

***Summary of Changes to***

**MedDRA<sup>®</sup> TERM SELECTION:  
POINTS TO CONSIDER**

*Release 3.11  
Based on MedDRA Version 11.1*

**ICH-Endorsed Guide for MedDRA Users**

**Application to Adverse Drug Reactions /Adverse Events  
&  
Medical and Social History & Indications**

**1 October 2008**

The following is a listing of changes made between releases 3.10 and 3.11 of *MedDRA Term Selection: Points to Consider*:

### **Throughout document**

- 1) Correction of general spelling, punctuation, spacing, and format errors
- 2) Replacement of references to MedDRA Version 11.0 to Version 11.1
- 3) Update of examples based on MedDRA version changes
- 4) Update of current and past members of the Points to Consider Working Group (Section 4, Appendices)

### **3.3 Suicide and Self-harm**

One of the examples in Section 3.3.2:

*Example: If “self slashing” or “cut her own wrists” is reported, select either “Intentional self-injury” or “Deliberate self-harm.” Both are linked to PT “Intentional self-injury.”*

Was changed as follows:

*Example: If “self slashing” or “cut her own wrists” is reported, select “Self inflicted laceration” which is linked to PT “Intentional self-injury.”*

### **3.10 Exposures During Pregnancy and Breast Feeding**

The following section:

- 3.10.2.2 Child or fetus experienced adverse event(s) and was exposed to the drug in utero; father received the product.

Appropriate term(s) should be selected for the adverse event(s). (Note that the patient is the child or fetus). In addition, “*Transmission of drug via semen*” can also be selected.

Was changed as follows:

- 3.10.2.2 Child or fetus experienced adverse event(s) and was exposed to the drug in utero; father received the product.

Appropriate term(s) should be selected for the adverse event(s). (Note that the patient is the child or fetus). In addition, “*Paternal drugs affecting fetus*” can also be selected.

### **3.13 Medical/Surgical Procedures**

The following section:

- 3.13.2 If a procedure is reported in combination with a diagnosis, it is considered sufficient to select a term for the diagnosis alone. It is preferable to select a term for the procedure in addition to a term for the diagnosis.

*Example: If “liver transplantation due to liver failure” is reported, either “Liver failure” alone or both “Liver failure” and “Liver transplantation” can be selected.*

*Example: If “surgery for bleeding gastric ulcer” is reported, either “Bleeding gastric ulcer” alone or both “Bleeding gastric ulcer” and “Gastric ulcer surgery” can be selected.*

Was changed as follows:

- 3.13.2 If a procedure is reported in combination with a diagnosis, it is preferable to select a term for the procedure in addition to a term for the diagnosis, since information concerning a procedure may indicate severity of the condition. Alternatively, it is considered sufficient to select a term for the diagnosis alone.

*Example: If “liver transplantation due to liver injury” is reported, both “Liver injury” and “Liver transplantation” can be selected. Alternatively, “Liver injury” alone can be selected.*

Note that the second example in this section concerning “surgery for bleeding gastric ulcer” has been deleted.

### **3.16 Transmission via medicinal product of infectious agent**

The following paragraphs have been added to the end of this section:

In some instances, the reporter may not have clearly stated that transmission of infection had occurred via a medical product. Medical judgment should be used as transmission may be implied by data within a single case. The term “*Suspected transmission of an infectious agent via a medicinal product*” may be selected.

Alternatively, “*Suspected transmission of an infectious agent via a medicinal product*” may be selected for the E2B field reserved for the sender’s diagnosis (B.5.3, “Sender’s diagnosis/syndrome and/or reclassification of reaction/event”).

### **3.25.5 Supplementation and Replacement Therapies**

The following example:

*Example: If “thyroid replacement therapy” is reported, “Thyroxine therapy” can be selected.*

Was changed as follows:

*Example: If “thyroid replacement therapy” is reported, “Thyroid hormone replacement therapy” can be selected.*