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