



International MedDRA MSSO User Group Meeting

Vienna, Austria

29 March 2007

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Pharmaceutical Manufacturers and Associations (IFPMA)



MedDRA International User Group

Vienna, Austria, 29 March 2007
Comment Sheet

Name:
Title:
Company:
Email:
Phone:

Ask us a question or provide us with comments

The MSSO invites you to submit comments or questions about MedDRA. These may be about today's agenda topics or other MedDRA-related topics.

We encourage subscribers to ask us questions at any time about developments with MedDRA. Thank you for participating in this User Group meeting.

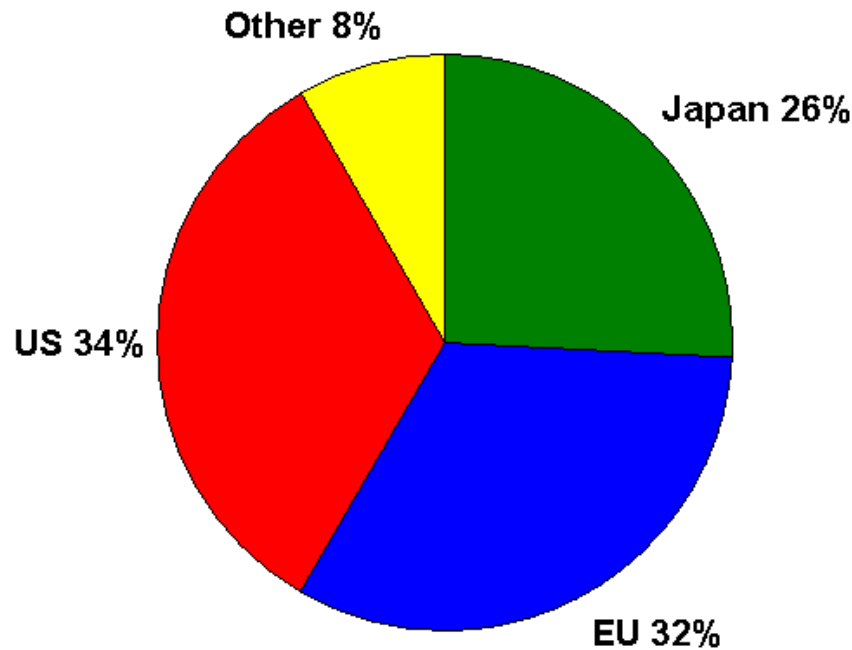


Agenda

0900 – 0930	Introduction and Welcome	Pat Revelle
0930 – 1015	MedDRA SMQs, Data Analysis, and Signal Detection	Sabine Brosch & Stefano Cappe (EMEA)
1015 – 1030	Friend of MedDRA Award Networking / Coffee Break	Pat Revelle
1030 - 1100	Subscriber Forum / Q&A	Patty Mozzicato
1100 – 1130	Role of the MedDRA Management Board	Barry Arnold AstraZeneca /MedDRA MB Member
1130 – 1200	Practical Implementation of SMQs at GSK	Christina Winter GlaxoSmithKline
1215 – 1300	Wrap Up / Lunch	

