The EMEA will request National Competent Authorities to update their list of experts on a yearly basis, or as the need may arise (e.g. for participation in Ad Hoc Expert Groups). In order to allow for an adequate flow of information between the EMEA, National Competent Authorities and experts, contact persons for each Competent Authority should be in place.

In addition, situations can arise where the need for additional expertise, not covered by nominations by Member States, is identified at the level of the EMEA Scientific Committee. In such circumstances, the nomination of the identified expertise should be undertaken by the EMEA.

II.2 Inclusion in the EMEA Experts Database

All members and experts need to be included in the EMEA experts database, prior to the first appointment resulting in involvement in EMEA activities (meeting attendance, scientific evaluation, guidance development, inspections, etc). Such inclusion is only possible once the following documents have been submitted to the EMEA:

- Nomination form

  The completed Nomination (NOM) form (attached as Annex 1) should either be submitted by the National Competent Authority who nominates an expert, or by the EMEA, if the expert is nominated by the Agency.

- Public Declaration of Interests and Confidentiality Undertaking form

  The Public Declaration of Interests and Confidentiality Undertaking (DI-CU) form (attached as Annex 2) consists of 2 parts, i.e. the Declaration of Interests and the Confidentiality Undertaking. Both parts should be duly completed, dated and signed by the nominee[5]. Such form should be completed on an annual basis, or whenever there is a change in the member's/expert's interests. In case of any changes, the member/expert should immediately notify the EMEA and complete a new form detailing the changes.

- Curriculum Vitae

  A Curriculum Vitae should be provided in addition to the above documents.

The nominating Authority has to ensure, in close collaboration with the nominated member/expert, that all relevant material necessary for the assessment process has been made available prior to the member's/expert's involvement in any EMEA activity. National Competent Authorities will be requested by the EMEA to update their list of experts on a yearly basis, or as the need may arise. In parallel, the DI-CU form should be completed on an annual basis, or whenever there is a change in the member's/expert's interests.

III RISK IDENTIFICATION

III.1 General Principles

Based on the information provided in the DI-CU form by the member/expert, the EMEA will evaluate whether a declared interest constitutes a conflict.

In the case of an identified conflict of interest, the Agency will subsequently assess the potential for bias in the member's/expert's opinion. As a result of such assessment, the member/expert will only be allowed to participate in the EMEA activities to an extent

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[5] It needs to be noted that any contract signed between the nominee and a pharmaceutical company (e.g. in relation to the nominee's involvement on Advisory Boards of pharmaceutical companies) cannot derogate in any way from the need for the nominee to complete fully the DI-CU form.

defined by the assigned risk level[6]. Since it has to be recognised that members/experts are not unlikely to have a high level of contact with pharmaceutical industry, it is important to emphasise that conflicts of interests relate to a specific product or situation, and not merely to the member's/expert's exposure to the pharmaceutical industry in general.

Clear criteria for risk identification will be used in order to assign the ultimate risk level. Three levels of risk are possible, whereby "3" represents the highest and "1" the lowest risk level. The level of risk associated with a given conflict of interest will be determined based on the information available to the EMEA.

III.2 Criteria for Risk Identification

The following criteria for risk identification will be used sequentially in order to establish the ultimate risk level:

- General screening criteria.
- Re-classification criteria.
- Fine-tuning criteria.

III.2.1 General screening criteria

General screening criteria are

(1) the professional background of the member/expert, and

(2) the nature of the interest declared.

The aim of such criteria is to perform a general screening of the declared interests, using the high-level information provided in the DI-CU form. The use of these criteria will lead to either a definitive assignment of the risk levels "1"and "3", or a preliminary assignment of the risk level "2". (It should be noted that, where the professional background or the nature of the interest declared could lead to the assignment of two different risk levels (e.g. involvement in both Academia and Regulatory Authority), the highest risk level will apply).

