


# **Overview of Current Activities at the MedDRA Japanese Maintenance Organization (JMO)**

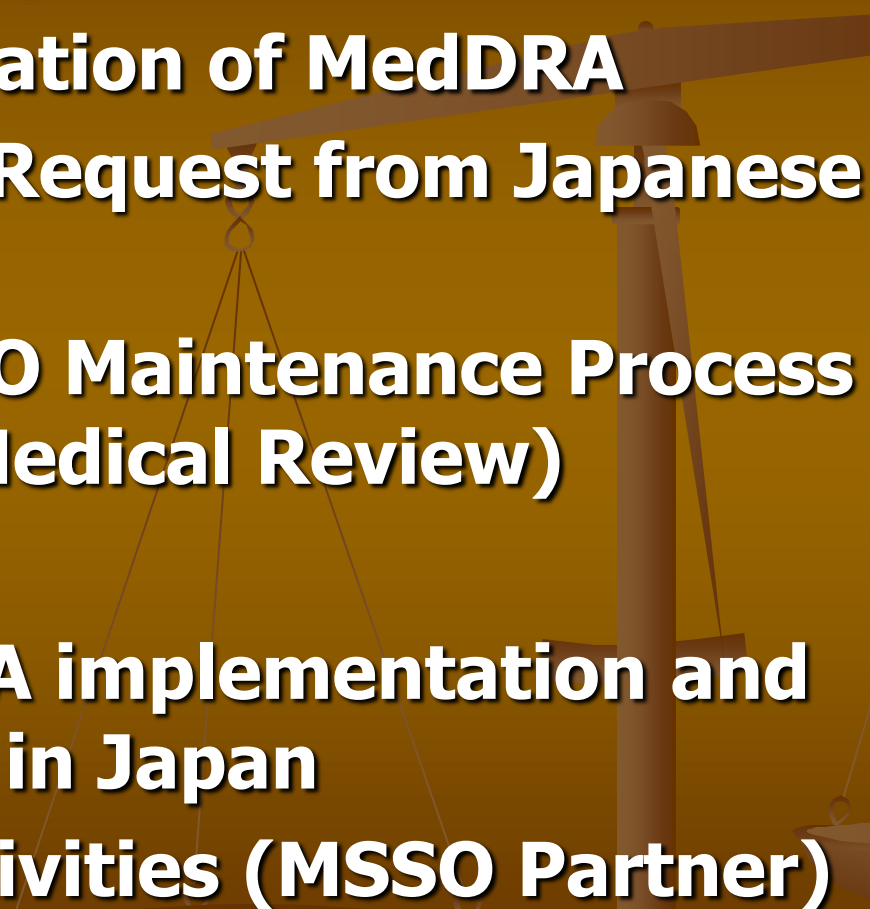
**November 12, 2003**

**Yasuo Sakurai**


# MedDRA Japanese Maintenance Organization (JMO)

- Established as a part of “Society of Japanese Pharmacopoeia”
  - Overseen by Japanese Management Board (MHLW & JPMA)
  - A MSSO Subscriber (MSSO/JMO Contract )
  - MedDRA/J Provider
  - Represent Japanese MedDRA Users
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# The Roles of JMO

