EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Pharmaceuticals and cosmetics

Summary report of meeting to discuss MedDRA implementation, EMEA, London 22 November 1999

Introduction

A meeting to discuss an implementation strategy for MedDRA in the EU was organised in the EMEA on 22nd November 1999. All Member States with the exception of Greece, were represented, and Norway and Iceland sent representatives as observers. This meeting was organised further to a discussion at the Pharmaceutical Committee in September, at which the Commission had tabled a discussion paper outlining the need to develop an implementation strategy for MedDRA in the EU.

1. Adoption of draft agenda

The preliminary agenda was adopted without modification.

2. MedDRA : Language and translation issues

Member State representatives outlined their current and future needs with respect to the implementation of MedDRA for both ADR reporting and for other regulatory activities.

It was agreed that it was possible to divide needs depending on the use of MedDRA. Since for the moment, most discussion and implementation at a practical level was focussed on the ADR reporting activities, the possibility of a phased approach to MedDRA implementation was envisaged. However it was agreed that a more long term strategy should address all potential uses of the terminology to facilitate communication of regulatory information in a multilingual environment.

The need for translations to LLT level was identified by Austria, Belgium, France, Portugal and Spain. Denmark, Finland and Sweden did not need translation for ADR reporting, but would need translation to PT level at least for regulatory submissions. Italy considered that for the purposes of use in the Italian Ministry, it would be possible to use MedDRA in English initially, but that to implement it further they would need translation at least to the PT level. In the Netherlands, a system of linking tables was being used, which meant that for ADRs no translations were necessary, but for regulatory purposes, translation to PT would be necessary. Germany was in the process of translating version 2.0 to PT level. In UK and Ireland, there were no translation implications, and implementation was expected to be possible at least by the second quarter of 2000.

UK is investigating usage of MedDRA in its other regulatory databases including for marketing authorisations. This work is likely to start in the second half of 2000.

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: AN88, 1/37.
Telephone: direct line (+32-2)295.82.74, switchboard 299.11.11. Fax: 296.15.20.
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

Although it was stressed that the value of MedDRA as a multilingual database was based on the availability and use of MedDRA in all EU languages, the possibility of agreeing a phased approach to implementation based on availability of translations was acceptable to most Member States. Spain outlined workload problems with the setting up of systems to deal with PTs initially and LLTs subsequently.

It was agreed that a request for funding based on the current needs identified above would be made, but that it was essential that there was a long term strategy to ensure that LLTs would be available in all countries where ADR reporting in English was not possible. Translation at least to PT level would be necessary in all officials languages for other regulatory uses and the real value of this terminology in Europe depended on having high quality data that could reflect current medical practice.

The possibility of identifying a sub-category of LLTs for translation purposes was raised. It was agreed that this could have wider implications on the structure of the terminology, but nonetheless it would be useful to investigate further.

It was agreed that funding for one or two languages to LLT level would be requested initially, but that these translation activities should be structured in such a way as to provide lessons for future translation purposes.

In addition it was agreed that the possibility of asking industry to assist with the funding of translations would be raised.

The MSSO should be asked to provide example of the type of terms that could be considered as a "sub-set" of the LLTs and should be asked to provide details from their experience in translating in three non-English languages of the terms between version 2.0 and 2.4 In addition the MSSO should be asked for its conception as to what constituted a multilingual database.

It was noted that the MSSO was currently maintaining the terminology in English, German, French and Spanish, but that no provisions for other languages appeared to be foreseen. This required clarification from a contractual perspective.

3. MedDRA : Mandatory implementation in the EU

It was agreed that it would be useful to give a clear message to the effect that the implementation of MedDRA in Europe would become mandatory within a defined timeframe.

It was suggested that this message would initially be expressed in a draft policy paper which would be circulated for comment. The final policy would then be implemented in the revision of the legislation foreseen in 2001 and supported by guidelines.

A number of participants expressed the need to link this mandatory implementation to the mandatory electronic reporting of ADR reports.

4. MedDRA : Deadlines for implementation

A provisional date for implementation was set as January 2002 for all single case reports received electronically and for all ADR reporting from January 2003. This would be applicable for both industry and regulators.

5. MedDRA : Use for other regulatory activities

The potential use of MedDRA in other regulatory authorities was discussed. Participants were reminded that the original development of MedDRA envisaged use in other regulatory areas, including dossier submissions, summary of product characteristics and patient leaflet. It was agreed that this should be developed further and that appropriate CPMP working parties (Efficacy, Safety, Pharmacovigilance), QRD and the Joint EMEA/EFPIA group addressing the electronic SPC should be invited to provide comments, firstly on MedDRA applicability in its current format to current activities and secondly on the consideration of future needs from such a terminology.

6. MedDRA : Training

With the exception of Germany and the Netherlands, all Regulatory Authorities identified the need for training on MedDRA, coding, analysis etc as a priority to facilitate implementation. It was agreed that the Commission would investigate the possibility of holding a group training session, possibly in conjunction with a meeting of the Pharmacovigilance working party, but not necessarily targeted at members of this working party.

7. MedDRA : Version control

Since MedDRA is updated on a quarterly basis, the need to establish a system for version control had been identified by some users. It was suggested that if reports used LLTs, the relevance of the version was small, but that for PSURs, it would probably be necessary to state which MedDRA version was used. In addition it was suggested that marketing authorisation holders could regenerate summary tables in the most recent version of MedDRA. Nevertheless, the implications of version changes is a topic that should be addressed by the working group set up by the Management Board.

