

Q&A on Membership and Observership

Questions about being a Member

1) What are the requirements to become a Member of ICH?

ICH welcomes applications from parties seeking to become a Member of the Association. Membership is open to any regulatory or industry party that fulfils the requirements set out in the Articles of Association.

There are a number of requirements for Regulatory Members, including responsibility for the regulation of pharmaceuticals for human use, certain past activity within ICH and also implementation of key set of ICH guidelines.

Industry Members must also fulfil a number of requirements, including representation of members from several countries in at least three continents, certain past activity within ICH and that its members are regulated or affected by ICH guidelines.

Full details of the requirements are given in the Articles of Association 11 and 12.

Applications for membership should be made using the forms available on the ICH website www.ich.org and sent to the ICH Secretariat at least two months before the following ICH Assembly meeting.

→ See also: Articles of Association Article 11 for eligibility requirements for Regulatory Members, and Assembly Rules of Procedure Section 1.1.

→ See also: Articles of Association Article 12 for eligibility requirements for Industry Members, and Assembly Rules of Procedure Section 1.2.

→ See also: Articles of Association Article 13 for details on the membership application process, and Assembly Rules of Procedure Section 1.3.

2) What are the rights and obligations of ICH Members?

ICH Members have certain rights and obligations, for example providing experts to the various working groups and attendance at Assembly meetings. Regulatory Members are required to implement ICH guidelines and Industry Members are required to support and encourage compliance with ICH guidelines. More generally, all Members shall also support the aims of the ICH Association.

Full details of all rights and obligations are set out in the Articles of Association.

→ See also: Articles of Association Articles 11 and 12 on rights and obligations of Regulatory and Industry Members

→ See also: Articles of Association Article 14 on termination of membership

→ See also: Assembly Rules of Procedure Section 7 on Supporting ICH

- 3) If a national regulatory authority has represented an RHI (Regional Harmonisation Initiative) and has participated for more than two consecutive years, can that be counted as participation of that national regulatory authority within the meaning of Article 11(1)(c) of the ICH Articles of Association?¹**

ICH recognises the role that RHIs have played in ICH in previous years and to the contribution of representatives. However, the role of an RHI observer is different from that of a national regulatory authority, and therefore such participation cannot be considered as participation in the meaning of Article 11(1)(c).

Questions about being an Observer

- 4) If a former Global Cooperation Group member (RHI or DRA) is accepted as an Observer, will that party have certain privileges to participate in Working Groups?**

No, all Observers have the same right to attend Assembly meetings, but do not have voting rights. The Assembly may invite Observers to appoint experts in Expert Working Groups, on the basis of recommendations of the Management Committee. Observers may also inform the ICH Secretariat of any request to participate in specific Working Groups, which is then taken into consideration by the Assembly.

→ See also: Articles of Association Article 17.3 on Observers

→ See also: Assembly Rules of Procedure Section 4.3.7

- 5) Do the DRA/DoH Pre-meetings or Global Cooperation Group (GCG) still exist?**

The GCG no longer operates following the creation of the ICH Association. Much of the activities of the GCG have now been absorbed into the role of the Assembly.

- 6) What are the rights and obligations of ICH Observers?**

ICH Observers have fewer rights and obligations than Members. In addition to the right to attend Assembly meetings, Observers can also be invited to nominate experts to Working Groups.

→ See also: Articles of Association Articles 16 and 17 on Observers

Other Membership or Observership questions

- 7) What kind of organisations could be accepted as an Observer?**

The eligibility criteria for Observership are described in the Articles of Association 17.

Observers may include legislative or administrative authorities (Article 17.1(a)), Regional Harmonisation Initiatives (Article 17.1(b)), international pharmaceutical industry organisations

¹ Article 11(1) "A regulatory or administrative authority of any jurisdiction is eligible to become a Regulatory Member if it can demonstrate that it: ... (c) has during the previous two (2) consecutive years prior to the application for membership participated in at least three (3) Assembly meetings or meetings held by [ICH] prior to the establishment of the Association; ..."

(Article 17.1(c)), and international organisations whose work and/or membership is regulated or affected by ICH Guideline(s) (Article 17.1(d)).

→ See also: Articles of Association Article 17 on Observers

→ See also: Assembly Rules of Procedure Section 2.2.1

8) Can an individual person or company apply to be a Member or Observer of ICH?

No, individual people or companies are not eligible to become Members or Observers of ICH.

The ICH Articles of Association describe in detail the criteria for organisations to become ICH Members or Observers, for example regulatory authorities, international organisations representing the pharmaceutical industry and international organisations with an interest in pharmaceuticals.

→ See also: Articles of Association Sections II and III on Membership and Observership

→ See also: Assembly Rules of Procedure Sections 1 and 2

Ad-hoc Observers

9) What sort of organisations or individuals could meet the criteria of Ad-hoc Observer under Article 18 of the Articles of Association? What are the criteria?

Invitations are likely to be extended to those who have shown interest in ICH activities or who are deemed to have an interest in ICH. Invitations are made for one or more specific Assembly meetings rather than ongoing participation.

→ See also: Articles of Association Article 18 on Ad-hoc observers

→ See also: Assembly Rules of Procedure Section 2.3

Member or Observer application process

10) What are the timelines for application for membership or observership?

