



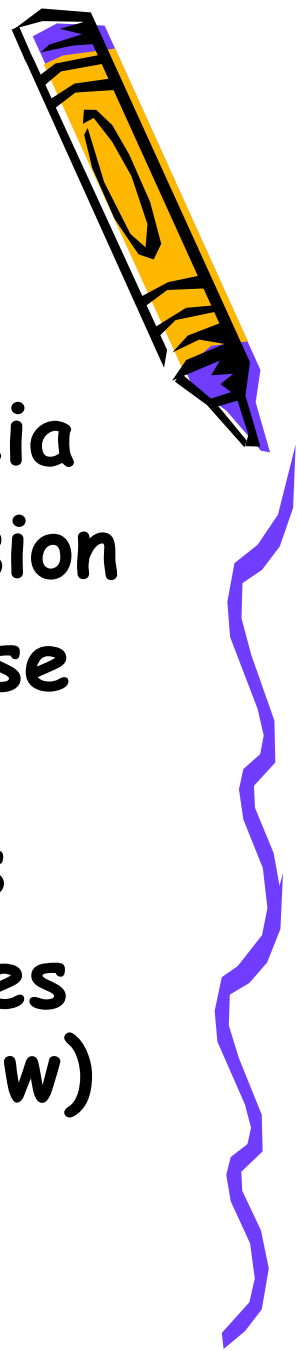
# MedDRA Regulatory Implementation in Japan

MedDRA MSSO UMG

Washington, 2004

Yasuo Sakurai, JMO





# JMO (MedDRA Japanese Maintenance Organization)

- A part of Japanese Pharmacopoeia
- Maintain MedDRA Japanese Version
- Distribute MedDRA/J to Japanese users
- Support MedDRA Japanese users
- Join MSSO Maintenance Activities (e.g. International Medical Review)



# JMO Contact Information



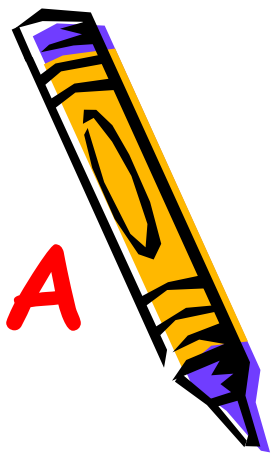
- Address: 2-12-15 Shibuya,  
Shibuya-ku Tokyo 150-0002
- Phone: +81-3-3400-5608
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- URL: <http://www.sjp.jp/~jmo2/>
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**MedDRA Regulatory  
Use in Japan**

# First notification from MHLW regarding MedDRA



- Date: December 28<sup>th</sup>, 1999
- Entitled: "Concerning the use of the Japanese Medical Dictionary for Regulatory Activities Terminology"  
(In October 2003, about 90% of PMS ADR reports are coded with MedDRA)
- Revised at March 25<sup>th</sup>, 2004



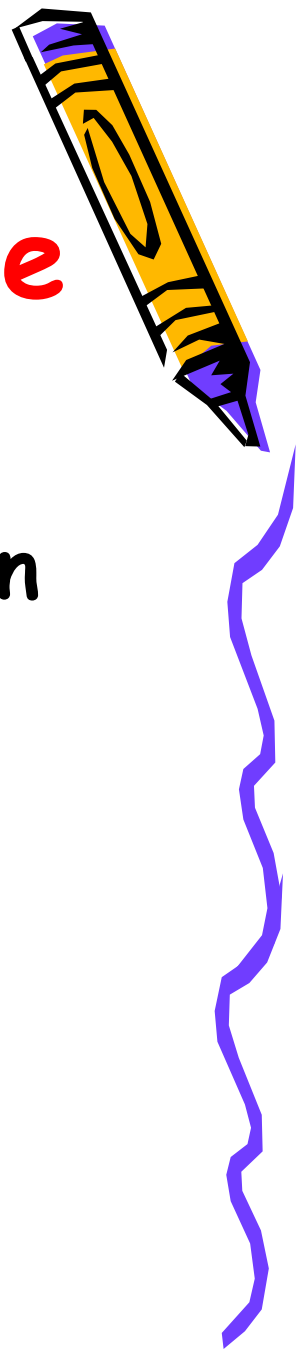


# MedDRA Mandatory Use

- Expedited Reports of ICSR for pre- and Post-marketed drugs
- Periodic Reports if Infection Cases suspected to be caused by Biological Products
- Periodic Safety Reports for New Drugs including PSUR



