Status of the Regulation on the Standalone Medical Device Software in Japan

2012 Nov. 3rd in AHWP Taipei

Susumu Takahashi
JIRA International Committee, Chair
• **JIRA**
  - Japan Medical Imaging and Radiological Systems Industries Association
  - Radiological systems, Health IT systems
  - **Founding member of DITTA**

• **DITTA**
  - The Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association
  - Global voice for diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers
  - Legally incorporated under US law since May, 2012
Today’s Point

1) Latest Legal Status of the Stand alone MD Software in Japan (finally came out)
   (CABINET DECISION: July 10th 2012)
   Good News!!

2) How Health Software should be ensured the Safety in health domain? <Many Stakeholders>
Today’s Point

1） Latest Legal Status of the Stand alone MD Software in Japan ( finally came out )
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2） How Health Software should be ensured the Safety in health domain ？ <Many Stakeholders>

Good News !!
1) Handling of the Standalone Software on existing Pharmaceutical Affairs Law (JPAL) : On going situation

▪ Standalone software is **NOT a “medical device”**
▪ Embedded software which is intended to operate the medical device is regulated as **unbroken part of the Hardware (MD)**.

2) Cross-national Comparison on the Standalone Software Regulation

<table>
<thead>
<tr>
<th></th>
<th>SW Embedded in hardware</th>
<th>Standalone SW as medical device</th>
<th>Standalone SW as non-medical device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
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<tr>
<td>EU</td>
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<tr>
<td>US</td>
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<tr>
<td>Canada</td>
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</table>
Challenge to Standalone MD Software

- Safety of Medical Procedures using Health Software (Global trend)
  (Example)
  - Preceding use of tablet PC / Smartphone in clinical site by doctors
- Increasing demand to global regulatory harmonization

**JIRA’s Basic Stance on the Standalone Software (history)**
Sep. 18th, 2010 Presentation: the basic stance to the handling of Software
@ APEC Life Science Innovation Forum
Apr. 13th, 2012 News release: the basic stance on the handling of Software

**New Legal Status on the Standalone MD Software in Japan**
CABINET DECISION: July 10th 2012
POLICY ON REGULATORY AND INSTITUTIONAL REFORM
(including the medical device)

Good News!!
HEREBY ADOPTED is “Policy on Regulatory and Institutional Reform” as attached, based upon the results of the examination conducted on regulatory and institutional reform by “the Committee on Regulatory and Institutional Reform” established under the Government Revitalization Unit (GRU).
(No.4) Review of the system based upon the characteristics of medical devices
  ← Separation of drugs and medical devices on JPAL →
  → establish a new “chapter” on medical devices, and to change the title of the Law
(No.5) Acceleration of approval review process for medical devices
  → Establish a new approval/certification system utilizing private certification bodies covering medical devices
(No.6) Rationalization and acceleration of approval procedures for partially changed medical devices
  → Expand the scope of partial change medical devices do not require approval
(No.7) Enhancement of international harmonization and streamlining of QMS audits
  → The revision on the QMS Ministerial Order improving the harmonization with international standards
(No.8) Improvement of “certification” system on medical devices
(No.9) Omission of package insert “Tempu-Bunsoyo” of medical devices
(No.10) Clarifying the position of stand-alone medical software in laws and regulations
  → Stand-alone computer-aided diagnosis software shall be classified as medical device
* Other reference numbers (No.1 – No.3 and others) are not medical domain.
(No.4) Review of the system based upon the characteristics of medical devices

The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken to establish new clauses in the Pharmaceutical Affairs Law, separately from clauses on pharmaceuticals, based upon the characteristics of medical devices, to establish a new “chapter” on medical devices, and to change the title of the Law, taking fully into account opinions from relevant stakeholders such as industrial associations on medical devices.

→ Timeline:

Examine issues and decide on actions to be taken in FY 2012

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures): Law

Responsible Ministry: MHLW
(No.10) Clarifying the position of stand-alone medical software in laws and regulations

The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken on the status of stand-alone medical software under laws and regulations, including clarification that stand-alone computer-aided diagnosis software shall be classified as medical device.

Timeline: Examine issues and decide on actions to be taken in FY2012.

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures): Law

Responsible Ministry: MHLW
After the Cabinet Decision (July, 10th)

→ Reform of regulations and systems Committee/Pharmaceutical Affairs Law Amendment Task Force

Take MD Software to their Agenda and continue their discussion.
Today’s Point

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2) How Health Software should be ensured the Safety in health domain? <Many Stakeholders>
How Software should be regulated in Health domain?

« Apps » are increasing.

- Software provides great capabilities and value.
- Software can minimize human error in clinical process.
- Software’s defect cause the significant effect on the patients.

Many Stakeholders in the Health Software (Medical and Non-medical Domain)!

- consistent direction to guarantee safety on them is required
  → Standardization work on software in the context of Health Software (ISO TC215/IEC TC62)
  → We need cross-sectional discussion among associations
  3J Joint WG on Standalone Software 2012 in Japan

★ Industry effort to provide consultation
Standardization work on software in the context of Health Software (ISO TC215/IEC TC62)

Make Use of the Scope to Solve the Requirements of Many Stakeholders

<table>
<thead>
<tr>
<th>Scope</th>
<th>Risk management process</th>
<th>Product</th>
<th>SW-life-cycle process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware only (MEE and MES)</td>
<td>ISO 14971</td>
<td>IEC 60601-1 -1-x</td>
<td></td>
</tr>
<tr>
<td>Software embedded in Hardware (e.g. MR scanner)</td>
<td>strong links</td>
<td>strong links</td>
<td></td>
</tr>
<tr>
<td>Stand-alone SW as medical device (e.g. Virtual Colonoscopy)</td>
<td>seamless transition</td>
<td>IEC 82304-1</td>
<td></td>
</tr>
<tr>
<td>Stand-alone SW as non-medical device (e.g. Clinical management)</td>
<td>scope extension</td>
<td>strong links</td>
<td></td>
</tr>
</tbody>
</table>

※ ISO-TC215-WG4_N0518  By COCIR  Wolfgang Leetz
JIRA/JAHIS/JEITA (3 J) joint WG on Standalone MD Software

- JAHIS: Japanese Association of Healthcare Information System Industry
- JEITA: Japan Electronics and Information Technology Industries Association

Goal: make recommendations on the range of the regulations on Software
Region of Regulation on Health Related Software: EU MEDDEV

- Small Patient Safety Risk → Large
- No Clinical Support Function, No Effect-Efficacy
- Clinical Support Function
- No Risk

- Guideline
  Voluntary regulation

- No Regulation
  No Guidelines

Law (Medical Device)

MEDDEV
Region of Regulation on Health Related Software: JAPAN (3J Consensus)

【Standalone Software Mapping Example according to the Function (Not Fixed)】

We have NO LAW, NO GUIDELINES on it!
Challenges

• Discussions on the range of the Health / Medical Software Regulations with its Risk Management.

  → Point is to insure the Safety on Health / Medical Software.

Headache: Post market (Especially, How customization by users should be regulated?)
Reds announce Toshiba deal
Manchester United has announced an agreement with Toshiba Medical Systems to become its Official Medical Systems Partner, the first partnership of its kind to be developed with a UK football club.
Thank you for your attention