

Consideration of Requests for New SMQs

In May 2007, the ICH MedDRA Management Board endorsed a procedure to assess subscriber Change Requests for new SMQs. Each request for a new SMQ should be accompanied by a rationale and supporting information. The supporting information should take the form of responses to the following questions:

- What is the scientific/pharmacovigilance question that led to the request for this SMQ?
- Is the current MedDRA hierarchy (e.g., HLTs, PTs) or any existing SMQ suitable to address the question? If not, what are the deficiencies in the hierarchy or existing SMQs that should be addressed?
- Would your organization be able to address this question without this new SMQ, and if so, how? (That is, what would be the strategy and terms used?)
- Which SMQ structure (i.e., broad/narrow, hierarchical, algorithm) do you think would best address the question?
- How often would your organization need this SMQ (e.g., only once to address a very specific emerging issue or regularly/routinely)?

Each new SMQ request, along with its complete supporting information, should be submitted to the MSSO or the JMO by the subscriber. The MSSO/JMO forwards the Change Request information for consideration by the ICH Advisory Panel on SMQs. A request for a new SMQ is part of the 100 Change Requests per month per MedDRA Core subscriber.

Each new SMQ request is carefully considered by the Panel to determine if the requested SMQ:

- Is consistent with the concepts and definitions adopted by the CIOMS Working Group (WG)
- Overlaps with existing SMQs

The ICH Advisory Panel also considers if the SMQ has application for ongoing pharmacovigilance activities, if it is clinically relevant, and if it would have the potential to be used by the broad MedDRA user community.

Based on its considerations, the Panel makes a recommendation to the CIOMS WG to proceed or not with development of the new SMQ. If the Panel recommends not proceeding, a rationale is provided to the requesting Subscriber and is also noted in the general Change Request rejection statements by MSSO.

For a list of suspended, discontinued, or rejected SMQ requests, visit the [Standardised MedDRA Queries](#) section of the MedDRA MSSO Web site.

Note: For Change Requests to existing SMQs (e.g., addition of a term), the established MSSO/JMO Change Request process should be used. Visit the [Change Requests](#) section of the MedDRA MSSO Web site.