MedDRA Version 30.0 Complex Changes

(October 2026)

1. **Add a New HLT Product recommendation errors and issues to HLGT**
   Medication errors and other product use errors and issues

Justification: This addition has been requested by one of our clinical teams with the following rationale: Recommendation is different/distinct from prescribing. We have many reported scenarios where medication was incorrectly recommended/advised without specific information that the product/drug was prescribed incorrectly. Product recommendation error/issue would exactly reflect such scenarios when no prescription issue was mentioned. The team went on to suggest the addition of specific LLT/PTs of PT/LLT: Product recommendation error and PT/LLT: Product recommendation issue.

Terminology Impact: If approved, new terms would be added as appropriate.

Implementation Status: This request was not approved. The concept of a "recommendation" in the medication use process is not sufficiently clear to warrant a specific HLT. A formal definition of product "recommendation" or product "recommendation error" is not easily found and the concept is neither uniformly understood nor universally accepted as a clearly defined scenario, making it challenging to distinguish between recommendation and prescribing related scenarios. Reporters may not be aware of the distinction and report the terms interchangeably. Furthermore, creating a formal separation between recommendation and prescription potentially increases ambiguity and complexity in cases reporting similar but differently worded situations, e.g. "instructions". Additionally, "recommendation" is unclear with respect to the person providing the recommendation, and therefore potentially overlapping with scenarios such as off-label use. A practical benefit of the requested HLT inclusion was not seen by the broader user community, as the proposed concept was considered ambiguous and unlikely to contribute additional clarity to the MedDRA hierarchy.

2. **Replace existing HLT *Product confusion errors and issues* under HLGT *Medication errors and other product use errors and issues* with new HLT *Product confusions***

Justification: As confusion is per se unintentional and a human intellectual failure there is no need to mention "Issues" vs "Errors" in the HLT name. Renaming it will bring this HLT in line with the naming of the HLT *Accidental exposures to product* and reduce the confusion about error vs issue terms.

Terminology Impact: Should this request be approved, the PTs under existing HLT *Product confusion errors and issues* would move to new HLT Product confusions.

Implementation Status: This request was approved. New HLT *Product confusions* aligns with the naming of its subsumed terms. Generally, all confusion scenarios related to medications are considered unintentional by their nature. The new HLT name *Product confusions* aligns with the name of HLT *Accidental exposures to product.* A new HLT *Product confusions* will be added to HLGT *Medication errors and other product use errors and issues,* rather than renaming the term as proposed. In a related change, existing HLT *Product confusion errors and issues* will be merged under HLT *Product confusions*.