What's New
MedDRA Version 18.1

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ICH
harmonisation for better health

ACKNOWLEDGEMENTS

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Table of Contents

1. DOCUMENT OVERVIEW 1

2. VERSION 18.1 CHANGE REQUESTS 2

2.1 TERMINOLOGY CHANGES 2

2.2 TRANSLATION CHANGES 3

2.2.1 French Translation Review 3

3. NEW DEVELOPMENTS IN VERSION 18.1 4

3.1 NEW SOC *PRODUCT ISSUES* TO BE IMPLEMENTED IN MedDRA VERSION 19.0 4

3.2 UPDATED MVAT 4

3.3 STANDARDISED MedDRA QUERIES (SMQS) 4

3.4 PROACTIVITY REQUESTS 4

3.4.1 Placement of haemorrhage and haematoma terms 5

3.4.2 Skin mycosis concepts 6

4. SUMMARY OF CHANGES 7

4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY 7

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES 9

4.3 MedDRA TERM COUNTS 10

4.4 MODIFIED PT AND LLT NAMES 13

4.5 LLT CURRENCY STATUS CHANGES 13

LIST OF FIGURES

Figure 2-1. Net Changes of Terms per SOC 3

LIST OF TABLES

Table 3-1 Primary SOC changes of hematoma terms 5
Table 3-2 New secondary links for hemorrhage terms 6
Table 4-1 Summary of Impact on SOCs, HLGTs, HLTs 7
Table 4-2 Summary of Impact on PTs 8
Table 4-3 Summary of Impact on LLTs 8
Table 4-4 Summary of Impact on SMQs 8
Table 4-5 Summary of Impact on Records in MedDRA Files 10
Table 4-6 MedDRA Term Counts 12
Table 4-7 Modified PT/LLT Names 13
Table 4-8 LLT Currency Changes 15

1. DOCUMENT OVERVIEW

This *What's New* document contains information on the origins and types of changes made to the Medical Dictionary for Regulatory Activities (MedDRA) between Versions 18.0 and 18.1.

Section 2, Version 18.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 18.1, highlights changes in Version 18.1 related to change request submissions, new initiatives, and information on Standardised MedDRA Queries (SMQs).

Section 4, Summary of Changes, contains details on:

- Term history
- The impact of this version on the terminology (in tables)
- Impact on the records in MedDRA files
- MedDRA term and SMQ counts
- Modified Lowest Level Terms (LLT) and Preferred Term (PT) names
- All LLTs in MedDRA that had a currency status change.

All updated documentation associated with this version is located in the distribution file in Adobe® Portable Document Format (PDF) or, for some documents, Microsoft Excel. Please refer to the !!Readme.txt file for a complete listing.

The Maintenance and Support Services Organization (MSSO) Help Desk can be reached at International AT&T Toll Free at 1-877-258-8280 or mssohelp@meddra.org.

2. VERSION 18.1 CHANGE REQUESTS

2.1 TERMINOLOGY CHANGES

Changes to MedDRA result from user change requests, from proactivity requests submitted by MedDRA users, and from internal change requests. Internal change requests result from MSSO maintenance activities and from special working group activities in which the MSSO participates.

MedDRA Version 18.1 is a simple change version which means that changes are made only at the PT and LLT levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 1,799 change requests processed for this version; 1,323 change requests were approved and implemented, and 431 change requests were not approved. There are, in addition, 45 change requests suspended for further consideration and resolution beyond this version.

Information on specific changes (e.g., new terms added, LLT promotions, PT demotions, PT primary SOC changes, etc.) which occurred since the prior MedDRA release can be obtained via the Version Report included with each respective MedDRA download. In addition, users may wish to use the MedDRA Version Analysis Tool (MVAT) which is an online tool that compares any two MedDRA versions– including non-consecutive versions – to identify changes. The output of MVAT is similar to the Version Report. MVAT is provided free of charge to MedDRA users as part of their subscription.

Between MedDRA releases, the MSSO makes available weekly supplemental update files, which are approved changes that will be implemented for the next MedDRA version. The supplemental files may be helpful for users to identify changes that will be implemented in the next release.

An explanation of all changes considered (approved and not approved) for MedDRA Version 18.1 is accessible as a cumulative Detail Report included in the MedDRA English version download. Users may review all change requests considered by the MSSO from MedDRA Version 5.1 to the present in WebCR.