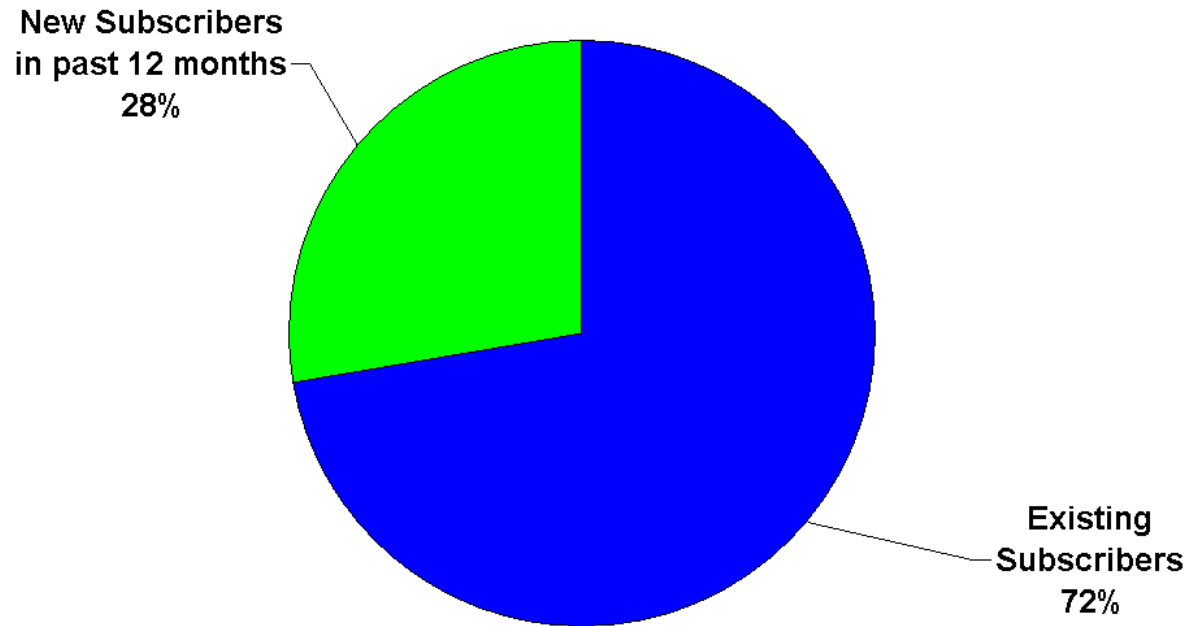


MedDRA Subscriber Update



1730 Subscribers
Worldwide

Subscriber Growth

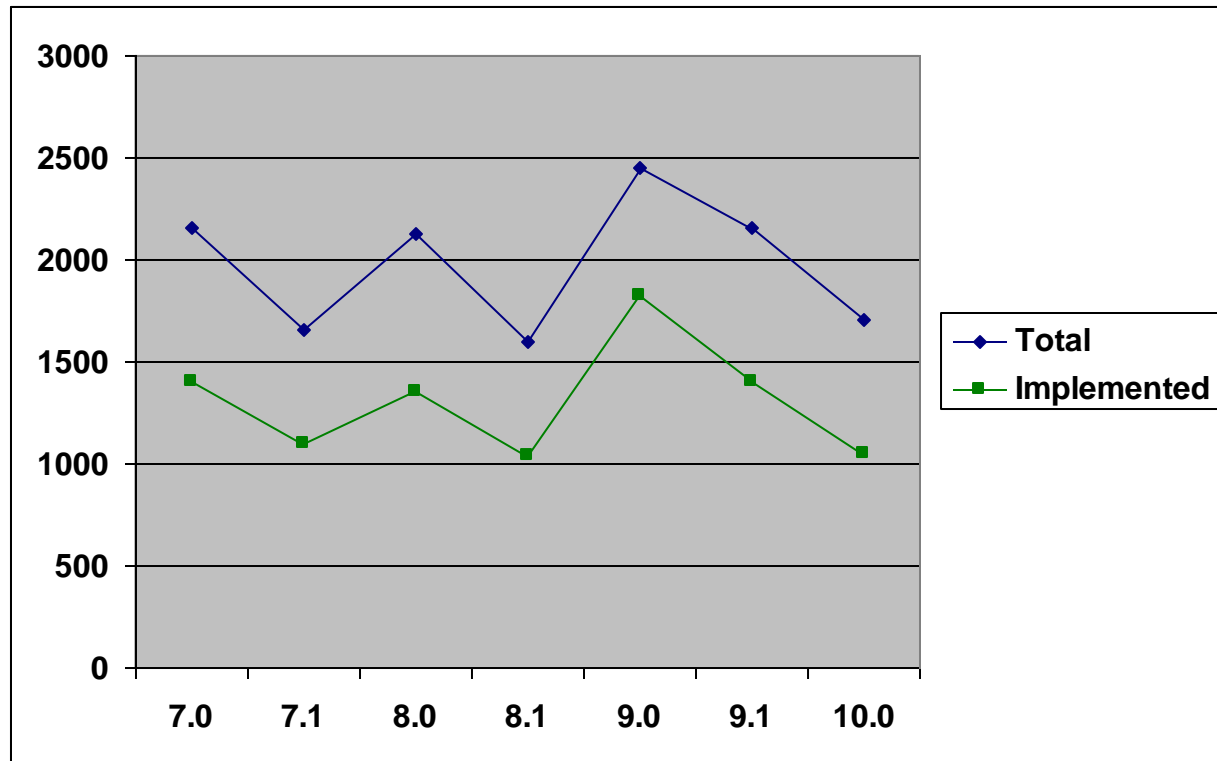




Change Request Summary

- A complex release
- Released on 1 March 2007
- MSSO considered 1707 change requests (including SMQ change requests)
 - 1,053 accepted
 - 553 disapproved
 - 101 suspended

