Blue Ribbon Panel
MedDRA and Product Labeling: Best Practices

16 March 2004
AstraZeneca
Zoetermeer, Netherlands

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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
“Best Practices” Paper - Outline (cont)

- Purpose and scope of MedDRA
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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, HLGT]); 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
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