

STATEMENT BY THE ICH STEERING COMMITTEE TOKYO, OCTOBER 1990

The Parties cosponsoring this Conference, represented at the 2nd Steering Committee Meeting in Tokyo, 23-24 October 1990 re-affirmed their commitment to increased international harmonisation, aimed at ensuring that good quality, safe and effective medicines are developed and registered in the most efficient and cost-effective manner. These activities are pursued in the interest of the 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.

This Conference will provide a unique opportunity for regulators and industry to reach consensus on the steps needed to achieve this objective through greater harmonisation of technical requirements and to set out practical and realistic targets for harmonising requirements where significant obstacles to drug development and the regulatory process have been identified.

Recognising the substantial progress which has already been made in achieving harmonisation within Europe and through bilateral contacts between Europe, Japan, USA and other regions, the Conference will seek to make further progress through a trilateral approach, with clearly defined priorities, methods of work and recommendations to both industry and regulatory authorities.

Whilst the Conference will be an important step forward, it is not seen as an end in itself, but as a stage in a developing process, at a high level, between regulators and industry.

The Conference, its preparations and follow-up activities will be conducted in an open and transparent manner and the presence of observers from other regulatory authorities and WHO is welcomed as a means of ensuring that the benefits of progress towards harmonisation can be utilised world-wide.

The Conference will not only look at existing issues but will, based on past experience, seek to minimise future divergence of new registration requirements, as a consequence of technical progress.