Total and Implemented Change Requests MedDRA Versions 7.0 - 10.0



What's New Document

Developmental Topics

3. DEVELOPMENTAL TOPICS

3.1 MEDICAL TRENDS IN VERSION 10.0

Change requests affecting specific SOCs: Of note, although no changes were made to existing SOC terms and no new SOCs were added in Version 10.0, it is noted with interest, the types of change requests in relation to the SOC *Surgical and medical procedures* and the SOC *Investigations*. For example, new concepts like PT *Bariatric gastric balloon insertion*, PT *Bladder hydrodistension*, PT *HIV tropism test*, and PT *Endoscopic ultrasound normal* were added in Version 10.0. "Complication of procedure" types of concepts such as PT *Stent related infection* and PT *In-stent coronary artery restenosis* were also added. The MSSO does not sense any specific correlation as to the type of change requests in these SOCs and believe it to be more indicative of concurrent advances in standard diagnostic medical tests and procedures.

Change requests at the HLGT and HLT levels

Being a complex change release, the changes at the HLGT and HLT levels are summarized in the "Complex changes" section of this document.

Change requests at the PT and LLT levels

There was an increase in requests during this version for concepts attributable to injector device studies, vaccines, and chemotherapeutic trials. For example, new concepts added include LLT *Injection site wheal*, LLT *Injection site abrasion*, PT *Injection site laceration*, PT *Injection site streaking*, LLT *Vaccine underdose*, PT *Injection site macule*, and PT *Immediate post-injection reaction*. Other notable trend includes change requests to move and re-align many ICD-9 related concepts that already exist in MedDRA.

- Content extended to discuss medical trends
- Given positive feedback, MSSO will continue to develop this area



SSCs and CDs

- First MedDRA release that did not include SSCs within the release
 - MSSO stopped maintenance with MedDRA Version 9.1
 - Available, if needed, from subscriber section of MSSO web site
- Last release in which MedDRA is distributed in CD-ROM format
 - All future access will be by Internet file download



MedDRA Version 10.1 Freeze Date

- Defined as the last day for subscribers to submit change requests
- Freeze date is 13 June 2007
- As always, subscribers are strongly encouraged to submit change requests prior to the freeze date



2007 Subscription Rates

Subscription Level	2005 Price	2006 Reduction	2006 Price	2007 Reduction	2007 Price	Reduction from 2005 Rates
Basic	\$3,377	85%	\$507	100%	\$0	\$3,377
Core 0	\$3,825	80%	\$765	74%	\$200	\$3,625
Core 1	\$7,825	80%	\$1,576	25%	\$1,177	\$6,648
Core 2	\$13,506	40%	\$8,104	24%	\$6,159	\$7,347
Core 3	\$25,887	40%	\$15,532	21%	\$12,270	\$13,617
Core 4	\$69,782	20%	\$55,826	10%	\$50,243	\$19,539
Core 5	\$92,292	20%	\$73,834	10%	\$66,451	\$25,841
Developer	\$5,629	30%	\$3,940	20%	\$3,152	\$2,477



Outcome of HLT/HLGT Blue Ribbon Panel (BRP)



Panel Recommendations

- “NEC” HLTs
 - “NEC” naming should not be revised unless there is a more medically meaningful name within the hierarchy
 - Large-sized “NEC” groupings should be analyzed for possible new groupings with the following priority:
 - Oversized HLTs (≥ 50 PTs)
 - HLT re-grouping should be based on medicine, such as pathology or physiology:
 - Avoid force fitting of PTs for the purpose of reducing HLT size



Panel Recommendations (cont)

