ICH INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL
REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Final Concept Paper
M2: Electronic Standards for the Transfer of Regulatory Information
27 October 1994

Problem Statement/Objectives

There is a need to communicate information on -medicinal products rapidly from Sponsors to Regulatory Authorities and. in particular, to disseminate information on safety between Authorities. This can be achieved most effectively using electronic communication.

Currently, a number of separate, unco-ordinated initiatives have been launched in different countries which creates the potential for having different standards adopted by different Authorities: this will inevitably lead to a duplication of work for Industry. Consequently, the potential for maximising the benefit from electronic communication is in danger of being compromised. In the interests of public health this situation cannot be allowed to continue.

As a prerequisite to international electronic information transfer, it is proposed that a common set of standards, be agreed to ensure the integrity of information and data exchange between Pharmaceutical companies and Authorities and between Authorities.

Background/Status quo

Traditionally, the majority of information on the quality, safety and efficacy of medicinal products is supplied to Authorities in the form of paper submissions or updates. Developments in communication technology and information systems now make it possible to transmit large volumes of this information by electronic means. Many Authorities are beginning to encourage electronic submissions for product approval and many Authorities have sponsored or are associated with projects whose objectives are to facilitate this process. Data and document management systems have been customised to satisfy individual Authority and Sponsor requirements. These systems are often based on very different underlying philosophies; they have evolved different data definitions and use different standards and coding dictionaries Communication between such systems is either very labour intensive or, in practical terms, not possible.

Proposal for Resolving the Problem

It is clear that the aim should be to use non proprietary, intermediate standards which could interface to all user specific hardware; it is not the intention to agree specific applications or systems.

Initiatives to harmonise the contents and terminology of the information to be exchanged should be conducted separately, and some are already in progress. The process of exchange will be carried out within an environment that will result from this concept paper.

- **Definition of Scope**

The objective under this topic will be to define logical electronic communication standards for communication with Regulatory Authorities. In effect, this means the adoption of those international standards essential for the direct communication of all information required ina submission and all associated information (primarily safety) required as part of the regulatory process.

- **Procedure**

It is proposed that a group with representatives from the six co-sponsors and observers will address communication in terms of Transport Vehicles and Logical Data Models. The group will be required to produce a uniform method of electronically exchanging information. This will be referred to as the "logical electronic communication standards" which will identify the elements and specify the standards needed to achieve uniformity. Where possible, existing international standards will be adopted and contact with other existing formally-constituted initiatives will be required.

- **Constraints**

It is suggested that the logical communication standards should be independent of the detailed format and content of a submission. It should relate to the information elements required in a submission. Although it is conceived that the electronic communication standards will change over time, the change should be primarily a response to developments in technology rather than as consequence of changes to information required in a submission.

It is also important to emphasise that the use of the word format when applied to the electronic storage of information is not synonymous with the physical formatting of information on paper. It should therefore be possible to reformat the physical presentation of a submission without consequent change to the communication standards.

Impact

The impact of internationally agreed logical communication standards will be significant. It will enable safety updates or submissions to be provided instantaneously to many Authorities and to facilitate communication between Authorities. There will be a number of advantages to the Authorities. These include the preparation of summaries and assessment of urgent reports, the administration of the submission, and improved retention and archiving of the submission.

There will be a primary benefit to public health as the international dissemination of product safety information will be rapid and instantaneous.

Additionally, there will be resource savings for Sponsors because the duplication in work required to tailor electronic submissions to a particular Authority requirement will disappear.

Timeframe

There is an urgent need to agree logical communication standards within the European Community, Japan and the USA, and to satisfy the needs of other Authorities.
It is possible that the major elements of the communication standards could be agreed for 1CH 3. This will require commitment and a demanding schedule of meetings and activities.

October 1994	Experts including technical experts to meet i) to assist ICH steering committee during discussion ii) to identify the standards and to formulate an action plan which must allow for input from other groups. The objective will be to produce a final draft of those standards that need to be agreed. In order to define the standards by January, it may be essential to phase the order in which standards will be addressed.
January 1995	Meeting of EWG. Final draft of the required standards agreed.
January - April	Reality test with existing topics e.g. E2 inside the `environment'.
April	Meeting of EWG (Washington ICH meeting). Define principal elements of Logical Communication Standards. Draft Step 2 proposal.

April - August Identify and recommend those international standards which are available and could be adopted.

November 1CH 3, Meeting of EWG. Step 2 proposal. Presentation of Communication Standards in terms of formal proposal.

Expert Group

This is a specialist area and a-new Expert Group will need to be created.

The Group will need to include expertise on both the information to be exchanged and on the technology standards. Input from other groups involved in overlapping activities such as the E2 EWG (Management of Clinical Safety Data) and the M1 *Medical Terminology* group, will be necessary.