Roche

Pharmaceuticals

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Docket No. 92S –0251
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD
20852

26 June, 2001

Comments on "Guidance for Industry, Providing Regulatory Submissions in Electronic Format – Post Marketing Expedited Safety Reports", dated 2 May 2001

Dear Sir or Madam

Please find below comments on the above document. Comments are organized according to the line number in the Guidance Document.

Lines 116 – 118. It is unclear from the guidance notes whether Individual Case Safety Reports (ICSRs) for initial and follow-up reports should be submitted on separate disks or on one disk identified as containing both initial and follow-up reports.

Lines 156 – 163. Given that ICSRs will be accepted in more than one version of the DTD concurrently (e.g. versions 2.0 and 2.1) the guidance should describe requirements for each DTD version rather than only those for version 2.1 of the E2B file as in the current document. In addition the guidance should give timelines with respect to requirements for a transition to a newer version of the DTD.

Line 193 Table 1. Table 1 is confusing because it addresses requirements for both version 2.0 and 2.1 of the E2B file. It would be clearer to provide two tables: one that gives an example for version 2.0 and another that provides an example for version 2.1.

For example, there is a discrepancy with the revised ICH E2B Guideline which states that no case should ever have both A.1.10.1 and A.1.10.2 populated yet the table has instances where both are filled in. The previous ICH E2B Guideline states that both identifiers may be transmitted if known (See notes for A.1.10.3). Additionally, it indicates that A.1.11.1 and A.1.11.2 should be used to provide suspected duplicate numbers and the other sender's identification yet **Lines 200 – 201** indicate that the company should capture its identification number in A.1.11.2.

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Lines 167 – 169. There will be a discrepancy between the case identifiers for some initial and follow-up reports where paper and electronic media are used for the submission of different reports for the same case. The FDA system should accept either the concatenated identifier or the MCN in A.1.10.2 rather than just the concatenated number as described in the document.
For example, if the ICSR being sent electronically is a follow-up to an initial report that was submitted on a paper Medwatch using only the MCN as an identifier and if the value in the A.1.10 field is the concatenation of country code, sender identification and report number, there will be a discrepancy between the identification numbers. The converse is also true: if an initial report is submitted as an electronic ICSR and uses the concatenated identification but a follow-up report is submitted as a paper Medwatch, with only an MCN as its identifier (as would occur in the instance where the submission is being accompanied by an attachment).

Lines 196 – 198. It is not clear which field should be used if an original report contained an incorrect identification number that is being corrected. An example of such a correction would be useful in this section.

Lines 271 – 273. If the name of the ICSR attachment is the manufacturer's control number it will not match with the unique identifier of the electronic ICSR that uses a concatenation of the country code, sender identification and report number. The value of A.1.0.1 in the ICSR and the name of the ICSR attachment should be identical to facilitate matching attachments to the proper ICSR. An alternative suggestion could be to use a combination of the Interchange sender ID code: sender code qualifier and the Interchange control reference (see Table 2 of the Guidance) for the ICSR as the name of the ICSR attachment. This suggestion pre-supposes that one ICSR is sent per transmission.

General comment: Guidance is needed of how to handle ICSRs that contain a field that exceeds the maximum ICH E2B field length.

Kind Regards

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