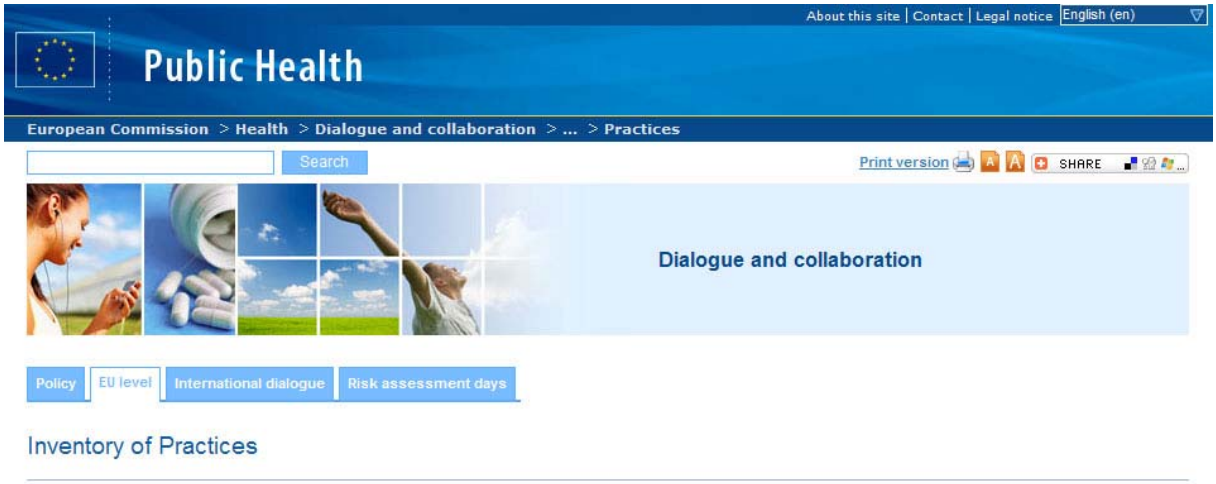

European Commission and Agencies Sientific Committees/Panels involved in Risk Assessment

The European Union is committed to ensuring the health and safety of all citizens residing in its territory. This means not only making sure that the products circulating in the EU market are safe, but also being able to take action against possible threats to health, such as for example infectious diseases.

This is ensured by carrying out thorough risk assessments before any important decision is taken. For this purpose, the EU has established specialised agencies to carry out risk assessments in a number of areas, ranging from food to pharmaceuticals and communicable diseases. In addition, in areas concerning consumer safety, environment and health or emerging risks, the European Commission has created specialised committees of independent scientific experts.

The Chairpersons of these scientific committees and agencies meet on an annual basis, in order to discuss and coordinate issues of common interest related to risk assessment. At the 2008 annual meeting it was proposed to collaborate for the establishment of a compilation of practices, related to the functioning of the Commission and Agency Scientific Committees and Panels. This compilation would include only aspects related to the organisation of the Committees/Panels and their work and not address any risk assessment methodological issues.

As a first phase, the focus for sharing information is on the following three aspects:

- Relations with Stakeholders
- Relationship between Risk Assessors and Risk Managers
- Criteria and Procedures ensuring independence of the Committees, Panels and Working Groups

At this first phase of the project information has been included for ECDC, ECHA, EMA and the European Commission's independent scientific committees (SCCS, SCHER, SCENIHR).

As a second phase, depending on the feedback on this initiative, more aspects will be covered, such as for example the use of confidential data, how are experts reimbursed etc.

General approaches

EC independent Scientific Committees

The Stakeholder Dialogue procedures are intended to enable structured, balanced, ordered and manageable engagement with stakeholders in the process of elaboration of scientific opinions by the Scientific Committees on Consumer Safety, on Health and Environment and on Emerging and Newly Identified Health Risks (SCCS, SCHER and SCENIHR respectively), whilst ensuring the effectiveness of the process and compliance with the principle of independency. These procedures will be implemented as part of the Rules of Procedure of the said Committees. It needs to be emphasised that the procedures described below are not intended to be used for each opinion and will be applied taking into account the expected added value in each specific case and the need for sound management of the limited resources available. [Annex IV of Rules of Procedure]

ECDC

According to the founding regulation (EC) No 851/2004 of the European Parliament and of the Council, the ECDC shall provide independent scientific opinions and scientific and technical assistance. The tasks of the Scientific Panels of the ECDC are to assist the Centre in these tasks. Scientific Panels are set up on an ad hoc basis by the Centre in response to a need for external or internal scientific advice and their remit and the duration of their work are stated in advance of their establishment.

ECHA

Representatives of stakeholder organisations regularly attend meetings of the ECHA Committees as observers following a request of members of the Committee or the Management Board. Other observers may be admitted on request of a member of the Committee or the Chair. These stakeholder observers shall conform to the 'ECHA Code of Conduct for observers from stakeholder organisations at ECHA meetings [Article 6(6) of the Committee for Risk Assessment rules of procedure]

EMA

For the EMA industry, patients, health care professionals are considered as the EMA stakeholders. Activities with stakeholders are defined in the legislation under article 78 of Regulation (EC) No 726/2004.