Professional background of the expert

In terms of involvement in EMEA activities, the EMEA may require the input of experts from Regulatory Authorities, international organisations, academia, NGOs[7] and, exceptionally, the pharmaceutical industry. The various professional backgrounds of the members/experts are represented in the table below:

Regulatory Authorities and/or international organisations	Academia and/or NGOs	Industry
EMEA and/or other EU Bodies and Institutions	Hospitals/Universities/ Veterinary and/or University hospitals	Pharmaceutical companies and CROs
National Competent Authorities, Ministries and other national, federal or	Learned societies, medical/ veterinary organisations, animal and human health-	Pharmaceutical consultancy

[6] In some cases (which should be the exception rather than the rule), a member/expert may indicate that, despite being assigned a risk level allowing participation in EMEA activities, he/she will not participate in a particular activity, due to personal reasons. In these exceptional cases, the non-participation of the member/expert in that activity will be recorded in the relevant documents.

[7] NGOs: Non-Governmental Organisations.

local governmental bodies (e.g. OMCLs[8])	care professionals organisations	
Non-EU Regulatory Bodies	Research institutes (national/international)	
International organisations e.g. WHO[9], EDQM[10]	Patients organisations, interest groups and charities	

Nature of the interest declared

Three situations can be identified:

(1) no interests are declared;

(2) an institutional interest is declared, and

(3) a personal interest is declared.

Institutional interests relate to institutional contracts or supervisory research interests. Personal interests relate to salaries, shares, share options or fees earned by acting as a consultant[11].

III.2.2 Re-classification criteria

Such re-classification criteria refer to the conflicts of interests level for each individual (relating to a specific product or situation).

Only in the case of a preliminary assigned risk level "2" will such re-classification criteria be used in order to further clarify the situation (Industry experts assigned risk level "3" following general screening, should be submitted to the EMEA Declaration of Interests Assessment Group (DIAG) for evaluation – see also Section V.2). Taking into account the detailed information provided in the DI-CU form, the use of these criteria should allow for a re-classification of a preliminary assigned risk level "2" into risk level "1", "2" or "3".

Conflicts of interests levels range from "C" to "A". The conflicts of interests level "C" leads to risk level "3", the conflicts of interests level "B" to risk level "2" and the conflicts of interests level "A" to risk level "1". The different levels of conflicts of interests are given below:

[8] OMCLs: Official Medicines Control Laboratories.
[9] WHO: World Health Organisation.
[10] EDQM: European Directorate for the Quality of Medicines.
[11] A consultant is defined as an expert who charges a fee (personal, institutional or both) for providing advice or services in a particular field.

Conflicts of Interests level "C"
Financial interest is declared in either the company or a competitor company of more than 50,000 Euro. It should be noted that investment funds and pension schemes are excluded, as the individual has no control over their management.
The individual currently acts, or has acted in the past year, as a **consultant** on the development of the product or a competitor product. The individual is or has been **employed** in the past year with primary responsibility for the product or a competitor product.
The individual is, or was in the previous year, the **principal investigator** for the development of either the product or a competitor product.
The individual is, or was in the previous year, a **member of a steering committee, an advisory board or an equivalent body** for a company producing either the product or a competitor product.
The individual (or his/her institution[12]) owns a **patent**[13] on either the product or a competitor product.

Conflicts of Interests level "B"
Financial interest is declared in either the company or a competitor company of 50,000 Euro or less. It should be noted that investment funds and pension schemes are excluded, as the individual has no control over their management.
The individual acted more than a year ago, but less than 5 years ago, as a **consultant** on the development of the product or a competitor product. The individual is or has been **employed** more than a year ago, but less than 5 years ago, with primary responsibility for the product or a competitor product.
The individual was more than a year ago, but less than 5 years ago, the **principal investigator** for the development of either the product or a competitor product.
The individual was more than a year ago, but less than 5 years ago, a **member of a steering committee, an advisory board or an equivalent body** for a company producing either the product or a competitor product.
The individual is currently, or was in the past year, an **investigator (not principal)** in the development of either the product or a competitor product.

[12] This is based on the knowledge of the individual concerned in relation to the institution's activities.
[13] This includes all forms of intellectual property.

Conflicts of Interests level "A"
The individual has acted more than 5 years ago as a **consultant** on the development of the product or a competitor product The individual is or has been **employed** more than 5 years ago with primary responsibility for the product or a competitor product.
The individual was more than 5 years ago the **principal investigator** for the development of the product or a competitor product.
The individual was more than 5 years ago a **member of a steering committee, an advisory board or an equivalent body** for a company producing either the product or a competitor product.
The individual was more than a year ago[14] an **investigator (not principal)** in the development of either the product or a competitor product.

