

Pharmacovigilance Risk Assessment Committee

RULES OF PROCEDURE

Directive 2001/83/EC and Regulation (EC) No 726/2004 (hereafter also referred to as the 'Regulation' and 'Directive'), lay down specific rules concerning the pharmacovigilance of medicinal products for human use and set up the Pharmacovigilance Risk Assessment Committee (PRAC) or 'the Committee'.

Article 55 of the Regulation establishes the European Medicines Agency with the responsibility for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The PRAC shall be responsible for providing recommendations to the Committee for Medicinal Products for Human Use and the coordination group on any question relating to pharmacovigilance activities in respect of medicinal products for human use and on risk management systems and it shall be responsible for monitoring the effectiveness of those risk management systems (Article 56(1) of the Regulation and Article 27 of the Directive).

The mandate of the PRAC shall cover all aspects of the risk management of the use of medicinal products for human use including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product for human use, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit.

Since the PRAC is part of the Agency, the Integrated Quality Management System, endorsed by the Agency Management Board on 11 March 2004, applies to the PRAC, its working parties and scientific advisory groups.

Each national competent authority shall monitor the level and independence of the evaluation carried out and facilitate the activities of nominated members and experts. Member States shall refrain from giving PRAC members and experts any instruction, which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.

Having regard to Article 61(8) of Regulation (EC) No 726/2004;

Having regard to Directive 2001/83/EC;

¹ Following the inclusion of the possibility to host virtual committee meetings in non-emergency situations, the possibility to participate through a remote connection to an in-person meeting in emergency situations, clarifications on the voting rules for chair and vice-chair elections, rewording of absolute majority, proxies for EEA-EFTA members and the possibility to hold oral explanations in person or virtually.



Having regard to Commission Implementing Regulation (EU) No 520/2012;

Having regard to the Decision of the EEA Joint Committee No 158/2013 of 8 October 2013 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement;

Having consulted the European Commission and the Management Board of the Agency on the basis of Article 61(8) of Regulation (EC) No 726/2004;

The PRAC adopts the following Rules of Procedure:

Composition

Article 1

1. The PRAC consists of:
 - a Chair;
 - one member and one alternate member appointed by each of the EU Member States;
 - one member and one alternate member appointed by each of the EEA-EFTA States;
 - six members appointed by the European Commission, with a view to ensuring that the relevant expertise is available within the PRAC, including clinical pharmacology and pharmacoepidemiology, on the basis of a public call for expressions of interest;
 - one member and one alternate member appointed by the European Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals;
 - one member and one alternate member appointed by the European Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.
2. All members and alternate members of the PRAC shall be appointed on the basis of their relevant expertise in pharmacovigilance matters and risk assessment of medicinal products for human use, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. For this purpose, Member States shall liaise with the Management Board and the European Commission in order to ensure that the final composition of the PRAC covers the scientific areas relevant to its tasks.
3. The members and the alternates, as appropriate, of the PRAC shall be appointed for a term of 3 years which may be prolonged once. After this second term and thereafter, appointment should be renewed following the appointment procedure as described in Article 61a of Regulation 726/2004 and could be prolonged once more.

Responsibilities of Chair and Vice-Chair

Article 2

1. The Chair, and in his/her absence the Vice-Chair, in close collaboration with the EMA Secretariat, is responsible for the efficient conduct of the business of the PRAC and shall in particular:
 - plan the work of the PRAC meetings;
 - monitor, with the EMA Secretariat, that the Rules of Procedure are respected;

- ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the PRAC;
 - aim to achieve consensus on issues discussed by the PRAC;
 - decide when a vote is necessary;
 - consult the PRAC to assess if oral explanations and/or public hearings may be necessary;
 - ensure, together with the PRAC, the regulatory, scientific consistency and high quality of the PRAC's recommendation/advice;
 - ensure and judge that scientific grounds are adequately reflected in the PRAC's recommendation/advice;
 - co-ordinate the work of this PRAC with that of the other Committees of the Agency and the CMDh.
2. The Vice-Chair will deputise for the Chair when the latter is unable to chair either all or part of the PRAC meeting. On such occasions the Chair will seek the agreement of the Vice-Chair as early as possible, prior to the meeting and the EMA Secretariat shall be informed immediately.
 3. If the Vice-Chair takes the Chair, his/her place and vote will be assigned to his/her alternate.

