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# What's New MedDRA Version 17.0

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**MSSO-DI-6001-17.0.0**

**March 2014**



**ACKNOWLEDGEMENTS**

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### 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 16.1 and 17.0.

Section 2, Version 17.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 17.0, highlights changes in v17.0 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](mailto:mssohelp@meddra.org).

## 2. VERSION 17.0 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 as well as from special working group activities in which the MSSO participates.

MedDRA v17.0 is a complex change version which means that changes can be made at all levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 1632 change requests processed for this version; 1308 change requests were approved and implemented, and 284 change requests were not approved. There are, in addition, 40 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 English language 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.

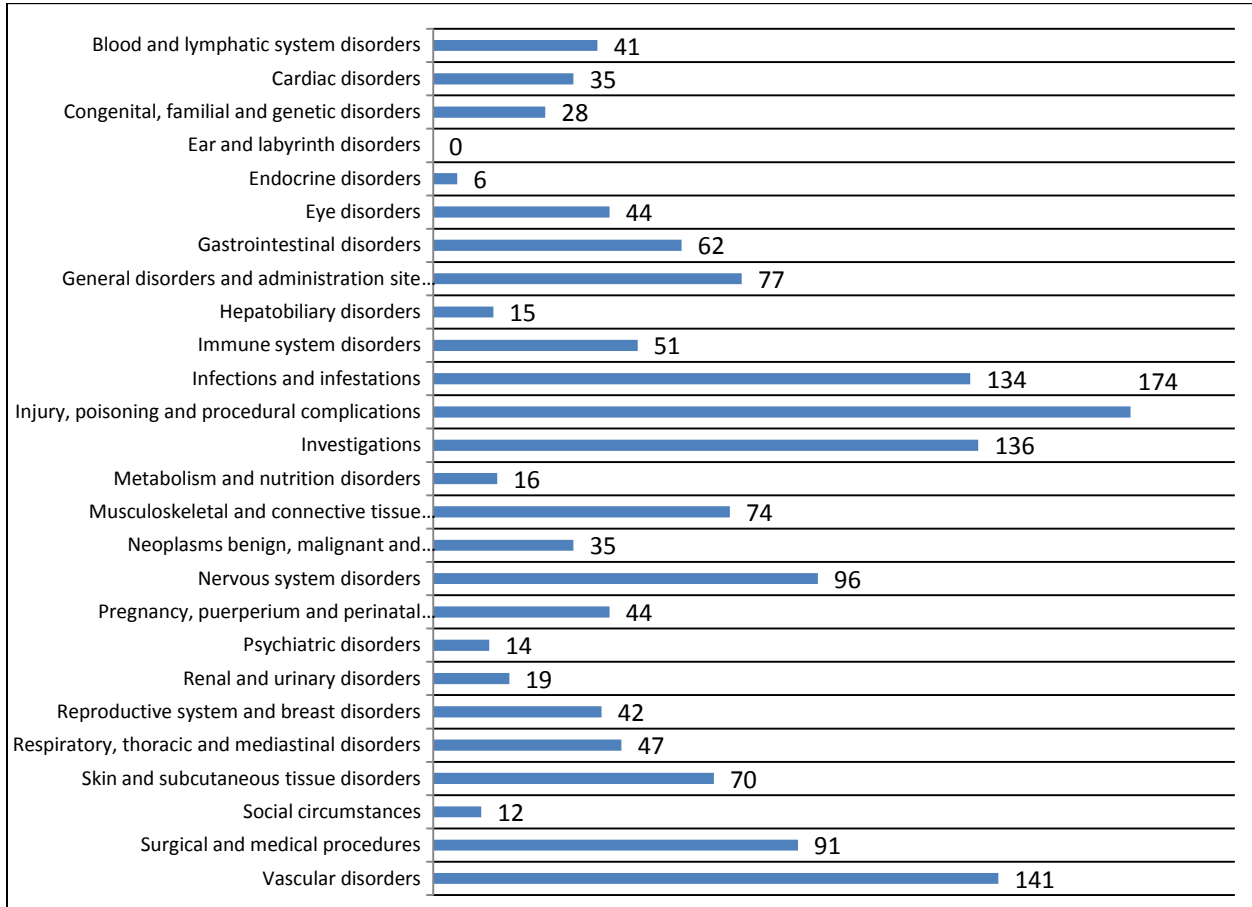
Between MedDRA releases, the MSSO makes available [weekly supplemental update](#) files which are approved changes that will be implemented for the next MedDRA version. The supplemental files may be helpful for users to identify changes that will be implemented in the next release.