Figure 2-1 (shown below) summarizes all changes made per System Organ Class (SOC) and may be useful to gauge the impact of changes to a specific area of MedDRA. The data are derived from the difference in counts of primary and secondary PT/LLTs, HLTs, and HLGTs for Version 18.1 (shown in Table 4-6) and the corresponding information for Version 18.0. Additionally, term name changes and LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 18.1.

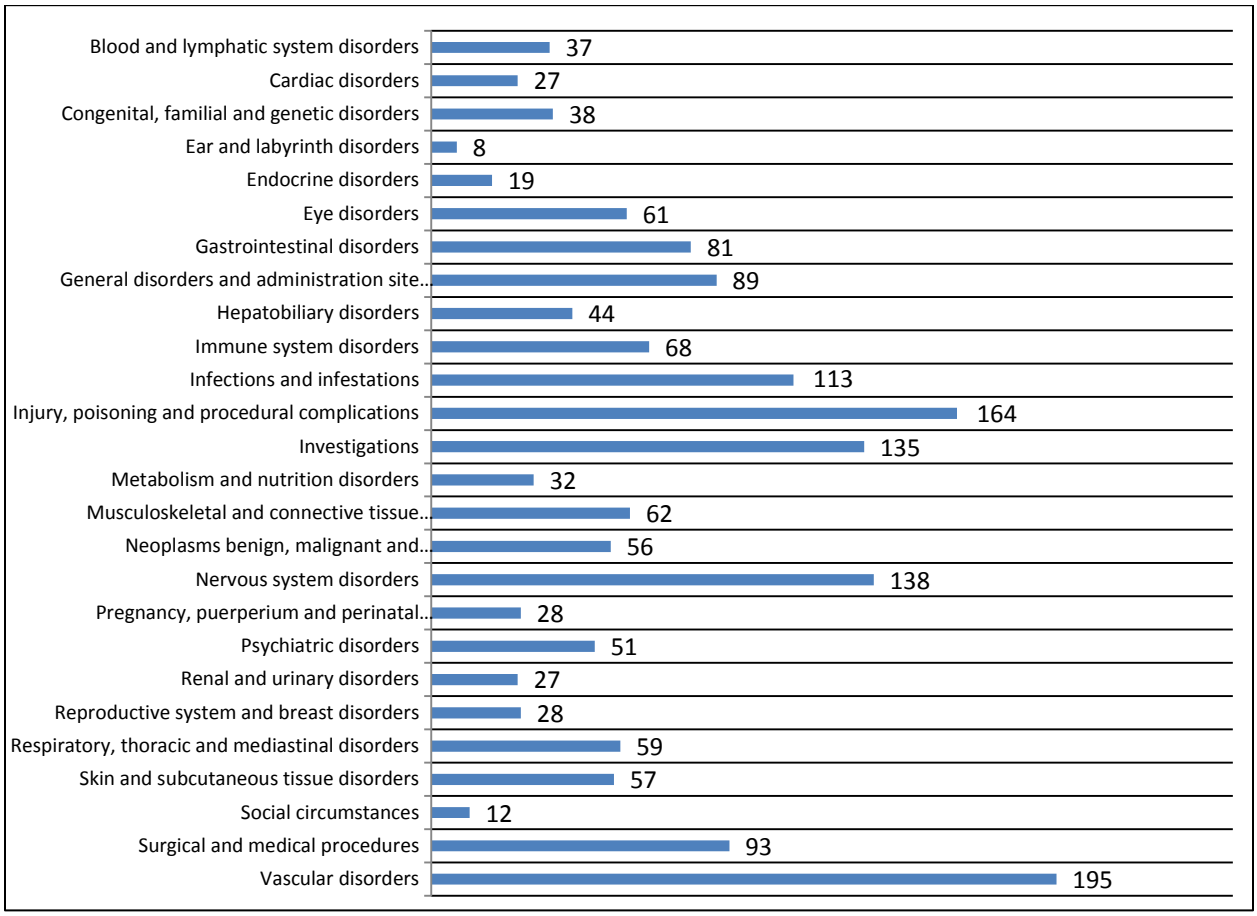

Figure 2-1. Net Changes of Terms per SOC

2.2 TRANSLATION CHANGES

2.2.1 French Translation Review

In an effort to review and improve the French translation of MedDRA, the MSSO is conducting a review of the translation of terms from English into French. This will be an ongoing effort that is expected to last several MedDRA releases. To assist MedDRA users to understand changes that have been implemented, the MSSO has included a spreadsheet in the French MedDRA Version 18.1 download which contains a list of all changes made. This spreadsheet indicates which translation changes are conceptual changes (i.e., change in meaning) versus those that are minor corrections such as spelling or modifications to diacritical marks. This spreadsheet will be included in all future versions of the French translation of MedDRA until the review is complete.

