance with templates and timetables agreed and adopted by the committee, and/or specified for the particular procedure(s) as defined in the European Pharmaceutical Legislation.
- **Sufficient cross-team complementary expertise:**

  The need for additional input from (external/internal) assessors/experts during the assessment and/or in the post-authorisation phase should be transparent and their scientific/regulatory competence should be ensured, since they will be part of the assessment team (see also Section 5.1 of this paper, 'Principles').
- **Quality Assurance System (QAS)**

  Availability of an adequate QAS ensuring an optimal quality of the scientific assessment and also regulatory consistency.

5.2.2. Individual objective criteria

- Individual objective criteria shall be taken into consideration for the appointment of rapporteur/co-rapporteur and their assessment team(s).
- Individual assessor(s)/expert(s) should have specific and in-depth scientific expertise and competence. Direct working experience in the relevant scientific area and regulatory experience are preferable (see Annex 1 of this paper).
- The competence of the individual assessor(s)/expert(s) should address, as appropriate, aspects of the quality, safety, efficacy and pharmacovigilance, as applied to the medicinal products. Sufficient

[6] The main criteria are the overall competence (scientific/regulatory) of the team to handle the scientific assessment and the Quality Assurance System of the NCA.

cross team complementary experience should be taken into consideration (as described above in Section 5.2.1. of this paper).

5.2.3. Proposed assessment teams with similar objective criteria

In case of proposed assessment teams with similar objective criteria (scientific competence and availability), the following criterion will be used: even distribution based on a statistical overview, taking into account other procedures as well.

5.3. Methodology

The methodology for the appointment of rapporteurs and co-rapporteurs is detailed in this procedural advice. The timing of such appointment shall be as follows:

Type of products	Initiation of appointment procedure	Appointment of rapporteur/co-rapporteur
Full Marketing Authorisations, similar biologicals	At the earliest 7 months prior to the intended MAA submission date	At the earliest 6 months prior to the intended MAA submission date
Generics/Hybrid	3-7 months prior to the intended MAA submission date	2-6 months prior to the intended MAA submission date

6. Rapporteurship appointments for re-examinations

6.1. Additional principles

- **A different CHMP/CAT rapporteur and, where necessary, a different CHMP co-rapporteur** from those appointed for the initial evaluation shall be appointed in order to assess the grounds for the re-examination of the CHMP opinion. These rapporteurs will coordinate the evaluation for the duration of the re-examination procedure only.
- For procedures where the co-rapporteur was not involved in the evaluation, no co-rapporteur for the re-examination shall be appointed.
- The appointed **PRAC rapporteur** will normally also act as rapporteur for the re-examination, unless the grounds for refusal specifically concern issues of risk management or in case of post-authorisation procedures led by the PRAC, where a different PRAC rapporteur will be appointed. In such cases, the PRAC rapporteur will be from the same delegation as the CHMP re-examination rapporteur.
- Regarding re-examination requests for **referrals assessed by the PRAC under Article 31 of Directive 2001/83/EC**, a **different** PRAC rapporteur and where necessary, a different co-rapporteur from those appointed for the initial evaluation shall be appointed in order to assess the grounds for the re-examination of the PRAC recommendation.
- The principles outlined in section 5 of this paper shall apply.
- The objective criteria as discussed in the relevant sections of this paper shall apply.

6.2. Specific methodology

- The rapporteur, co-rapporteur (if applicable) appointment process will be initiated as soon as the EMA/CHMP/PRAC receive written notice that the applicant/MAH wishes to request a re-examination of the CHMP opinion/PRAC recommendation.
- Strict timeframes apply as there is no clock stop in the re-examination procedure and the maximum timeframe is 60 days.

7. Rapporteurship appointments for referral procedures

7.1. Additional principles

Due to the particularities of the referral procedures (such as non-predictability of a referral notification), with consequences on the workload and availability of CHMP, CAT and PRAC members and alternates, the following additional principles shall be considered for the appointment of CHMP/CAT/PRAC rapporteur/co-rapporteur.

7.1.1. Referrals assessed by CHMP

The principles outlined in sections 5.1 and 5.2 of this paper shall apply, in addition to the following ones:

- Normally, for the scientific evaluation in respect of a referral procedure, a CHMP rapporteur and a CHMP co-rapporteur shall be appointed.
- In the case of class referrals involving several active substances, a lead rapporteur and more than one co-rapporteur could be appointed. The role of the lead rapporteur would primarily be to prepare an overall Assessment Report, considering all active substances, and taking into account the assessment reports from each co-rapporteur.
- In line with the principle of impartiality, the rapporteur(s) to be appointed shall, where possible, be members or alternates from Member States that have not adopted a decision on the same subject matter(s) identified in the referral notification (or in the request for opinion, in case of procedures under Article 5(3) of Regulation (EC) No 726/2004), and/or are not involved in court proceedings related to the same subject matter(s) identified in the notification (or request for opinion). The foregoing does not apply to referral procedures initiated under Article 13 of Commission Regulation (EC) No 1234/2008, Article 29(4) of Directive 2001/83/EC and Article 29 of the Paediatric Regulation (EC) No 1901/2006.