Relations with stakeholders are also provided in specific Rules of Procedure (e.g. for the Committee for Medicinal Products for Human Use (CHMP) Article 23 and 24 of CHMP Rules of Procedure)

Specific practices

	ECHA	ECDC	EMA	EC independent Scientific Committees
Hearings	**N/A**	**No**	**Yes, as a notice to applicants!** There is a possibility of an oral explanation prior to the finalisation of a scientific opinion of the Committee for Proprietary medicinal products (CPMP) on a centralised procedure (see relevant guidance document for more details on procedures)	**Yes** according to § 8.1, 9.3.9 and 11.4 of the Rules of Procedure (RoP), as well as section 5.1 of the Stakeholder Dialogue Procedures (Annex IV of the RoP).
Expert workshops	**N/A**	**No** Panels are usually consisting of experts assembled to answer a specific question on an ad hoc basis	**Yes** On specific issues, announced in advance and outcome generally published. Regular meetings with industry organisations (EFPIA, EGA and AESGP)	**Yes** According to § 9.9.6 and 16 of the Rules of Procedure.
Public consultations on mandates	**No**	**No**	**No**	**Yes** According to § 9.3.4 of the Rules of Procedure

				(RoP), as well as section 3 of the Stakeholder Dialogue Procedures (Annex IV of the RoP).
Public consultations on opinions	**No, for the Member State Committee** **No, for the Risk Assessment Committee (RAC) opinions** **Yes, for the Committee for Socio-economic Analysis.** There are no public consultations on the RAC opinions. There is however a public consultation on the draft opinion of the RAC's sister Committee for Socio-economic Analysis on a restriction dossier (Article 71(1) of the REACH Regulation). RAC opinions on restriction, CLH and authorisation shall be made publicly available once adopted (Article 72(2) of the REACH Regulation).	**No** No public consultations for opinions. However, all opinions are discussed and possibly revised by the ECDC Advisory Forum.	**N/A** The way of handling opinions for marketing authorisation issues is specified in the legislation and does not provides for public consultation. EMA handles public consultation for guidelines or policies (e.g. policy on transparency that is currently on going.	**Yes** According to section 5.2 of the Stakeholder Dialogue Procedures (Annex IV of the Rules of Procedure).

Calls for information	**Yes**	**No**	**No**	**Yes** According to section 4 of the Stakeholder Dialogue Procedures (Annex IV of the Rules of Procedure).
Public access to documents	**Yes (to non-confidential documents)** Article 118 of the REACH Regulation has a specific provision with regards to the access to information. Requests for access to documents according to Regulation (EC) No 1049/2001 are dealt with according to this provision and an ECHA Management Board decision (MB/12/2008 final) implementing this Regulation	**None during the work of a panel.**	**Yes**	**Yes** Requests for access to documents are handled in accordance with the provisions of Regulation n° 1049/2001. In addition, the documents listed in § 6 of the Rules of Procedure are published on the Commission's web site, subject to respect of confidentiality requirements as well as protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.
Presentation of work to Conferences / public events	**Yes** ECHA organises stakeholder days on a	**No** Dissemination to the public is done via the ECDC website.	**Yes** "Policy on representation of EMA scientific	**Yes** According to § 14 of the Rules of Procedure (RoP), as well

	regular basis, to inform stakeholders of key developments and to discuss their particular needs in relation to applying the provisions of the REACH Regulation and related legislation. Two stakeholder days have taken place so far, the second one took place on 29 May 2009 (see press release) and the next is scheduled for autumn 2009.		committees by its members" Inclusion of Communication issue as part of Committee for Medicinal Products for Human Use (CHMP) Work Programme topic – ongoing work in this regard	as section 3 of the Stakeholder Dialogue Procedures (Annex IV of the RoP).

Criteria for ensuring independence and efficiency regarding relations with stakeholders

Independence

EC independent Scientific Committees

Main requirements:
The scientific advice delivered by the Committees must not be influenced by any consideration other than the scientific assessment of the risks in question. This principle implies in particular the independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical or any other non-scientific considerations. The principle of independence refers to the organisation and results of the process, including in particular the independence criteria and conditions and arrangements for the participation of members, advisors and experts. [§ 3.2 of Rules of Procedure.]

The stakeholder dialogue procedure shall apply when and as compatible with the fundamental requirement to ensure the full independence and autonomy of the Scientific Committees in elaborating, determining and deciding the contents and conclusions of their opinions and to preserve the integrity of the process for the establishment of scientific advice. The Secretariat shall suspend the application of the procedure in a particular case if there is any risk to the independence and integrity of the process and shall alert the Commission of the nature and extent of such risk. No aspect of the stakeholder procedure and its actual application may be invoked as a reason to delay the adoption of, modify or reconsider a scientific opinion. [§ 8.3 of Rules of Procedure.]