Election of Chair and vice Chair

Article 3

1. The Chair and Vice-Chair of the PRAC shall be elected by and from amongst its members for a term of three years, which may be prolonged once.
Without prejudice to paragraph 5 of the present Article, the Chair may be elected for a second mandate if a nomination for a prolonged term is submitted before the end of his/her first mandate.
2. Nominations for Chair and Vice-Chair should be submitted in writing to the EMA secretariat no later than the start of the PRAC's meeting at which the election is to take place. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.
3. The election of the Chair and the Vice-Chair shall be by absolute majority of the members (i.e. favourable votes by more than half of the total number of PRAC members eligible to vote) and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. If there is a tie amongst the candidates with the lowest number of votes, all tied candidates are eliminated, and a further voting round is organised with the remaining candidate(s) only. In the case of a tie when only two candidates remain, a new voting round is organised with these two remaining candidates. If, during the new round, the candidate with the highest number of votes does not get an absolute majority, a further voting round is organised with this candidate only. If there is only one (remaining) candidate, she/he needs favourable votes from more than half of the total number of PRAC members eligible to vote, to be elected Chair or Vice-Chair, as the case may be. If the remaining candidate(s) do(es) not get an absolute majority, the election is annulled, and a new election is convened for the next scheduled meeting of the PRAC following the same procedure as stated in paragraphs 2 to 3 of the present Article.
4. The members appointed by the EEA-EFTA States may not vote nor be elected Chairperson or Vice-Chair of the Committee.
5. Once a Chair has been elected, the Chair shall lose her/his vote as member from the start of the mandate as Chair. If a member is elected as Chair, the Member State or, as appropriate, the European Commission who appointed her or him will appoint a new member of the PRAC.

6. In the event of resignation of the Chair, the Vice-Chair shall take the Chair until a new election is convened.

Alternates to nominated PRAC members

Article 4

1. Alternates shall represent and vote for the nominated member in the absence of the member, when he/she is not in attendance at the meeting.
2. They may act as rapporteurs, with the exception of alternates representing healthcare professionals and patient organisations. At the request of the member, the alternate may respond on behalf of the member in case of written procedures or any request for urgent advice from members between meetings.
3. Alternates may not be elected as Chair or Vice-Chair of the PRAC, but may vote for the election of the Chair or Vice-Chair in the absence of the member.

Delegation of tasks

Article 5

1. A Member State may delegate its tasks in the PRAC to another Member State. Each Member State may represent no more than one other Member State.
2. Delegation is subject to mutual agreement between two Member States.
3. The delegation period will run for an unlimited period until the Member State withdraws it.
4. Delegation can be withdrawn at any time and a Member State always retains the right to withdraw the delegation and take up its tasks at the PRAC itself at any given time.
5. A delegate representing another Member State in the PRAC will have two votes and will be counted as two present members.

Rapporteur and Assessment Team

Article 6

1. For specific activities listed under Article 7 of these Rules of Procedure, a (Co)-Rapporteur (hereafter referred to as PRAC rapporteur) shall be appointed by the PRAC from amongst its members or alternates in accordance with Articles 61a(1) and 62(1) of Regulation (EC) No 726/2004. The appointment of the rapporteur shall be made on the basis of objective criteria.
2. The role of the PRAC rapporteur is to prepare a recommendation or an advice, as applicable, together with an assessment report, if appropriate, on the relevant issue raised to the PRAC according to the timetable agreed for the procedure, taking into account the timeframe laid down in the relevant legislation. The PRAC rapporteur shall closely collaborate with the CHMP rapporteur or the CMDh lead Member State/RMS for the medicinal product for human use as appropriate.
3. Whenever meetings between the PRAC rapporteurs and applicants or marketing authorisation holders take place, minutes of all contacts shall be made available to the PRAC and the EMA Secretariat. For centrally authorised products, whenever possible, CHMP rapporteurs/co-rapporteur and EMA Secretariat should participate in such meetings. For nationally authorised products,

whenever possible, the CMDh lead Member State/RMS and EMA Secretariat should participate in such meetings.