  The paragraph above also applies to the appointment of (co-)rapporteur in re-examinations for referral procedures, where applicable.

  For the purpose of the above, 'Decision' means any formal act adopted by a national competent authority before the start of the referral procedure, affecting negatively the status of a marketing authorisation of a medicinal product involved in the referral procedure. For example, a decision refusing the granting of the marketing authorisation(s), a decision not renewing the marketing authorisation(s), a decision on the suspension/revocation of the marketing authorisation(s) or a decision to remove indication(s). Temporary measures taken in the course of the referral procedures are not considered as 'decisions'.

'Same subject matter(s) identified in the referral notification' means any scientific issue concerning the quality, safety and/or efficacy raised in the referral notification and involving the same medicinal product(s) covered in the referral procedure.

'Temporary measure' means the actions taken by Member States at any stage of the referral procedure, in exceptional cases, where urgent action is necessary to protect public health and until a definitive decision is adopted at EU level through the adequate referral procedure.

- The following shall be considered for the appointment of CHMP rapporteur/co-rapporteur as per the particular referral procedure:

Article	Rapporteur	Co-rapporteur
Article 13 of Commission Regulation (EC) No 1234/2008	CHMP member from the Reference Member State	CHMP member from a concerned (divergent) Member State
Article 20 of Regulation (EC) No 726/2004	Priority given to the CHMP rapporteur already identified for the CAP(s)[7]	Priority given to the CHMP co-rapporteur already identified for the CAP(s)[7]
Article 29(4) of Directive 2001/83/EC	CHMP member from the Reference Member State	CHMP member from a concerned (divergent) Member State
Article 29 of the Paediatric Regulation (EC) No 1901/2006	Open to all CHMP members	Open to all CHMP members
Article 30 of Directive 2001/83/EC	Open to all CHMP members	Open to all CHMP members
Article 31 of Directive 2001/83/EC	Open to all CHMP members	Open to all CHMP members
Article 5(3) of Regulation (EC) No 726/2004	Open to all CHMP members	Open to all CHMP members

- The CHMP Chairperson will decide on the final appointment of rapporteur/co-rapporteur.
- If no CHMP member volunteers in the rapporteur/co-rapporteur appointment procedure, the CHMP Chairperson will propose the CHMP rapporteur/CHMP co-rapporteur.

7.1.2. Safety referrals assessed by PRAC: Urgent Union procedures (Article 107i), Article 31 Pharmacovigilance and Article 20 Pharmacovigilance

The principles outlined in sections 5.1 and 5.2 of this paper shall apply, in addition to the following ones:

- Normally, for the scientific evaluation in respect of such referral procedures, a PRAC rapporteur and a PRAC co-rapporteur shall be appointed.
- In the case of class referrals involving several active substances, a lead rapporteur and more than one co-rapporteur could be appointed. The role of the lead rapporteur would primarily be to

[7] If more than one CAP is involved, the CHMP referral (co-)rapporteur should be appointed from amongst the CHMP (co-)rapporteurs for the CAPs involved in the referral. Note: In case the referral procedure is not product specific, the CHMP Chairperson may advise to open rapporteurship to all CHMP members.

prepare an overall Assessment Report, considering all active substances, and taking into account the assessment reports from each co-rapporteur.

- In line with the principle of impartiality, the rapporteur(s) to be appointed shall, where possible, be members or alternates from Member States that have not adopted a decision on the same subject matter(s) identified in the referral notification and/or are not involved in court proceedings related to the same subject matter(s) identified in the referral notification.

  The paragraph above also applies to the appointment of (co-)rapporteur in re-examinations for referral procedures, where applicable.

  For the purpose of the above, the same definitions provided in section 7.1.1 shall apply.

- The following shall be considered for the appointment of PRAC rapporteur/co-rapporteur as per the particular referral procedure:

Article	Rapporteur	Co-Rapporteur
Article 20 of Regulation (EC) No 726/2004	Priority given to the PRAC rapporteur already identified for the CAP(s)[8]	Priority given to the PRAC co-rapporteur already identified for the CAP(s)[8]
Article 31 of Directive 2001/83/EC	Open to all PRAC members	Open to all PRAC members
Articles 107i of Directive 2001/83/EC	Open to all PRAC members	Open to all PRAC members

- The PRAC Chairperson will decide on the final appointment of PRAC rapporteur/co-rapporteur.
- If no PRAC member volunteers in the rapporteur/co-rapporteur appointment procedure, the PRAC Chairperson will propose the PRAC rapporteur/PRAC co-rapporteur.

