BRP3

Title/subject: MedDRA and Product Labelling: Best Practices

Date/location: 16 March 2005, AstraZeneca, Zoetermeer, the Netherlands

Purpose of BRP 3
The purpose of this BRP was to consider a set of general recommendations on how MedDRA-coded data should be used in biopharmaceutical product labelling. These recommendations were to take into account the multiple purposes of product labelling and the characteristics of MedDRA.

Panel members/affiliations
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Panel recommendations
Based on the input made by the panelists of BRP3, the following were the MSSO's specific recommendations:

- A flexible, pragmatic approach to using MedDRA for labelling is advocated
- MedDRA Labelling Entities (MLEs) are proposed as a new concept
- Natural language is recommended for labelling (health professional [HP] and patient/consumer labelling)
    - MSSO should review MedDRA terms for more natural language representation in the context of the then ongoing HLT/HLGT feasibility study
- A pragmatic approach is recommended for labels developed with legacy terminologies but with present-day data being coded using MedDRA
- Encourage use of term groupings for both company core data sheets and HP labelling
- Typically, unmodified MedDRA terms should not be used for patient/consumer product labelling

Outcomes
The MedDRA Management Board, at their meeting in May 2005, discussed the BRP3 recommendations on MedDRA and product labelling. To address the needs of subscribers and for further clarification of this complex issue, the Management Board decided to solicit input from at least one other MedDRA expert organization. Ultimately, it was concluded that the development of MedDRA Labelling Entities (MLEs) would not go forward.