

Updates of Regulatory Requirements in Japan

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MedDRA/J

- **March 1999**
The first MedDRA/J was released.
- **December 1999**
MHW issued an official notification recommending the use of MedDRA terms for reporting of post-market ADR cases on and after Mar. 31, 2000.
- **April 2000**
MHLW started to receive MedDRA-coded ADR case reports.
Both J-ART (the Japanese version of WHO-ART) terms and MedDRA/J terms became to be acceptable for ADR case reporting.

Usage of MedDRA

- **September 2000**

20 % of post-market ADR case reports submitted by companies to MHLW were coded with MedDRA terms.

- **October 2003**

About 90 % of post-market ADR case reports are coded with MedDRA terms.

Pilot Study for E2B/M2 Implementation

- **MHLW has conducted the several pilot studies for the implementation of the ICH E2B/M2 Guidelines including the use of MedDRA.**
 - **December 2000** **Small-Scale Pilot**
System Validation
 - **January-March 2001** **Middle-Scale Pilot**
Reporting Form Field Validation
 - **June-October 2001** **Middle-Scale Pilot**
Instruction Manual Field Validation
 - **October-November 2002** **Large-Scale Pilot**
Generation and transmission of ICSRs
 - **August-October 2003** **Final Test**

Final Test

- **MHLW conducted the large scale, final test during August - October 2003.**
 - **To ensure that companies can generate ICSR SGML data files properly**
 - **To check companies' EDI tools for electronic transmission of ICSR data**

Final Test

- **ICSR SGML data file check**
 - **300 companies joined this study.**
 - **More than 2000 cases submitted by about 250 companies.**
- **EDI tool test**
 - **More than 30 companies participated the test of their EDI tool for electronic transmission of ICSR SGML data files .**

Implementation of E2B/M2

- On August 28 2003, MHLW issued the final administrative notification about the regulatory implementation of the ADR reporting based on the ICH E2B/M2 Guidelines.
- On and after October 27, 2003, companies are requested to submit ICSR SGML data files with MedDRA-code via Internet or by FD for pre- and post –market ADR reporting.

Implementation of E2B/M2

Experience of the first two week

- We received more than 500 ICSRs from 17 companies via Internet.**

SMEs Issue

- **For the regulatory implementation of the ICH E2B/M2, it is necessary that all companies who submit ADR case reports can have access to MedDRA/J.**
- **JMO started the new special license service for small and medium size enterprises (SMEs) in August 2003.**

Other Usage of MedDRA Terms

ADR information is provided by using MedDRA/J terms via KIKO Drug information homepage.

副作用症例一覧 - Microsoft Internet Explorer

アドレス http://www.pharmasys.er.jp/cgi-bin/sidedetail_i.cgi?drag=%A5%A4%A5%F3%A5%D5%A

“インフルエンザHAワクチン 注射薬”で検索

注意事項 | 検索画面へ | 既知症例へ | 報告副作用一覧(平成13年度)

【未知症例】 以下と同様の症例の報告をお願いします。

報告年度	性	年齢	原疾患等	被疑薬/経路	副作用	転帰	併用被疑薬
2001	女	50代	インフルエンザ接種必要者	インフルエンザHAワクチン 注	血圧上昇 嘔吐NOS	回	
2001	女	30代	インフルエンザ接種必要者 全身性紅斑性狼瘡	インフルエンザHAワクチン 注	多形紅斑	回	
2001	男	70代	完全房室ブロック 急性膵(臓)炎 心不全 NOS 痘瘡接種必要者	インフルエンザHAワクチン 注	肝機能異常NOS 急性膵炎 急性腎不全	未	非ピリン系感冒剤(4)
2001	女	10才未満	痘瘡接種必要者	インフルエンザHAワクチン 注	ギラン・バレー症候群	未	
2001	女	40代	インフルエンザ接種必要者	インフルエンザHAワクチン 注	脊髄炎NOS	回	
2001	男	10代	感染予防	インフルエンザHAワクチン 注	頭痛 悪心	回	
2001	男	10代	痘瘡接種必要者	インフルエンザHAワクチン 注	ネフローゼ症候群	未	
			感染予防	インフルエンザHAワクチン 注			

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ADR terms are MedDRA/J terms