

MHLW Notification on MedDRA Usage

MSSO Note: This is an unofficial translation. Please contact MHLW for the official Japanese language version.

Yakushokuanhatsu Notification No. 0325001
Yakushokushinsahatsu Notification No. 0325032
March 25, 2004

To: Director of Hygiene, Prefectural Government

Director, Safety Division, Pharmaceutical and Food Safety Bureau (PFSB), Ministry of Health, Labour and Welfare (MHLW)

Director, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau (PFSB), Ministry of Health, Labour and Welfare (MHLW)

Re: Use of “Japanese version of Medical Dictionary for Regulatory Activities (MedDRA/J)”

“MedDRA/J: Medical Dictionary for Regulatory Activities/J” (hereinafter referred to “Japanese version of MedDRA”) is the terminology developed and agreed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human Use (ICH). In the light of essential necessity of international communication of drug safety information, facilitation of MedDRA use in Japan is desired. Managing how to use Japanese version of MedDRA is decided as indicated in the separated statements. It is requested to have them well understand by the concerned parties under your jurisdiction.

As to the ADR etc. reporting based on the Pharmaceutical Affairs Law (PAL), use of MedDRA is mandatory on and after October 27, 2003. MedDRA's use for other documents such as Periodic Infection Report will be treated as indicated in the separated statements for the submission on and after April 1, 2004. As a result of application of this notification, the notification titled “Re: Use of ‘Japanese version of Medical Dictionary for Regulatory Activities (MedDRA/J)’” (Iyakuan Notification No. 164/Iyakushin Notification No. 1843, issued by the Director of Safety Division and the Director of Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau (PMSB), Ministry of Health and Welfare (MHW) dated on December 28, 1999) will be abrogated on April 1, 2004.

Separated Statements

Re: Use of Japanese Version of MedDRA

1. Fundamental Policy

- (1) ADR terms etc. to be indicated in the documents regulated by PAL; i.e. Periodic Infection Report based on PAL (Article 68-8 of the PAL and Article 62-9 of the Enforcement Regulations of the PAL), ADR/Infection Case Report for drug product (Article 77-4-2, Paragraph 1 of the PAL and Article 64-5-2, Paragraph 1 of the Enforcement Regulations of the PAL), ADR/Infection Case Report for clinical trial drug (Article 80-2, Paragraph 6 of the PAL, however excluding the reporting by investigator him/herself; and Article 66-7 of the Enforcement Regulations of the PAL), and Periodic Safety Report (Article 21-4-2 of the Enforcement Regulations of the PAL), Japanese version of MedDRA should be used. Items required the use of MedDRA should follow the relevant notifications.
- (2) As to the application documents for approval (including other clinical trial documents (Article 14-3 of the PAL)), for re-examination (Article 14-4, Paragraph 4 of the PAL) and for re-evaluation (Article 14-5, Paragraph 4 of the PAL), terms such as ADR should be used wherever possible.
- (3) For term selection by using MedDRA, "MedDRA Term Selection: Points to Consider" prepared by ICH activities (posted on ICH Home Page (Address: <http://www.ich.org>)) should be referred.

2. MedDRA Version to be Used

- (1) ADR/Infection Case Report for drug product and drug for clinical trial
For ADR/Infection Case Report for drug product and drug for clinical trial, the most recent or the previous version of MedDRA should be used from the day following the release of new version (if the authority's office is closed on the day, from the following first opening day of the authority's office).
- (2) Periodic Infection Report and Periodic Safety Report
When Japanese version of MedDRA is used for the Periodic Infection Report, used MedDRA version should be clearly indicated in the white space of the attachment format which is defined in the notification titled "Re: Survey Contents and Presentation Manner of the Periodic Infection Report for Biological Product" (Yakushokuanhatsu Notification No. 1024006 issued by Director of Safety Division, PFSSB, MHLW dated October 24, 2003). When Japanese version of MedDRA is used for the Periodic Safety Report, used MedDRA version should be clearly indicated in the white space of the attachment format which is defined in the notification titled "Re: Attachment Forms for Periodic Safety Report and their Preparation Manner" (Iyakushinhatsu Notification No. 1111004/Iyakuanhatsu Notification No. 1111001 issued by Director of Safety Division and Director of Evaluation and Licensing Division, PMSB, MHLW dated on November 11, 2002).
- (3) Application Documents for Approval (including other clinical trial documents), for re-examination and for re-evaluation, etc.
When Japanese version of MedDRA is used for the following documents, used MedDRA version should be clearly indicated in the white space of the documents defined by the relevant notifications:
Application documents for approval of drug product which are ordained by the notification titled "Re: Application for Approval of Drug Product" (Iyakuhatu No. 481 issued by Director-General of PMSB, MHW dated on April 8, 1999), by the notification titled "Re: Management of the Documents to be Attached to the Application for Drug Product Approval" (Iyakuhatu Notification No. 663 issued by Director-General of Pharmaceutical Bureau(PB), MHLW dated on June 21, 2001) and by the notification titled "Re: Preparation Manner of the Documents to be Attached to the Application for Drug Manufacturing and Import Approval and

Licenses” (Iyakushinhatsu Notification No. 899 issued by the Director of Evaluation and Licensing Division, PB, MHLW dated on June 21, 2001); application documents for re-examination ordained by the notification titled “Re: Documents to be Attached to the Application of Re-examination for New Prescription Drug” (Iyakushinhatsu Notification No. 610 issued by the Director of Evaluation and Licensing Division, PB, MHLW dated on May 10, 2001); and application documents for re-evaluation which are ordained by the notification titled “Re: Implementation of Re-evaluation for Prescription Drugs” (Yakuhatsu Notification No. 4 issued by Director-General of Pharmaceutical Affairs Bureau, MHW dated January 7, 1985) and notification titled “Re: Documents to be Attached to the Application of Re-evaluation for Prescription Drugs” (Yakuhatsu Notification No. 951 issued by Director-General of Pharmaceutical Affairs Bureau, HMW dated October 20, 1987)

For the clinical overview summarizing entire documents of clinical studies, when Japanese version of MedDRA is employed, use of the most recent or the previous version of MedDRA is preferable.

3. Points to Consider

- (1) For ADR terms etc. indicated in the Precaution section in package insert of drug product, Japanese version of MedDRA could be used.
- (2) According to ICH agreement, distribution and maintenance of Japanese version of MedDRA is conducted by JMO (Japanese Maintenance Organization). Please inquired specific questions regarding Japanese version of MedDRA to JMO (Telephone No.: 03-3400-5608, e-mail: helpdesk.jmo@sjp.or.jp).