Approach:
While the stakeholder dialogue procedures contribute to the implementation of the principle of transparency and are part of the Commission's efforts to engage with stakeholders in a spirit of openness and accountability, it should be clear that the work of the Commission Scientific Committees is, and must remain, independent of any influence. These procedures must therefore, not be seen as, and must not be used to interfere with the internal work of the Committees, claiming a right or trying to be involved in such work or exerting pressure on Committees' members. The overall aim of these procedures is to contribute to ensure the highest quality of the scientific opinions adopted by the Committees. In case of any evidence of significant risks for the independence of the committees due to the application of these procedures, the Commission will discontinue their application in part or in total as appropriate. [Annex IV of Rules of Procedure.]

The practical arrangements regarding the ensurance of independence regarding relations with stakeholders are laid down in § 5 and Annex II of the Rules of Procedure..

ECHA

In order to put its founding principles of transparency, efficiency and independence into practice and to meet and go beyond the direct legal requirements governing the issue, ECHA wants to develop efficient channels of communication, dialogue and engagement with its stakeholders. This policy of openness and engagement is part of the fundamental corporate philosophy of ECHA.

For more details on the provisions concerning the integrity and independence of the Committees and the Forum, please see the document ' Proactive engagement with all ECHA stakeholders ', approved by the ECHA Management Board. This document also refers to the code of conduct for stakeholders, endorsed by the ECHA Management Board.

ECDC

Main requirements:
According to Article 6(1) of the Founding Regulation of ECDC (EC) No 851/2004 of the European Parliament and of the Council: "the Centre shall provide independent scientific opinions, expert advice, data and information."

Approach:
All scientific opinions are discussed in the ECDC Advisory Forum before they are issued by the ECDC Director. The Advisory Forum includes public health experts from all Member States, the Commission, the WHO, learned societies, and patient organisations.

All the members of the Advisory Forum can give their views on the final opinion. However, they only advice the Director: no consensus is needed, and the Director does not have to take any views into consideration.

A policy on interactions with pharmaceutical industry, including regular update meetings at ECDC premises on a pre-defined topic set up in collaboration with industry umbrella organizations is currently developing. This has no impact on the work of the scientific panels.

EMA

Main requirements:
Please see the Annex II of the Procedural Advice to CHMP members: Committee for Medicinal Products for Human Use (CHMP) Members Interactions with Applicants/Marketing Authorisation Holders during the Centralised Procedure.

Approach:
In the case of applicants/marketing authorisation holders the relation is limited to the dossier of the applicants.
In the case of health care professionals or patients it's on a case by case basis. For patients in very

few cases specific meetings have been set up. For others than industry e.g. patients organisations it's very rare and on a case by case basis.

Efficiency

EC independent Scientific Committees

The Secretariat shall be responsible for providing scientific and administrative support necessary to facilitate the efficient functioning of the Scientific Committees, to monitor compliance with the rules of procedure, particularly in relation to the requirements for excellence, independence and transparency, to ensure communication on the Committees' activities and the appropriate stakeholder dialogue, including in particular organisation of hearings on the activities of the Committees, and publication of the opinions and other public documents. Moreover, the Secretariat shall provide support to the Committees and organise and apply quality control of the opinions, as provided for in the rules of procedure, as far as completeness, consistency, clarity, correspondence with requests and with editorial standards are concerned. [Chapter 5, §3 of Commission Decision 2008/721/EC]

ECHA

See documents referred to above in 'independence'

EMA

Performance Indicators agreed with Industry association:

http://www.ema.europa.eu/pdfs/conferenceflyers/EMEA_EFPIA_Info_Day-24-02-09.pdf
http://www.ema.europa.eu/pdfs/conferenceflyers/EMEA-EFPIA_24Feb2009/Lisette_Vromans-Performance_Indicators.pdf

Legislation

EC independent Scientific Committees

The Scientific Committees receive their mandates from the European Commission services, as provided by the Commission Decision 2008/721/EC

ECDC

The ECDC Advisory Forum receives its mandate from the ECDC Founding Regulation. The role of the ad hoc Scientific Panels is defined in these same regulations, Article 6.

ECHA

Based on Article 77(3) of Regulation (EC) No 1907/2006 (the REACH Regulation), Articles 69(4) and 70 of the REACH Regulation provide two mandates for Risk Assessment Committee (RAC) to consider proposals for Community-wide restrictions:

Article 64(1) of the REACH Regulation requires RAC to give an opinion on an application for authorisation.

Article 37(4) of the Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation) of substances is the mandate for RAC to provide an opinion on harmonised classification & labelling (CLH):

It should also be noted that the roles of two other ECHA Committees, the Member State Committee (MSC) and the Committee for Socio Economic Analysis (SEAC), are closely related to that of RAC.

