



Register of Commission expert groups and other similar entities

Commission Expert Group

Name: Expert Group - notice to applicants - human (E02469)
(Active - Group which operates on a permanent basis)

Policy Area: Public Health

Lead DG: SANTE - DG Health and Food Safety

Type: Informal, Permanent

Scope: Limited

Mission: Draw up and discuss the "Notice to Applicants" which is guidance intending to facilitate the interpretation and the application of the EU pharmaceutical human legislation. It is not legally binding and, in case of doubt, reference should be made to the appropriate EU Directives and Regulations.

Task: Other

Provide expertise to the Commission when drafting the Notice to applicants

Contact: sante-pharmaceuticals-b5@ec.europa.eu

Publication in RegExp: 03 May 2010

Link to Website: http://ec.europa.eu/health/documents/eudralex/vol-2_en

Last updated: 23 Jun 2017

Additional Information

Activity Report

SANTE B5 representative chairs meetings (approx. 2 per year). The main issues discussed are the review of Notice to applicant. The NtA group is composed of representatives from Member States and from EMA. The notice to applicants documents are intended to facilitate the interpretation and application of EU pharmaceutical law. They are published on the website.

http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm

Selection Procedure (members)

For the purpose of this group it was decided that the members needed to be relevant competent authorities in the Member States, competent authorities in Iceland and Norway as well as the European Medicines Agency (EMA).

Internal Rules of Procedure

Expert groups usually operate in an informal setting without any formal rules of procedure. This is the case for this group.

Members

Type D - Member State Authority

Country		Membership Status
Austria	1 Public Authorit(y-ies)	Member
Belgium	1 Public Authorit(y-ies)	Member
Bulgaria	1 Public Authorit(y-ies)	Member
Croatia	1 Public Authorit(y-ies)	Member
Cyprus	1 Public Authorit(y-ies)	Member
Czech Republic	1 Public Authorit(y-ies)	Member
Denmark	1 Public Authorit(y-ies)	Member
Estonia	1 Public Authorit(y-ies)	Member
Finland	1 Public Authorit(y-ies)	Member
France	1 Public Authorit(y-ies)	Member
Germany	1 Public Authorit(y-ies)	Member
Greece	1 Public Authorit(y-ies)	Member
Hungary	1 Public Authorit(y-ies)	Member
Ireland	1 Public Authorit(y-ies)	Member
Italy	1 Public Authorit(y-ies)	Member
Latvia	1 Public Authorit(y-ies)	Member
Lithuania	1 Public Authorit(y-ies)	Member
Luxembourg	1 Public Authorit(y-ies)	Member
Malta	1 Public Authorit(y-ies)	Member
Netherlands	1 Public Authorit(y-ies)	Member
Poland	1 Public Authorit(y-ies)	Member
Portugal	2 Public Authorit(y-ies)	Member
Romania	1 Public Authorit(y-ies)	Member
Slovakia	1 Public Authorit(y-ies)	Member
Slovenia	1 Public Authorit(y-ies)	Member
Spain	1 Public Authorit(y-ies)	Member
Sweden	1 Public Authorit(y-ies)	Member
United Kingdom	1 Public Authorit(y-ies)	Member

Type E - Other public entity

Subgroups

No Subgroups assigned to this group.

Statistics

Number of Members: 29

Type A - Individual expert appointed in his/her personal capacity: 0 female: 0 male: 0

Type B - Individual expert appointed as representative of a common interest: 0 female: 0 male: 0

Type C - Organisation: 0

Type D - Member State Authority: 28

Number of Alternate Members: 0

Type A - Individual expert appointed in his/her personal capacity: 0 female: 0 male: 0

Type B - Individual expert appointed as representative of a common interest: 0 female: 0 male: 0

Type C - Organisation: 0

Type D - Member State Authority: 0

Number of Observers: 2

Type A - Individual expert appointed in his/her personal capacity: 0 female: 0 male: 0

Type B - Individual expert appointed as representative of a common interest: 0 female: 0 male: 0

Type C - Organisation: 0

Type D - Member State Authority: 0