



MedDRA
User Group Meeting
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Dr. Sabine Brosch
EMEA, 7 Westferry Circus, London
E14 4HB, UK





Overview



✍ Use of MedDRA in Pharmacovigilance
Post-Authorisation Activities



✍ Timeframes



✍ Mandatory Use and Format



✍ Eudra Vigilance Database Management
System

✍ Use of MedDRA in the SPC

PhV-Post-Authorisation Activities

- ✍ Implementation time frame for MedDRA pharmacovigilance post-authorisation activities in the Community:

Agreement on mandatory dates at 50th Pharmaceutical Committee meeting (September 2000)

- ✍ Single Case Reports received electronically January 2002,
- ✍ All adverse drug reaction reporting January 2003.

PhV-Post-Authorisation Activities

- ★
- ★
- ★
- ★
- ★
- ✍ Mandatory use of MedDRA in pharmacovigilance post-authorisation activities in the Community:
 - ✍ Individual Case Safety Reports (ICSRs)
 - ✍ **MedDRA Lowest Level Terms** should be provided as either text (i.e. English MedDRA term) or code according to the regional preferences until January 2003 when codes only will be used in all regions.



ICH ICSR Patient Characteristics



Structured info relevant medical history



Relevant past drug history indication



Reported cause(s) of death



Autopsy-determined cause(s) of death



Relevant medical history parent

Relevant past drug history/parent indication



ICH ICSR Section Reaction(s)



Reaction in MedDRA terminology



ICH ICSR Section Drug(s) Information



Indication for use in the case



Which reaction(s) recurred?



ICH ICSR Section Narrative case summary



Sender's reclassification of reaction



ICH ICSR Section Tests and Procedures



Tests/investigation of the patient



PhV-Post-Authorisation Activities

- ★
 - ★
 - ★
 - ★
 - ★
- ✍ Use of MedDRA in pharmacovigilance post-authorisation activities in the Community:
 - ✍ Periodic Safety Update Reports (PSURs)
 - MedDRA Preferred Terms in line listings and/or summary tabulations.

PhV-Post-Authorisation Activities

- ★ EudraVigilance Database Management System
 - ★ MedDRA version 5.0 fully integrated
 - ★ Strict quality control on all incoming data based on MedDRA LLTs and MedDRA version;
 - ★ Browsing and coding tools;
 - ★ Data analysis tools based on complete MedDRA hierarchy;



Policy to be agreed



✍ MedDRA MSSO Guidance on MedDRA Terminology Version Control for Semi-Annual Releases:



✍ EU regulators to agree on harmonised implementation schedule (define **exact date** during 60 days implementation schedule),



✍ Proposal to support two MedDRA versions during implementation schedule,



✍ After two months utilise only latest MedDRA version.



Policy to be agreed



✍ Implementation and Management of MedDRA Supplementary Terms during semi-annual releases;



✍ EU regulators currently do not accept supplementary terms as many pharmaceutical companies,



✍ Has to be addressed in case MedDRA release policy is changing to annual releases.





Use of MedDRA in the SPC



✍ Guideline on Summary of Product Characteristics (Notice to Applicants)



✍ SPC section 4.8 Undesirable Effects



✍ Table of adverse reactions according to a standard system organ class (SOC) such as in MedDRA



✍ MedDRA SOC List in internationally agreed order



Use of MedDRA in the SPC



✍ Guideline on Summary of Product Characteristics
(Notice to Applicants)



✍ SPC section 4.8 Undesirable Effects

✍ Adverse reaction descriptions should be based on the most suitable representation within the terminology.



✍ Usually the PT Level, although there may be instances where the use of the LLT Term or exceptionally group terms such as HLTs may be appropriate.





Further specifications required



✍ Agreement on timeframe for update of the SPC in accordance with SPC guideline,



✍ Legacy terminology may have a different primary SOC for a particular event i.e. the position of the adverse reaction will change with the first update,



✍ Placement of reactions that appear in several SOC's (internationally agreed order)



✍ Need for some flexibility: i.e. most clinically important adverse reactions should appear on the top of the table.



Further specifications required



✍ Controlled management of descriptive terms outside the scope of MedDRA (e.g. acute, chronic, persistent, recurrent).



✍ Management of SPC translations where no official MedDRA translations are yet available.



Questions ?

