15 December 2016
EMEA/CHMP/SAWP/69686/04 Rev 12
Product Development Scientific Support Department

Mandate, objectives and rules of procedure of the Scientific Advice Working Party (SAWP)

1. General considerations

Having regard to Article 56(3) of European Parliament and Council Regulation (EC) 726/2004, which provides that *"The Executive director, in close consultation with the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use, shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in Article 57(1)(n), particularly regarding the development of new therapies. Each committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings."*

Having regard to Preamble (25): *"The field of activity of the scientific committees should be enlarged and their operating methods and composition modernised. Scientific advice for future applicants seeking marketing authorisation should be provided more generally and in greater depth. Similarly, structures allowing the development of advice for companies, in particular, small and medium-sized enterprises should be put in place ..."*

Having regard to Article 57(1) of European Parliament and Council Regulation (EC) 726/2004, which provides that *"the Agency, acting particularly through its committees, shall undertake the following tasks: (n) advising undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products"*;

Having regard to Article 58(1) and (2) of European Parliament and Council Regulation (EC) 726/2004 which provides that

> *(1) "The Agency may give a scientific opinion, in the context of cooperation with the World Health Organisation, for the evaluation of certain medicinal products for human use intended exclusively for markets outside the Community. For this purpose, an application shall be submitted to the Agency in accordance with the provisions of Article 6. The Committee for Medicinal Products for Human Use may, after consulting the World Health Organisation, draw up a scientific opinion in accordance with Articles 6 to 9. The provision of Article 10 shall not apply".*
>
> *(2) "The said Committee shall establish specific procedural rules for the implementation of paragraph 1, as well as for the provision of scientific advice."*

Having regard to Article 78(2) of European Parliament and Council Regulation (EC) 726/2004 which provides that *"The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that article shall in general matters establish contacts,*

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on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations. Rapporteurs appointed by these committees may, on an advisory basis, establish contacts with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product concerned."

Having regard to Recital 12 and Article 20 of the Regulation (EC) 1394/2007 and Article 51(1)(n) of the Regulation (EC) 726/2004, to ensure scientific consistency and the efficiency of the system, the Agency should ensure the coordination between the Committee for Advanced Therapies (CAT) and its other Committees, advisory groups and working parties, notably the Scientific Advice Working Party.

Having regard to Article 23 (g) of Regulation (EC) 1394/2007, the CAT shall "*contribute to the scientific advice procedures referred to in Article 16 of this Regulation and in Article 57(1)(n) of Regulation (EC) No 726/2004*".

Having regard to Article 6 of the Regulation (EC) No. 141/*2000 "The sponsor of an orphan medicinal product may, prior to the submission of an application for marketing authorisation, request advice from the Agency on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of the medicinal product, in accordance with [Article 51 (j) of Regulation (EEC) No 2309/93, as amended[1]]."*

The Committee for Medicinal Products for Human Use (CHMP) and the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) establish the Scientific Advice Working Party (SAWP) as a standing working party with the sole remit of providing scientific advice and protocol assistance to applicants[2].

[1] Article 51 (j) of Regulation (EEC) No 2309/93, as amended corresponds to article 57(1)(n) of Parliament and Council Regulation (EC) 726/2004

[2] Throughout the document the term applicant is used and encompasses sponsors, companies, enterprises, research institutes and WHO.

2. Objectives and mandate

As a main objective, the Scientific Advice Working Party shall provide scientific advice for medicinal products for human use and protocol assistance (i.e. scientific advice available for companies developing designated orphan medicines) to facilitate timely access of safe and efficacious medicinal products to patients and users of medicines by optimising Research and Development, reducing uncertainties in regulatory outcomes, and accelerating time to approval of a marketing authorisation application. Furthermore, the Scientific Advice Working Party will bring forward scientific advice to facilitate proactive pharmacovigilance planning, and integrated advice on safety, quality and efficacy through-out the lifecycle of the product. The SAWP shall therefore encourage Applicants to engage, as early as possible, in an ongoing dialogue with the Agency on the development of their product. The European Medicines Agency shall establish the best possible environment for the provision of scientific advice and protocol assistance, ensuring through its scientific committees flexibility towards applicants and consistency between scientific advice and protocol assistance given to applicants.