It should be noted that, in the context of this procedure, the following definition of a "competitor product" applies: a medicinal product[15] that targets the same indication whatever the severity or stage of the disease/condition. This definition includes products under clinical development, products submitted for marketing authorisation or for orphan drug designation, as well as authorised medicinal products.

III.2.3 Fine-tuning criteria

Fine-tuning criteria are

(1) the availability of alternative experts in the field;

(2) the nature of the input needed from the member/expert, and

(3) the role of the member/expert or the phase during which the involvement is required.

Availability of alternative experts in the field

This criterion will be used for assigned risk levels "2" (where the outcome of the DIAG evaluation is negative) and "3"[16] (in advance of any request to DIAG for evaluation).

The availability of alternative experts in the field in the EU must be checked, on the basis of information available to the EMEA (with the help of the EMEA Experts Database). Such checking should be performed within 48 hours.

Nature of the input required

The areas where the input is required are

(1) either specific product-related matters and/or therapeutic class matters[17], or

(2) general matters[18] such as guidelines.

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[14] Information relating to interests older than 5 years need not be provided.

[15] Including herbal medicinal products registered under the simplified registration procedure in accordance with Directive 2001/83/EC as amended.

[16] Note: With regard to pharmaceutical industry experts, whose involvement in a particular activity is considered essential, no alternative experts need to be sought. The Scientific Administrator should consult the DIAG for a waiver for such experts.

[17] Therapeutic class matters relate to a specific disease, product or class of products (e.g. antihypertensives, rabies vaccines, etc.).

[18] General matters means any guidance (in the form of guidelines, concept papers, reflection papers, etc.) not related to either a product or a disease (e.g. TSE, genotoxicity, methodology guidance).

Role of the member/expert or the phase of involvement

This refers either to the role in the scientific evaluation process (e.g. (Co)-Rapporteur, Co-ordinator) or the role in the development of guidelines (topic leader) and/or general matters. With regard to the phase, one should distinguish between the evaluation and decision-making phases of the scientific assessment processes and the drafting and adoption phases of guidance development.

IV ASSIGNMENT OF THE RISK LEVEL

IV.1 General Principles

As already indicated, the assignment of the risk level will be performed in a phased approach:

- the first phase is a general screening using the general screening criteria (i.e. professional background of the expert and nature of the interest declared);
- the second phase, which applies to a preliminary assigned risk level "2", is a re-classification phase, using the conflicts of interests levels, and
- the third phase consists of a fine-tuning, applying the above described fine-tuning criteria.

This will ultimately lead to the assignment of the final risk level. The level of risk posed by a declared interest will be determined using the Evaluation of Conflicts of Interests (ECI) form (attached as Annex 3).

The outcome must be recorded in the relevant product master file, product related meeting minutes or Working Party minutes (the latter in case of guidelines).

IV.2 Procedure for the Assignment of the Risk Level

IV.2.1 First phase: general screening

As indicated earlier, the screening criteria to be considered in the first phase are the professional background of the expert and the nature of the interest declared. Using such criteria and the three categories of risk (whereby "3" represents the highest and "1" the lowest risk level), the following result is obtained:

Nature of the interest declared	Professional background of the expert		
	Industry	Academia	Regulators
Personal interest	3	2	2
Institutional interest		2	1
No interest declared		1	1

It should be noted that industry experts are always considered as being at risk level "3".

The outcome of the first phase is either the definitive assignment of a risk level (for risk levels "1" and "3"), or the preliminary assignment of a risk level (for risk level "2").

IV.2.2 Second phase: re-classification

This second phase is only necessary if, as a result of the first phase, a risk level "2" is assigned.

Each person initially graded at risk level "2" needs to undergo an in-depth analysis using the re-classification criteria. This will lead to a re-classification of a preliminary assigned risk level "2" into a risk level "1", "2" or "3".

Where none of the re-classification criteria are relevant for the member/expert in relation to the activity for which his/her involvement is sought, the member/expert will be re-classified at risk level 1.