# MedDRA recommended Use

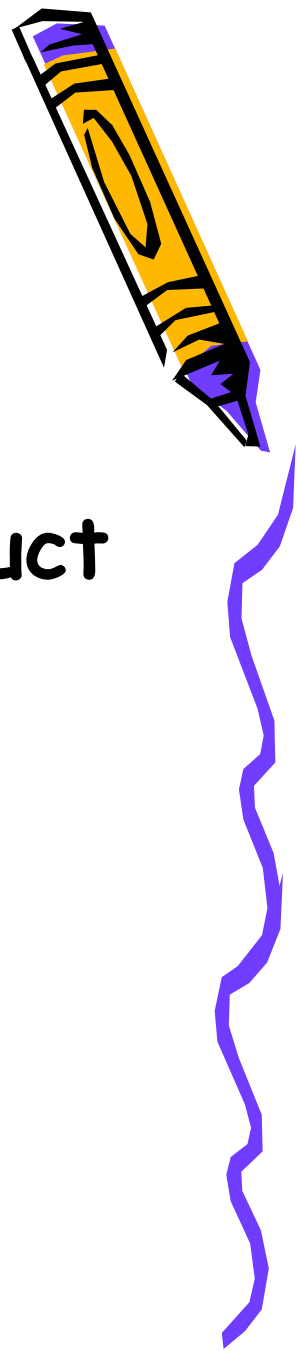


- Approval Application Documents
- Re-evaluation and Re-examination Application Documents



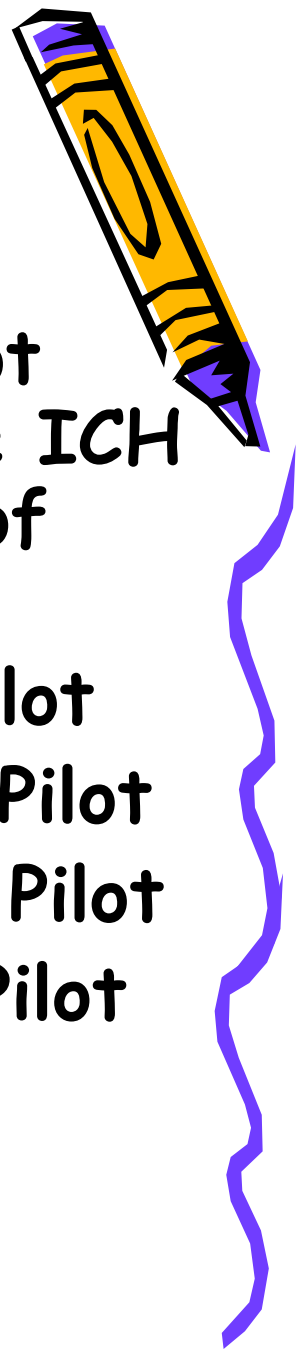
# MedDRA can be used

- ADR terms in the section  
“Precaution for Use” in the Product  
Information





# E2B/M2 Regulatory Implementation in Japan



# Pilot Study for E2B/M2

- 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
  - Jan. - March 2001 Middle-Scale Pilot
  - June - Oct. 2001 Middle-Scale Pilot
  - Oct. - Nov. 2002 Large-Scale Pilot
  - Aug. - Oct. 2003 Final Test