Contacts by other members and alternates with applicants and marketing authorisation holders in the context of the procedures conducted at the level of the PRAC are not considered appropriate prior to adoption of a recommendation /advice and should be avoided during assessment procedures. Should such contacts take place, these shall be reported to rapporteurs and to the EMA.

4. In relation to the specific activities of the PRAC, listed under Article 7 of these Rules of Procedure (resulting in a recommendation / advice), rapporteurs may establish contacts on an advisory basis, with representatives of patient organisations and relevant health-care professionals' associations. Any such contacts should be organised in liaison with the EMA Secretariat with the prior agreement of the PRAC. The EMA rules for involvement of members of patients'/consumers' and healthcare professionals' organisations in committees related activities will apply. The rapporteur should provide a report on the outcome of such contacts to the PRAC and it should be reflected in the assessment report.
5. For centrally authorised products, the provision of services by rapporteurs or experts shall be governed by a written contract between the Agency and the person concerned, or where appropriate, between the Agency and his/her employer. The person concerned, or his/her employer, shall be remunerated in accordance with a scale of fees to be included in the financial arrangements established by the Management Board.
6. The PRAC may consult the relevant scientific advisory group if the need arises for a specific product without prejudice of the legal deadlines established. In such case the draft assessment report prepared by the PRAC rapporteur, where appropriate, shall be forwarded to the scientific advisory group for advice in accordance with the procedure to be agreed by the PRAC. The PRAC may consult the relevant EMA working parties and/or relevant experts from the European expert list as appropriate.
7. The format of the assessment report/advice shall be agreed by the PRAC in close collaboration with the EMA Secretariat.

Tasks of the PRAC

Article 7

1. The mandate of the PRAC shall cover all aspects of the risk management of the use of medicinal products for human use including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product for human use, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit.
2. The PRAC is responsible for providing recommendations to the CHMP and the CMDh on any question relating to pharmacovigilance activities in respect of medicinal products for human use and on risk management systems, including the monitoring of the effectiveness of those risk management systems. In addition, the PRAC is responsible for providing advice either to the CHMP, CMDh, EMA Secretariat, Management Board and European Commission, as applicable.
3. In practice this means:
 - 3.1. PRAC tasks common to both centrally and non-centrally authorised products:

- (i) For urgent Union procedures, Article 31 and Article 20 procedures triggered for safety reasons: the PRAC shall issue a recommendation.
- (ii) For PSUR single assessment: the PRAC shall issue a recommendation.
- (iii) For PASS protocols: the PRAC shall issue a letter of endorsement or objection.
- (iv) For PASS study results: the PRAC shall issue a recommendation.
- (v) For signals: the PRAC shall issue a recommendation.
- (vi) For the establishment and subsequent updating of the list of EU Reference Dates (EURD) and the frequency of PSURs submission: the PRAC shall be consulted.
- (vii) For the updating of the list of medicinal products requiring additional monitoring: the PRAC shall be consulted.
- (viii) For “for cause” pharmacovigilance inspections: the PRAC shall issue an advice.

3.2. PRAC tasks specific to centrally authorised products:

- (i) For risk management plans/systems: the PRAC shall issue an advice.
- (ii) For PSURs for individual centrally authorised products: the PRAC shall issue a recommendation.
- (iii) For renewals, annual re-assessments: the PRAC shall issue an advice.
- (iv) For safety type II variations: the PRAC may issue an advice, at the request of the CHMP.

3.3. PRAC tasks specific to non-centrally authorised products:

- (i) For PSUR single assessment: the PRAC shall issue a recommendation.
- (ii) For risk management plans/systems, renewals, safety type II variations: the PRAC may issue an advice, at the request of a Member State.
- (iii) For Member States’ safety announcements and communications: the PRAC shall issue an advice, at the request of the EMA Secretariat, on the timing and message content.

3.4. Other PRAC tasks:

- (i) For the functionalities of the EudraVigilance database and the PSUR repository: the PRAC shall issue an advice.
- (ii) For the choice of the black symbol for additional monitoring: the PRAC shall issue an advice.
- (iii) For literature ADR monitoring: the PRAC may issue an advice, at the request of the EMA Secretariat.

