VICH/13/063
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Draft 2

VICH Electronic Standards Implementation Expert Working Group
(ESI EWG)

CONCEPT PAPER ON MODIFICATION OF VICH GL42

(Guidance on Pharmacovigilance: Data Elements for Submission of Adverse Event Reports)

1. Introduction

The former Pharmacovigilance Expert Working Group worked for many years to finalize GL42. However, even during this period, it was foreseen that difficulties might emerge during the eventual attempt to translate the data elements as set forth in GL42 into the technical framework necessary for electronic submission of these data elements. This work was undertaken by the Electronic Standard Implementation Expert Working Group, in the finalization of GL35 (Electronic Standards for Transfer of Data).

2. Problem Statement

As work proceeded on GL35 and the accompanying technical documents (StepByStep Document and Validation Procedures Document), it was found that many areas of GL42 were presented in a way that prevented straightforward and logical mapping of data elements within the message. The ESI EWG documented these in the hopes they could be addressed for future revision. Temporary solutions, or workarounds, were reached. Some critical areas within GL42 have not been satisfactorily resolved, such as the ability to identify the products of the reporting MAH, and to differentiate between biologics and non-biologics.

3. Discussion

The structure set forth to describe the data elements in GL42 is outdated in some areas. For example, the use of a set vocabulary list for the length of time from exposure to onset does not allow sufficient granularity for analysis. Some sections are grouped together such that their logical association is impaired. As our culture has become more technically advanced and electronic submission has become a reality rather than a dream, gaps have been identified that prevent the accurate translation of data elements into the electronic framework because of the structure presented in GL42. The ESI EWG wants to set forth a more straightforward and accurate framework for future versions of harmonized electronic submissions.

4. Recommendation (Points to be addressed)

ESI EWG members ask that the Steering Committee allow the group to revisit GL42 to make necessary changes. A list of identified change requests (~~ESI EWG Bucket List~~Points to be Addressed) is appended to this concept paper. As implementation of electronic submissions is achieved in the different regions, a need for more structural changes could be

identified that would allow better analysis of the transmitted data. An example would be structured transmission of laboratory data, which currently can only be captured in the narrative. ~~Necessary~~ Suggested revisions of this nature could be ~~addressed~~ discussed annually by the Maintenance Committee as is envisaged for GL30 and GL35.

5. Timetable

The current work on implementation of GL35 and its accompanying technical documents precludes immediate work on revision. We would ask to commence on the discussions for revision of GL42 beginning in the ~~fall~~ first quarter of ~~2013~~2014. Once the revisions are agreed on, the changes would be incorporated into the GL35 and its accompanying technical documents to be used in the next ~~version~~ GL35 implementation.

6. Resource Requirements for Preparation

ESI EWG personnel would participate through telephone conferences and email discussions. From past experience, at least one physical meeting would be required to facilitate smooth progress and finalization.

7. Impact Assessment

The updated GL42 would provide a more straightforward framework for providing electronic pharmacovigilance data. It is hoped this would facilitate further harmonization among the regional annexes.

- **Impact for Industry**
  The updated GL42 will provide a consistent and logical approach for the electronic submission of adverse event data.

- **Impact assessment for Regulatory Authorities and other Interested Parties**
  The updated GL42 will provide a consistent and logical approach for the electronic submission and receipt of adverse event data by regulators and allow a more complete set of readily analyzable data for pharmacovigilance evaluation.

8. Interested Parties

Regulators, veterinary pharmaceutical industry, veterinarians and consumers.

9. REFERENCES

VICH GL42 Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports (AERs)
(Step 7-FINAL)

VICH GL35 Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data

VICH Electronic Submission of Animal Adverse Events - Electronic Transmission Implementation Specifications VICH Step By Step Document

VICH Electronic Submission of Animal Adverse Events - Electronic Transmission Implementation Specifications VICH Validation Procedure Document

~~Bucket List for ESI EWG~~Points To Be Addressed For Revision of GL42