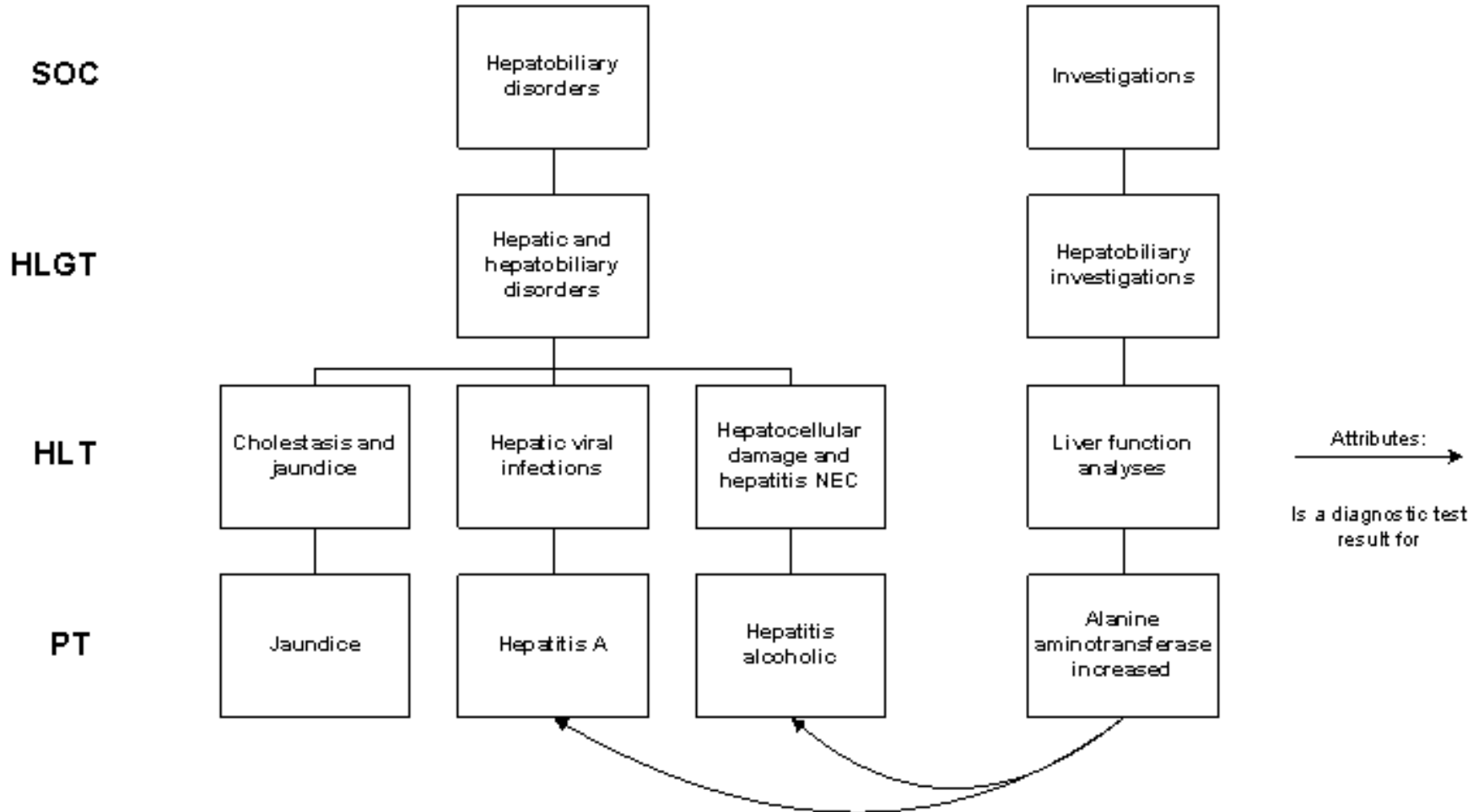
- *SOC Investigations:*
 - Recommend a pilot study on concept attribute approach:
 - MSSO to develop a sample set of investigation terms with concept attributes
 - To be tested by regulators and industry volunteers



Concept Attributes

- In some cases, the MedDRA rules and hierarchy separate terms that are related
 - Example: Investigation terms and specific medical conditions and diseases

Concept Attributes (cont)





Concept Attributes (cont)

- MSSO is developing a pilot test to see if it is feasible and useful to link some SOC *Investigations* terms to other terms in MedDRA
 - Add an attribute linking mechanism
 - Not changing current distribution file structure but add a new attribute file

Concept Attributes (cont)

- Concept attributes are handled by an additional file – “attrib.asc”