Scientific recommendations and advice

Article 8

1. The quorum required for the adoption of scientific recommendations/advice by the PRAC shall be reached when two thirds of the total members of the PRAC eligible to vote are present, either

directly or by nominated proxy. A member of the PRAC, or his/her alternate, may represent only one other member, when this member and his/her alternate is unable to participate in a meeting. The member that is being represented shall inform the PRAC Secretariat in advance. Pending appointments of members made by the European Commission shall not be taken into account for the purpose of determining the quorum. The votes shall be positive or negative (unless a member is unable to participate due to a declared conflict of interest).

2. Whenever possible, scientific recommendation/advice of the PRAC shall be taken by consensus. If such a consensus cannot be reached, the scientific recommendation/advice will be adopted if supported by an absolute majority of the members of the PRAC (i.e. favourable votes by more than half of the total number of PRAC members eligible to vote).
3. The names of the members expressing divergent positions shall be mentioned in the recommendation/advice of the PRAC and in the minutes of the PRAC. Members having divergent positions shall provide them in writing, stating clearly the reasons on which they are based. The reasons for the divergent positions shall be publicly available together with the documentation made publicly available in relation to the PRAC's recommendation/advice.
4. The members from the EEA-EFTA States may participate to the meeting either directly or by nominated proxy given to another EEA-EFTA member. They may not vote but their positions (given either directly or by nominated proxy) shall be stated separately in the recommendations and advice of the PRAC and, where relevant, in the minutes of the PRAC and in case of divergent positions appended to the PRAC recommendations and advice. Their position is not taken into consideration for the purpose of counting the votes for the adoption of the PRAC conclusions.
5. In the event of no absolute majority position in favour of the concerned recommendation/advice, the PRAC's recommendation/advice is deemed to be negative.
6. For Referral procedures in accordance with Directive 2001/83/EC (including article 107i procedures) and with Article 20 of Regulation (EC) No 726/2004 if the PRAC cannot achieve a majority vote in support of the question(s) presented, the PRAC's recommendation will be to maintain the initial regulatory position.

Procedure for urgent adoption of recommendations

Article 9

1. In some instances, it may be necessary to take an urgent decision with regard to pharmacovigilance, serious concerns on public health or quality defects with impact on safety.

This may be done by:

- Adoption of a recommendation during the course of a scheduled meeting (using an accelerated timeframe if necessary), when the need for adoption of the urgent opinion /agreement on course of action has been identified during the course of the meeting (or within 48 hours before the meeting);
- The convening of an extraordinary meeting, if considered necessary and if feasible to organise within the necessary short timeframe. This meeting should take place in the presence of a quorum allowing the PRAC to adopt a recommendation i.e. when at least two thirds of the total members of the PRAC eligible to vote are available to participate (see also Article 8.1);
- Written procedure in accordance with Article 10 of the PRAC's Rules of Procedure.

2. The decision on the need for the adoption of an urgent recommendation outside of a scheduled PRAC meeting will be taken by the EMA Secretariat in discussion with the PRAC Chair. The procedure for the adoption of such urgent recommendation should be in line with the EU Regulatory network incident management plan.

Written procedure

Article 10

1. Draft recommendations/advice can, after approval of the Chair, be submitted by the EMA Secretariat to the PRAC for adoption by written procedure. However, such written procedures should be restricted to measures required to be taken between scheduled meetings.
2. Draft recommendations/advice are addressed to members of the PRAC, who may raise objections within a specified time period, to be established in agreement with the Chair. The EMA Secretariat shall present a full report on the outcome of the written procedure at the following meeting of the PRAC.
3. In the case of serious objections, the Chair decides whether the written procedure should be suspended and the adoption of the draft recommendation/advice postponed to the next meeting of the PRAC.

Re-examination

Article 11

In the event of a request for re-examination of one of its recommendation where this possibility is provided for in Union law (Article 31 of Directive 2001/83/EC), the PRAC shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the initial recommendation. The re-examination procedure may deal only with the points of the recommendation initially identified by the applicant/marketing authorisation holder and may be based only on the scientific data available when the recommendation was adopted. This re-examination shall be made by using the best endeavours to ensure a new examination, independent from the first opinion. The applicant/marketing authorisation holder may request that the PRAC consult a scientific advisory group in connection with the re-examination. In this case, the PRAC shall request the advice of additional available expertise.