The MSC, amongst other things, provides an opinion for recommending priority substances to be included in Annex XIV (list of substances subject to authorisation) under Article 58(3) of the REACH Regulation. SEAC evaluates restrictions suggested by a Member State or ECHA and the related socio-economic impacts. Comments and socio-economic analysis submitted by the interested parties will also be assessed (Article 71 of the REACH Regulation). Both Committees work in a closely similar way to RAC. Further details are available here.

EMA

The legal basis (including all details) for the relationship between risk manager and risk evaluators is the pharmaceutical legislation itself. For the scientific committees and the centralised procedure and

referrals in the Regulation (EC) No 726/2004. and in the codified Directives 2001/83/EC. (medicinal products for human use) and 2001/82/EC. (medicinal products for veterinary use) for other procedures.

Mandate

EC independent Scientific Committees

As listed in Commission Decision 2008/721/EC, Art.2 §1,2,3:

1. The Commission shall request a scientific opinion from the Scientific Committees in the cases laid down by Community law.

2. The Commission may also request an opinion from the Committees on questions: (a) of particular relevance to consumer safety, public health and the environment; and (b) not falling within the mandate of other Community bodies.

3. The Commission may also request the Scientific Committees to provide rapid advice on the state of scientific knowledge concerning specific risks in case of urgent needs

Mandates may be put to public consultation according to the procedures set out in Annex IV of the Rules of Procedure. of the Scientific Committees. The Commission will welcome motivated and documented suggestions for new topics for the Scientific Committees, provided the suggested topics follow the conditions set in the Annex IV of the Rules of Procedure [§ 9.3 and Annex IV and of the Rules of Procedure.].

ECDC

Terms of reference of panels are set up by ECDC, no public consultation is currently foreseen

ECHA

As indicated above the mandates for the Committee's tasks are derived directly from the legislation.

Proposals for restrictions may be prepared by the Agency, on request of the Commission, or by the MSCAs. Proposals for harmonised classification and labelling are submitted by MSCAs or, in those cases where a substance is without an entry in Annex VI of the CLP Regulation, there is a new provision which allows manufacturers or downstream users of a substance to submit a proposal for harmonised classification and labelling (CLH).

Proposals for restrictions, CLH and the uses of a proposed authorisation are published on the ECHA web site. (see stakeholder relations section B).

EMA

Mandates set out in relevant legislation and implemented via Rules of Procedure for individual Committees (adopted by Committee and agreed by EMA Management Board and European Commission for CHMP and CVMP)

Execution of work

How closely/actively is the Risk Manager following the Assessors' work?

EC independent Scientific Committees

Commission services with responsibilities relating to the topics on the agenda shall be entitled to be present in the meeting. They may assist for the purposes of clarification or provision of information but shall not seek to influence the outcome of discussions. [§ 9.8.9 of the Rules of Procedure.].

ECDC

The Risk Manager does not participate in panel meetings, however the Commission is represented in the ECDC Advisory Forum.

ECHA

In its role as Risk Manager, the Commission may attend meetings of Risk Assessment Committee as an observer. The Commission has no role to play in commenting or influencing the formulation of the opinion, which should be drawn up by the Committee on the basis of scientific and technical considerations only.

EMA

The Risk Manager participates to the meetings and responds to specific questions relating to legal / procedural issues. No intervention in scientific issues unless scientific issues are not clear enough for the Commission to take the decision. As a general principle the comments relate to legal/regulatory/procedural issues not on scientific issues.
The Commission and the EMA have established working arrangements.

Adoption

Are the Risk Managers involved in the adoption of an opinion?

EC independent Scientific Committees

Commission services with responsibilities relating to the topics on the agenda shall be entitled to be present in the meeting. They may assist for the purposes of clarification or provision of information but shall not seek to influence the outcome of discussions. [§ 9.8.9 of the Rules of Procedure.].

ECDC

No, the Risk Managers are not involved in the adoption of an opinion

ECHA

No. The Commission however prepares a draft decision in relation to restrictions (Article 73 REACH regulation), authorisation (Article 64(8) REACH regulation) and CLH (Article 37(5) of regulation (EC) No 1272/2008 (CLP Regulation)) taking the opinions into account. A final decision is taken in the Committee procedure as laid down in Decision 1999/468/EC.

EMA

The Risk Assessors are in charge of the adoption of the opinion for marketing authorisation/referrals. The Risk Manager is in charge of the decision making process and is responsible for the adoption of the decision. If the decision of the Risk Manager is not in accordance with the opinion the Risk Manager has to explain the reasons. If a Member State raise new scientific issues not being addressed in the opinion the Risk Manager can send back the opinion to the EMA.
For orphan drugs designation it's the same procedure.
For the Paediatric Investigation Plans that are adopted by the Paediatric Committee (PDCO) the Executive Director signs off the decisions.

Publication

EC independent Scientific Committees

A list of documents which are published on the Commission's website with regard to the activities of the Scientific Committees can be found on § 6.3 of the Rules of Procedure..

The Secretariat, in agreement with the interested Commission Services, will decide about the publication of memoranda, position statements, documents resulting from scientific meetings and thematic workshops [§ 11.14 of the Rules of Procedure.].

