Recommendations for the Implementation of MedDRA® Supplemental Terms

Purpose

The purpose of this document is to provide the MedDRA Maintenance and Support Services Organization's (MSSO) recommendations regarding the issue of utilization of MedDRA supplemental terms.

Overview

The maintenance of MedDRA by the MSSO was designed, and has been implemented, to provide a rapid and accurate response to subscriber Change Requests. When Change Requests are received by the MSSO, the subscriber receives an initial acknowledgement of the receipt of the request within 48 hours of receipt by the MSSO. The Change Request is then processed through an international medical team, and a final disposition is sent to the subscriber within 7 calendar days from initial receipt by the MSSO. Approved Change Requests are designated as supplemental changes to MedDRA and are posted on the MSSO web site for review by all subscribers. In the original plan of the MedDRA Change Request process, it was anticipated that a situation might occur where, following a final pre-release review of the terminology, a supplemental term may not be included in the next official MedDRA release; this has not happened to date. The MSSO has modified it processes so that, once a supplemental term is added, it is considered part of the MedDRA terminology and will not be deleted.

There is, however, an issue with using supplemental MedDRA terms. Supplemental releases are not considered "official" MedDRA releases. Companies that use supplemental MedDRA terms do so at risk. The risk is not that the term will not be included in the next release of MedDRA, but that not all companies and regulators are able to accept them as current valid terms. From a regulator standpoint, the risk for a submitting company will be a possible slow down in processing because the submission will be viewed as an exception. Exception processing may include manual recoding or rejection of the submission. One needs to take into consideration the validation processing that is implemented as part of the acceptance of e-submissions when forming a policy on the use of supplemental MedDRA terms in a filing.

Recommendations

The MSSO makes the following recommendations:

1. Companies should use supplemental terms internally based on their business needs.
2. Companies that share data with other companies need to have a clear understanding of the other company's position on the use of supplemental terms.

3. Companies submitting regulatory reports need to be aware of the receiving regulatory agency's position on the use of supplemental terms, e.g. – MHLW is not opposed to the use of supplemental terms.
4. If a regulatory agency does not use supplemental terms, a company should limit use of supplemental terms for reporting.
5. If the use of supplemental terms is necessary, the company should coordinate its reporting with the regulator.