



MedDRA

European User Group Meeting

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Sabine Brosch

EMA, 7 Westferry Circus, London E14
4HB, UK





Overview



■ Use of MedDRA in Pharmacovigilance Post-Authorisation Activities



- ◆ Timeframes

- ◆ Mandatory Use and Format



- ◆ EudraVigilance Database Management System



■ Use of MedDRA in the SPC

■ Next Steps



PhV-Post-Authorisation Activities



- Implementation time frame for MedDRA pharmacovigilance post-authorisation activities in 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 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 March 2003 when codes only will be used in all regions.



ICH ICSR Section B.1 Patient Characteristics

B.1.7.1a.2	Structured information on relevant medical history
B.1.8f.2	Relevant past drug history indication
B.1.9.2.b	Reported cause(s) of death
B1.9.4b	Autopsy-determined cause(s) of death
B.1.10.7.1a.2	Relevant medical history and concurrent conditions of parent-Structured Disease/Surgical procedure
B.1.10.8f.2	Relevant past drug history of parent Indication
B.3.1c	Structured Information (tests) relevant to the investigation of the patient





ICH ICSR Section B.2 Reaction(s)

B.2.i.1.b	Reaction in MedDRA terminology
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ICH ICSR Section B.4 Drug(s) Information

B.4.k.11b	Indication for use in the case
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B.4.k.17.2b	If yes to item B.4.k.17.1 (did reaction recur on readministration), which reaction(s) recurred?
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ICH ICSR Section B.5 Narrative case summary and further information



B.5.3b	Sender's diagnosis/syndrome and/or reclassification of reaction
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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 4.1 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;



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.



Next Steps



■ Agreement on



- ◆ MedDRA terminology version control for semi-annual releases;



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





Next Steps



◆ MedDRA multi-lingual use



- ◆ French and German translations of MedDRA, with English LLTs, available for distribution around 11 March 2002;



- ◆ Portuguese, with English LLTs, before the end of March 2002;



- ◆ The Spanish translation including LLTs in early April 2002;



Next Steps



- ◆ MedDRA and SPC



- ◆ EudraVigilance Drug Dictionary initiative:



- ◆ Extended use of MedDRA in other SPC sections as an absolute requirement for improved future signal detection and generation tools



Questions ?

