European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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CHMP Workplan 2008-2010 "Specialised Experts and SAGs: Optimisation of Consultation process from CHMP"

Note: Final version including comments made at the July CHMP (report adopted)

REPORT FROM THE SAGs' WORKING GROUP

1. Introduction

The CHMP adopted the respective Briefing Note on Specialised Experts and SAGs: Optimisation of Consultation process from CHMP which summarised the project as follows:

1.1 Problem statement

There are currently 7 active SAGs (Scientific Advisory Groups):

Anti-infective (AI)
Cardiovascular (CVS)
CNS
Diabetes/Endocrinology (D/E)
Diagnostics (D)
HIV/Viral Diseases (HIV)
Oncology (O)

In the light of the experience of SAG meetings and considering the increased complexity of several applications for marketing authorisation -including re-examinations- there is a need for better and increased involvement of SAGs in the whole system for the evaluation of centralised procedure products.

1.2 Objectives to be achieved

- Review of:
  - Mandates
  - Composition in terms of both the best available expertise and the number of members
  - Procedures to involve SAGs in product scientific discussions; and on drafting guidelines
- To set up a policy concerning when SAGs should be consulted
- To draft a proposal to address the issue of the SAG members' conflict of interest
- To address the lack of adequate involvement of SAGs in the whole regulatory system
- To draft a proposal to ensure adequate training of SAG members regarding their mandate and rules of procedure
- To draft a proposal for cases where CHMP members don't consider some of the SAG outcomes appropriate.

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1.3 Expected impacts

- Increase clarity of the mandate and in the relationship between CHMP and WPs and SAGs
- Clarify and provide guidance when SAGs should be consulted
- Optimise SAGs' composition
- Improve the involvement of experts with a certain degree of conflict of interest in SAG activities
- Increase transparency
- Clarification on the use of SAGs by other Committees
- Review of feedback from SAGs to CHMP
- Improve organisation of SAG meetings, including clarification on the role of (Co)Rapporteurs during SAG meetings
- Implementation of monitoring and control systems

1. 4 Sponsors

CHMP: Barbara van Zwieten-Boot, Karl Broich, Pierre Demolis, Jean-Louis Robert, Tomas Salmonson (on CoI issues)

EMEA: Xavier Luria and Kristiina Puusaari

2. Development of the project

The kick-off meeting was held on 23 of June 2008 and the following topics were discussed with the intention to provide the lines to take on the following steps: Mandates, Role of (Co)Rapporteurs at SAG meetings, Conflict of Interest, Experts approached by companies, Questions in general and on re-examinations, EMEA's SOPs (organisation, meetings, secretariat support), Video/teleconference facilities, Regular communications with SAG members, Training/awareness of SAG members (rules of procedures), Role of SAGs regarding guidelines and similar documents, Increase number of core members, Questionnaire to SAG members, Meeting with SAG Chairs. Due to time constraints the following topics were not discussed, but have been addressed afterwards: New SAGs, Timelines to arrange SAG meetings, Relationship between SAGs and WPs (drafting groups), Experts from PDCO and CAT.

After the first meeting, the group attempted to meet (face to face and/or via teleconference) several times, however, almost all meetings were cancelled at the last minute due to key members being unexpectedly unavailable. The group has mainly been interacting through emails and ad hoc meetings with one or two members at the time when the scheduled meetings were cancelled. Initially the group has basically focused its main efforts to produce the two surveys described below.

Survey to SAG and CHMP members: Two questionnaires were drafted to reflect a wide spectrum of SAG related issues and they were tailored to reflect the different perspectives of SAG members and CHMP members. After consulting with the group a number of times both were presented to the CHMP during the December 2008 CHMP meeting and distributed to SAG members and CHMP members on 12th December 2008. The deadline for replies for both questionnaires was 7th January 2009, with a reminder sent out on 5th January. Completed questionnaires were received back from 36 SAG members and from 15 CHMP

members. The results were analysed by the group and on 6th February 2009 a teleconference was organised to review them and to coordinate the presentations on this topic at the informal CHMP (Prague 9-10 March 2009).