An explanation of all changes considered (approved and not approved) for MedDRA v17.0 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 v5.1 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 v17.0 (shown in Table 4-6) and the corresponding information for v16.1. 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 v17.0.

## Version 17.0 Change Requests



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

## 2.2 COMPLEX CHANGES

The proposals for complex changes considered during v17.0 included those submitted by users, special initiatives, and those internally identified by the MSSO during change request processing.

Complex change proposals were posted on the MedDRA website for feedback from the MedDRA user community from 8 July 2013 to 31 July 2013. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 17 complex changes.

The complex changes implemented in v17.0 are summarized below. Please see the “Related Documents” on the [Change Request section](#) of the MedDRA website for specific details.

**At the SOC level:** No changes were made to existing SOC.

**Version 17.0 Change Requests**

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**At the HLGT level:** One new High Level Grouping Term (HLGT) was added and one HLGT was merged as a result of complex changes in v17.0. The changes are as follows:

**New HLGTs**

<b>New HLGT</b>	<b>To SOC</b>
Menopause related conditions	Reproductive system and breast disorders

**Table 2-1 New HLGTs**

**Merged HLGTs**

<b>Merged HLGT</b>	<b>To HLGT</b>	<b>SOC</b>
Menopause and related conditions	Menopause related conditions	Reproductive system and breast disorders

**Table 2-2 Merged HLGTs**

**At the HLT level:** There were 9 new High Level Terms (HLTs) added and 6 HLTs merged as a result of complex changes in v17.0. The changes are as follows:

**New HLTs**

<b>New HLT</b>	<b>To SOC</b>
Bone and joint injuries NEC	Injury, poisoning and procedural complications
Burkholderia infections	Infections and infestations
Central nervous system aneurysms and dissections	Nervous system disorders
Connective tissue disorders NEC	Musculoskeletal and connective tissue disorders
Exserohilum infections	Infections and infestations
Nervous system autoimmune disorders	Immune system disorders
Plasma cell myelomas	Blood and lymphatic system disorders and Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Stoma complications	Injury, poisoning and procedural complications
Transplantation complications	Injury, poisoning and procedural complications

**Table 2-3 New HLTs**

**Merged HLTs**

<b>Merged HLT</b>	<b>To HLT</b>	<b>SOC</b>
Central nervous system aneurysms	Central nervous system aneurysms and dissections	Nervous system disorders
Colonic neoplasms malignant	Colorectal neoplasms malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Connective tissue disorders (excl LE)	Connective tissue disorders NEC	Musculoskeletal and connective tissue disorders
Limb injuries NEC (incl traumatic amputation)	Bone and joint injuries NEC	Injury, poisoning and procedural complications
Multiple myelomas	Plasma cell myelomas	Blood and lymphatic system disorders  and  Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Rectal neoplasms malignant	Colorectal neoplasms malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)

**Table 2-4 Merged HLTs**

**2.3 TRANSLATION CHANGES**

In an effort to review and improve French MedDRA, the MSSO is in process of 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 French MedDRA users to understand changes that have occurred, the MSSO has included a spreadsheet in the French MedDRA v17.0 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 French 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 17.0

#### 3.1 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs were introduced into MedDRA v17.0, but there were 241 approved changes to existing SMQs. Only minor changes were made to the SMQ Introductory Guide.