# Final Test (1)

- 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

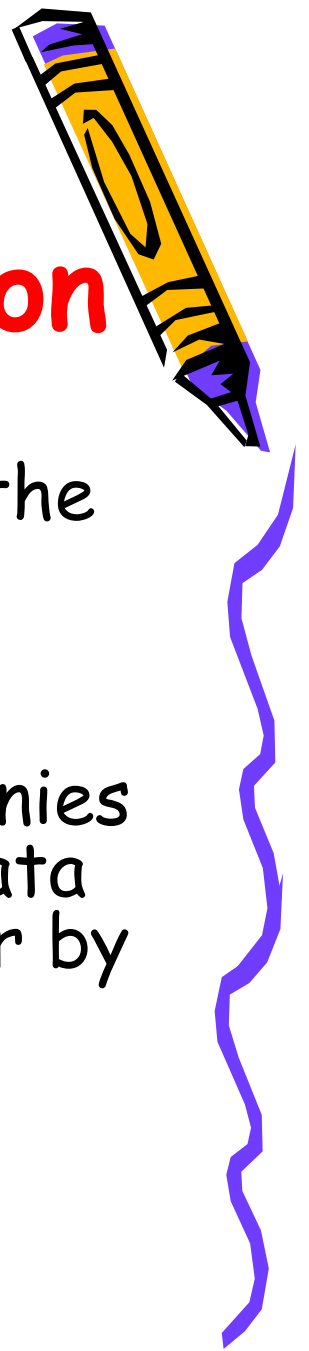


# Final Test (2)



- 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 .





# Administrative Notification

- 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.

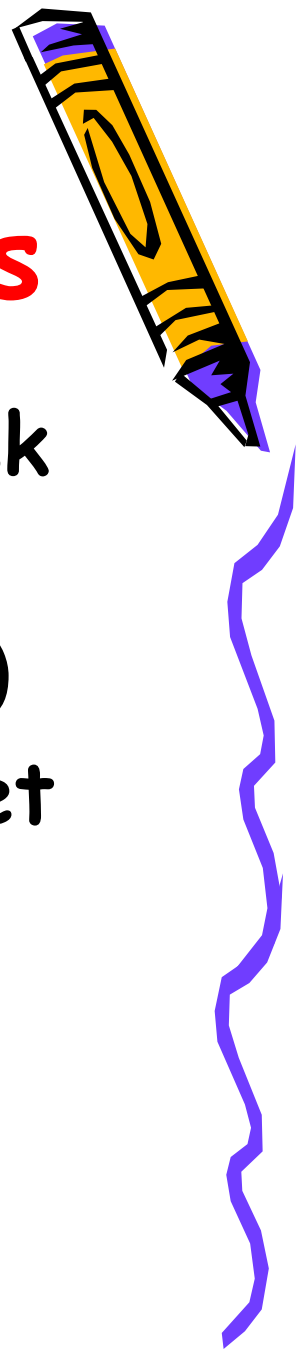


# SMEs Issue

- 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.