3. Conclusions and recommendations

The following conclusions and recommendations have been agreed based on the group's analysis and were presented at the informal March 2009 CHMP. Afterwards, they were reviewed by the SAGs' working group and by the SAG secretariats.
It should be pointed out that some of them are under discussion by other CHMP-EMEA projects, i.e. Conflict of Interest (point 1), relationships with other Committees (point 15) and Working Parties membership.

1) **Conflict of Interest:** This will be looked at in a wider context. EMEA has embarked on a review of the Conflict of Interest Policy and procedures during 2009.

2) **Mandate:** A new standard mandate is attached (Annex 1). EMEA will develop a SOP/WIN as appropriate

3) **SAG meetings frequency:** All SAGs should initially plan for a frequent number of meetings per year, but special consideration for SAGs that currently only meet once or twice a year will be given. Meetings will be scheduled every 30-45 days and then the ones that are not required will be cancelled. The need to organise a SAG should be foreseen well in advance, ideally already at or after the LoQ/RSI if there are Major clinical objections that are "unlikely" to be solved.

4) **Number of core members:** From the expertise point of view it seems that there is no need to increase it. However, for organisational reasons in order to ensure presence of a sufficient number of core members, it is proposed to increase its number up to a maximum of 12. Additionally, to streamline the identification of additional experts, it is proposed that SAG secretariats keep updated lists of experts to cover most probable areas.

5) **The Briefing Note:** It should be made simpler and previous steps during the evaluation process should be clearly listed in a tabular format. A template will be developed by EMEA.

6) **Overall conduct of the meeting:** No changes proposed. A SOP will mainly cover this issue. In case of an ad-hoc expert group, the meeting will be co-chaired by one expert elected according to the procedure set up by the SAG mandate and the EMEA scientific secretariat.

7) **Use of Video/Teleconference:** Video/Teleconferences will not replace the meetings. However, it could be used as part of the meeting, in particular to allow participation of certain experts (e.g. expertise very focused in 1 or 2 questions, restriction of participation due to CoI, etc.).

8) **At the end of each SAG meeting the Chair should get formal verbal agreement on the main conclusions and answers to the CHMP**. This summary will be the content of the debriefing to the applicant and should be the core of the minutes and therefore well communicated to SAG members and participants.

9) **Feedback to Applicants:** The debriefing to applicant will be led by the SAG Chair and the (Co) Rapporteur will contribute. EMEA will ensure that what was said at debriefing is later on well reflected in minutes. During the debriefing with applicants, the discussion of subsequent steps in the procedure should not be part of the minutes, but captured by the PTL.

10) **Training (initial and refresher) for SAG members:** To prepare first time experts and SAG members better, they will receive a general briefing package on background of the SAGs. Refresher training will be organised for all SAGs and make training material available to all SAG members.

11) **Improving feedback to SAGs:**

a) SAG Chairs' annual meetings
b) Consider SAGs members meeting (EMEA-SAG info day)
c) Feed-back at the start of each SAG meeting
d) Email from EMEA secretariat to SAG members following the CHMP outcome
e) Electronic news letters using a standard format for all SAGs

12) **Applicants will attend (Co) Rapporteur presentations.** As agreed at the July 2009 CHMP meeting, appropriate space for direct interaction between (Co)Rapporteurs and SAG members should be ensured.

13) **Patients representatives could be invited to SAG meetings**

14) **Additional experts**

a) Include experts nominated by PDCO when the indication of the products is for paediatric populations. They should not be PDCO members
b) It should be discussed if a permanent expert nominated by PDCO should be incorporated in the SAGs
c) Use of statisticians in most SAG meetings
d) Increase consultation with learned societies to identify experts

15) **Use of the SAGs and their experts by other Committees:** This should be considered in the future

16) **CNS SAG to be split into two:** Neurology SAG and Psychiatry SAG

17) **Benefit/Risk assessment by the SAG:** CHMP shouldn't pose to SAGs questions that directly address benefit/risk assessment for a particular medicinal product. However, this point was discussed during the July 2009 CHMP meeting and it was decided to bring it for further discussion in the future.