#### 3.2 PEDIATRIC TERMS

The MSSO is participating in efforts by the National Institute of Child Health and Human Development (NICHD) to create a pediatric terminology that is interoperable with MedDRA. The purpose of the pediatric terminology is to facilitate electronic data collection and sharing across clinical research portfolios to support child health research. A total of 31 new terms and 7 changes to existing terms related to cardiac issues were implemented for MedDRA v17.0 as a result of this initiative. This will be an ongoing effort that will continue in MedDRA v17.1 and beyond. This initiative will have a positive impact on MedDRA, as it will result in new concepts that will be helpful for coding and data analysis. See the table below for examples of new terms added:

Term Name	Level
Absent baseline fetal heart rate variability	LLT
Junctional ectopic tachycardia	PT
Sinusoidal foetal heart rate pattern	PT

**Table 3-1 Examples of pediatric terms added**

#### 3.3 PROACTIVITY REQUESTS

The proactive maintenance process allows MedDRA users to propose general changes to MedDRA outside of the established change request process to address inconsistencies, make corrections or suggest improvements. The MSSO evaluated and implemented two proactive maintenance proposals from MedDRA users in MedDRA v17.0. See below for details. The MSSO publishes and updates a list of all proposals received and their status on the Change Request section of the MedDRA web site.

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.

### 3.3.1 Infective/ Noninfective Terms

In a proactivity request submitted by a MedDRA user, the MSSO was asked to review inconsistencies in the representation of existing infectious and noninfectious concepts and to identify missing infectious and noninfectious counterpart terms that could be useful for coding and analysis. As a result of this initiative, 18 new valid medical concepts were added and 54 changes to existing terms were made. Below are examples of new terms added (see Table 3-2). The preferred wording for the new terms is “infective” and “noninfective” (without a hyphen), in accordance with the format of most existing MedDRA terms.

Term name	Level
Noninfective conjunctivitis	PT
Infective uvulitis	LLT
Noninfective epididymitis	PT
Infective aortitis	PT

**Table 3-2 Examples of infectious / noninfectious terms added**

Primary SOC allocations for new PTs were made in accordance with section 6.11.2 of the MedDRA Introductory Guide.

### 3.3.2 Stoma Terms

The MSSO added 37 catheter PTs and LLTs in MedDRA v16.1 to improve coding and data analysis based on a proactivity request submitted by a MedDRA user to consider a set of catheter and stoma terms. In MedDRA v17.0, new HLT *Stoma complications* was added to SOC *Injury, poisoning and procedural complications* to better accommodate new and existing stoma terms for this proactivity request. A total of 16 new terms were added and 15 terms moved under new HLT *Stoma complications*. Not all PTs added or moved to HLT *Stoma complications* are primary to SOC *Injury, poisoning and procedural complications*. Some stoma concept PTs are secondarily linked to HLT *Stoma complications*. See Tabel 3-3 below for examples.

Term name	Level	Primary HLT	Primary SOC
Stoma site abscess	PT	Infections NEC	Infections and infestations
Stoma site candida	PT	Infections NEC	Infections and infestations
Stoma site haemorrhage	PT	Stoma complications	Injury, poisoning and procedural complications
Stoma site ulcer	PT	Stoma complications	Injury, poisoning and procedural complications

**Table 3-3 Stoma Terms**

## 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 v17.0. These tables are intended only as a reference. For detailed information on the changes to v17.0, please see the MedDRA Version Report included within the English language download.

#### SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v16.1	v17.0
<b>SOC</b>	Total SOCs	0	26	26
<b>HLGT</b>	New HLGTs	1	0	1
	Merged HLGTs	1	0	1
	Total HLGTs <sup>1</sup>	0	334	334
<b>HLT</b>	New HLTs	9	0	9
	Merged HLTs	6	0	6
	Total HLTs <sup>1</sup>	3	1717	1720

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

<sup>1</sup> Total net change of HLGTs or HLTs equals the number of new HLGTs or HLTs minus the number of respective merged HLGTs or HLTs.

**Summary of Changes**

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**PT Changes**

<b>Level</b>	<b>Change Request Action</b>	<b>v16.1</b>	<b>v17.0</b>
<b>PT</b>	New PTs	269	280
	Promoted LLTs	24	41
	Demoted PTs	43	69
	Net Change <sup>1</sup>	250	252
	Total PTs	20307	20559

**Table 4-2 Summary of Impact on PTs**

<sup>1</sup>Net change of PTs equals the number of new PTs plus the number of promoted LLTs minus the number of demoted PTs.