Please see the Change Request section of the MedDRA website if you wish to request an improvement in the translation of a term or terms in any non-English version of MedDRA.

3. NEW DEVELOPMENTS IN VERSION 18.1

3.1 NEW SOC *PRODUCT ISSUES* TO BE IMPLEMENTED IN MedDRA VERSION 19.0

The ICH MedDRA Management Board has confirmed the implementation of a 27th SOC in March 2016 for MedDRA Version 19.0 which will be called *Product issues*. This new SOC will include terms relevant for issues with product quality, devices, product manufacturing and quality systems, supply and distribution, and counterfeit products which are important as they may affect patient safety. More detailed information on SOC *Product issues* can be found on the MedDRA website.

MedDRA users have the opportunity to review and comment on complex changes (e.g., HLGT and HLT changes) related to the new SOC which are posted on the change request section of the MedDRA website. Comments are due by 25 September 2015.

3.2 UPDATED MVAT

The MSSO is pleased to announce that an update to the MedDRA Version Analysis Tool (MVAT) is available as of 28 May 2015. A MedDRA User ID and Password are required to use the application. The MVAT's new features include:

- User interface available in all MedDRA languages
- Report output available in all MedDRA languages
- An improved history function
- An option to filter report output by SOC
- Improved report output related to MedDRA and SMQ changes

MVAT is free to all MedDRA users as part of a MedDRA subscription. Please view or download a videocast from the Training Materials section of the MedDRA website located under "Tools" to learn how to log into and use MVAT.

3.3 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs were introduced into MedDRA v18.1, but there were 292 approved changes to existing SMQs. Only minor changes were made to the SMQ Introductory Guide.

3.4 PROACTIVITY REQUESTS

The proactive maintenance process allows MedDRA users to propose general changes to MedDRA outside of the established change request process. These proactivity requests may address inconsistencies, make corrections, or suggest improvements. During the Version 18.1 change request processing period, the MSSO evaluated four

proactivity proposals submitted by MedDRA users. Of the four proposals, two were implemented and two were not approved. See below for details on the implemented requests. The MSSO publishes and updates a list of all proposals received and their status on the Change Request section of the MedDRA website.

The MSSO is interested in learning about any ideas that users may have about "proactive" improvements to MedDRA. Please email your ideas for "proactive" MedDRA improvements to the MSSO Help Desk. Be as specific as possible in describing your suggestion(s), and include a justification which explains why you think your proposal should be implemented.

3.4.1 Placement of hemorrhage and hematoma terms

A MedDRA user asked the MSSO to review the primary SOC allocation for hemorrhage and hematoma PTs to ensure consistency in the primary SOC allocation and to provide criteria for when the primary SOC of these terms should be to SOC *Injury, poisoning and procedural complications*.

The MSSO reviewed the placement of hemorrhage and hematoma terms in MedDRA and, after careful consideration, 19 changes were implemented in MedDRA Version 18.1. Pairs of hemorrhage and hematoma terms that were not identically mapped in their primary SOC representation were changed so that their primary mappings are identical based on the site of manifestation or cause (i.e., injury). See the table below for examples.

PT Name	18.0 Primary SOC	18.1 Primary SOC
Adrenal haematoma	Injury, poisoning and procedural complications	Endocrine disorders
Intra-abdominal haematoma	Vascular disorders	Gastrointestinal disorders
Umbilical haematoma	Congenital, familial and genetic disorders	Skin and subcutaneous tissue disorders

Table 3-1 Primary SOC changes of hematoma terms

Additional secondary links were made for hemorrhage terms to SOC *Injury, poisoning and procedural complications* . See examples below.