18) **Definition on when to use SAGs:** As per current regulation it is up to the discretion of the CHMP to convey a SAG meeting (see standard mandate, Annex 1). However, in order to avoid inconsistent decisions with regard to the need for a SAG meeting, it is recommended that such a meeting should be considered whenever there are diverging views/split opinions within the CHMP on clinical grounds. Furthermore, it would be useful

in situations where an Article 20 procedure is envisaged that a SAG is consulted within the formal context of such procedure.

Finally, the group proposed a number of considerations making clear WPs vs SAGs remits and improving clarity of SAGs mandate:

a) The CHMP may delegate certain tasks associated with scientific discussion of guidelines or drafting guidelines to the relevant WPs
b) The CHMP may also delegate to WPs product related issues and they will only be discussed on CHMP request
c) The task identified by the CHMP should be included in the Work Programme of each WP to be adopted by CHMP
d) SAG are created by CHMP to deliver answers, on a consultative basis, to questions addressed to them by the Committee, mainly in the context of the CHMP process of evaluation of products
e) The CHMP, while taking into account the opinion expressed by the SAG, remains responsible for its final opinion
f) The SAG is convened on request of the CHMP
g) SAGs could be consulted on referrals, guidelines and scientific advice and in all cases the way is through specific questions adopted by CHMP
h) SAGs may identify other scientific issues warranting further discussion subject to the agreement of CHMP
i) Members of SAGs need to be external experts
j) Members of WPs need to have regulatory experience
k) Similarity: WPs and SAGs work under the responsibility of CHMP
l) Differences: SAGs are to some extent CHMP anchor line in clinical practice and ensure external validation
m) WPs are the place to discuss differences in regulatory requirements and to get a harmonised view

It is proposed that an assessment of implementation of actions agreed is carried out by EMEA by mid 2010 and presented to CHMP.

Table ACTION PLAN

AREAS	RECOMMEN-DATIONS	SPECIFIC ACTIONS	RESPON-SIBLE	TIMELINES
General	Mandate	– Updated Mandate *	EMEA/CHMP	1Q 10
	Replace the current CNS SAG with two more specialised SAGs	– Establishment of Neurology SAG and Psychiatry SAG – Accommodation of budget	EMEA/CHMP EMEA	1Q 10 3Q 09
	Improving feedback to SAGs	– SAG Chairs annual meetings – Consider SAG members meeting (EMEA-SAG info day) – Feedback at the start of each SAG meeting – E-mail to SAG members following the CHMP outcome – Electronic news letters using a standard format for all SAGs	EMEA EMEA EMEA EMEA EMEA	3Q 10 tbd Regular, start 4Q 09 Regular, start 1Q 10 Regular, start 1Q 10
	Consider implementation of cross-use of the SAGs and their experts by other Committees	– Proposals to be discussed by EMEA management and bring to CHMP	EMEA	2Q 10
Composition	Increase of number of core members	– Updated mandate – Accommodation of budget – Nomination of additional core members	EMEA/CHMP EMEA CHMP	1Q 10 4Q 09 2Q 10
	Patients representatives to attend SAGs meetings	– Updated mandate and SOP	EMEA/CHMP	1Q 10