In view of the above:

1. The SAWP shall bring forward an integrated view as regards quality, non-clinical and clinical safety including pharmacovigilance and risk/minimisation aspects, and efficacy, relating to the development of medicinal products and orphan medicinal products across all patient age ranges to the CHMP for adoption within a defined timeframe and format. This also includes follow-up advice given with a view to optimise the development of medicinal products and orphan medicinal products.
2. The SAWP shall provide advice for products intended for the mandatory centralised procedure, i.e. acquired immune deficiency syndrome, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions and viral diseases as well as for orphan medicinal products. The SAWP may also provide advice for products not falling in the scope of the mandatory centralised procedure.
3. For advice on Post authorisation safety studies designs, the SAWP shall provide protocol assistance or scientific advice relevant to the design of the study to be conducted post authorisation, and bring its view forward to the PRAC for review and endorsement within a defined timeframe and format.
4. When applicable, the SAWP shall provide protocol assistance as regards demonstration of significant benefit relating to orphan medicinal products, and bring its view forward to the COMP for adoption within a defined timeframe and format.
5. The SAWP shall provide broader advice on product or non-product specific scientific questions covering e.g. a class of medicinal products, several indications, general manufacturing issues.
6. The SAWP shall provide scientific advice to support the qualification of innovative drug development methods (e.g. use on a novel biomarker as an acceptable technical standard for a specific intended use in the context of pharmaceutical R&D). This qualification process, leads to the provision of either

    a. CHMP **Qualification Opinion** on the acceptability of a specific use of the proposed method (e.g. use of a novel methodology or an imaging method) in a research and development (R&D) context (non-clinical or clinical studies), based on the assessment of submitted data, or

b. CHMP **Qualification Advice** on future protocols and methods for further method development towards qualification, based on the evaluation of the scientific rationale and on preliminary data submitted.

7. The SAWP shall provide advice about the justification on whether a specific medicinal product being developed for a specific therapeutic indication falls within one of the categories set out in Article 2 and fulfils the condition laid down in Article 4(1)(c) of Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use, which are defined in Article 14(7) of Regulation (EC) No 726/2004.

8. The SAWP shall provide advice on the acceptability of the development programme for conditional marketing authorisations, which are defined in Article 14(7) of Regulation (EC) No 726/2004.

9. The SAWP shall provide advice about the justification for applying for a marketing authorisation under exceptional circumstances (Guideline on procedures for the granting of a marketing authorisation under exceptional circumstances, pursuant to Article 14(8) of Regulation (EC) No 726/2004; EMEA/357981/2005).

10. The SAWP shall provide advice on the acceptability of the development programme for marketing authorisation application under exceptional circumstances, pursuant to Article 14(8) of Regulation (EC) No 726/2004.

11. The SAWP shall provide advice on the design of trials to assess safety and efficacy in a new indication expected to bring significant clinical benefit compared to existing therapies as defined in Article 14(11) of Regulation (EC) No 726/2004 or Article 10(1) fourth subparagraph of Directive 2001/83/EC.

12. The SAWP shall provide advice on the design of trials to assess safety and efficacy in a new indication for a well-established substance in accordance with Article 10(5) of Directive 2001/83/EC as amended as by Directive 2004/27/EC.

13. The SAWP shall provide scientific advice for products intended for marketing outside the European Union, in the context of co-operation with the WHO, as per Article 58(2) of Regulation (EC) No 726/2004.

