

MedDRA- Status of regulatory implementation in the EU

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MedDRA Implementation in EU

- Legal Aspects
 - Modification to Directive 75/319/EEC
 - Draft Volume 9 of The Rules Governing Medicinal Products in the European Union
- Practical Aspects
 - Level of use
 - Implementation schedule
 - Training
 - Translations and implications

Legal Aspects

- Directive 2000/38 of 5 June 2000
- ICH definitions of adverse reaction, serious adverse reaction, unexpected ADR reaction
- Slight changes to reporting requirements for ADRs
- Data processing network to facilitate exchange of Pharmacovigilance info
- Commission guidance “publish a reference to an internationally agreed terminology”
- Commission guidance includes reference to internationally agreed formats

Legal Aspects continued

- Notice to Marketing Authorisation holders published in January 1999
- Three references to MedDRA (when implemented)
- Currently being revised to take account of new directive
- December version will include reference to dates of implementation

Practical Aspects

- Level of use
- Commission organised meeting Brussels July 2000
- Agreement to use PT and LLT in verbatim field of E2B message
- Slight modifications in San Diego
- Acceptable international solution found

Implementation schedule

- Agreed at Brainstorming meeting November 1999
- Included in minutes of 50th Pharmaceutical Committee October 2000
 - News on <http://pharmacos.eudra.org>
- Dates agreed:
 - **January 2002 for single case reports received electronically**
 - **January 2003 for all ADR reporting**
 - **Details still to be worked out.**

Translations

- German and Portuguese completed
- Spanish and French nearing completions
- Greek – contract engaged
- Dutch – funding available
- Validation?
- Cross language consistency?
- Meeting with Translators and MSSO end 00-Q101
- Timing for addition of new terms?
- Involvement of EU regulatory authorities

Training

- Need identified
- Various stages of implementation
- Commission will organise initial training
- ‘Train the trainer’ approach

Conclusion

- Commitment to implement
- Some issues to be resolved
- Much progress has been made
- Real potential for multilingual terminology
- Benefit for European patients
- More efficient pharmacovigilance
- Tool for other multilingual activities