IV.2.3 Third phase: fine-tuning

In the third phase the fine-tuning criteria (i.e. availability of alternative experts in the field, nature of the input needed, role of the individual or phase of involvement) will be applied.

Availability of alternative experts in the field

For persons that have been assigned the risk level "3" following re-classification, the availability of alternative experts in the field has to be considered prior to any submission to the DIAG[19] for evaluation. The DIAG should only be consulted in relation to such experts when a search for alternative experts has already been carried out and the outcome of that search is negative.

For persons that have been assigned the risk level "2" following re-classification, the availability of alternative experts needs only to be considered further to a negative evaluation by the DIAG.

Where a search is performed for alternative experts, it will be considered that no alternative expert is available, if the outcome of the search is negative,

- after asking at least 2 members of the EMEA Scientific Committee for alternative experts;
- if there is a negative outcome of such enquiry, after a search of the EMEA's Experts Database, and
- if there is still a negative outcome after the EMEA's Experts Database search, after asking the EMEA Scientific Committee (either during a meeting of such Committee, or by e-mail, depending on the procedural timelines).

In the case of inspectors, the outcome of the search will be considered negative if the Competent Authority responsible for the inspection is unable to nominate a replacement and no suitable replacement can be found after following the established procedures for the delegation of inspections to another Competent Authority. A negative outcome is, therefore, highly unlikely.

If experts with an equivalent level of expertise are found, the expert posing the lowest risk level for the specific topic should be appointed.

Nature of the input required and role of the member/expert or the phase of involvement

[19] For pharmaceutical industry experts who have been assigned the risk level "3" following general screening and whose involvement in a particular activity is considered essential, no alternative experts need to be sought. The Scientific Administrator should consult the DIAG for a waiver for such experts.

The nature of the input needed from the member/expert (general matters such as guidelines versus specific product-related matters/therapeutic class matters) will influence the level of participation in EMEA activities. This input should take into account the role of the member/expert or the phase during which the person's involvement is required. The following maximum permitted involvement level should be applied to define the level of participation in EMEA activities:

Role/phase	Nature of the input required	
	Specific product-related matters and/or therapeutic class matters	General matters such as guidelines
Rapporteurship (or equivalent leading/co-ordinating role)	1	1
Evaluation/drafting phase[20]	2[21]	2[21]
Decision phase/adoption	2[21]	2[21]

V DETERMINATION OF PARTICIPATION LEVEL IN EMEA ACTIVITIES

V.1 General Principles

The DIAG[22] has been established in order to assess the acceptability for involvement of members/experts in EMEA activities. It should be noted that the DIAG is a virtual group, providing the outcome of its assessment in writing and within a very short timeframe (24 hours). The group will only meet when no unanimous decision can be reached. If no consensus can be obtained at DIAG level, the Executive Director, or responsible Head of Unit (by delegation), will be required to take a final decision. In view of their direct impact on third parties all decisions taken by the DIAG need to be signed off by EMEA (senior) management. All decisions made will be recorded in the relevant product master file and/or meeting minutes for the audit trail.

V.2 Procedure for the Determination of Participation Level

Such procedure can be described as follows:

1. When the outcome of the assignment of the risk level is risk level "2" or "3", the Scientific Administrator should consult the DIAG in order to decide on the acceptability for involvement of the person concerned in EMEA activities.

   The DIAG will decide:

   - in case of the assigned risk level "2", either to grant a waiver leading to level 1 permitted involvement in the specific EMEA activity(ies), for which involvement is requested, or to maintain level 2 permitted involvement, and

[20] Ad Hoc Expert Groups are considered to be part of the evaluation/drafting phase.

[21] Level 2 refers to the outcome of the DIAG evaluation, i.e. either the maintenance of level 2 permitted involvement or a waiver (from an assigned risk level "3" to level "2" for the specific activity).

[22] The rules of procedure are provided as Annex 4.

- in case of the assigned risk level "3", either to grant a waiver leading to level 2 permitted involvement in the specific EMEA activity(ies), for which involvement is requested, or to exclude such individual from involvement in those activities.

The consultation performed by the DIAG should lead to a unanimous decision. If no consensus can be reached, the EMEA Executive Director, or responsible Head of Unit (by delegation), must take the final decision.