Interaction with other Committees

Article 12

1. In accordance with Article 64(d) of Regulation (EC) No 726/2004, appropriate coordination between EMA scientific Committees needs to be ensured.
2. In view of the specific tasks of the PRAC, it is acknowledged that coordination with CHMP, CAT and CMDh is essential for the functioning of the PRAC.
3. For any assessment where a rapporteur has been appointed from the PRAC, he/she shall closely collaborate with the CHMP rapporteur or the CMDh leading Member State/RMS for the medicinal product for human use concerned.

4. PRAC, CHMP and CMDh Secretariats should liaise with each other prior to their monthly meetings to facilitate flow of information and coordination of the Committees' work.
5. Agendas and minutes of each of the above-mentioned Committees and CMDh should be made available to each other on a monthly basis.

Organisation of meetings

Article 13

1. The PRAC shall normally meet monthly at the Agency with the exception of the month of August during which no meeting is convened unless explicitly required. The PRAC may hold in-person or virtual meetings. In the event of virtual meetings, members participate through a remote connection. The meeting shall be convened by the Executive Director or his/her representative after consultation with the Chair.
2. The dates of meetings are decided on an annual basis in consultation with the PRAC. In exceptional circumstances and on motivated grounds agreed with the Chair, an extraordinary meeting may be convened at short notice.
3. The meetings will be held and minuted in English without interpretation.
4. The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMA Secretariat, in consultation with the Chair, at least 8 calendar days before the meeting.
5. In order to cope with situations of emergency, possibly coupled with the activation of the Agency's Business Continuity Plan in compliance with internal guidelines, the following rules shall apply:
 - 5.1. In case of in-person meetings, members who are prevented from participating in person, can participate through a remote connection. The quorum required for the adoption of scientific recommendations/advice by the PRAC shall be reached when an absolute majority of the members of the PRAC is present (i.e. more than half of the total number of members eligible to vote), either directly (in person or remotely) or by nominated proxy. The votes shall be positive or negative (unless the provision concerning the conflicts of interest is applied). The members from the EEA-EFTA States may participate to the meeting either directly or by nominated proxy given to another EEA-EFTA member.
 - 5.2. Whenever possible, scientific recommendations/advice of the PRAC shall be taken by consensus. If such a consensus cannot be reached, the scientific recommendation/advice will be adopted if supported by an absolute majority of the members of the PRAC (i.e. favourable votes by more than half of the total number of PRAC members eligible to vote). The members from the EEA-EFTA States may not vote but their positions (given either directly or by nominated proxy) shall be stated separately in the recommendations and advice of the PRAC and, where relevant, in the minutes of the PRAC and in case of divergent positions appended to the PRAC recommendations and advice. Their position is not taken into consideration for the purpose of counting the votes for the adoption of the PRAC conclusions.
 - 5.3. Members connected remotely can cast their votes remotely. In case a PRAC member/alternate temporarily faces difficulties to connect remotely, it is acceptable that his/her vote is cast via email to be sent before the voting is closed. In this latter scenario, the email must clearly indicate the member who is casting the vote, the product/procedure for which the vote is being cast and the matter that is being voted upon, as well as the vote cast (against or in favour). For transparency reasons, the vote cast by email shall be brought immediately to the attention of the Chair and other members/alternates of the PRAC.

Public Hearings

Article 14

1. Where the urgency of the matter permits, the PRAC may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern.
2. Where a marketing authorisation holder or another person intending to submit information has confidential data relevant to the subject matter of the procedure, the concerned party may request permission to present that data to the PRAC in a non-public part of the hearing. This type of request should be duly justified.
3. Hearings shall be indicated clearly in the draft agenda and timeschedule of the meeting.
4. The PRAC shall not make any conclusions during these public hearings.
5. The PRAC together with the EMA Secretariat will have to make it clear how the public contributions were taken into account in the decision-making process.