14. The SAWP shall provide advice on paediatric developments as defined in Article 15 of Regulation (EC) No 1901/2006.

15. The SAWP shall provide advice on the development of medicines for older people, particularly for innovative medicines and novel therapeutic approaches.

16. The SAWP shall review all eligibility requests for the PRIME scheme and provide its recommendation to the CHMP to accept or to reject such a request. Requests related to ATMPs will also be circulated by the SAWP to the CAT, for review and recommendation prior to finalisation and adoption by CHMP.

17. The SAWP shall pay special attention to development and methodology issues of products intended for small populations and adaptive designs in drug development.

18. Taking into account the limited experience of small and medium-sized enterprises (SMEs) in development, the SAWP shall offer the necessary support to facilitate the understanding of its advice by SMEs.

19. The SAWP, in consultation with the CAT, shall provide protocol assistance or scientific advice on the (Pre/Post-MAA) development of ATMPs, in accordance with the Regulation (EC) 1394/2007.

20. The SAWP, in consultation with the CAT, where appropriate, shall provide scientific advice and protocol assistance and mobilise appropriate and specific expertise, especially for new and emerging therapies such as gene therapy and associated cell therapies, and xenogenic cell therapy (including advance therapy medicinal products defined in Article 12 of Regulation (EC) 1394/2007) and for questions related to pharmacogenetics/pharmacogenomics.

21. Scientific advice can be used as a tool to prepare certification for advanced therapy products.

22. The SAWP shall establish contact with patients' organisations and health-care professionals' associations. Where appropriate, the SAWP shall consult them for the provision of scientific advice or protocol assistance.

23. The SAWP shall cooperate with the other EMA committees, working parties, drafting groups, scientific advisory groups and the EMA scientific secretariat, in particular to create a guideline document in a specific therapeutic area, publish standard Questions & answers documents for frequently asked questions, and organise workshops and think-tank meetings on specific and rapidly evolving topics.

24. The SAWP shall ensure consistency between scientific advice and protocol assistance given to applicants, available EU guidance documents and CHMP assessment.

25. The SAWP shall provide opportunities to applicants to discuss with other regulatory agencies their global development programmes, in particular with the FDA. This should follow a request from the applicant to the EMA to arrange such parallel advice procedure.

26. The SAWP shall provide scientific advice and protocol assistance as part of the multi-stakeholder consultations in early-stage drug development. Applicants are invited to consider engaging HTA bodies when requesting scientific advice or protocol assistance to the EMA.

27. Scientific advice on the proposed safety and efficacy data requirements or the approach to addressing relevant criteria for an application to change the classification for the supply of a medicinal product from subject to a medical prescription to not subject to a medical prescription. See European Commission on “A Guideline on changing the classification for the supply of a medicinal product for human use”.

28. The SAWP shall not be responsible for providing regulatory assistance for medicinal products and orphan medicinal products.

29. The SAWP shall not be responsible for advice prior to submission for qualification of a request for an accelerated assessment procedure [Guideline on the Procedure for Accelerated Assessment Pursuant to Article 14(9) of Regulation (EC) No 726/2004 (EMEA/419127/05)].

30. The SAWP shall not be responsible for Paediatric Investigational Plans as defined in the regulation on medicines for children.

31. The SAWP shall not be responsible for pre-assessment of data that will be used to support future marketing authorisation applications**.**

32. The SAWP shall not be responsible for compassionate use as defined in Article 83 of Regulation (EC) No 726/2004.

33. The SAWP shall not be responsible for providing recommendations on classification as provided for under the ATMP regulation.

