

Notice Related to Medication Error Terms in MedDRA Version 29.0

The MedDRA Term Selection (MTS): Points to Consider (PTC) document is updated annually, and the PtC Companion Document is updated on an as-needed basis. As a result, the hierarchy and currency of MedDRA terms shown in PtC examples may differ from the ones in the most recent MedDRA version. In addition, a more appropriate match may be available for a given coding scenario due to the introduction of new MedDRA terms since the last document release.

In MedDRA Version 29.0, some LLTs containing descriptive qualifiers such as “wrong”, “incorrect”, etc., as well as descriptive LLTs not having a qualifier were moved from an “error” PT to an “issue” PT.

These recent LLT changes will be reversed for Version 29.1 to ensure that cases coded as medication errors can be identified and retrieved for surveillance and pharmacovigilance purposes. In the meantime, see example below with current options for coding. Please apply general coding principles to determine the most appropriate term for your specific cases.

Example:

In Version 29.0, the LLT Wrong drug dispensed was moved from PT Product dispensing error to PT Product dispensing issue. Therefore, when “wrong drug dispensed” is currently reported, the following two options are available for coding:

If coded to the exact match, LLT Wrong drug dispensed, the error type is captured. However, the medication error case will not be retrieved by the narrow scope of SMQ Medication errors because this LLT links to the “issue” PT Product dispensing issue in Version 29.0. Users will need to manually add such LLTs to the narrow scope of SMQ Medication errors in a customized search in Version 29.0 or use the broad scope of this SMQ. In Version 29.1, these LLTs will be reversed back to an “error” PT.

If coded to LLT/PT Product dispensing error, the medication error case is captured with the narrow scope of the SMQ Medication errors. However, the error type of wrong drug is not coded in the case. As the error type is crucial for regulatory pharmacovigilance, this report should be re-coded in Version 29.1 to LLT Wrong drug dispensed which will be reverted under PT Product dispensing error.

A list of terms affected by changes between Version 28.1 to 29.0 is available in the annex and includes the assigned PT in MedDRA Version 29.1.

Both the PtC Companion Document and MTS:PTC, have not been updated to reflect these LLT changes. Following an ongoing systematic review of these terms in HLGT Medication errors and other product use errors and issues by the MSSO and the ICH M1 PtC Working Group, the documents will be updated where needed.

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Annex

LLT	PT Name v.28.1	PT Name v.29.0	PT Name v.29.1
Expired device dispensed	Device dispensing error	Device dispensing issue	Device dispensing error
Wrong device dispensed	Device dispensing error	Device dispensing issue	Device dispensing error
Device placement at incorrect location	Device implantation error	Device placement issue	Device placement error
Inappropriate device programming	Device programming error	Device programming issue	Device programming error
Injector positioned upside down	Device use error	Device use issue	Device use error
Accidental dose decrease	Wrong dose	Dosing error	Wrong dose
Accidental dose increase	Wrong dose	Dosing error	Wrong dose
Inappropriate drug titration	Drug titration error	Drug titration issue	Drug titration error
Duplicate therapy with same active substance	Duplicate therapy error	Duplicate therapy issue	Duplicate therapy error
Unintentional intravascular injection	Incorrect route of product administration	Product administration error	Incorrect route of product administration
Drug maladministration	Product administration error	Product administration issue	Product administration error
Drug misadministration	Product administration error	Product administration issue	Product administration error
Deteriorated drug dispensed	Product dispensing error	Product dispensing issue	Product dispensing error
Drug not dispensed in original container	Product dispensing error	Product dispensing issue	Product dispensing error
Expired drug dispensed	Product dispensing error	Product dispensing issue	Product dispensing error
Pharmacy label placed incorrectly	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong directions typed on label	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong dosage form dispensed	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong drug concentration dispensed	Product dispensing error	Product dispensing issue	Product dispensing error

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LLT	PT Name v.28.1	PT Name v.29.0	PT Name v.29.1
Wrong drug dispensed	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong drug product dispensed	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong drug strength dispensed	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong label placed on medication during dispensing	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong patient package insert selected during dispensing	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong quantity of drug dispensed	Product dispensing error	Product dispensing issue	Product dispensing error
Wrong route of administration dispensed	Product dispensing error	Product dispensing issue	Product dispensing error
Active ingredient not added to diluent	Product preparation error	Product preparation issue	Product preparation error
Diluent not added to active ingredient	Product preparation error	Product preparation issue	Product preparation error
Product concentrate not diluted	Product preparation error	Product preparation issue	Product preparation error
Product used prior to being brought to recommended temperature	Product preparation error	Product preparation issue	Product preparation error
Vaccine incorrect diluent used	Product preparation error	Product preparation issue	Product preparation error
Vaccine incorrect diluent volume	Product preparation error	Product preparation issue	Product preparation error
Wrong concentration prepared	Product preparation error	Product preparation issue	Product preparation error
Wrong diluent used	Product preparation error	Product preparation issue	Product preparation error
Wrong drug strength compounded	Product preparation error	Product preparation issue	Product preparation error
Wrong drug strength prepared	Product preparation error	Product preparation issue	Product preparation error
Wrong eluent used	Product preparation error	Product preparation issue	Product preparation error
Wrong solution used in drug reconstitution	Product preparation error	Product preparation issue	Product preparation error

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LLT	PT Name v.28.1	PT Name v.29.0	PT Name v.29.1
Wrong drug prescribed	Product prescribing error	Product prescribing issue	Product prescribing error
Incorrect dose selected	Product selection error	Product selection issue	Product selection error
Wrong drug concentration selected	Product selection error	Product selection issue	Product selection error
Wrong drug product selected	Product selection error	Product selection issue	Product selection error
Wrong drug selected	Product selection error	Product selection issue	Product selection error
Wrong drug strength selected	Product selection error	Product selection issue	Product selection error
Wrong product selected	Product selection error	Product selection issue	Product selection error
Device stored with needle attached	Product storage error	Product storage issue	Product storage error
Drug stored in wrong location	Product storage error	Product storage issue	Product storage error
Improper storage of product in use	Product storage error	Product storage issue	Product storage error
Improper storage of unused product	Product storage error	Product storage issue	Product storage error
Incorrect product storage	Product storage error	Product storage issue	Product storage error
Incorrect storage of drug	Product storage error	Product storage issue	Product storage error
Reconstituted product storage time exceeded	Product storage error	Product storage issue	Product storage error
Product cleaning error by user	Wrong technique in product usage process	Wrong technique in product usage process performed in error	Wrong technique in product usage process
Tablet split by mistake	Wrong technique in product usage process	Wrong technique in product usage process performed in error	Wrong technique in product usage process
Wrong technique in product usage process performed in error (non-current)	new term in version 29.0	Wrong technique in product usage process performed in error	Wrong technique in product usage process