Oral Explanations

Article 15

1. The PRAC shall invite a marketing authorisation holder to provide oral explanations in person or remotely in connection with an evaluation procedure where requested by the marketing authorisation holder, unless urgent measures need to be adopted for reasons of public health. The PRAC may also invite, on its own initiative, a marketing authorisation holder to provide oral explanations in person or remotely. The oral explanation should normally be based on data submitted in advance and assessed by the Rapporteur. Exceptionally, other data to be presented at the oral explanation should be submitted in advance
2. Oral explanations shall be indicated clearly in the draft agenda and timeschedule of the meeting.
3. The PRAC shall not make any conclusions during these presentations in the presence of the company representatives or third parties.
4. The marketing authorisation holder is informed of the trend at PRAC level at the end of the scientific discussion ahead of any formal vote to conclude the evaluation process.

Transparency

Article 16

1. The names and scientific qualifications of the members and alternate members of the PRAC shall be published on the Agency's website together with their up to date Declaration of Interests.
2. Agendas and adopted minutes of the PRAC meetings shall be made publicly available at pre-defined monthly time points.
3. High level outcomes of the PRAC key recommendation/advice shall be published on a European medicines web-portal (created and maintained by the Agency) without undue delay after the PRAC meeting and in any case ahead of CHMP/CMDh meetings. On a case by case basis, additional documents to support communication may be made available.

4. Full scientific recommendations and advice of the PRAC shall be published on the European medicines web-portal together with final outcomes of CHMP/CMDh procedures.
5. When the PRAC is of the opinion that a public hearing should be convened, the hearing shall be held in accordance with the modalities and rules specified by the Agency and shall be announced by means of the European medicines web-portal. The announcement shall also specify the modalities of participation.

Working parties, scientific advisory groups and drafting groups

Article 17

1. Whenever considered appropriate, the PRAC may consult the Agency's working parties/scientific advisory groups/drafting groups on any scientific issue related to their field of expertise. The PRAC may also delegate certain tasks associated with drafting of guidelines to the relevant EMA working parties.
2. The recommendation from the EMA working parties/scientific advisory groups/drafting groups or other Committees shall be transmitted to PRAC for information/adoption.
3. The PRAC shall put in place measures to ensure that there is coordination of work and exchange of information between the PRAC and the EMA working parties.
4. Temporary working parties/drafting groups may be established, in consultation with the EMA Secretariat, when work of a temporary or ad hoc nature is required, such as preparation of proposals on a specific scientific topic, preparation of responses to specific questions raised by the PRAC, drafting of new guidelines, or revision of existing ones in relation to specific scientific fields

Participation of experts in meetings

Article 18

1. When necessary, the PRAC may avail themselves of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of medicinal products or in their field of expertise and be included in the European experts list.
2. Specialised experts included in the European experts list may be invited to support the PRAC in advice or recommendations regarding pharmacovigilance issues further to a proposal from the rapporteur, any member of the PRAC or the Agency and with the agreement of the PRAC in accordance with the procedure established by the PRAC.
3. In addition, members of the PRAC may be accompanied by the experts mentioned in paragraph 1 (at their own expense). The names of these experts shall be notified to the EMA Secretariat before the meeting which they are due to attend. This is also applicable for any experts attending a meeting virtually via telephone/web links.

Guarantees of independence

Article 19

1. The specific provisions for handling declaration of interests (DoIs) and confidentiality undertakings as defined in the EMA policy on the handling of competing interests of Scientific Committees'

members and experts are applicable to members of the Committee. The members and alternates of the PRAC shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality.

2. The members and alternates of the PRAC shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests or update when any new information appears. All indirect interests, which could relate to the pharmaceutical industry, shall be entered in a register held by the Agency which is accessible to the public, on request at the Agency's office.
3. The members and alternates of the PRAC are obliged to update their DoIs on an on-going basis when a new interest emerges and at least once a year.
4. Any incomplete and/or incorrect DoIs will be handled according to the Agency's breach of trust procedure on conflicts of interests for scientific committee members and experts.
5. The members and alternates of the PRAC (and experts attending these meetings) shall declare at the beginning of each meeting any other conflict of interest which has not yet been declared. These declarations shall be recorded in the minutes of the PRAC's meeting and DoIs shall be updated after the meeting to reflect these interests.
6. The members and alternates of the PRAC shall not accept from the Member States any instructions incompatible with the tasks incumbent upon them within the Agency. It is essential for these tasks to remain strictly scientific in nature.