7.2. Specific methodology

- Normally, the CHMP or PRAC rapporteur/co-rapporteur appointment process (as applicable) will be initiated as soon as the EMA/CHMP/PRAC receive the referral notification.
- In case the referral notification is received during a CHMP/PRAC meeting and depending on the urgency of the matter (e.g. notification of safety issue(s)), the CHMP or PRAC rapporteur/co-rapporteur appointment process may take place during such meetings (as applicable).

7.3. Appointment of rapporteurs for re-examinations of referral procedures

- For referrals procedures, re-examination requests are foreseen for referrals under Articles 29(4), 30, 31 of Directive 2001/83/EC, for Article 13 of Commission Regulation No 1234/2008 and Article 29 of the Paediatric Regulation (EC) No 1901/2006 only.
- The procedure for the re-examination of a referral is mentioned in sections 6.1 and 6.2 of this document.

[8] If more than one CAP is involved, the PRAC referral (co-)rapporteurs should be appointed from amongst the PRAC (co-)rapporteurs for the CAPs involved in the referral. Note: In case the referral procedure is not product specific, the PRAC Chairperson may advise to open rapporteurship to all PRAC members.

8. Rapporteurship appointments for signals

8.1. Additional principles

Type of product	Rapporteur
Centralised products	PRAC rapporteur as identified for the centralised product
Nationally authorised products	PRAC member/alternate from Member State identified in the List of active substances subject to worksharing for signal management or in the List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs)
Nationally authorised products not included in the list or signals referring to a therapeutic class (either mix of centralised and nationally authorised products or nationally authorised products only)	Priority given to the PRAC Member from Member State who confirmed the signal[9] For signals referring to a therapeutic class, the appointed rapporteur can also be one of the identified PRAC rapporteurs for any centralised product or lead Member States identified for substances part of the List of active substances subject to worksharing for signal management

For products where no lead delegation has been identified (i.e. not included in the List of active substances subject to worksharing for signal management, signal including multiple CAPs and NAPs), the appointment of rapporteur will be confirmed at the first PRAC meeting at which the signal is discussed.

9. Rapporteurship appointments for PSURs/PSUSAs

9.1. Additional principles for CAP(s), CAP(s)/NAP(s), NAP(s)

Type of product	Rapporteur
For active substances as identified in the list of Union Reference Dates and frequency (EURD) list with Centrally Authorised products only	PRAC rapporteur as identified for the centralised product[10]
For active substances as identified in the list of Union Reference Dates and frequency (EURD) list with Centrally and Nationally Authorised products involved	Priority given to the rapporteur of the first approved centralised product[11]
For active substances authorised via NAP/MRP/DCP	CMDh is responsible for the appointment of a Lead Member State

[9] Subject to ability/availability of Member State to take on this role. In case of non-availability, open to all PRAC members.
[10] Where there is more than one CAP, priority is given to the rapporteur of the first approved centralised product.
[11] In case other members would express an interest in taking on the rapporteurship, the PRAC Chairperson will decide on the final appointment of rapporteur.

10. Rapporteurship appointments for imposed Post-Authorisation Safety Study (PASS) protocols and results

10.1. Additional principles

Type of product	Rapporteur
PASS protocol and results for a Centrally Authorised Product	PRAC rapporteur as identified for the centralised product
PASS protocol (and results) imposed as a result of a safety referral and conducted in more than 1 Member State	Priority will be given to the PRAC rapporteur for the referral
PASS protocol (and results) imposed by Member States and conducted in more than 1 Member State	Priority will be given to Member State that imposed the obligation on the MAH

For nationally authorised products, including those authorised via MRP/DCP, a PRAC rapporteur will be appointed upon receipt of a PASS protocol submission. The name of the appointed PRAC rapporteur will be communicated to the Marketing Authorisation Holder during the EMA check (period defined between the submission and the start of the procedure).

11. Changes affecting the appointment of rapporteur/co-rapporteur

The following issues may be encountered and affect the appointment of rapporteur/co-rapporteur:

- **Applicant informs the EMA on a revised intended MAA submission date:**

  Applicant informs the appointed rapporteur/co-rapporteur and committee secretariat in writing.

  If appointed rapporteur and/or co-rapporteur and their assessment teams are no longer available, a new appointment procedure shall take place.

- **A previously withdrawn MAA is re-submitted:**

  A new appointment procedure of rapporteur/co-rapporteur shall take place.

  Note: There is no automatic link to the previously appointed rapporteur/co-rapporteur and their assessment teams for such MAA.