3. Rules of procedure

Composition

Article 1

1. The SAWP is a multidisciplinary expert group and includes the chairperson and up to 36 members, among which 1 vice-chairperson and at least 1 and not more than 3 members from each of the other EMA scientific committees. Each SAWP member may have an alternate who can attend the meeting instead of or, if justified, in addition to the member, if coordinating procedures.
2. The SAWP includes at least the following expertise:
    - non-clinical safety;
    - pharmacokinetics;
    - methodology and statistics;
    - pharmacoepidemiology;
    - therapeutic fields for which there are frequent requests and/or defined in the annex of the regulation, e.g. cardiology, oncology, diabetes, neurodegenerative disorders, immunology and infectious diseases;
    - advanced therapies;
    - paediatrics;
    - geriatrics.
3. The chairperson of the different committees, working parties and drafting groups can be invited to the SAWP meetings.
4. The two coordinators of each qualification team must be members or alternates of the SAWP or the CHMP; the qualification team is appointed by the CHMP for each individual qualification advice/ qualification opinion request.

Appointment of chairperson, vice-chairperson and SAWP members

Article 2

1. The CHMP shall appoint 24 SAWP members for a term of three years renewable, upon proposals from CHMP members based on required expertise. These SAWP members may be CHMP members or European experts from regulatory authorities or academia.
2. The COMP shall nominate at least 1 and not more than 3 of its members as COMP representatives for a term of 3 years renewable.
3. The CAT shall nominate at least 1 and not more than 3 of its members as CAT representative for a term of 3 years renewable.
4. The PDCO shall nominate at least 1 and not more than 3 of its members as PDCO representative for a term of 3 years renewable.

5. The PRAC shall nominate at least one and not more 3 of its members as PRAC representatives for a term of 3 years renewable.

6. The CHMP may appoint more than 24 SAWP members, in accordance with the Article 2(1) requirements, if the maximum capacity of 36 members has not been reached after the nomination of the other EMA scientific committees' representatives.

If the members mentioned in Articles 2.2 to 2.5 are no longer members of their respective committees, then their membership of the SAWP also ceases at the same time.

In keeping with the CHMP rules of procedures:

7. The chairperson of the SAWP shall be elected by the members of the CHMP for a term of 3 years, which may be renewed. A committee member, an alternate or a member of the SAWP may be elected by the committee to fulfil this responsibility. Where the chairperson does not belong to the CHMP, he/she shall be invited to attend plenary CHMP meetings to report on the activities on the SAWP and ensure liaison with the work of the CHMP. The vice-chairperson of the SAWP shall be elected by the CHMP for a term of 3 years, which may be renewed.

8. Nominations should be submitted in writing to the EMA secretariat no later than the start of the CHMP meeting at which election of SAWP chairperson is to take place.

9. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

10. The election of the chairperson and the vice-chairperson shall be by absolute majority of the CHMP members (i.e. favourable votes by at least half of the total number of CHMP members eligible to vote plus one) and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. In the case of a tie in the decisive round, another round is organised with two remaining candidates. If, at the decisive round, the candidate with the highest number of votes does not get an absolute majority, a further voting is organised with this candidate only, where he/she needs favourable votes by at least half of the total number of committee members eligible to vote plus one, to be elected chairperson or vice-chairperson, as the case may be.

11. One year after the chairperson has been elected, the CHMP shall re-examine and confirm the composition of the entire SAWP, based on expected activities and expertise required (see Article 1(2). All existing members and new candidates for nomination are invited to submit, to the EMA secretariat, their proposed (re)nomination together with a chosen alternate, accompanied by a confirmation of access to the capacity and range of competences to function as a SAWP co-ordinator, together with updated CVs to support their specific expertise. The term of the appointed member shall be 3 years, or until the composition of the SAWP is re-examined, i.e. one year after the chairperson election, renewable.

12. The CHMP re-examination and confirmation resets the start of the term for all members and alternates, regardless of when the mandate of each member commenced. In the event of a departure of a SAWP member before the end of the 3-year term, new candidates are invited to submit their proposed nomination, as described in Article 2(11).

13. Each member of the SAWP referred to under Article 1(1) may have one defined alternate. In the event of the departure of an alternate before the end of his/her term, the member is invited to replace him/her.