8. MedDRA : Level of use

The decision of the CPMP Pharmacovigilance Working Party to exchange Individual Case Safety Reports using the LLTs was reinforced. There was real concern that the use of PTs would adversely impact on the intended use of the terminology and its potential use in high quality multilingual activities. It was agreed that a EU position paper on the subject should be issued, a draft paper will be prepared by NL, SP and UK delegates which would be forwarded to the Commission before 9th December.

9. AOB

- Extension of availability to healthcare professionals

Most Member States supported the idea of encouraging health care professionals to use MedDRA, but problems of different dictionaries used by insurers and the lack of access of GPs to computer facilities were identified. Member States were asked to consider the practical implications of such a step in their respective countries.

- Implications of EU enlargement on language and translations requirements

It was noted that translation and management of translation activities would be an increased challenge in an enlarged EU.

- Elaboration of a SOP on verification of consistency of language versions and subsequent expedited and regular maintenance in co-operation with MedDRA MSSO

It was agreed that it was necessary to further develop such an SOP and that some initial contacts between the MSSO and the persons actually performing the different national translations could be useful.

- Implication of obligations with respect to WHO.

The Commission representative indicated that members of the ICH Steering Committee were hoping to hold a meeting with WHO to address this issue as well as the inclusion of subsequent WHO-ART versions into MedDRA.

List of Participants

Chairperson: Emer Cooke, European Commission DG Enterprise

Austria- Eva Hofbauer, Veronica Plank

Belgium-Xavier Kurz

Denmark- Doris Stenver

Finland- Erkki Palva

France- Dominique Masset, Bertrand Séné

Germany - Norbert Paeschke

Ireland- Niamh Arthur, Shirley Mulvey

Italy- Giuseppe Pimpinella

Luxembourg- J, Genoux-Hames

Netherlands- Arthur Meiners

Portugal- Antonio Lourenco

Spain- Dolores Montero

Sweden- Kerstin Jansson

UK- Peter Arlett

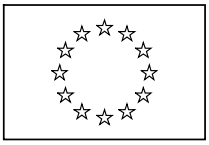
Observers:

Norway: Harald Lislevand

Iceland: Ingolf Petersen

EMEA- François Maignen

Annex 1 – Follow up letter to MSSO arising from MedDRA meeting



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Pharmaceuticals and cosmetics

Brussels, 8th November 1999
EC D(99)

Dear Kathy,

I am writing to you, as representative of the MSSO, to draw you attention to a number of issues on behalf of the EU, which we have recently discussed in the context of an internal EU meeting on MedDRA implementation.

The EU is committed to the implementation of MedDRA and believes that a realistic date for implementation is 1 January 2002 for single case ADR reports. We are currently developing a strategy to ensure that we have translations in the EU languages required to support this.

However there are a number of issues on which we would be grateful for your input.

MSSO concept of a multilingual database

We would be grateful if you could clarify your concept of a mutilingual database. This is important with respect to the final operation of a functioning system in the EU. We would also be pleased if you could let us know how you intend to handle cross-language consistency.

Lower Level Terms – exclusion of synonyms for translation purposes

During our recent brief meeting in Brussels, you indicated that, for translation purposes, it may be possible to envisage a subset of LLTs. We are very interested in this idea, but would be grateful if it could be developed further and the MSSO could provide some examples that we could share with practitioners working in different Member States.

Experience from recent translation work

We understand that the MSSO has translated all new terms from MedDRA version 2.0 to MedDRA version 2.4 in three of the EU languages. In order to facilitate our internal translation work, we would be very pleased if you could provide us with some details from your experience in this regard - difficulties encountered, cross-language consistency, feedback from the actual translators, etc.

Maintenance of translations

Let me first assure you, that the EU is ready to work closely with the MSSO to ensure the best and most appropriate maintenance of the terminology in EU languages. However we believe that it is important to sort out some of the contractual issues before we can develop such a system.

According to Article 1, definition 1.11 "licensed terminology" shall mean "the MEdDRA V2.0 database in ASCII file format with documentation describing the tables, database schemes and introductory guide. Translations of MedDRA in other languages will be included when available."

Article 5.1 requires MSSO to provide services to the IFPMA in accordance with the service specifications contained in Annex 1.

Annex 1, paragraph 1.1, specifically refers to translation in other languages held within the database.

It was the EU understanding from the discussions prior to signature of the contract that there was no limitation put on the number of languages which would be maintained by the MSSO. This would be determined only by which languages were "available".

During the last two Management Board meetings, the MSSO has indicated that it has no obligation to maintain translations in any languages other than the four currently available. We would be interested in hearing the basis for the MSSO's understanding on this issue.

Training

You will have received a copy of Mr. Sauer's letter to the ICH Steering Committee querying the cost of the training provided by the MSSO and the cost of other purchasable services. It is clear that exorbitant prices for purchasable services will cause difficulties for all regulators and will certainly not facilitate the use of the terminology. In view of the implications of such costs for all regulators and particularly for regulators within the EU, it would be useful if the MSSO could clarify its position in this regard at the teleconference tomorrow.

Apart from the concerns identified above, for the efficient operation of the terminology in the EU, most countries have indicated the need for training, particularly on coding and analysis. We would like to explore the possibility that this could be provided in the form of a user group meeting, to which user representatives from EU member states could be invited. The EU would be ready to facilitate this meeting from a logistical perspective.

I am sending this letter to you in advance of the Management Board teleconference tomorrow, in the knowledge that you will be unlikely to respond on all issues at that time. Nonetheless, I would be very pleased if you could give these issues some very preliminary consideration with a view towards a fuller reply at a later stage.

Emer Cooke
Principal Administrator

cc. Mr. Ph. Brunet, Mr. F. Sauer, Members of the Pharmaceutical Committee, Members of the MedDRA Management Board.