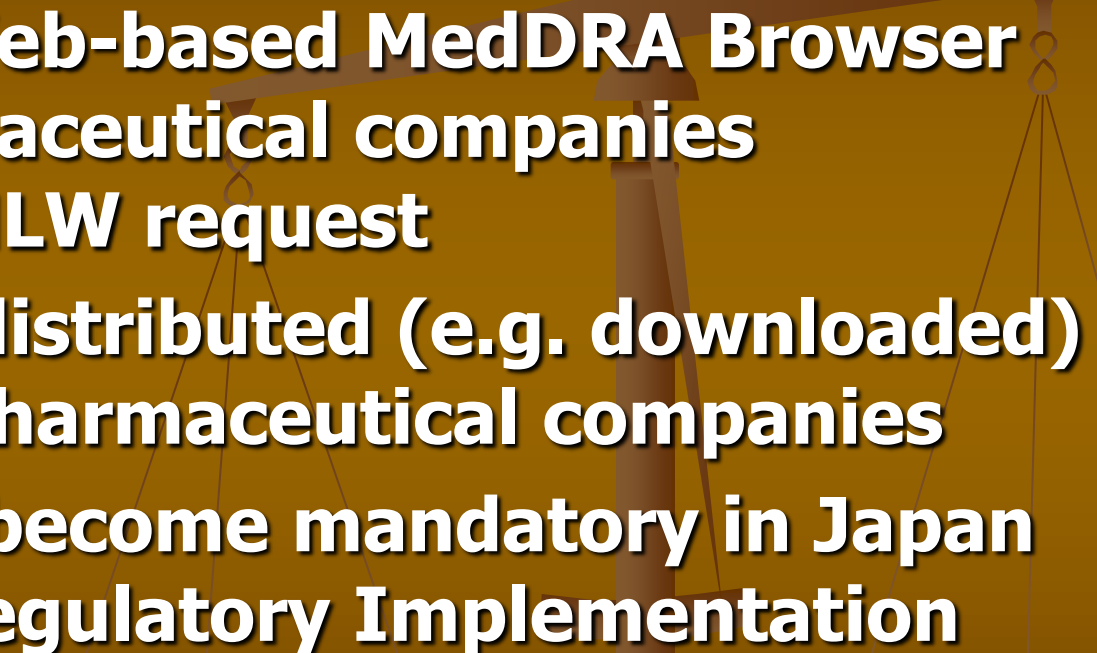
- **Provide MedDRA/J to JMO Subscribers**
  - **Japanese Translation of MedDRA**
  - **Submit Change Request from Japanese Users to MSSO**
  - **Participate MSSO Maintenance Process (International Medical Review)**
  - **Support MedDRA implementation and appropriate use in Japan**
  - **Assist MSSO Activities (MSSO Partner)**
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# JMO Subscribers



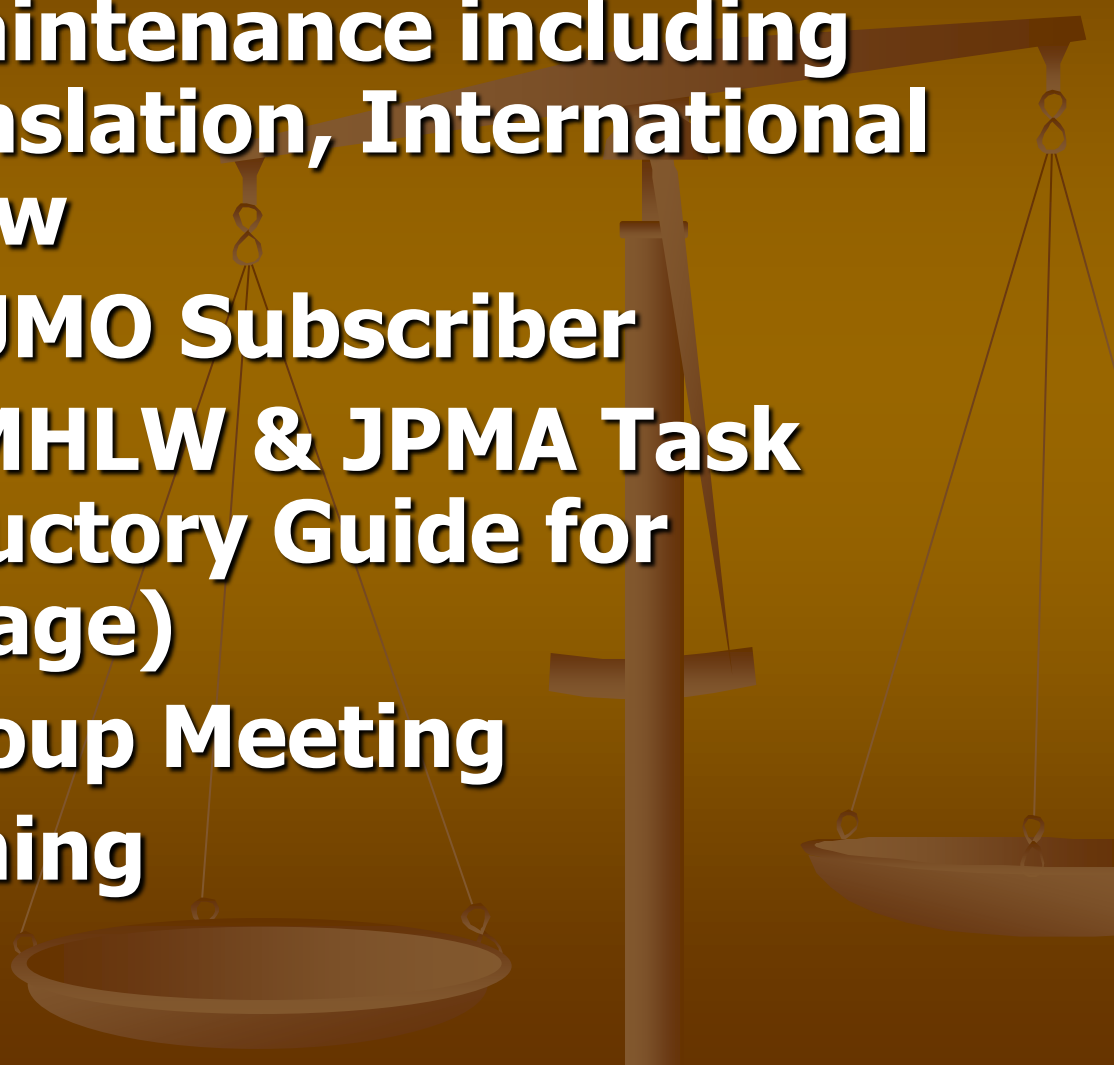
	<b>Total</b>	<b>Pharmaceutical Companies</b>
<b>2000 March</b>	<b>202</b>	<b>157</b>
<b>2001 March</b>	<b>235</b>	<b>170</b>
<b>2002 March</b>	<b>253</b>	<b>171</b>
<b>2003 March</b>	<b>284</b>	<b>189</b>
<b>2003 October</b>	<b>360</b>	<b>264</b>