14. Other operating Committees are asked to re-examine the nomination of their joint Committee-SAWP representative(s) at the time of the confirmation of the SAWP by the CHMP.

Responsibilities of chairperson and vice-chairperson

Article 3

1. The chairperson shall be responsible for the efficient conduct of the business of the SAWP. The chairperson has, in particular, the following responsibilities:

    - To ensure that the best possible advice is given.
    - To ensure consistency of advice given within the same therapeutic area.
    - To manage the business of the agenda by:
        - ensuring all members have equal opportunity to express their views, taking into account time constraints;
        - formulating questions and proposals, summarising discussions, concluding on all items of discussions.
    - To endeavour to achieve consensus in the adoption of scientific advice and protocol assistance letters while taking into account other positions should a consensus not be reached.
    - To ensure that any potential conflicts of interest which have been declared to the secretariat are resolved before the particular item is discussed by the SAWP.
    - To ensure that the rules of procedures are respected.
    - To ensure that the co-ordinator's report is of the agreed format and of good quality.
    - To liaise regularly with the EMA Secretariat to plan the work of the SAWP.

2. When the chairperson is not available to chair the meeting, the vice-chairperson shall take the chair.

Co-ordinators and assessment teams

Article 4

1. For any scientific advice or protocol assistance procedures, appointment of SAWP co-ordinators and committees representatives contributing to the assessment, will be made as needed and in accordance with the WINs in place, with the aim of establishing and maintaining good cooperation and consistency between the different scientific committees, in accordance with the regulation. For every PRIME eligibility request, one SAWP co-ordinator will be appointed.

2. To be appointed as co-ordinators, SAWP members and/or their alternates shall provide the EMA secretariat with a notification of interest prior to the SAWP meeting. The secretariat of the SAWP shall allocate the requests according to expertise and equal opportunity for each member and alternate. Regular SAWP members will have priority over the alternates for co-ordinatorship. The appointment of scientific advice or protocol assistance co-ordinators is decided independently from any previous appointment of rapporteurs/co-rapporteurs for centralised applications, nevertheless engagement and communication with (co) rapporteurs is essential.

3. Each appointed SAWP co-ordinator shall form their assessment team with external experts and/or internal assessors. The appointed SAWP co-ordinator can also form a multinational assessment team in collaboration with other SAWP members. In this case the appointed co-ordinator will have to ensure that a letter is sent by the Head of the Lead NCA to the Executive Director notifying the EMA on the intention to form a multinational team and clearly stating the participating NCAs and the percentage of remuneration to each participating NCA.

4. The co-ordinators are responsible for providing reports in response to the scientific advice or protocol assistance requests taking into account the procedure and timetable for evaluation of such requests. If necessary, the co-ordinators may ask the applicant for any additional documents or clarifications during the procedure. Should such contacts take place, these should be reported to the EMA/SAWP.

5. The co-ordinators shall draft the list of issues for the discussion meeting. The discussion meeting shall be chaired by one of the two co-ordinator(s).

6. The provision of services by co-ordinators or their assessment teams shall be governed by 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*.*

7. The SAWP may consult relevant committees, working Parties, drafting Groups or scientific advisory groups in relation to the evaluation of non-clinical and/or clinical questions including safety, for a specific product within the agreed timelines. The SAWP shall also delegate the task of evaluating quality related issues to the Biotechnology Working Party (BWP) or Quality Working Party (QWP). Situations where such consultation or delegation is done should be defined in a Standard Operating Procedure (SOP) or Working Instruction (WIN).

   In such cases, the applicant's request and draft co-ordinator's report(s) shall be forwarded to the relevant committee, working party, drafting group or scientific advisory group. If no working party or scientific advisory group meeting are planned within the agreed timelines, a written consultation of the relevant working party or scientific advisory group shall be carried out.

   In all situations, the committees, working party, drafting group or scientific advisory group shall report to the SAWP. The co-ordinators shall compile the comments received and the SAWP remains responsible for the consolidated advice forwarded for adoption.