PT Name	HLT	Secondary SOC
Adrenal haemorrhage	Abdominal injuries NEC	Injury, poisoning and procedural complications
Laryngeal haemorrhage	Site specific injuries NEC	Injury, poisoning and procedural complications
Renal haemorrhage	Renal and urinary tract injuries NEC	Injury, poisoning and procedural complications

Table 3-2 New secondary links for hemorrhage terms

Placement rules for the primary SOC of most PT concepts are dictated by the site of manifestation and as such it is not possible to consistently align corresponding hemorrhage and hematoma PTs throughout all of MedDRA. Therefore, in order to retrieve all relevant cases of hemorrhage/hematoma, it may be necessary to leverage other resources such as SMQ *Haemorrhages*.

In addition, the proactivity request asked the MSSO to review and determine the criteria for when the primary SOC is *Injury, poisoning and procedural complications*. The MedDRA Introductory Guide Version 18.1 in section 6.12.1 provides information on placement of concepts primary to SOC *Injury, poisoning and procedural complications*.

3.4.2 Skin mycosis concepts

The MSSO was requested to review the placement of “tinea” concepts for better and more accurate placement in MedDRA. After reviewing this proposal, the MSSO made 10 changes to better align tinea concepts. Many tinea PTs link to HLT *Tinea Infections* but there were LLTs under these “tinea” PTs which did not indicate "tinea" but are more general in nature. For example, LLT *Foot infection fungal NOS* was under PT *Tinea pedis* and was moved to PT *Fungal skin infection* for more accurate placement. Additionally, two PTs – PT *Microsporum infection* and PT *Trichophytic granuloma* were moved from HLT *Fungal infections NEC* to HLT *Tinea infections* to better align these concepts.

4. SUMMARY OF CHANGES

4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below (Tables 4-1 through 4-5) summarize the impact on MedDRA in Version 18.1. These tables are intended only as a reference. For detailed information on the changes to Version 18.1, please see the MedDRA Version Report included within the MedDRA download.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v18.0	v18.1
SOC	Total SOCs	0	26	26
HLGT	New HLGTs	0	0	0
	Merged HLGTs	0	0	0
	Total HLGTs[1]	0	335	335
HLT	New HLTs	0	0	0
	Merged HLTs	0	0	0
	Total HLTs[1]	0	1,721	1,721

Table 4-1 Summary of Impact on SOCs, HLGTs, HLTs

MedDRA v18.1 is a simple change version which means changes are only made at the PT and LLT levels of the MedDRA hierarchy; hence there are no changes in the number of HLTs and HLGTs.

[1] Total net change of HLGTs or HLTs equals the number of new HLGTs or HLTs minus the number of respective merged HLGTs or HLTs.

PT Changes

Level	Change Request Action	v18.0	v18.1
PT	New PTs	557	296
	Promoted LLTs	23	21
	Demoted PTs	43	50
	Net Change[1]	537	267
	Total PTs	21,345	21,612

Table 4-2 Summary of Impact on PTs

[1]Net change of PTs equals the number of new PTs plus the number of promoted LLTs minus the number of demoted PTs.

LLT Changes

Level	Change Request Action	Net Change	v18.0	v18.1
LLT	Total LLTs[1]	751	74,229	74,980

Table 4-3 Summary of Impact on LLTs

[1]Total LLTs include PTs as they are also represented as LLTs.

New SMQs

Level	Net Change	v18.0	v18.1
1	0	98	98
2	0	82	82
3	0	20	20
4	0	12	12
5	0	2	2

Table 4-4 Summary of Impact on SMQs

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below summarizes the impact on MedDRA in Version 18.1. The table is intended only as a reference.

INTL_ORD.ASC	Added	0
	Removed	0
	Modified	0
SOC.ASC	Added	0
	Removed	0
	Modified	0
SOC_HLGT.ASC	Added	0
	Removed	0
	Modified	0
HLGT.ASC	Added	0
	Removed	0
	Modified	0
HLGT_HLT.ASC	Added	0
	Removed	0
	Modified	0
HLT.ASC	Added	0
	Removed	0
	Modified	0
HLT_PT.ASC	Added	543
	Removed	106
	Modified	0
MDHIER.ASC	Added	589
	Removed	142
	Modified	0
PT.ASC	Added	317
	Removed	50
	Modified	16
LLT.ASC	Added	751

	Removed	0
	Modified	317
SMQ_LIST.ASC[1]	Added[1]	0
	Removed	0
	Modified	214
SMQ_CONTENT.ASC	Added	884
	Removed	0
	Modified	164

Table 4-5 Summary of Impact on Records in MedDRA Files

[1] The number of SMQs added includes both top level (Level 1) and sub-search SMQs.