- **Member State appointed member informs the Committee, at any time, that she/he is no longer available as rapporteur/co-rapporteur for the assessment:**

  Normally, the rapporteurship will be taken over by the successor committee member or by his/her alternate to work with the previously identified assessment team.

  If this is not feasible, then a new appointment procedure of rapporteur/co-rapporteur and her/his assessment team shall take place.

- **Co-opted member (CHMP) informs the committee, at any time, that she/he is no longer available as rapporteur/co-rapporteur for the assessment:**

Co-opted member affiliated to an EEA NCA:

The EEA NCA to identify a member/alternate to take over the responsibility for (co-)rapporteurship and to work with the previously identified assessment team. The committee shall confirm this appointment.

Co-opted member not affiliated to an EEA NCA:

The appointment procedure of rapporteur/co-rapporteur and her/his assessment teams shall take place.

- **Independent scientific expert (PRAC) informs the committee, at any time, that she/he is no longer available as rapporteur/co-rapporteur for the assessment:**

  The appointment procedure of rapporteur/co-rapporteur and her/his assessment teams shall take place.

12. References

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001
- CMDh standard operating procedure on the processing of PSUR single assessment procedures for nationally authorised products (CMDh/322/2014)
- EMA policy on the handling of competing interests of scientific committees' members and experts (Policy/0044)

Abbreviations

- AHEG Ad-Hoc Expert Group
- ATMPs Advanced Therapy Medicinal Products (ATMPs)
- CAP(s) Centrally Authorised Product(s)
- CAT Committee for Advanced Therapies
- CHMP Committee for Medicinal Products for Human use
- PRAC Pharmacovigilance Risk Assessment Committee
- CMDh Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human
- DCP Decentralised procedure
- EEA European Economic Area
- EU European Union
- MAA Marketing Authorisation Application
- MAH Marketing Authorisation Holder
- MRP Mutual Recognition Procedure
- NAP(s) Nationally Authorised Product(s)
- NCA National Competent Authority
- PhV PharmacoVigilance
- PSURs Periodic Safety Update Report(s)
- PSUSAs Periodic Safety Update Report Single Assessment(s)
- PASSs Post-Authorisation Safety Studies
- QAS Quality Assurance System
- RMS Reference Member State
- SAGs Scientific Advisory Groups
- WP Working Party

Annex 1

Individual objective criteria to be taken into consideration for the appointment of the rapporteur/co-rapporteur and their assessment teams

Individual objective criteria

The following Individual Objective Criteria should be considered for the appointment of the assessor(s)/expert(s):

- **Academic expertise** in the relevant scientific area, such as:

  Internationally recognised academic qualification(s) /accreditation(s) (e.g. Degrees, Diplomas, Post Graduate Qualifications (e.g. PhD), Professional Affiliations etc.)

  Delivering scientific expert views/opinions to National/European/International scientific bodies

- **Direct working experience** in the relevant scientific area, such as:

  Clinical Co-ordinator/Investigator in clinical trials

  Clinical expertise (e.g. specialisation) in the relevant area

  Pre-clinical research and expertise (e.g. in toxicology, pharmacology)

  Scientific research (e.g. in epidemiological studies, animal studies etc.)

  Research in the relevant "quality" areas, relating to the research and development of medicinal products (e.g. molecular biology, gene technology etc.)

  Formulation, manufacture and control of medicinal products

  Inspection (GXP inspections)

  Pharmacovigilance and Risk Management

  Targeted Publications in recognised and peer-reviewed scientific journals

  Peer Reviewing activities for scientific journals

  Advisory experience in committees'/scientific bodies' activities (e.g. experience in providing scientific advice for central and/or national MAs, involvement in WHO, EDQM, FDA activities etc.)

  Previous involvement in EU Commission activities, such as receipt of grants within the Framework Programs leading for example to publication in well recognised scientific journals

  Regulatory experience such as writing Assessment Reports, participating in Scientific Advice etc.

  Medical Device

  Regulatory experience with assessment of non-prescription medicinal product or in changes of the legal status of a medicine from prescription to non-prescription

  experience in communication with patients

Annex 2

Appointment of PRAC rapporteur: centralised marketing authorisation applications

The PRAC rapporteur and co-rapporteur will be appointed at the same time as the CHMP rapporteur and co-rapporteur, if possible.

The following principles apply:

For Initial marketing applications

	CHMP	**PRAC**
Rapporteur	**Delegation A**	**Delegation X**
Co-rapporteur	**Delegation B**	**Delegation A**

For re-examination procedures

	CHMP	**PRAC**
Rapporteur	**Delegation C**	**Delegation X**[12]
Co-rapporteur	**Delegation D**	**Delegation A**

[12] Same as per the initial marketing authorisation application, unless the grounds for refusal specifically concern issues of risk management.