	Additional experts: – Include PDCO experts when the indication of the products is for the paediatric populations – Reflection if a permanent expert nominated by PDCO should be incorporated in the SAGs	– Updated mandate and SOP – Proposals to be discussed by EMEA management and bring to CHMP	EMEA/CHMP EMEA	1Q 10 2Q 10
	– Use of statisticians in most SAG meetings	– Updated mandate and SOP	EMEA	1Q 10
	– Consultation with learned societies to identify experts	– Updated SOP	EMEA	1Q 10
Planning and conduct of the meetings	SAGs meeting frequency	– Pre-planning of potential SAG meeting dates	EMEA	4Q 09
	Briefing Note	– Template to be developed	EMEA	1Q 10
	Conflict of Interest	– New Policy to be adopted by Management Board	EMEA	4Q 09
	Use of Video/Tele-conference	– To be considered on case-by-case basis	EMEA	Regular
	Chair to get formal verbal agreement on the main conclusions and answers to the CHMP	– Updated mandate	EMEA/CHMP	1Q 10
	Feedback to Applicants	– Updated mandate	EMEA/CHMP	1Q 10
	Training and refresher for SAG members	– To provide training to new experts and refresher training to the entire SAG on a regular basis	EMEA	Regular
	Applicants to attend (Co) Rapporteur presentations	– Updated mandate	EMEA/CHMP	1Q 10

Consultation of the SAG	Benefit/Risk assessment by the SAG	– CHMP not to pose questions that directly address benefit/risk assessment. This will be re-discussed by CHMP	EMEA/ CHMP	2Q 10
	Definition on mandatory and optional to use SAGs	– Updated mandate	EMEA/CHMP	1Q 10

* “Mandate” refers to the “Mandate, objectives and rules of procedure for the CHMP Scientific Advisory Group on …….. (SAG-….)”

ANNEX 1

MANDATE, OBJECTIVES AND RULES OF PROCEDURE FOR THE CHMP SCIENTIFIC ADVISORY GROUP ON …….. (SAG-….)

I. LEGAL BASIS

- Article 56(2) of Parliament and Council Regulation (EC) No 726/2004 of 30 April 2004, the CHMP may establish SAGs in connection with the evaluation of specific types of medicinal products or treatments, to which the Committee may delegate certain tasks associated with drawing up the scientific opinions
- Article 61(8) of Parliament and Council Regulation (EC) No 726/2004 of 30 April 2004, the CHMP shall in particular lay down procedures relating to working parties and SAGs
- Article 62(1) of Parliament and Council Regulation (EC) No 726/2004 of 30 April 2004, the applicant may request that the Committee consult a scientific advisory group in connection with the re-examination of its opinion
- Article 78(2) of Parliament and Council Regulation (EC) No 726/2004 of 30 April 2004, SAGs shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and heath care professionals' associations relevant to the of the indication of the medicinal product concerned
- Article 80 of Parliament and Council Regulation (EC) No 726/2004 of 30 April 2004, the internal rules and procedures of the Agency, its committees and its working groups shall be made available to the public at the Agency and on the Internet

II. GENERAL CONSIDERATIONS

Scientific Advisory Groups (SAGs) are created by the CHMP to deliver answers, on a consultative basis, to specific questions addressed to them. The Committee, while taking into account the position expressed by the SAG, remains responsible for its final opinion. SAGs report back to the CHMP.

III. MANDATE AND OBJECTIVES

The SAG-… will be convened at the request of the CHMP and any decisions on issues discussed by the SAG-… will be made by the CHMP.

The SAG-… is established to provide an independent recommendation on scientific /technical matters related to products under evaluation through centralized regulatory procedures by the CHMP or any other scientific issue relevant to the work of the Committee.

The SAG-… could also be consulted through the CHMP on Scientific opinions (e.g. requested by the Commission, in collaboration with the WHO), Scientific advice/protocol assistance, Referrals, and Guidelines.

The SAG-… has the opportunity to identify scientific issues that may need further discussion within the SAG subject to the agreement of the CHMP.

IV. COMPOSITION AND RULES OF PARTICIPATION

The SAG-… is composed of experts selected according to their specific expertise.

The SAG-… will comprise both a core group –which ensures continuity and consistency within the group- and additional experts who may be called upon to participate to a given

meeting or series of meetings on a specific issue about which they have relevant professional education, training and experience therefore bringing additional expertise in specific domains and on a case-by-case basis.