4.3 MedDRA TERM COUNTS

The table below shows term counts by SOC for HLGTs, HLTs, primary and secondary PTs and LLTs, and primary PTs and LLTs.

SOC	LLTs* (Primary)[1]	PTs (Primary)[1]	LLTs* (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Blood and lymphatic system disorders	1,118	276	4,100	950	87	17
Cardiac disorders	1,379	311	2,263	562	36	10
Congenital, familial and genetic disorders	3,306	1,242	3,306	1,242	98	19
Ear and labyrinth disorders	420	83	766	193	17	6
Endocrine disorders	639	178	1,687	496	38	9

SOC	LLTs* (Primary)[1]	PTs (Primary)[1]	LLTs* (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Eye disorders	2,388	568	3,588	949	64	13
Gastrointestinal disorders	3,694	816	7,266	1,635	108	21
General disorders and administration site conditions	2,874	1,078	3,613	1,333	49	9
Hepatobiliary disorders	625	182	1,416	404	19	4
Immune system disorders	435	129	2,444	646	26	4
Infections and infestations	6,951	1,839	7,267	1,924	149	12
Injury, poisoning and procedural complications	6,187	1,007	8,475	2,013	69	8
Investigations	13,215	5,345	13,215	5,345	106	23
Metabolism and nutrition disorders	935	270	2,512	707	63	14
Musculoskeletal and connective tissue disorders	2,385	425	6,160	1,176	59	11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8,373	1,893	9,032	2,163	201	39

SOC	LLTs* (Primary)[1]	PTs (Primary)[1]	LLTs* (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Nervous system disorders	3,427	892	6,784	1,793	107	20
Pregnancy, puerperium and perinatal conditions	1,611	213	2,809	551	48	8
Psychiatric disorders	2,229	502	3,031	714	78	23
Renal and urinary disorders	1,180	336	2,499	690	32	8
Reproductive system and breast disorders	1,693	464	4,039	1,116	52	16
Respiratory, thoracic and mediastinal disorders	1,620	500	3,977	1,068	48	11
Skin and subcutaneous tissue disorders	1,970	466	4,498	1,282	56	10
Social circumstances	613	260	613	260	20	7
Surgical and medical procedures	4,433	2,045	4,433	2,045	141	19
Vascular disorders	1,280	292	6,361	1,503	68	11
Total	**74,980**	**21,612**				

Table 4-6 MedDRA Term Counts

[1]Primary count only includes the number of terms that are primarily linked to the designated SOC at either the LLT level or the PT level. The sums of primary LLTs and PTs match those in Tables 4-2 and 4-3.

[2]Total count includes the number of terms that are both primarily and secondarily linked to the designated SOC at either the LLT level or the PT level. Therefore, the sums of total LLTs and PTs are greater than those in Tables 4-2 and 4-3.

[3]The HLT and HLGT counts are not necessarily unique values given MedDRA's multi-axiality (see Section 2.2 of the Introductory Guide for a discussion of multi-axiality). There are some HLTs that are counted in more than one SOC. For example, HLT *Connective tissue disorders congenital* and HLGT *Musculoskeletal and connective tissue disorders congenital* are counted in both SOC *Congenital, familial and genetic disorders* and SOC *Musculoskeletal and connective tissue disorders*. The sums of HLTs and HLGTs are greater than those found in Table 4-1.

4.4 MODIFIED PT AND LLT NAMES

As part of ongoing MedDRA maintenance activities, existing PTs and LLTs can be modified (renamed) to correct for misspelling, double spacing, capitalization, or other errors that meet the renaming criteria in MedDRA. This rename provision retains the original MedDRA code of the term and preserves its original meaning, and facilitates the reuse of the same MedDRA code for the renamed PT/LLTs.

The table below lists the two terms renamed in English MedDRA Version18.1.

