



Blue Ribbon Panel MedDRA and Product Labeling: Best Practices

**16 March 2004
AstraZeneca
Zoetermeer, Netherlands**

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of Pharmaceutical Manufacturers and Associations (IFPMA)



Agenda

09h00 – 10h30

Opening remarks – introductions, logistics, etc.
Discussion of “Best Practices”

10h30 – 11h00

Break

11h00 – 12h30

Discussion of “Best Practices” (cont)

12h30 – 13h30

Lunch

13h30 – 15h00

Review/revision of BRP recommendations
Summary, Q&A



Opening remarks

- Introductions
- Logistics
- Roles and responsibilities
 - BRP
 - Observers
 - MSSO
 - MedDRA Management Board



MedDRA and Labeling: Background

- Continues to be a consistent subscriber question
 - “What should we do with labels developed with COSTART/WHO-ART now that we are coding in MedDRA?”
 - Consistent determination of “labeledness/expectedness/listedness”
 - What level of MedDRA terms should be included in the label?



MedDRA and Labeling: Background (cont)

- MSSO took the action to develop a “Best Practices” paper on labeling and MedDRA
 - Similar in intent to the MedDRA version “Best Practice” documents endorsed by the MedDRA Management Board
- Goal of Blue Ribbon Panel is to review and revise MSSO recommendations as needed



“Best Practices” Paper

- To present a set of general recommendations on how MedDRA-coded data should be used in product labeling
- Taking into account:
 - Multiple purposes of product labeling, including different end-users
 - Characteristics of MedDRA
- Any recommendations should be considered in light of local regulations



“Best Practices” Paper - Outline (cont)

- Purpose and scope of MedDRA
- Purpose of product labeling
- “*Data Retrieval and Presentation: Points to Consider*”
- Review of general content of product labeling
- Review of general principles of MedDRA’s use in labeling
- Special considerations (e.g., labels using legacy terminology)
- Summary and conclusions/recommendations



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General comments on “Best Practices”

- Too general; needs more details, possible examples
- Not appropriate forum to discuss three-tiered system *vs.* other approaches to design of labeling
- Too much background information



Purpose of product labeling

- Multiple purposes
 - Communication
 - Regulatory compliance
- Two- *vs.* three-tiered approach
- Product labeling for patients/consumers not within scope of document



General principles – MedDRA in labeling

- Company core information
 - Flexibility encouraged
 - Generally PTs in adverse reactions section
 - Where applicable, use grouping terms (HLTs, HLGTS), SMQ/SMQ-like groupings
 - Lists of LLTs to facilitate assessment of expectedness



General principles – MedDRA in labeling (cont)

- Prescriber information
 - Use familiar wording, natural language
 - Use logical medical groupings (standardized and/or *ad hoc*)



Special considerations

- Legacy terminology in existing label
 - Generally, not necessary to “convert” label to MedDRA
 - If new information added based on MedDRA coding, discrepancies may need to be addressed



Review/revision of recommendations

- A flexible approach to the use of MedDRA for labeling is advocated, keeping in mind relevant local regulations governing content.
- MedDRA's usage in labeling should be primarily in the Adverse Events/Adverse Reactions sections.
- For the CCDS (manufacturer/regulator labeling), MedDRA terms (generally PTs) should be used.



Recommendations

1. A flexible approach to the use of MedDRA for labeling is advocated, keeping in mind relevant local regulations governing content.
2. MedDRA was intended for the communication of safety information (e.g., product labeling)
3. MedDRA Labeling Entities (MLEs) are proposed:
 - Develop within ICH framework to enforce harmonization
 - Extend remit of PTC WG to address this task
 - Maintained by MSSO
 - Distributed with MedDRA to all subscribers

Whenever suitable, should be an existing MedDRA term (e.g., a grouping term [HLT, HLG]); implementation should not create conversion issues



Recommendations (cont)

4. Natural language is recommended for labeling
 - SPC Guideline recommends MedDRA
 - MedDRA translations are useful here
 - MSSO should review MedDRA terms for more natural language in context of HLT/HLGT study



Recommendations (cont)

5. Labels developed with legacy terminologies but now coding in MedDRA
 - Document the method of data conversion
 - Verbatim conversion vs. legacy term conversion
 - Label may not need to be rewritten with the change to MedDRA, however, exceptions may occur
 - Pragmatic approach is recommended
 - Acceptable to combine MedDRA and legacy terms in a single table if necessary when new information is received
 - In all instances, minimize confusion for end-user (e.g., add explanations where needed)



Recommendations (cont)

6. For both the CCDS and the prescriber labeling
 - Encourage the use of term groupings – hierarchy terms such as HLTs and HLGTS and other standard grouping such as “MLEs”
 - Link conceptually covered PTs (and LLTs) under a single concept based on a physician’s understanding of that concept (not too broad, but not as granular as single PTs)
 - When needed to more easily communicate a particular concept



Recommendations (cont)

8. Support for MLEs as a basis for expectedness, but not a substitute for medical judgment
 - May be instances where certain terms on this list could be considered not listed
 - Pragmatic approach is supported



Questions, comments, additional
discussion