# MedDRA/J Special license for Small Pharmaceutical Companies

- **JMO Provides Web-based MedDRA Browser for Small Pharmaceutical companies according to MHLW request**
  - **MedDRA is not distributed (e.g. downloaded) to these small Pharmaceutical companies**
  - **MedDRA usage become mandatory in Japan after E2B/M2 Regulatory Implementation**
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# JMO Activities & Support

- **MedDRA/J Maintenance including Japanese Translation, International Medical Review**
- **Help Desk to JMO Subscriber**
- **Cooperation MHLW & JPMA Task Force (Introductory Guide for MedDRA/J usage)**
- **JMO Users Group Meeting**
- **MedDRA Training**



# MedDRA/J Meeting

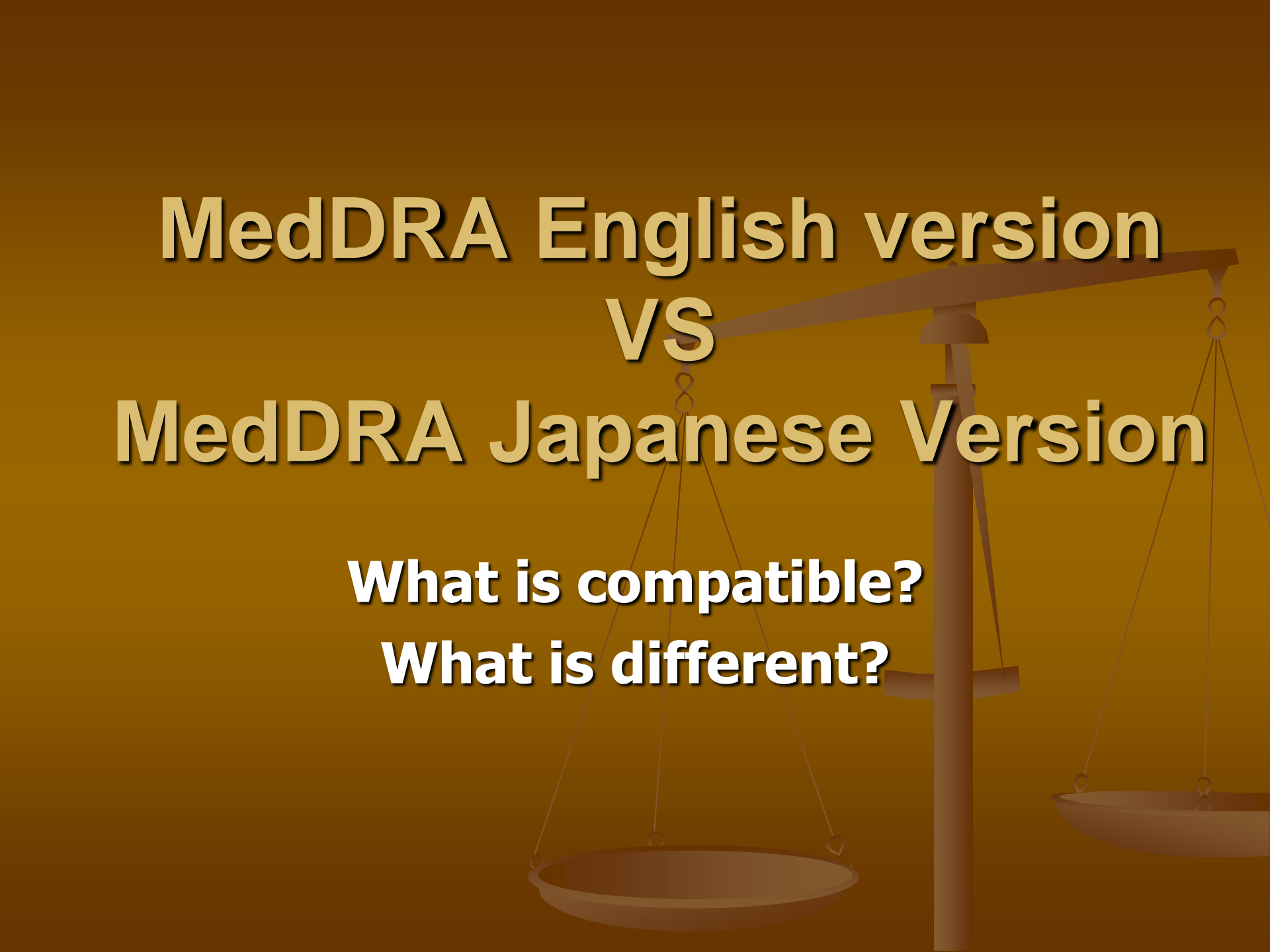
- **JMO MedDRA Users Group Meeting (Tokyo & Osaka)**
- **MSSO Users Group Meeting in Japan**
- **MedDRA/J version-up Seminar (Tokyo & Osaka; each version)**