Code	Level	Term Name in v18.0	Term Name in v18.1
10075460	PT	Blastic plasmacytoid dendritric cell neoplasia	Blastic plasmacytoid dendritic cell neoplasia
10066379	LLT	Rhomboencephalitis	Rhombencephalitis

Table 4-7 Modified PT/LLT Names

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 20 terms at the LLT level in MedDRA Version 18.1 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Agranulocytic angina	Current	Agranulocytic angina is a valid synonym for Agranulocytosis and LLT *Angina agranulocytic* is a current LLT in MedDRA. Therefore, the status of natural word order LLT *Agranulocytic angina* was changed to current.
Infection systemic	Current	Systemic infection was added to MedDRA for Version 18.1 as a PT under HLT *Infections NEC*. Non-current LLT *Infection systemic* was moved from PT *Sepsis* to the new PT *Systemic infection* and its status changed to current.
Ischaemic feet	Current	Based on a MedDRA user request, LLT *Ischaemic feet* was changed from a status of non-current to current as it is a recognized concept.
Ischaemic foot	Current	Based on a MedDRA user request, LLT *Ischaemic foot* was changed from a status of non-current to current as it is a recognized concept.
Ischemic feet	Current	Based on a MedDRA user request, LLT *Ischemic feet* was changed from a status of non-current to current as it is a recognized concept.
Ischemic foot	Current	Based on a MedDRA user request, LLT *Ischemic feet* was changed from a status of non-current to current as it is a recognized concept.
Pseudoaneurysm	Current	The currency status of LLT *Pseudoaneurysm* was changed to current because it is a commonly used valid synonym of existing LLT *False aneurysm.*
Refeeding syndrome	Current	The status of LLT *Refeeding syndrome* was changed to current as it is a recognized clinical concept. Additionally LLT *Refeeding syndrome* was promoted to a PT under primary HLT *Electrolyte imbalance NEC* in SOC *Metabolism and nutrition disorders*.
Blot haemorrhages	Non-current	For clarification and to avoid translation issues, LLT *Blot haemorrhages* was made non-current and replaced by a new LLT *Retinal blot haemorrhages.*
Blot hemorrhages	Non-current	For clarification and to avoid translation issues, LLT *Blot hemorrhages* was made non-current and replaced by a new LLT *Retinal blot hemorrhages.*
CHAD2DS2-VASc score decreased	Non-current	LLT *CHAD2DS2-VASc score decreased* was made non-current because of misspelling and its inappropriate qualifier "decreased". New PT *CHA2DS2-VASc-score* was added under HLT *Neurologic diagnostic procedures* as a replacement.
CHAD2DS2-VASc score increased	Non-current	LLT *CHAD2DS2-VASc score increased* was made non-current because of misspelling. PT *CHA2DS2-VASc*

Lowest Level Term	Currency Status Changed to	Rationale
		annual stroke risk high was under HLT *Neurologic diagnostic procedures* as a replacement.
Dot and blot haemorrhages	Non-current	For clarification and to avoid translation issues, LLT *Dot and blot haemorrhages* was made non-current and replaced by a new LLT *Retinal dot and blot haemorrhages.*
Dot and blot hemorrhages	Non-current	For clarification and to avoid translation issues LLT *Dot and blot hemorrhages* was made non-current and replaced by a new LLT *Retinal dot and blot hemorrhages.*
Dot haemorrhages	Non-current	For clarification and to avoid translation issues LLT *Dot haemorrhages* was made non-current and replaced by a new LLT *Retinal dot haemorrhages.*
Dot hemorrhages	Non-current	For clarification and to avoid translation issues LLT *Dot hemorrhages* was made non-current and replaced by a new LLT *Retinal dot hemorrhages.*
Drug dispensed with falsified packaging	Non-current	LLT *Drug dispensed with falsified packaging* was made non-current since it is a combination term which can be coded to LLT *Drug dispensing error* and/or an existing counterfeit term.
Loss of teeth due to accident, extraction, or local periodontal disease	Non-current	LLT *Loss of teeth due to accident, extraction, or local periodontal disease* is an ICD-inherited term and represents a combination of several potential causes and effect. Changing the status of the term to non-current is in accordance with existing MedDRA rules.
Ocular injection	Non-current	The status of LLT *Ocular injection* was changed to non-current because it is ambiguous in meaning as it may pertain to a procedure or a synonym for ocular hyperaemia ("red eye").
Unintentional device misuse	Non-current	Appendix B of the MedDRA Introductory Guide describes “misuse” as "the intentional and inappropriate use of a product - over the counter or prescription - other than as prescribed or not in accordance with the authorized product information”. Therefore, LLT *Unintentional device misuse* was made non-current because misuse is an intentional act, not unintentional.

Table 4-8 LLT Currency Changes