8. CHMP members are encouraged to take an active role in the activities of the SAWP.

Peer review of scientific advice and protocol assistance

Article 5

1. For each procedure at least one SAWP member shall act as peer reviewer for the final letter.

2. CHMP members selected by the SAWP chairperson are appointed as CHMP peer reviewers.

Qualification team for novel methodologies

Article 6

1. The qualification team is appointed based upon a proposal by the EMA secretariat in conjunction with the CHMP and SAWP chairs and led by two coordinators who are members or alternate members of the CHMP or the SAWP.
2. The qualification team shall consist of minimum 5 members and will be tailored to each individual qualification advice request. Resources will be derived from the CHMP, SAWP, working parties, drafting groups and the larger EU experts' network.

Involvement of additional expertise[3]

Article 7

1. The SAWP may involve additional expertise (including patients representatives if necessary) in scientific advice and protocol assistance for all aspects (pharmaceutical, preclinical, clinical and significant benefit). Additional expertise shall be consulted in particular for the provision of protocol assistance for orphan and advance therapy medicinal products.
2. Any SAWP member (including SAWP member not being a co-ordinator) or the EMA may propose additional experts.
3. Additional expertise should be identified as early as possible and notified to the EMA. The SAWP may appoint additional expertise to ensure the highest level of scientific knowledge in particular at the discussion meetings.
4. Additional expertise is regularly involved in the qualification of novel methodologies.

Final Scientific Advice and Protocol Assistance letters

Article 8

1. The SAWP shall consolidate an EMA position for scientific advice and protocol assistance in consultation with the relevant Committees, for formal adoption by the CHMP within a defined timeframe and format.
2. The SAWP shall present, to the relevant working parties and Committees, the issues considered critical for the development and/or the future marketing authorisation application assessment.
3. The final adopted advice letter shall be sent to Applicants following its adoption.
4. The applicant may request a clarification after receipt of the final advice letter. This is only intended to provide the applicant with the opportunity to comment on parts of the SA/PA that are not clear enough. The steps for requesting clarification after receipt of the final advice letter shall be defined in an SOP or WIN.
5. CHMP scientific advice letters including qualification advice on future protocols and methods for further method development towards qualification are confidential (II4a). CHMP qualification

[3] Additional expertise includes either experts not belonging to the National Authorities, or internal assessors not being part of the coordinators' assessment team, or both. Expertise is defined here by relevant work performed in the area, e.g. clinical practice, performance of studies or trials, publications.

opinions on the acceptability of a specific use of the proposed method (II4b) are published for public consultation before qualification and the final opinion is also made publicly available.

6. Having regard to Directive 2001/20/EC, the SAWP will need to reflect on potential ethical issues associated with different possible trial designs, both for those submitted by applicants and for alternatives considered during discussions. However, this position shall not substitute for the opinion of appropriate Ethics Committees.

Organisation of the meetings

Article 9

1. The SAWP shall meet 11 times a year at the Agency. The meeting shall generally be held 2 weeks before the CHMP and its duration shall be 4 days. SAWP members should endeavour to attend all meetings.
2. The dates of meetings are decided on an annual basis in consultation with the SAWP.
3. The meetings shall be held in English.
4. The draft agenda for every meeting shall be circulated together with the related documents by the EMA secretariat in consultation with the chairperson at least 4 calendar days before the meeting.
5. When a member of the SAWP is unable to participate to a meeting, he/she must inform the secretariat in advance in writing and request his/her replacement by his/her appointed alternate.