**LLT Changes**

<b>Level</b>	<b>Change Request Action</b>	<b>Net Change</b>	<b>v16.1</b>	<b>v17.0</b>
<b>LLT</b>	Total LLTs <sup>1</sup>	565	72072	72637

**Table 4-3 Summary of Impact on LLTs**

<sup>1</sup>Total LLTs include PTs as they are also represented as LLTs.

**New SMQs**

<b>Level</b>	<b>Net Change</b>	<b>v16.1</b>	<b>v17.0</b>
<b>1</b>	0	94	94
<b>2</b>	0	82	82
<b>3</b>	0	20	20
<b>4</b>	0	12	12
<b>5</b>	0	2	2

**Table 4-4 Summary of Impact on SMQs**

## Summary of Changes

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### 4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below summarizes the impact on MedDRA in v17.0. The table is intended only as a reference.

<b>INTL_ORD.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>SOC.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>SOC_HLGT.ASC</b>	Added	1
	Removed	1
	Modified	0
<b>HLGT.ASC</b>	Added	1
	Removed	1
	Modified	0
<b>HLGT_HLT.ASC</b>	Added	11
	Removed	8
	Modified	0
<b>HLT.ASC</b>	Added	9
	Removed	6
	Modified	0
<b>HLT_PT.ASC</b>	Added	745
	Removed	322
	Modified	0
<b>MDHIER.ASC</b>	Added	814
	Removed	372
	Modified	0
<b>PT.ASC</b>	Added	321
	Removed	69
	Modified	22

## Summary of Changes

<b>LLT.ASC</b>	Added	565
	Removed	0
	Modified	362
<b>SMQ_LIST.ASC<sup>1</sup></b>	Added <sup>1</sup>	0
	Removed	0
	Modified	210
<b>SMQ_CONTENT.ASC</b>	Added	691
	Removed <sup>2</sup>	0
	Modified	208

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

<sup>1</sup> The number of SMQs added includes both top level (Level 1) and sub-search SMQs.

<sup>2</sup> The number of removed PTs represents terms moved from one SMQ to another or inactive PTs removed. See section 3.1 for details.

### 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.

<b>SOC</b>	<b>LLTs* (Primary)<sup>1</sup></b>	<b>PTs (Primary)<sup>1</sup></b>	<b>LLTs* (Primary and Secondary)<sup>2</sup></b>	<b>PTs (Primary and Secondary)<sup>2</sup></b>	<b>HLTs<sup>3</sup></b>	<b>HLGTS<sup>3</sup></b>
<i>Blood and lymphatic system disorders</i>	1068	258	4005	910	87	17
<i>Cardiac disorders</i>	1342	300	2190	539	36	10
<i>Congenital, familial and genetic disorders</i>	3214	1201	3214	1201	98	19
<i>Ear and labyrinth disorders</i>	419	81	752	186	17	6

### Summary of Changes

SOC	LLTs* (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs* (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Endocrine disorders</i>	599	164	1628	468	38	9
<i>Eye disorders</i>	2329	547	3483	907	64	13
<i>Gastrointestinal disorders</i>	3607	782	7103	1561	109	21
<i>General disorders and administration site conditions</i>	2447	804	3044	1003	49	9
<i>Hepatobiliary disorders</i>	607	174	1361	389	19	4
<i>Immune system disorders</i>	409	120	2293	595	26	4
<i>Infections and infestations</i>	6790	1785	7091	1865	149	12
<i>Injury, poisoning and procedural complications</i>	5997	940	7906	1708	67	7
<i>Investigations</i>	12876	5174	12876	5174	106	23
<i>Metabolism and nutrition disorders</i>	911	262	2432	682	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2309	408	5967	1092	60	11