Test result	Relationship	Diagnosis
Alanine aminotransferase increased	Is a diagnostic test for	Hepatitis A
Aspartate aminotransferase increased	Is a diagnostic test for	Hepatitis A
Blood albumin decreased	Is a diagnostic test for	Hepatitis A
Blood alkaline phosphatase increased	Is a diagnostic test for	Hepatitis A
Blood bilirubin increased	Is a diagnostic test for	Hepatitis A
Hepatitis A antibody positive	Is a diagnostic test for	Hepatitis A
Hepatitis A antigen positive	Is a diagnostic test for	Hepatitis A
Hepatitis A positive	Is a diagnostic test for	Hepatitis A
Alanine aminotransferase increased	Is a diagnostic test for	Cirrhosis alcoholic
Albumin globulin ratio decreased	Is a diagnostic test for	Cirrhosis alcoholic
Aspartate aminotransferase increased	Is a diagnostic test for	Cirrhosis alcoholic
Blood albumin decreased	Is a diagnostic test for	Cirrhosis alcoholic
Aspartate aminotransferase increased	Is a diagnostic test for	Myocardial infarction
Blood creatine phosphokinase MB increased	Is a diagnostic test for	Myocardial infarction
Blood lactate dehydrogenase increased	Is a diagnostic test for	Myocardial infarction
Electrocardiogram ST segment depression	Is a diagnostic test for	Myocardial infarction
Electrocardiogram ST segment elevation	Is a diagnostic test for	Myocardial infarction
Electrocardiogram T wave inversion	Is a diagnostic test for	Myocardial infarction
Myoglobin blood increased	Is a diagnostic test for	Myocardial infarction
Troponin I increased	Is a diagnostic test for	Myocardial infarction
Troponin increased	Is a diagnostic test for	Myocardial infarction
Troponin T increased	Is a diagnostic test for	Myocardial infarction

Test result	Relationship	Diagnosis
Alanine aminotransferase increased	Is a diagnostic test for	Cirrhosis alcoholic
Alanine aminotransferase increased	Is a diagnostic test for	Hepatitis A
Aspartate aminotransferase increased	Is a diagnostic test for	Cirrhosis alcoholic
Aspartate aminotransferase increased	Is a diagnostic test for	Hepatitis A
Aspartate aminotransferase increased	Is a diagnostic test for	Myocardial infarction
Blood albumin decreased	Is a diagnostic test for	Cirrhosis alcoholic
Blood albumin decreased	Is a diagnostic test for	Hepatitis A



Panel Recommendations (cont)

- *SOC Social circumstances*
 - No change to current SOC structure, keep as single axial SOC
 - Request PTC Working Group to provide additional guidance on *SOC Social circumstances*, specifically, addict/dependence/abuse terms



Panel Recommendations (cont)

- Multi-axial HLTs in cumulative data output:
 - Create separate HLTs for cyst and polyps terms
 - Consult expert pathologists and oncologists
 - Review all multi-axial HLTs to ensure primary SOCs are appropriate



Next Step

- BRP recommendations will be presented to MedDRA Management Board for approval



MedDRA and SNOMED



US Labeling Regulations

- US FDA Physician Labeling Rule (PLR) and Guidances January 2006
 - Effective 30 June 2006
 - Implementation schedule over 7 years for all products approved within previous 5 years
 - Structured Product Labeling (SPL) - electronic format
 - Does not specify a terminology
 - Format and content changes to labeling
 - Highlights section
 - High level summary (maximum half page)



Highlights Section

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use [drug name] safely and effectively. See full prescribing information for [drug name].

[Proprietary name] (established) [dosage form] [route of administration]

Initial U.S. Approval: [year]

WARNING

See full prescribing information for complete boxed warning.

- 1 [text]
- 2 [text]

RECENT MAJOR CHANGES

[section] (X.X) [m/year]
[section] (X.X) [m/year]

INDICATIONS AND USAGE

[Drug] is a [name of class] indicated for

- [text]
- [text]

DOSAGE AND ADMINISTRATION

- [text]
- [text]

DOSAGE FORMS AND STRENGTHS

- [text]
- [text]

CONTRAINDICATIONS

- 1 [text]

WARNINGS AND PRECAUTIONS

- [text]
- [text]

ADVERSE REACTIONS

Most common adverse reactions are [text].

To report SUSPECTED ADVERSE REACTIONS, contact (manufacturer) at (phone # and Web address) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- [text]

USE IN SPECIFIC POPULATIONS

- [text]

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: [m/year]



Problem List Subset

- On 19 April 2006, FDA announced the adoption of the “Problem List” Subset of SNOMED for use in electronic labeling
- Created through Department of Veterans Affairs (VA) and Kaiser Permanente
- Effective 30 June 2006, Problem List Subset used to code certain terms in Highlights section
 - “Behind the scenes” computer-readable coding
 - No effect on human-readable labeling



Problem List Subset (cont)

- Other terminologies used in SPL as well (e.g., LOINC, NCI Thesaurus, NDF-RT)
- Allow exchange of coded information in label with electronic health records



Recent FDA Announcement

- FDA acknowledged the challenges with the SPL requirement and the Highlights section “coding”
- FDA will be developing a draft guidance to industry regarding adding the Highlights section data elements to the SPL
 - Soliciting input from all users
- Meantime, FDA will not require that the Highlights section of the SPL to be “coded”



Discussion