Discussion meetings

Article 10

1. The SAWP may invite an applicant to attend a discussion meeting in connection with a scientific advice procedure. For protocol assistance, the SAWP shall endeavour to organise discussion meetings. Discussion meetings shall also be organised where the SAWP does not agree with any important aspect of the programmes proposed by the applicant or when no consensus within the SAWP members can be reached.
2. When the SAWP has delegated tasks associated with the evaluation of quality related issues, discussion meetings may be held with the Biotechnology Working Party (BWP) or Quality Working Party (QWP). Any additional issues should be systematically reported to the co-ordinators. Co-ordinators and the relevant experts of their assessment teams may attend the meeting.
3. When the need for a discussion meeting is agreed by the SAWP, the co-ordinators and other SAWP members may nominate additional experts to participate in the discussion meeting. In addition, the meeting shall be open to all SAWP members and members of other working parties or scientific committees.
4. A detailed list of issues to be addressed by the applicant during the discussion meeting shall be adopted and sent to the applicant following the SAWP meeting. The applicant shall be informed of the exact timing of the discussion meeting well ahead of the meeting.
5. The applicant may also propose in writing additional points for discussion not part of the adopted list of issues. These additional points must be strictly related to the specific scientific advice/protocol assistance request submitted by the applicant. If the applicant intends to present

major amendments to the development initially proposed, the changes to the development programme should be detailed to the Agency/SAWP in writing ahead of the discussion.

6. The discussion meeting shall be held in accordance with an SOP or WIN.

Guarantees of independence

Article 11

1. The names of SAWP members and alternates shall be made public.

2. SAWP members, alternates and experts mentioned in various articles of the present rules of procedure shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial and other interests. The declarations of interests shall be made available on the Agency's website.

3. SAWP members, alternates and experts attending meetings shall declare, at the beginning of each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall be recorded.

4. SAWP members, alternates and experts participating in the EMA's activities shall abide by the principles set out in the European Medicines Agency Code of Conduct. The specific provisions for handling declaration of interests and confidentiality as defined in the European Medicines Agency Policy on the handling of declarations of interests of scientific committees' members and experts shall be applicable to SAWP members, alternates and experts participating in the scientific activities of the Agency. The handling of declaration of interests and confidentiality of the SAWP members' assessment team/internal experts involved in the drafting of the SAWP activities at a national level, remains the responsibility of the national agencies, in accordance with the memorandum of understanding between the EMA and the National Competent Authorities (NCA) on the monitoring of the scientific level and independence of the evaluation carried out by the NCA for services to be provided to the Agency.

5. Any incomplete and/or incorrect declarations of interests will be handled according to the Agency's breach of trust procedure on declarations of interests for scientific committees' members and experts.

6. SAWP members and alternates 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.

EMA secretariat

Article 12

Under the authority of the Executive Director, the EMA secretariat shall provide scientific, technical, and administrative support to the SAWP with a view to the performance of its duties and shall provide secretarial services to:

- Organise pre-submission and briefing meetings with applicants.
- Prepare the work of the SAWP in consultation with the chairperson.

- Ensure compliance with the timelines and procedures for the adoption of the final letters.
- Forward convening papers and all available documents at least 7 calendar days before the meeting of the SAWP.
- Propose additional expertise including patients' representatives if necessary.
- Carry out the validation of the applications.
- Facilitate the necessary contacts between the SAWP and the applicants.
- Prepare the table of decision of the SAWP meetings.
- Prepare the final letter for adoption.
- Prepare the critical summary report and outcome letter for the PRIME eligibility requests.
- Ensure adequate co-ordination of the work carried out within the SAWP.
- Provide legal and regulatory support to the SAWP.
- In the framework of the quality management and quality assurance of procedures, ensure consistency among advice given, guidelines and committees / working parties assessment within the same therapeutic area, and contribute to the peer review of scientific advice/protocol assistance.
- Ensure that all relevant information is shared among the relevant Committees and working parties.
- Ensure that all relevant information from scientific advice and protocol assistance is included in the scientific advice database, which shall contribute to the scientific support brought about by EMA both in terms of regulatory and scientific memory.

Adopted by the CHMP on 15 December 2016.

Entry into force: 1 January 2017.