Members of SAG-… will be independent experts and will not be members of any EMEA Committee nor EMEA staff.

Visiting experts (including experts from outside the non-EEA countries) may act as observers and should also be appointed by the CHMP.

EMEA confidentiality and conflict of interest rules apply to all SAG experts (core and additional) as well as observers.

Appointment of the core members

Core members will be selected for their clinical/technical expertise in the field of interest.

- The core group should reflect a balanced composition of scientific expertise and therefore members should have diverse professional education, training and experience.
- An expert in clinical trials methodology and biostatistics should always be considered for participation in a SAG meeting.
- The inclusion of experts on paediatrics and on advanced therapies should be considered
- The composition of the core group should as far as possible reflect different schools of thinking or European therapeutic practices.
- The CHMP Members/EMEA shall propose experts to be core members of the SAG-….. The SAG-… Secretariat appointed by the EMEA will collect all proposals and will propose a panel of core members for appointment by the CHMP.
- A maximum of 12 core members will be nominated for a period of 3 years.
- Core members will be included in the EMEA Experts Database.
- The core members of the SAG-… shall commit to active participation to the activities of the group. Should a member fail to attend for any reason for more than 3 meetings in less than 2 years (or less than 50% of the meetings during the same period), replacement of the member will be considered by the CHMP.

V. MEETING FREQUENCY

The SAG-… will meet on CHMP request.

VI. DURATION OF ACTIVITY

The duration of the SAG-… activity will be decided on by the CHMP.

VII. RULES OF PROCEDURE

1. Responsibilities of Chairperson and Vice-Chairperson

1.1. The Chairperson, and in his absence the Vice-Chairperson, is responsible for the efficient conduct of the business of the SAG-… and shall in particular:

- Plan the work of the SAG-... meetings together with the EMEA Secretariat
- Monitor, together with the EMEA Secretariat, that the rules of procedure are respected
- Ensure the fulfilment of the mandate of the SAG-…
- Ensure that at the beginning of each meeting any potential conflict of interest is declared

- Ensure that scientific grounds are adequately reflected in the SAG-… Answer and Comments document
- Co-ordinate together with the EMEA Secretariat the work of this SAG-… with that of the Committees and Working parties of the Agency as appropriate
- Assume responsibility for the conduct and running of the meetings.
- Ensure that the CHMP Questions for the SAG-… and any additional topics of the agenda are discussed
- Ensure that all SAG-… members have the opportunity to express their views.
- Ensure that all the views expressed by the SAG-… members are reflected and justified in the SAG-… Answers and Comments to the CHMP
- Summarise the conclusions of the SAG-… on each question raised by the CHMP for inclusion in the SAG-… Answers and Comments to the CHMP
- Provide feedback from the SAG-… discussions including divergent views to the CHMP plenary meeting, where requested
- Propose to the CHMP to invite additional experts to a SAG-... meeting as appropriate
- Propose to the CHMP to invite the concerned company/third party to provide clarifications to the SAG-… on the topics related to the CHMP questions, when necessary

1.2. The Vice-Chairperson will deputise for the Chairperson when the latter is unable to undertake all or part of the above-listed responsibilities. On such occasions the Chairperson will seek the agreement of the Vice-Chairperson as early as possible, and if related to chairing of the meeting prior to the meeting, and the EMEA Secretariat shall be informed immediately.

2. Election of Chairperson and vice Chairperson

2.1. Core members of the SAG-… shall elect one of its core members to be proposed to the CHMP to act as Chairperson for the SAG and one to act as Vice-Chairperson. The CHMP thereafter appoints the Chairperson and the Vice-Chairperson. The Chairperson and Vice-Chairperson of the SAG-… shall be elected for a term of three years, which may be renewed once. Regardless of the time of election, the Chairperson and Vice-Chairperson shall be appointed for the term of the SAG-….