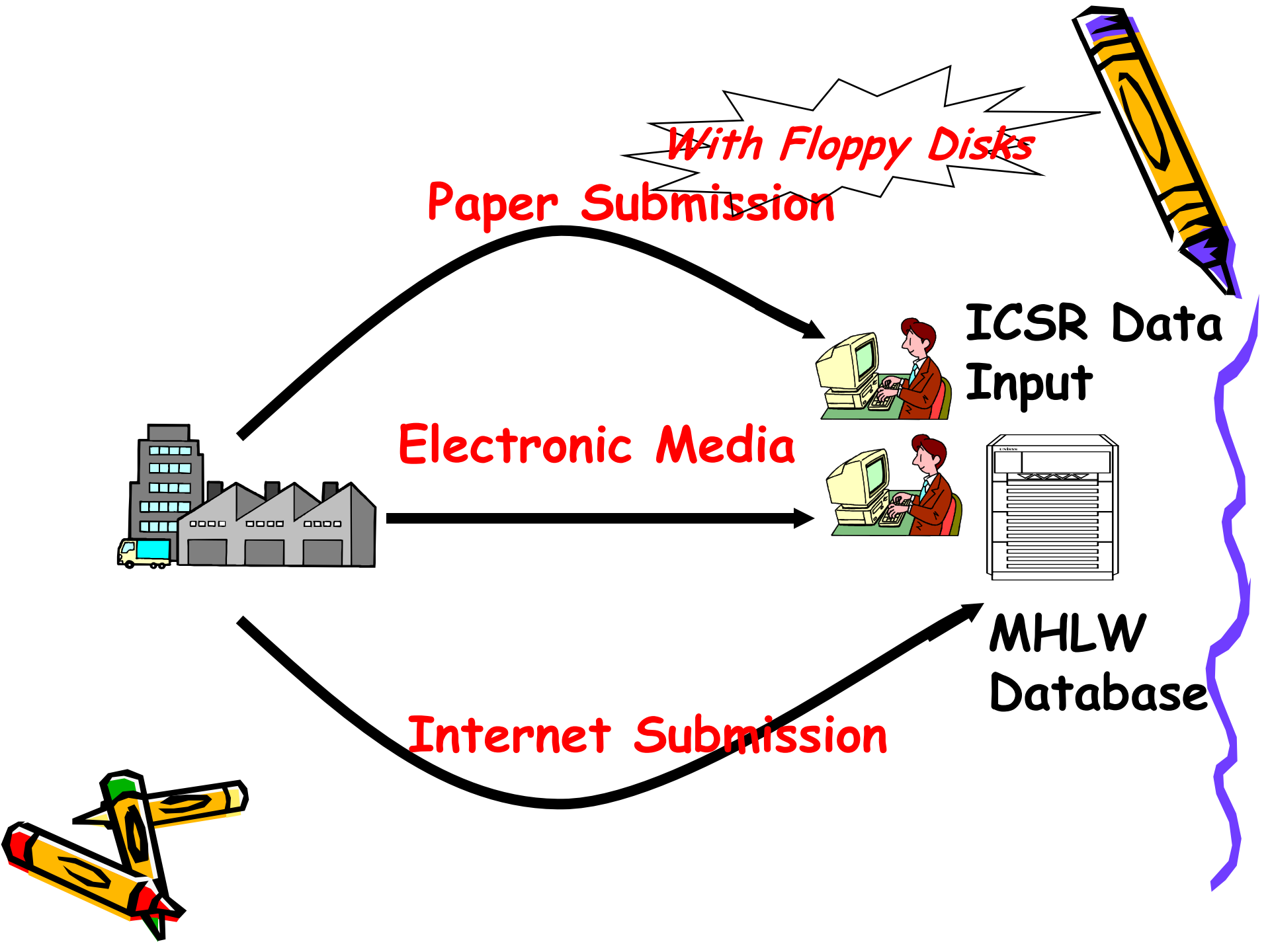


# Current Status - Methods



- Paper Submission with Floppy Disk (E2B format data)
- Electronic Media Submission (FD)
- Electronic Submission via Internet





**Paper Submission**  
*With Floppy Disks*

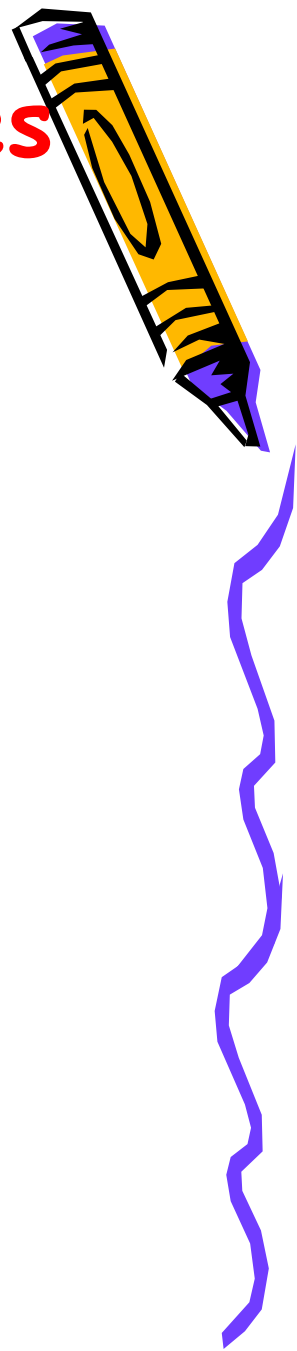
**Electronic Media**

**Internet Submission**

**ICSR Data Input**

**MHLW Database**

# No. of Company and % of cases transmitted via Internet



	No. Companies	% of cases
Nov. '03		26%
Dec. '03	20	32%
Jan. '04	30	46%
Feb. '04	31	50%
Mar. '04	36	50%
Apr. '04	41	55%





*Thank you !*

If you have any Query on  
MedDRA Japanese Version or  
MedDRA Utilization status in  
Japan, Please contact with  
JMO ([Helpdesk.jmo@sjp.or.jp](mailto:Helpdesk.jmo@sjp.or.jp))