All documents mentioned under paragraph 6.3 of the rules of procedure and in particular the adopted Scientific Opinions shall be published on the Internet without undue delay by the Secretariat [§ 13.1 of the Rules of Procedure.].

For any other document, the Secretariat, in agreement with the interested services shall decide about the publication and dissemination case by case [§ 13.2 of the Rules of Procedure.].

ECDC

Technical reports and guidance produced by panels are published primarily electronically on ECDC website. In some cases a written report is prepared and disseminated.

ECHA

The opinions are published on the ECHA website..

EMA

Publication of opinions by the EMA (European Public Assessment report, Summary of Opinion etc.) – post Decision adoption and publication of decisions in the official journal, both electronic and paper.
Publication of Article 5(3) of the regulation on pharmaceuticals concerning opinions on any scientific matter related to medicinal products.
Many other documents are published in the EMA website guidelines, press releases, public statements, reflection papers, recommendations, procedural advices, etc.
"Procedure for European Union Guidelines and related documents within the pharmaceutical legislative framework"

Communication to public

EC independent Scientific Committees

Without prejudice to Art 16 of Decision 2008/721/EC, the Commission shall be responsible for determining the appropriate level of publicity to be given to a scientific opinion and may request the assistance of the chairs, rapporteurs or other members and advisors to ensure the scientific validity of its press releases or related communication actions. [§ 6.6 of the Rules of Procedure..

ECDC

Dissemination to public is ensured in close collaboration with ECDC Health Communication Unit.

ECHA

See information on Mandate and Publication. The public may be informed to the adoption of an opinion via an ECHA press release or news alert.

EMA

The EMA is mainly responsible for the communication to the public.

Feedback on risk management measures

EC independent Scientific Committees

The Secretariat will organise the appropriate dialogue between the Committees and the requesting services at the various stages, including feedback from the services on the adopted opinions [§ 11.10 of the Rules of Procedure.].

ECDC

Feedback is obtained in close collaboration with the European Commission and Member States.

ECHA

The risk management measures are Community–wide restrictions included in Annex XVII of the REACH Regulation; listing of the Community-wide harmonised classification and labelling of substances in Part 3 of Annex VI of the classification, labelling and packaging (CLP) Regulation; or in the case of applications for authorisation, once a decision has been taken, a summary of the decision with authorisation number and reasons for the decision are published in the Official Journal.

EMA

Non applicable as all the details of the procedure setting up the relationships between the EMA and the Commission are in the pharmaceutical legislation.

Procedures and criteria for selecting members and external experts

EC independent Scientific Committees

The conditions regarding the appointment of the members of the Scientific Committees and their term of office are described under Chapter 2 of the Commission Decision 2008/721/EC (setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC).

For the current mandate, the Committee members, advisors, members of the Pool have been selected after a call for expression of interest (2008/C 245/05).

The procedure regarding the selection of Advisors and external experts to participate in Working Groups is described on § 9.7 of the Rules of procedure..

ECDC

A scientific opinion from the ECDC is always produced in three steps (see paper on Relation with Stakeholders)

1. A draft opinion is produced either internally or by and ad hoc external Scientific Panel.
2. This opinion is revised by the ECDC Advisory Forum (AF) who advises the Director.
3. The Director issues the opinion.

The Members of the ECDC Advisory Forum declare interests in writing annually and orally at each meeting (4 times per year).

The text below describes the process in the ad hoc Scientific Panels:

According to the Internal procedure (work instruction) on handling Requests for Scientific Advice at the European Centre for Disease Prevention and Control (approved and being implemented in 2009, attached): *"In a case where no ECDC expertise is available, or where the Chief Scientist agrees that there is a need to involve external expertise, external experts are selected to create an ad hoc scientific panel (MB6/9/9).*
The process of external expert selection and nomination includes:

a) Consulting internal ECDC Expert Database; and/or:
b) Approaching AF members/ ECDCs list of learned societies/competent bodies to nominate experts; and/or:
c) Literature search to identify additional names.
Applicants for the scientific panels should have extensive expertise in the area of communicable diseases and/or related areas with a proven capacity to handle multidisciplinary scientific questions related to communicable disease threats.
Identified experts are asked about the availability on short notice to respond to ECDC requests. The names of experts are publicly available on ECDC website."

ECHA

According to Article 85 of Regulation (EC) No 1907/2008 (the REACH Regulation), Members of Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis are appointed by the ECHA Management Board following their nominations from a Member State. For the Member State Committee. Each Member State shall appoint one member. In addition, the Committees may co-opt a maximum of 5 members chosen on the basis of their specific competence (Article 85(4) of the REACH Regulation).

