

**Statement by the ICH Steering Committee on the occasion of the Fourth
International Conference on Harmonisation
16-18 July 1997, Brussels**

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 Fourth International Conference on Harmonisation (ICH 4) Brussels, 16-18 July 1997, marks the **completion of the first phase** of ICH activities in which significant progress has been made towards the goal of reducing duplication in the process for developing new medicinal products and submitting technical data for registration.

Continuation of Harmonisation Activities

The six-party structure will continue as the operational basis for harmonising technical requirements for new medicine development and registration of products containing new drug substances.

The six founder members of ICH have agreed that a second phase of harmonisation activities should continue after ICH 4 in order to ensure that:

- there is a mechanism to harmonise new technical requirements resulting from scientific progress and developments in innovative drug research;
- there is a process for updating and supplementing the current ICH guidelines, when necessary and monitoring their use, so that the benefits of harmonisation achieved so far are not lost;
- future disharmony is prevented through early collaboration and exchange of information on newly emerging issues, originating in one of the regions.

Scientific Consensus

It is recognised that some of the topics selected for harmonisation have implications for regulatory agencies and sectors of industry not represented by the six parties to ICH. Since it first started, the ICH Steering Committee has included observers from WHO and regulatory authorities in EFTA and Canada and participation in the Expert Working Groups has been extended, according to the subjects discussed, to Pharmacopoeial authorities, generic industry associations and representatives of the non-prescription pharmaceutical industry.

This wider participation in the expert working groups will continue and may be extended on a topic-by-topic basis. This will apply to Expert Working Groups which are convened to discuss new topics or the updating or extension of current ICH guidelines, especially where the topics have implications beyond the registration of new drug products in the three ICH regions.

Notwithstanding the wider participation in technical discussions, the adoption and implementation of new, updated or extended harmonised ICH guidelines will continue to be the responsibility of the regulatory parties in the three ICH regions, taking into account the results of the regulatory consultative process, within each region.

Conferences and Workshops

The biennial International Conferences on Harmonisation (Brussels, 1991; Orlando, Florida, 1993; Yokohama, Japan, 1995; and Brussels, 1997) have been important for disseminating information on ICH and for ensuring that harmonisation is conducted in an open and transparent manner. Periodic Conferences and Workshops will continue to be organised by ICH as a vehicle for communication and discussion of harmonisation issues.

Globalisation of the Benefits of Harmonisation

The success of the ICH initiative and its first phase of activities has resulted in considerable interest from regulatory and industry bodies outside the three ICH regions.

With the successful completion of the first phase of international harmonisation, it will be increasingly important to ensure that the objectives and outcome of ICH are well understood and widely disseminated. This challenge will be taken up by the six parties to ICH, WHO and through the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), in conjunction with other interested parties.

The important role of WHO, both in actively disseminating the guidelines and encouraging the wide-spread adoption and use of ICH guidelines is warmly welcomed and is essential if the long-term benefit of international harmonisation, in terms of quicker access to effective new medicines, is to be available to patients throughout the world.

Second Phase of International Harmonisation

ICH activities will move into a second phase with a continuing commitment to increased international harmonisation, aimed at ensuring that good quality, safe and effective medicines are developed in the most expeditious and cost effective manner. These activities are pursued in the interest of the patient, consumer and public health, to prevent unnecessary duplication of clinical trials in humans and to minimise the use of animal testing without compromising the regulatory obligations of safety and effectiveness.

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 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.