Purpose of BRP 8
The purpose of this 8th BRP meeting was to discuss how the scope of MedDRA should be defined in its role as an international medical and regulatory terminology and how to address issues pertaining to the possible expansion of the terminology into new topic areas. Such issues included how to establish general criteria when considering potential areas for expansion (e.g., manufacturing product quality concepts and additional device-related concepts) and where new topic areas can be placed in MedDRA.

Panel members/affiliations
Barry Hammond (Terminologieze)
Norbert Paeschke (BfArM)
Stewart Geary (Eisai)
Daisuke Sato (PMDA)
Sonja Brajovic (FDA)
Lisa Lawrence-Miyasaki (Santen).

Panel recommendations
The Panelists were presented with a series of questions about the scope of MedDRA to serve as the framework for the discussions and their recommendations.

Question 1.
What should be defined as the scope of MedDRA, taking into account its function as an international medical and regulatory terminology?

- The scope of MedDRA should encompass both medical/health-related and regulatory concepts.
- Products intended for human use are within the scope and medical terms related to safety issues for products such as food, cosmetics, tobacco, etc. can be included even if these products are not subject to regulation in all regions.
- If any additional components or new topic areas are added in the form of a 27th SOC, maintained lists, or other formats, the current structure of MedDRA’s 26 SOCs should be maintained.
- The addition of colloquial or vernacular terms to MedDRA to support direct patient regulatory reporting or active surveillance of social media is not recommended. The terms used by patients can be very imprecise and thus are difficult to interpret and map consistently to MedDRA terms, as well as presenting considerable challenges in translation to all languages supported by MedDRA.
Industry and regulatory users should make their best efforts to perform coding based on the context of the information received, using the principles in the MedDRA Term Selection: Points to Consider document.

**Question 2.**

What are the general criteria to be applied when considering new topic areas for expansion in the future?

The Panelists considered four specific examples of new topic areas to help formulate general criteria for expansion. Below are the recommendations for the four potential topic areas followed by the recommendations concerning the general criteria for expansion.

1. **Manufacturing product quality terms**
   - Harmonization of quality issue reporting and patient safety reporting is a benefit
     - A single terminology or interoperability between terminologies is the goal
   - These terms should be separated from the rest of MedDRA (a 27th SOC is the favored option)
   - Terms need to be unambiguous at all levels to avoid confusion in coding (including autocoding) and in retrieval
   - Terms should focus on product defects and process issues, less on human factors

2. **Additional device-related terms**
   - Coordinate with other stakeholders on device-related projects to harmonize multiple device reporting requirements and terminologies
   - Terms need to be unambiguous at all levels to avoid confusion in coding (including autocoding) and in retrieval
   - Consider human use factor terms to identify root causes and systems/process errors, not individual human errors

3. **Drug utilization terms**
   - Identify use cases to learn how these terms are used (likely to be more applicable for pharmacoeconomic analyses rather than ICSRs and patient safety reporting)
   - The addition of these terms is a low priority

4. **Labeling qualifiers**
   - Identify use cases to learn how these terms are used (reference EMA and MSSO’s review of the use of MedDRA in coding indications in labeling for centrally authorized products)
   - The addition of these terms is a low priority
• If added, the circumstances for using these qualifiers should be clearly defined
• Labeling qualifiers should be in a maintained list outside of MedDRA’s current structure

General Criteria

• New topics/areas for expansion should be developed based on collaborative efforts involving relevant experts
  o Establish working groups with industry and regulatory representatives
  o Coordinate with ICH M1 Points to Consider Working Group
• There should be adequate lead times to allow users to implement the changes
• The addition of new topic areas should undergo the usual MSSO change request process for simple and complex changes

Question 3.

What are the criteria for accepting terms that include human use factors or causality related concepts?

• Terms should focus on the event but not on the individual at fault, e.g., “prescription error” is an acceptable concept.
  o Terms should not attribute blame; “finger pointing” should be avoided
• The granularity of concepts should be kept at a general level, e.g., “instructions not followed”. The specifics of the cause such as “nurse was distracted” or “person was inadequately trained” should not be included in MedDRA, i.e., an individual’s role should not be identified
• Terms that could represent a liability issue should be avoided, e.g., “reckless use”

Question 4.

Where should new concepts/topics be placed in MedDRA?

• A 27th SOC is the favored option for product-related terms that are separate from patient safety and clinical information
• The proposed initial contents for a 27th SOC are:
  o New product manufacturing quality terms
  o Existing product quality terms (HLGT Product quality issues)
  o Existing device terms (HLGT Device issues)
  o Human use factors (general terms that could be applied to issues with product manufacturing processes or the use of devices)
• HLGT Complications associated with device should remain in SOC General disorders and administration site conditions because these terms represent patient safety issues
• HLGT Medication errors should remain in SOC Injury, poisoning and procedural complications because these terms are directly related to patient safety. As defined as errors, the terms already include the concept of a human use factor.
• A 27th SOC should maintain the same 5-level hierarchy as the current structure of MedDRA with multi-axial links to the existing SOCs as appropriate
• The MSSO should give an adequate lead time, e.g., 3 releases for users to implement a 27th SOC
• The MSSO should form a working group with quality experts and safety experts from regulatory authorities and industry from ICH countries to conduct field testing of different hierarchy options for the 27th SOC. Working group members are to provide sample manufacturing quality terms to the MSSO to demonstrate and test how these terms would be incorporated in the MedDRA files and appear in a browser.

Outcomes
These recommendations were considered by the ICH MedDRA Management Board at its meetings in June and November 2014. The MSSO consulted the MedDRA Expert Panel and presented an in-depth analysis of the impact of the recommendation for a 27th SOC.

The main outcome was that the MedDRA Management Board has endorsed the creation of an additional (27th) System Organ Class in MedDRA. The 27th SOC (which is yet to be named) is being created to accommodate non-clinical/non-patient related concepts. These terms cover issues related to medical products which are important from regulatory and public health perspectives as they may affect patient safety.

The new SOC will include product quality issue terms which are defined as abnormalities that may be introduced during the manufacturing/labeling, packaging, shipping, handling, or storage of medical products. Existing product quality terms in MedDRA will be moved to the new SOC and will be supplemented by new terms related specifically to the manufacturing process.

The 27th SOC is planned to be implemented in March 2016 in MedDRA Version 19.0. The MSSO will provide more detailed information on the 27th SOC through webinars, broadcast emails, and other communications, such as a dedicated web page on the MedDRA website well in advance of the planned implementation date in 2016.

Additionally, the Management Board approved wording revisions to the MedDRA Introductory Guide section 1.5 regarding MedDRA’s scope. These reflect the BRP’s recommendations and pertain to the types of medical products and concepts that MedDRA supports and potential areas for future expansion. The revised wording was included in the Introductory Guide for MedDRA Version 18.0, released in March 2015.

Regarding the addition of more medical device related terms to support combination product (drug-device/biologic-device) adverse event reporting, the Management Board agreed with the Panel’s recommendation to coordinate with stakeholders on device-related projects to explore harmonization of device reporting requirements and terminologies.

The MSSO reviewed a set of drug utilization terms for possible inclusion in MedDRA. These terms relate to reasons why patients stop, start, or change medications. Most of the concepts were already in MedDRA but three new terms were added and one term was made non-current in MedDRA Version 18.0 in March 2015.