EMA

The membership of the scientific committees and the handling of its members' conflicts of interest are governed by the following rules, which have put in place a system that allows the EMA to benefit from the best scientific expertise available, whilst guaranteeing the impartiality of the Committee's opinions:

- Regulation 726/2004/EC. (Articles 61 to 63) EC
- CHMP Rules of Procedure (Article 19)
- EMA Code of Conduct (Annex I)
- EMA Policy on the handling of conflicts of interests of Management Board and scientific committee members and EMA experts (Section IV) (EMA/H/31653/03/Rev1 final)
- EMA Procedure on the handling of conflicts of interests for EMA scientific committees members and EMA experts (EMA/H/5475/04/Rev1 Final)
- EMA Standard Operating Procedures on Checking of Experts (SOP/EMA/0040)

These rules are publicly available and can be downloaded from the EMA website.
The relevant Rules of Procedure for the different Committees outline the composition of each committee.

The Expert needs to provide a completed nomination form (signed by the relevant nominating authority), detailing areas of expertise and a Declaration of Interest and to provide a CV. An updated Declaration of Interest form should be provided on an annual basis (paper format, since this must be signed). In addition, members and experts are invited to make any oral declarations of interest specific to a meeting agenda at the start of the relevant meeting.
The EMA Management Board is involved in the consultation with respect to members and alternates of the CHMP and CVMP.

Declarations of Interest (DoI)

EC independent Scientific Committees

An Annual Declaration of Interests is required from all members of the Scientific Committees and scientific advisors from the Pool. These declarations shall be made in writing and published in the Commission's website [Commission Decision 2008/721/EC, §5.2 and Annex II of Rules of Procedure].

A Specific Declaration of Interests is required from all Advisors and experts participating in Working Groups (including the relevant Scientific Committee members) and the Advisors associated to a Scientific Committee. [Commission Decision 2008/721/EC and Annex II of Rules of Procedure].

Members, Scientific Advisors and external experts participating in meetings of the Scientific Committees or in a Working Group or in any other activity of the Advisory Structure shall declare at each meeting or event any activity, situation, circumstance or other fact potentially involving a direct or indirect interest, as indicated in the explanatory notes included in the relevant Annex in order to allow the Scientific Committee and/or the Commission to identify those interests which might be considered prejudicial to their independence in relation to the items on the agenda for that meeting or event. This declaration shall be made in writing or verbally, following a request of the Chair or the Commission [§5.3 of Rules of Procedure.].

Trainees attending the Scientific Committees' meetings as provision in Art 8 of Commission Decision 2008/721/EC shall sign a declaration of interest [§17 of Rules of Procedure.].

A detailed guidance on the completion of the declaration of interest, as well as an example of the form, can be found in Annex II of the Rules of Procedure.

ECDC

Before being appointed for working in a panel, experts are informed on the code of conduct for experts (ethical principles and rules about confidentiality, discretion, non disclosure, integrity, independence, objectivity, impartiality, the obligations to declare at each meeting conflicts of interest, the sanctions in case of non compliance, false declaration) and must fill out (or update) a conflict of interest form, confidentiality declaration and a declaration of interest. An explanatory leaflet is provided to guide experts on how to complete the declaration of interest. In addition an oral declaration will be obtained from each member at each meeting of any interests which might be considered prejudicial to expert's independence in relation to items on the agenda.
The declaration of interest forms are filled in by experts before they are appointed for working in a panel (written) and at each meeting (oral).

ECHA

Declarations of interests (DoIs) are made as follows:

Initial declaration: Upon his/her appointment, each member is required to fill in and sign a declaration of interests form.

Appointment as rapporteur: A member should not accept appointment as a rapporteur or co-rapporteur if he/she indicates any interest that might be prejudicial to the independent consideration of that case. For each case, the rapporteurs and co-rapporteurs must make a declaration of commitment and a declaration of interests in writing according to Article 87(1) of the REACH Regulation.

Update of the initial declaration: Declarations must be updated annually or without delay once relevant changes have occurred.

Spontaneous declarations: At each of their meetings, members, their advisers and invited experts or its working group must declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall not participate in any voting on the relevant agenda point. The spontaneous declarations will be recorded in the minutes of the meeting.

The Declaration of Interest is to be completed according to Article 9 of the RAC Rules of Procedure..

EMA

All scientific Committees members and alternates are required to complete an Annual Declaration of Interest, which is published on the EMA webpage. In addition, members, rapporteurs and experts who participate in scientific committees meetings shall declare, at 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 also be made available to the public.

Where a scientific committee member has declared an interest, this interest will be evaluated in accordance with the procedure for the Handling of Conflicts of Interest for EMA Scientific Committees Members and Experts and the expert will only be allowed in EMEA activities to the extent defined by the assigned risk level (EMA Procedure on the handling of conflicts of interests for EMA scientific committees members and EMA experts - Revision 1)

On a general point, it should also be noted that experts are required to provide information on all declared interests within the previous 5 years. Experts are invited (but not obliged) to provide information on interests over 5 years ago. Such information is not used in the evaluation of declared interests but is useful in the context of an increased transparency as regards previous interests.