Applications can be made at any time, but it is recommended to submit applications at least two months before an ICH Assembly Meeting (generally held in May/June and November/December each year).

This will allow time for appropriate review and consideration of a recommendation by the Management Committee ahead of the Assembly meeting.

→ See also: Assembly Rules of Procedure Section 1.3.3

11) What is the process to become an Observer or a Member? Do you need to sign an international agreement with ICH?

Applicants should use the appropriate application form available on the ICH website and provide the documentation and information to demonstrate that they meet the appropriate eligibility criteria.

ICH is a non-profit Association (under Swiss law) composed notably of regulatory authorities and international industry associations. It is not an international governmental organisation, and no international or inter-governmental agreement is required when becoming a Member or Observer.

Please note for international pharmaceutical industry organisations wishing to apply for Observership under category 17.1(c), and international organisations whose work and/or membership is regulated or affected by ICH Guideline(s) wishing to apply for Observership under category Article 17.1(d), that prior to submitting an application, organisations should first submit a written expression of interest to the ICH Secretariat seeking to exceptionally attend an Assembly meeting as an Ad-hoc Observer, within the meaning of Article 18. Organisations should note that such participation would be at their own expense.

→ See also: Assembly Rules of Procedure Section 2.2.2

12) How does ICH evaluate applications to become a Member or Observer?

All applications are reviewed against the eligibility criteria set out in the Articles of Association. These are set out in Articles 11 (Regulatory Members), 12 (Industry Members) and 17 (Observers) of the Articles of Association. During the application process, the applicant may be asked to clarify or provide additional information.

The ICH Secretariat may reject any expressions of interest/applications where an applicant clearly does not meet the eligibility criteria and provide the applicant with information about the reasons for the rejection. The applicant may choose to resubmit its expression of interest/application and provide any necessary clarification on its eligibility.

Applications are provisionally reviewed by a membership subcommittee of the Management Committee before they are considered by the entire Management Committee, in line with the Rules of Procedures. The decision on whether or not to accept each application is taken by the Assembly on the basis of a recommendation of the Management Committee.

Decisions on applications are made by the Assembly, which meets twice a year; it is therefore recommended to make applications preferably at least two months before the following Assembly meeting (generally held in mid-June and late-November/early-December each year).

→ See also: Articles of Association Article 13 on membership admission

→ See also: Articles of Association Article 17 on Observers

→ See also: Application form on the ICH website www.ich.org

→ See also: Assembly Rules of Procedure Sections 1.3.1 and 2.2.1

13) Are there different review processes for regulators and industry applications to be a Member or Observer?

The review process is the same for all applications, although the process will take into consideration the different eligibility criteria for each type of applicant.

14) Would an applicant be advised of the Management Committee recommendation before it is forwarded to the Assembly?

Yes. Applicants for membership or observership, whose application has been provisionally assessed and considered by the Management Committee as fulfilling the relevant criteria, should in principle be invited as Ad-hoc Observers no later than one month prior to the following Assembly meeting where their application will be dealt with.

→ See also: Articles of Association Article 13 on membership admission

→ See also: Articles of Association Article 17 on Observers

→ See also: Assembly Rules of Procedure Sections 1.3.2 and 2.2.1

15) Can an organisation re-submit an application at a later date if it is not accepted first time round?

Yes.

16) Who within an organisation can make the application? Does it need to be the chief executive?

Applications should be made by a representative of the applicant entity who is appropriately authorised to bind that entity with regard to agreements with third parties.

17) Can an applicant attend the next Assembly meeting after submitting its form or does it have to wait until a decision has been taken on its application?

Applicants will need to wait until they receive a response. The Management Committee will work diligently to review applications with a view to inform the applicant of the provisional decision as early as possible. An invitation to attend as an Ad-hoc Observer will be sent to the applicant no later than 1 month prior to the Assembly meeting in general.

ICH governance structure

18) What is the process to become a member of the Management Committee?

At the legal creation of the Association on 23 October 2015, the Management Committee was composed of 16 representatives ('Permanent Management Committee Representatives'). These were nominated – 2 each – by the 3 Founding Regulatory Members, the 3 Founding Industry Members, and the 2 Standing Regulatory Members. In addition, WHO and IFPMA were able to nominate 2 Permanent Observer delegates each.

No later than 1 January 2018, the Management Committee is expected to have a different composition. In addition to the 16 Permanent Management Committee Representatives, there may be up to 12 Elected Management Committee Representatives.

These will be appointed by the Assembly, after consultation with the Management Committee, with up to 8 representatives from up to 4 Regulatory Members and up to 4 representatives from up to 2 Industry Members.

→ See also: Articles of Association Articles 28-32 on the Management Committee

Financial and related questions

19) What are the annual membership fees for Members and Observers?

Fee levels are set by the ICH Assembly, and are published on the ICH website.

Different fee levels are agreed depending on the different category of membership. Founding Regulatory Members and Founding Industry Members pay the highest level of fees. Standing Regulatory Members and Regulatory Members/Industry Members have different fee levels.

To date, there are no fees for any category of Observer.

→ See also: Membership fees on www.ich.org

→ See also: Assembly Rules of Procedure, section 5