

Final Concept Paper
E2C: Clinical Safety Data Management:
Periodic Safety Update Reports for Marketed Drugs
Dated and endorsed by the Steering Committee on 26 October 1994

Problem statement/Objectives

The requirements for periodic safety updates are not the same in the three regions. In order to avoid the duplication of effort and to ensure that important data are not lost/delayed in submission to competent authorities, it is proposed to establish an international consensus on the format, contents and timing for periodic safety updates of marketed medicinal products.

Background/Status quo

Periodic safety reports are intended to provide an update on the safety experience at defined times post marketing. This update is prepared by holders of marketing authorisations and transmitted to competent authorities at a frequency determined by regional regulation/administrative requirements and also dependent on how long the product has been on the market. A standard report format is also required.

Account should be taken of work in this area carried out by the CIOMS Working Group II (Geneva, 1992). Draft regulations within the EU and US have included large parts of the CIOMS II proposal; however, complete harmonisation and adoption of these standards have yet to be achieved.

Impact

The period within which safety update reports must be submitted in each of the regions differs (e.g., in the European Union: every 6 months for the first 2 years, annually for the subsequent 3 years and 5 yearly thereafter). In addition, it is necessary to prepare either different data sets or different formats for the submission of data in the different regions.

Time frame

The submission of periodic safety updates is familiar in all regions. Thus, it should be possible to reach Step 2 at ICH3.

Expert Group

As there is an expert group already in existence which has developed the ICH guideline on *Definitions and Standards for Expedited Reporting*, it is proposed that the same group form the basis for undertaking this topic. It will also be useful to liaise with CIOMS to benefit from the work already done.

(Membership to be confirmed by the six ICH parties)