Nature of interest to be declared

EC independent Scientific Committees

Members of the Scientific Committees, Advisors as well as external experts shall declare current and past activities in the Annual and Specific Declaration of Interest (same form) in the following areas:

1. Ownership of shares or other investments.
2. Membership in a Management Body or equivalent structure.
3. Membership in another Scientific Advisory Body
4. Employment
5. Consultancy/Advice
6. Research
7. Intellectual property rights (IPR)
8. Other membership or affiliation
9. Interests of close family members
10. Other

A detailed guidance on the completion of the declaration of interest, as well as an example of the form, can be found in Annex II of the Rules of Procedure..

ECDC

Several types of interests can be identified, including (1) financial holdings in companies, (2) activities resulting in personal payments, (3) activities resulting in payments to an organization where the expert is a member, and (4) other unpaid links.

ECHA

Annex 2 of the rules of procedure for the ECHA Committees contains a model for the annual declaration of interests by Committee members. The interests required to be declared include relevant work and activities during the previous five years; financial interests and any other relevant interests or facts.

EMA

Direct interests:
Interests of personal benefit to the individual at any point in time, likely to influence or give the appearance of influencing his behaviour (e.g. employment with a pharmaceutical company, financial interests of a certain magnitude)

Personal interests:
Relate to salaries, shares, share options, or fees earned by acting as a consultant – (A consultant is defined as an expert who charges a fee (personal, institutional or both) for providing advice or services in a particular field).

Financial interests:
Any financial interests in the pharmaceutical industry, including holding of stocks and shares, stock options, equity, bonds, partnership interests in the capital of a pharmaceutical company, one of its subsidiaries or a company in the capital of which it has a holding.
The holding of financial interests connected with a pension scheme previously contracted prior to the nomination as committee or working party member or expert or appointment as EMA staff and/or interests in non-nominal unit trusts or similar arrangements would not, in principle, have particular consequences providing the individual has no influence on financial management.
Contract /collaborative research or clinical trials would normally be defined as institutional interests – (see definition of institutional interest – related to institutional contracts or supervisory research interests).

Institutional interests:
Relate to institutional contracts or supervisory research interests.

Indirect interests:
Other interests that may have some influence over the individual's behaviour.

Criteria and practises for decision on possible conflict of interest

EC independent Scientific Committees

Declarations of Interest are addressed by an expert to his/her peers and the Secretariat as an indication of where conflicts of interest could arise and do not require from the author to assess whether there is a conflict. The assessment of whether there is a potential conflict is performed by the peers (i.e. the Chair and the other members of the SC) and the Secretariat [Annex II of Rules of Procedure.].

The Chair, in collaboration with the Secretariat examines the declarations of interest, deciding, in consultation with the Committee and in agreement with the Commission the relevant conclusions and action in order to ensure the effective application of the independence requirements [§ 9.2.1 of Rules of Procedure.].

It is well understood that, in general, individuals who are involved in a particular process have an inherent professional interest in the subject and in being involved in the process as such. In particular, interests of an intellectual nature are considered as essential to safeguard the quality and overall objectivity of the scientific work. The Commission recognizes that high quality and up-to-date scientific expertise is by nature based on prior experience, connection to the scientific world and involvement in current research. Therefore, having an "interest" declared does not necessarily mean having a conflict of interest. [Annex II of Rules of Procedure.].

ECDC

The declaration of interest and conflict of interest forms are reviewed and an appropriate action recommended by:

- The Chairman of a specific panel, if in doubt, the case will be referred to:
- The ECDC Chief Scientist, if still in doubt, the case will be reviewed by:
- The Conflict of Interest Committee.

ECHA

The declared conflict of interest is checked against the Rules of Procedure. and guidance.

EMA

The first general screening takes into consideration the background of the expert and the nature of the interest declared (personal / institutional). This screening would not consider the activity for which the involvement of the expert is required, at this stage. Risk level 2 / 3 at initial screening is assigned to any expert who has indicated any declared interest on his / her Declaration of interest form.

The declared interests of such experts (risk level 2 at initial screening) are then screened with respect to the specific EMA activity for which their involvement is proposed. The re-classification criteria are outlined in the EMA procedure on the handling of conflicts of interest for EMA scientific committees members and experts document (section III.2.2)

In the majority of cases, the interests declared are either in an area other than that for which involvement is requested, or the type and timeframe of their involvement will be such that their declared interests are not considered to represent a conflict of interest with respect to the specific activity. However, in some instances, this second phase analysis will lead to a re-classification of Risk level 2 or 3, with respect to the specific activity for which involvement is requested. Such experts are then referred to the Declaration of Interest Assessment Group.

Modulation of involvement of experts declaring interest

EC independent Scientific Committees

In case of conflict of interest of the Chair with an item on the agenda, he/she may be replaced by one of the Vice-Chairs or failing that another member chosen in common accord by the members [§ 9.2.3 of Rules of Procedure.].