# MedDRA/J Training

- **Introductory Course**
- **Basic Course**
- **Coding Course**
  
- **On-site training**



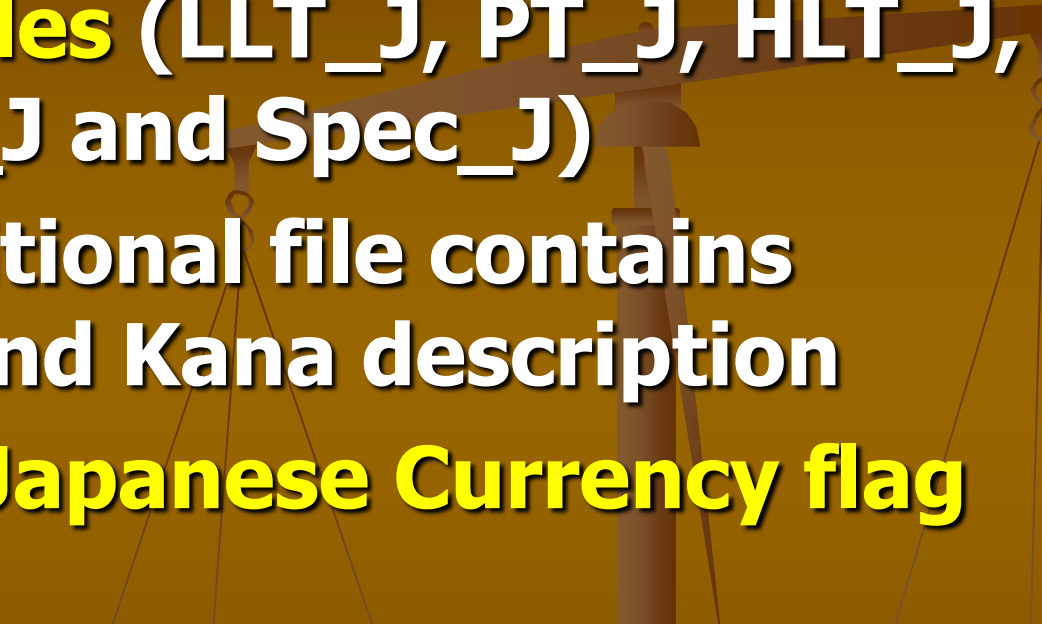


**MedDRA English version  
VS  
MedDRA Japanese Version**

**What is compatible?  
What is different?**

- MedDRA/J is **bilingual** version of MedDRA in Japanese and English. MedDRA Japanese version and MedDRA English version are **exactly compatible**. Most of their aspects are the same, but MedDRA/J has **some additional information** specific to Japanese language and usage.
- The structures and the contents of all ASCII files in MedDRA English version are not changed in MedDRA Japanese version, but Japanese specific ASCII files containing Japanese description are added.
- MedDRA Japanese version has **17 ASCII** files while English version has **11 ASCII** files.

