

The Future of ICH - Revised 2000

Statement by the ICH Steering Committee on the occasion of the Fifth International Conference on Harmonisation, 9-11 November 2000, San Diego

The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 as a joint regulatory/industry project to improve, through harmonisation, the efficiency of the process for developing and registering new medicinal products in Europe, Japan and the United States, in order to make these products available to patients with a minimum of delay.

The six parties to ICH represent the regulatory bodies and research-based industry in the three regions, Europe, Japan and the USA, where the vast majority of new medicines are currently developed.

The ICH process has achieved success because it is based on scientific consensus developed between industry and regulatory experts and because of the commitment of the regulatory parties to implement the ICH tripartite, harmonised guidelines and recommendations.

The Fifth International Conference on Harmonisation (ICH 5) San Diego, November 2000, marks the end of 10 years of activity thus providing an opportunity to evaluate results and to identify future needs in the area of international harmonisation.

Continuation of harmonisation activities

The ICH Steering Committee and other interested parties have agreed to continue in their commitment to pursue future harmonisation activities.

ICH has been successful in achieving harmonisation, initially of technical guidelines and more recently on the format and content of registration applications. All parties agree that there is a need to maintain this harmonisation in the interest of the patient and public health to prevent unnecessary duplication without compromising the regulatory obligations of safety, quality and efficacy. New approaches to the maintenance of the products of harmonisation is needed. In addition, further harmonisation activities should be continued in a focused manner.

- **Implementation and monitoring**

The current magnitude of successful harmonisation actions and the need for these to remain current in a rapidly changing international environment calls for focusing more effort on the implementation and monitoring of ICH commitments. These will be key to the success, in particular, of the Common Technical Document (CTD), in which the creation of implementation groups or task forces will be important.

- **Selection of new topics**

The Steering Committee agrees that it is important to continue with the work of harmonisation after ICH 5, provided that the selection of possible new topics continues to be carried out in a systematic and focused manner. Experience with recent harmonisation activities have identified a need for an even more careful advance examination of a potential topic for future harmonisation in order to ensure that it is feasible, able to be implemented in a timely manner, and provides a high added value for all of the ICH partners. New activities will most likely be in areas where there are new technological advances, new innovative medicines, or in post marketing areas. Topic selection should be preceded, where necessary, by a feasibility study and/or a scientific pre-screening.

Recent interactions between the regulators involved in ICH have identified post marketing activities as a future area where increased regulatory co-operation can help to contribute to the enhancement of the protection of the health of citizens on a more international basis.

Steering Committee structure and participation

The existing Steering Committee structure continues to be appropriate. In the interests of greater transparency, the Steering Committee, however, welcomes the appropriate participation of other interested parties in a flexible and ad hoc manner on topics which affect them.

The Steering Committee continues to believe that regular large conferences help to communicate the results of the harmonisation activities to the widest possible audience.

Global co-operation

The recent emphasis on global co-operation actions by ICH acknowledges the important role of WHO in disseminating information and providing input beyond the ICH regions. The Steering Committee recognizes the need to expand its communication and dissemination of information with non-ICH parties. A more active involvement of WHO through its regional centres is welcomed.

New ways of working together

There is a need to explore alternate approaches to the traditional ICH model of expert working groups (EWGs), particularly in areas where constantly changing scientific information has been identified. The possibility of making better use of techniques such as videoconferencing and electronic communication can only serve to enhance the communication between the ICH parties, as well as with other involved parties.

Revised ICH Terms of Reference

- To maintain a forum for a constructive dialogue between regulatory authorities and the pharmaceutical industry on the real and perceived differences in the technical requirements for product registration in the EU, USA and Japan in order to ensure a more timely introduction of new medicinal products, and their availability to patients;
- To contribute to the protection of public health from an international perspective;
- To monitor and update harmonised technical requirements leading to a greater mutual acceptance of research and development data;
- To avoid divergent future requirements through harmonisation of selected topics needed as a result of therapeutic advances and the development of new technologies for the production of medicinal products;
- To facilitate the adoption of new or improved technical research and development approaches which update or replace current practices, where these permit a more economical use of human, animal and material resources, without compromising safety;
- To facilitate the dissemination and communication of information on harmonised guidelines and their use such as to encourage the implementation and integration of common standards