2.2 Nominations for Chairperson and Vice-Chairperson should be submitted in writing to the EMEA secretariat no later than the start of the SAG-… meeting at which the election is to take place and if the SAG has frequent meetings the expression of interest should occur at the meeting prior to the proceeding of the election.

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

2.4. The election of the Chairperson and the Vice-Chairperson shall be by absolute majority of the core members of the SAG-… and by secret ballot. If absolute majority is not reached, 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 SAG-… core members eligible to vote plus one, to be elected Chairperson or Vice-Chairperson, as the case may be.

2.5. In the event of resignation of the Chairperson, the Vice-Chairperson shall take the chair until a new election is convened.

3. Organisation of meetings and reporting arrangements

3.1. The SAG-… shall meet at the Agency.

3.2. The dates of meetings are decided on by the EMEA in agreement with the CHMP.

3.3. The meetings will be held and minuted in English.

3.4. The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMEA Secretariat, in consultation with the Chairperson, in good time before the meeting.

3.5. The list of meeting documents (unless deemed confidential) and participating experts shall be made available by the EMEA secretariat to the applicant 48 hours before the SAG-... meeting.

3.6. When a member of the SAG-... is unable to participate to a meeting, part of meeting, or discussion of a topic due to conflict of interest, he/she must inform the Secretariat in advance in writing.

3.7. The proposal for a SAG-... meeting and the conduct and objectives of such a SAG-... meeting shall particularly consider the following points:

- Rapporteurs, or CHMP members shall comment on the potential need for a SAG-... meeting as early as possible, such as at the time of the list of questions, list of outstanding issues or request for supplementary information during the centralised procedure. In addition, the applicant may request that the Committee consult a scientific advisory group in connection with the re-examination of its opinion.
- The SAG-... has the opportunity to identify scientific issues that may need further discussion subject to the agreement of the CHMP. Any such proposal containing adequate justifications shall be transmitted to the CHMP for endorsement.
- The need to convene a SAG-... shall be confirmed by the CHMP. The SAG-... Secretary shall liaise with the SAG-... Chairperson, to propose the agenda of the meeting, and to propose the list of participants.
- The list of participants for each SAG-... meeting is sent to the CHMP for endorsement.
- The SAG-... Secretary will invite participants, naming the products or company/applicant concerned in the CHMP List of Questions for the SAG-..., and request updated declarations of conflict of interest.
- Provided that any conflicts of interest are resolved, the SAG-... Secretary will ensure that the CHMP List of Questions for the SAG-... adopted by the CHMP and all relevant supporting documents are sent to the SAG-... members in good time before the meeting.
- The CHMP Rapporteur and the Co-rapporteur (medicinal products), the WP (Co)Rapporteur (guidelines) or the scientific advice Co-ordinators (scientific advice) shall be invited to attend the SAG-... meeting, to present the List of Questions for the SAG-..., and to provide any additional information to the SAG-..., if requested. Assessors from the (Co)-Rapporteur' and Coordinators' team could also attend the meeting when necessary.
- The applicant or a third party may be invited to provide an oral explanation in front of the SAG-... following agreement from the CHMP and they will attend the (Co)-Rapporteur' presentations.
- The SAG-... shall not make conclusions during or after these presentations in the presence of the applicant or any third party.
- A debriefing meeting with the applicant will normally occur after the end of the SAG meeting. It will be led by the SAG Chair and the (Co) Rapporteur will contribute. EMEA will ensure that what was said at debriefing is later on well reflected in

minutes. During the debriefing with applicants, the discussion of subsequent steps in the procedure should not be part of the minutes, but captured by the PTL.