### Summary of Changes

SOC	LLTs* (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs* (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8290	1860	8920	2106	201	39
<i>Nervous system disorders</i>	3289	835	6501	1686	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1590	211	2738	533	48	8
<i>Psychiatric disorders</i>	2186	485	2978	688	78	23
<i>Renal and urinary disorders</i>	1149	322	2459	670	32	8
<i>Reproductive system and breast disorders</i>	1667	452	3966	1078	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1556	472	3880	1030	48	11
<i>Skin and subcutaneous tissue disorders</i>	1915	440	4209	1144	56	10
<i>Social circumstances</i>	595	249	595	249	20	7
<i>Surgical and medical procedures</i>	4282	1969	4282	1969	140	19
<i>Vascular disorders</i>	1194	264	6030	1379	68	11



## Summary of Changes

SOC	LLTs* (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs* (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<b>Total</b>	<b>72637</b>	<b>20559</b>				

**Table 4-6 MedDRA Term Counts**

<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>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 12 terms renamed in MedDRA v17.0.

Code	Level	Term Name in v16.1	Term Name in v17.0
10003975	LLT	Bacillus anthracis infection	Bacillus anthracis infection
10004026	LLT	Bacterial infection due to bacillus fragilis	Bacterial infection due to Bacillus fragilis
10051978	LLT	Enterococcal faecalis infection	Enterococcus faecalis infection
10055501	LLT	Enterococcal fecalis infection	Enterococcus fecalis infection

## Summary of Changes

Code	Level	Term Name in v16.1	Term Name in v17.0
10073952	PT	Hypocarnitinaemia	Hypocarnitinaemia
10021860	LLT	Infection pseudomonas aeruginosa	Infection Pseudomonas aeruginosa
10027855	LLT	Monoclonal antibody conjugated with pseudomonas extoxin therapy	Monoclonal antibody conjugated with pseudomonas exotoxin therapy
10035691	LLT	Pneumonia due to Pseudomonas	Pneumonia due to pseudomonas
10051190	LLT	Pneumonia pseudomonas aeruginosa	Pneumonia Pseudomonas aeruginosa
10058988	PT	Superior vena caval occlusion	Superior vena cava occlusion
10064771	PT	Superior vena caval stenosis	Superior vena cava stenosis
10054090	LLT	Wound infection due to pseudomonas aeruginosa	Wound infection due to Pseudomonas aeruginosa

**Table 4-7 Modified PT/LLT Names**

### 4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 5 terms at the LLT level in MedDRA v17.0 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Postherpetic polyneuropathy	Current	The MSSO has changed the status of LLT <i>Postherpetic polyneuropathy</i> to current, because a review of medical literature revealed that postherpetic polyneuropathy has been used synonymously with postherpetic neuralgia. Therefore, LLT <i>Postherpetic polyneuropathy</i> is appropriately placed as a synonym LLT to PT <i>Post herpetic neuralgia</i> .
Drug shock	Non-current	Drug shock may refer to either anaphylactic or anaphylactoid shock caused by drugs and, as such, is an ambiguous term. For this reason LLT <i>Drug shock</i> was made non-current.
Drug toxicity due to accidental overdosage	Non-current	This is a combination term that represents two independent concepts: cause and effect. In the <i>MedDRA Term Selection: Points to Consider</i> document, section

**Summary of Changes**

Lowest Level Term	Currency Status Changed to	Rationale
		3.18.1 Overdose reported with clinical consequences, it states that (individual) terms for both overdose and for the clinical consequences reported in association should be selected. Therefore, this term which combines the overdose and the resulting toxicity was made non-current in order to allow selection of separate terms for the overdose and its consequences.
Drug toxicity due to intentional overdose	Non-current	This is a combination term that represents two independent concepts: cause and effect. In the <i>MedDRA Term Selection: Points to Consider</i> document, section 3.18.1 Overdose reported with clinical consequences, it states that (individual) terms for both overdose and for the clinical consequences reported in association should be selected. Therefore, this term which combines the overdose and the resulting toxicity was made non-current in order to allow selection of separate terms for the overdose and its consequences.
Exercise	Non-current	The unqualified LLT <i>Exercise</i> is an ambiguous term when used alone, and therefore was made non-current. A therapeutic concept is represented by <i>LLT Exercise therapy</i> under PT <i>Kinesitherapy</i> .

**Table 4-8 LLT Currency Changes**