# MedDRA Japanese Version

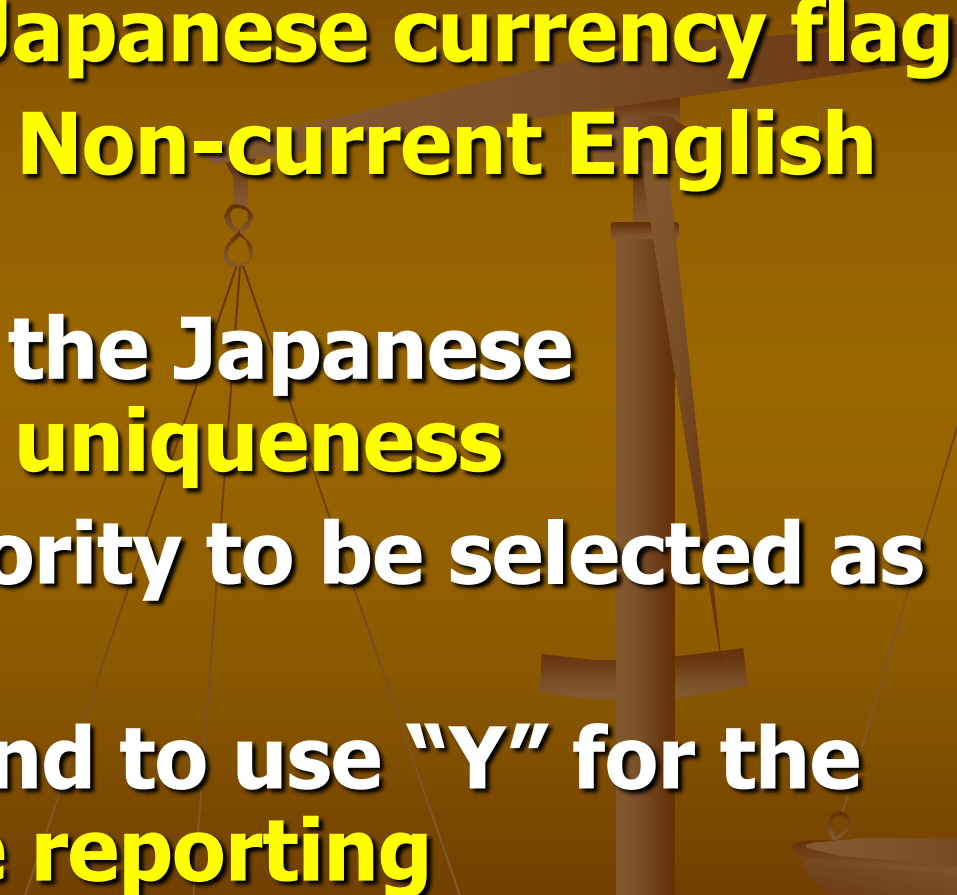
- Additional **6 files** (LLT\_J, PT\_J, HLT\_J, HLGT\_J, SOC\_J and Spec\_J)
  - Japanese additional file contains codes, Kanji and Kana description
  - Each LLT has **Japanese Currency flag** in LLT\_J file
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# Linguistic/Cultural differences



- **Not a Translation problem**
- **Multiple English terms are translated into the same Japanese term (British/American spellings, word order etc.)**
  - Japanese Currency flag (done from the beginning)
- **Multiple Japanese terms are translated into the same English term**
  - Japanese Synonym file (JMO proposal now)

# Japanese Currency Flag

- Each LLT has **Japanese currency flag**
  - Define “N” for **Non-current English terms**
  - Define “Y” for the Japanese description as **uniqueness**
  - PT has the priority to be selected as “Y”
  - It is recommend to use “Y” for the **Domestic case reporting**
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# Japanese Synonym file

- JMO is **proposing now**
- It is assumed “In production in 2004”
- Multiple Japanese medical descriptions are translated into the same English medical description.
- These additional Japanese medical descriptions are **not allowed to add MedDRA terminology.**
- A **common Japanese Synonym sharing mechanism** is proposed from JMO.
- Japanese synonym is defined “**to have the same English translation as the existing MedDRA English term**”.

# JMO Contacts



- **Website**

<http://www.sjp.or.jp/~jmo2/index.shtml> (including Helpdesk, Change Request)

- **E-mail**

[helpdesk.jmo@sjp.or.jp](mailto:helpdesk.jmo@sjp.or.jp)

[comments.jmo@sjp.or.jp](mailto:comments.jmo@sjp.or.jp)

- **Phone, Fax**

Phone: 03-3400-5608

Fax : 03-3400-5609