- The SAG-... Answers and Comments to the CHMP will contain answers to the CHMP List of Questions for the SAG-..., and a justification for each answer. Where consensus cannot be reached on an answer, the conclusion reached by the majority together with any divergent positions within the SAG-... will be noted in the SAG-... Answers and Comments to the CHMP. The divergent positions shall be explained in that document and where relevant in the minutes of the meeting. Members having divergent positions shall convey these clearly stating the reasons on which they are based.
- The SAG-... Secretary and Chairperson will be responsible for finalising the SAG-... Answers and Comments to the CHMP to be adopted by the SAG-... and circulated to the CHMP, together with minutes of the meeting.
- After finalisation, the part of the draft "SAG-... Answer and Comments to the CHMP" that relate to the product will be released to the concerned applicant.
- In the case of issues being initially raised by CHMP working parties (WP), the SAG-... will report to the CHMP and simultaneously will inform the WP. The SAG-... chairman could be invited to the WP in order to further inform the WP.
- The CHMP List of Questions for the SAG-..., and the SAG-... Answers and Comments to the CHMP shall be reflected in the CHMP assessment reports, as appropriate, and thus appended to the CHMP opinion. If, on request by the applicant the Committee has consulted with the SAG-... in connection with the re-examination of its opinion, the views of the SAG-... should also be included in the CHMP assessment report adopted by the Committee.
- Whenever possible, the Chairperson of the SAG-... shall be available during a CHMP meeting, to provide feedback from the SAG-... discussions including divergent views to the CHMP.

4. Participation of Additional Experts in SAG-... meetings

- CHMP Members, SAG Chair and the EMEA make proposals for experts on the basis of their expertise in the therapeutic area or field to be covered by the particular SAG-... meeting, according to the CHMP List of Questions for the SAG
- They may already be included in the EMEA Experts Database and if not they will be included after the CHMP nomination as SAG experts
- The list of participants for each SAG-... meeting is sent to the CHMP for endorsement

5. Guarantees of independence

5.1. The experts referred to above 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 interests. 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.

5.2. Members and experts attending the SAG-... 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 points of the agenda. These declarations shall be made available to the public.

5.3. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMEA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, in its current version as adopted by the Management

Board, are applicable to members of the SAG-... and experts participating in the activities of the SAG-....

5.4. The experts 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.

6. Code of conduct

Experts participating in the EMEA's activities shall abide by the principles set out in the EMEA Code of Conduct.

7. EMEA Secretariat

7.1. Under the authority of the Executive Director, the EMEA secretariat shall provide technical, scientific and administrative support to the SAG-.... This includes the following:

- Provide technical and scientific support to the SAG
- Provide legal and regulatory support to the SAG
- Prepare - in consultation with the Chairperson - the relevant documents to be conveyed to the CHMP
- Prepare and co-ordinate the work of the SAG in consultation with the Chairperson
- Organise meetings of the SAG ensuring timely circulation of meeting documents
- Ensure adequate co-ordination of the work carried out within SAG and as relevant with the CHMP and its working parties
- Ensure scientific and regulatory consistency of the recommendations of the SAG-... in cooperation with the Chairperson
- Prepare the minutes of the SAG meetings in consultation with the Chairpersons
- Contribute to the debriefing meetings with the applicant and ensure consistency

7.2. The Executive Director of the Agency, members of the EMEA secretariat, CHMP members and representatives of the Commission, may attend all meetings of the SAG-.... as observers.

8. Contacts with Interested Parties

8.1. The SAG-... will establish contacts in agreement with the CHMP, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations.

8.2. When considered appropriate by the Committee, oral presentations by interested parties can be made during SAG-... meetings. The SAG-... may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of the Committee and under specific conditions to be agreed by the Committee.

8.3. The SAG-... shall neither conduct deliberations nor reach any formal decisions in the presence of members of interested parties.

9. General Provisions

The Members of the SAG-... 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 individual professional secrecy. The EMEA Guidance on Confidentiality and Discretion applies.

When participating in scientific/technical meetings or other fora on behalf of the Committee, members shall ensure, the views expressed are those of the Committee.

When participating in scientific/technical or other fora not specifically on behalf of the Committee, members shall make clear that the views expressed are their own views and not those of the Committee.