In view of their direct effect on third parties all decisions taken by the DIAG need to be signed off by EMEA (senior) management.

The outcome (acceptance or exclusion) of the DIAG's consultation must be recorded in the product master file, and/or the minutes of the EMEA Scientific Committee, EMEA Scientific Committee Working Party, SAG, Ad Hoc Expert Group, drafting group, etc.

2. The consequences of the assignment of the participation level, where appropriate, through involvement of the DIAG, are as follows in terms of the individual's involvement in EMEA activities:

2.1 EMEA Scientific Committees chairpersons and Working Party[23] chairpersons

As a general rule, any conflict of interest is incompatible with the duty of such chairperson. Although a total absence of any conflict of interest is preferable for chairpersons, the maximum permitted risk level is "1".

Once elected, and for the duration of the mandate, the chairperson should endeavour not to engage in activities that may result in a change in his/her risk level, and in any case shall immediately declare to the EMEA any changes that may affect this risk level. If the risk level increases, a new chairperson should be appointed.

2.2 Members and experts

Risk Level 3

The expert is excluded from participating in EMEA activities. Another expert in the field should be found.

Only in cases where no suitable alternative expert can be found, e.g., in extremely specialised areas of expertise, the Scientific Administrator should consult the DIAG for a waiver.

It should be noted that, with regard to pharmaceutical industry experts, whose involvement in a particular activity is considered essential, no alternative experts need to be sought. The Scientific Administrator should consult the DIAG for a waiver for such experts.

If a waiver is granted by the DIAG, the expert will be considered to be at level "2" as regards the involvement in the EMEA activity(ies) for which involvement is sought.

Risk Level 2

The Scientific Administrator should always consult the DIAG.

The level of involvement of the member/expert will depend on (1) the nature of the input required and (2) the role of the individual or the phase during which the person's involvement is required.

[23] Refers to all permanent Working Parties of the EMEA Scientific Committees.

Role/phase	Nature of the input required	
	Specific product-related matters and/or therapeutic class matters	General matters such as guidelines
Rapporteurship (or equivalent leading/co-ordinating role)	Not permitted.	Not permitted.
Evaluation phase/drafting phase	The individual addresses orally or in writing specific questions raised during the evaluation of products, but cannot draft assessment reports or parts of them.	The individual may contribute to the drafting of general guidance documents. The individual can participate in workshops, or report on his/her professional experience.
Decision phase/adoption	The individual cannot actively participate in the final discussion. However, he/she is present to answer questions addressed specifically to him/her. The individual is required to leave the room when a final decision or a vote takes place.	The individual can participate in the discussion and, were relevant, can vote.

Risk Level 1

Involvement in all EMEA activities is permitted.

VI SPECIFIC ARRANGEMENTS FOR MEETINGS

The following specific arrangements will apply for meeting proceedings:

In order to allow the EMEA Secretariat to perform the checking of conflicts of interests for all attendees, the Agency needs to be informed of the names of all persons attending the meeting prior to the start of such meeting.

At the opening of every EMEA Scientific Committee/EMEA Scientific Committee Working Party/SAG/Ad Hoc Expert Group, drafting group meeting, the chairperson shall request that all attendees declare any conflicts of interest on the matters for discussion[24]. Such declarations will be minuted.

Where the evaluation of an expert has lead to the conclusion that participation is permitted for a specific agenda item of a meeting, the expert should participate only in the discussion of that item and should not be present in the meeting room for any other discussions.

[24] In particular, attendees have to specify changes, omissions and errors appearing in their DI-CU form. Members/experts will then have to provide the EMEA within the shortest possible timeframe with an amended DI-CU form.

In unexpected and exceptional circumstances, an unforeseen conflict may arise. For example, during a discussion advice might be requested on a different matter for which an expert feels he/she has a conflict. The expert should notify the conflict to the chairperson. In this case, the Scientific Administrator providing the Secretariat for the meeting takes on board the task of evaluating the extent of the risk and the acceptability of the expert on the basis of the principles outlined in this document. If the expert is invited to express his/her opinion, the conflict has to be clearly stated in the minutes.