Code of conduct

Article 20

Members of the PRAC participating in the EMA's activities shall abide by the principles set out in the EMA Code of Conduct.

EMA Secretariat

Article 21

1. Under the authority of the Executive Director, the EMA Secretariat shall provide technical, scientific and administrative support to the PRAC with a view to the performance of its duties as defined in Article 57 of Regulation (EC) No 726/2004. This includes in particular the following:
 - Provide technical and scientific support and expertise to rapporteurs, and other members of the PRAC concerning the tasks listed in Article 7 of these Rules of Procedure;
 - Provide legal and regulatory support to the PRAC and consulted EMA working parties, scientific advisory groups and drafting groups;
 - Prepare the content and make public information related to the activities of the PRAC such as press releases, public statements, Q&A documents and EPARs after consultation of the PRAC, where appropriate;
 - Evaluate declared interests of PRAC members and put in place risk mitigating measures prior to the start of each meeting;
 - Prepare and co-ordinate the work of the PRAC in consultation with the Chair;

- Ensure that the periods laid down by Union legislation for the adoption of the recommendations/advice are complied with;
 - Organise meetings of the PRAC, EMA working parties, scientific advisory groups and drafting groups, ensuring timely circulation of meeting documents;
 - Facilitate the necessary contacts between the PRAC, rapporteurs and applicants or persons responsible for the placing on the market of the product;
 - Ensure scientific and regulatory consistency of the recommendations/advice of the PRAC in co-operation with the Chair or Vice-Chair, as appropriate;
 - Prepare the minutes of the meetings in consultation with the Chair;
 - Communicate the relevant recommendations/advice of the PRAC to relevant stakeholders;
 - Communicate the views of the PRAC in international fora.
2. The Executive Director of the Agency, members of the EMA Secretariat, and representatives of the European Commission, may attend all meetings of the PRAC, its working parties, scientific advisory groups and drafting groups.

Contacts with interested parties

Article 22

1. The PRAC and its working parties will establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations. The PRAC may agree to invite representatives of such interested parties to address a plenary meeting.
2. Concept papers, draft guidelines and general regulatory developments will be subject to public consultation of all interested parties (industry, health care professionals, patients/consumers or other).
3. In any case, the PRAC and working parties shall not reach any formal decisions in the presence of members of interested parties.
4. Before any consultation session, interested party representatives and PRAC members will communicate to the EMA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the PRAC Chair and circulation by the EMA Secretariat.

International Co-operation between the PRAC and Regulatory Authorities/Health Institutions

Article 23

1. The PRAC may establish cooperation with other Regulatory Authorities/Health Institutions in compliance with the terms of the respective Confidentiality Agreements.
2. At the initiative of the European Commission and in agreement with the Management Board, the PRAC may admit representatives of international organisations with interests in the harmonisation of regulations applicable to medicinal products as observers to the PRAC and EMA working parties'

meetings or meetings arranged for this purpose to discuss topics of common interest. The conditions for participation shall be agreed beforehand by the European Commission.

3. For the purposes of regulatory cooperation, visiting experts or representatives from other regulatory authorities may also participate as observers to the PRAC and EMA working parties. Participation shall be agreed with the respective Chair in advance of the meeting.
4. The observers shall be bound by the rules of confidentiality mentioned in Article 26.

General Provisions

Article 24

For tasks incumbent on the Agency, other than those of evaluation, the PRAC may propose that the Agency has recourse to rapporteurs within the meaning of Article 6 paragraph 1 or to experts within the meaning of Article 18.

Article 25

The PRAC may if, they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.

Article 26

The members of the PRAC, EMA working parties as well as observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by professional secrecy.

Article 27

The decision to adopt or to amend these Rules of Procedure shall be taken by an absolute majority of the members of the PRAC (i.e. favourable votes by more than half of the total number of PRAC members eligible to vote).

Article 28

The Rules of Procedure or any amendment to them shall enter into force after receiving a favourable opinion from the European Commission and the EMA Management Board and will be made publicly available.

Adopted by the PRAC on 2 September 2021

Agreed by the Management Board on 7 October 2021

Agreed by the European Commission on 29 September 2021

Date of entry into force 18 October 2021