Any member, Advisor or external expert who, in accordance with his/her declaration or in the opinion of the Scientific Committee, the Working Group or the Commission, may not be able to act independently, shall be excluded from the activities considered or may only be allowed to participate to the extent and in a way compatible with the objective to preserve the process from any undue influence. In such a case, the member, advisor or expert may not act as Rapporteur or as Chair in relation to the specific matter and may not participate in decision-making. The extent of the concerned individual's participation in the Committee's work shall be decided by the Chair in consultation with the Committee or Working Group members and in agreement with the Commission within the framework of these Rules of Procedure. Measures may include the physical withdrawal from the meeting for the point under discussion, or participation limited to the provision of factual information [§ 5.5 of Rules of Procedure.].

Conclusions and decisions taken in relation to the declarations of interest, as well as their rationale, shall be recorded. In the case of declarations presented during meetings, such records will be part of the minutes [§ 5.6 of Rules of Procedure.].

ECDC

The declaration of interest indicates either the absence of any interest which might be considered prejudicial to the expert's independence or any direct or indirect interests which might be considered prejudicial to his/her independence.
In such cases an expert is disqualified from the relevant discussions and decisions.

ECHA

See Articles 9 and 19 of the Risk Assessment Committee Rules of Procedure.

EMA

Referral to Declaration of Interest Advisory Group (DIAG) in the absence of alternative experts of a lower risk level.

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

In line with EMA's procedure on Handling of Conflicts of Interest, specifically relating to participation in specific product/class related matters, an expert classified at risk level 2 can participate addressing orally or in writing specific questions raised during the evaluation, but cannot draft assessment reports or parts of it. The expert should leave the room when a final decision or a vote takes place. The interests of this expert should be clearly declared and minuted.

Measures taken in cases of non-declared interests

EC independent Scientific Committees

Failure to fulfil in a timely and complete manner any of the obligations detailed above will be considered as a prima facie breach of trust towards the Commission. As a consequence, the

Commission will take any actions deemed necessary, including the dismissal of the concerned persons from the Advisory Structure [Annex II of Rules of Procedure.].

ECDC

Situation will be reviewed by and an appropriate action recommended by:

- The Chairman of a specific panel, if in doubt, the case will be referred to:
- The ECDC Chief Scientist, if still in doubt, the case will be reviewed by:
- The Conflict of Interest Committee.

ECHA

The Chair of the Committee for Risk Assessment (RAC) would be the one to deal with this issue in the first instance, i.e. to discuss with the member and evaluate the alleged conflict of interest. The Chair would discuss with the member their reasons for not declaring. If no agreement is achieved, the Chair will consult the general issue with the Committee in a Closed Session. Depending on the nature of the issue, the Committee may consider appropriate to appoint one or several members to discuss the specific issue with the Member and the Chair; the ECHA Secretariat will provide legal support if required. If no agreement is achieved, the case will be considered by ECHA in consultation with the Committee.

If the Agency considered there was a conflict of interest, and it was identified before adoption of the opinion, where the conflict related to the Rapporteur drafting the opinion he/she would be requested to stand down, or in the case of a member, not to participate in voting. If the conflict of interest was discovered after voting had taken place it would be necessary to check with the Committee whether the vote of the biased member had influenced the result. Generally speaking, it is the responsibility of the member to declare a conflict of interest. If this is not declared, the member is in breach of their obligations and this could be a point for Article 5(2) of the RAC Rules of Procedure to submit a justified proposal to the Executive Director of the Agency to ask the member to resign.

EMA

The EMA can only evaluate interests declared. If an interest is not declared, and subsequently comes to light, EMA management will discuss the potential impact of this declared interest on the activity with which the expert was involved and decide on any necessary action.

Publication of Declarations of Interest

EC independent Scientific Committees

In accordance with the provisions on transparency foreseen by Commission Decision 2008/721/EC, the Annual and the Specific Declarations of Interest are made public [§ 6 and Annex II and of the Rules of Procedure.].

ECDC

The register of scientific advice, including composition of panels, but not declaration of interest, is planned to be published on ECDC website.

ECHA

Annual declarations and updates are published on the ECHA website:

Declarations for rapporteurships are kept on file and spontaneous declarations at the beginning of meetings are recorded in the minutes. These are kept on register at ECHA premises available to the public on request.

EMA

Declarations of interest and confidentiality undertakings are available to the public on request at the Agency's offices. As part of the Agency's efforts to promote transparency, the declarations of interests of and confidentiality undertakings of Board and committee members are also available on the following EMA webpages:

http://www.ema.europa.eu/htms/general/contacts/MB.html
http://www.ema.europa.eu/htms/general/contacts/CHMP/CHMP_members.html
http://www.ema.europa.eu/htms/general/contacts/CVMP/CVMP_members.html
http://www.ema.europa.eu/htms/general/contacts/COMP/COMP_members.html
http://www.ema.europa.eu/htms/general/contacts/HMPC/HMPC_members.html
http://www.ema.europa.eu/htms/general/contacts/PDCO/PDCO_members.html
http://www.ema.europa.eu/htms/general/contacts/CAT/CAT_members.html