Towards a Global Vision on Medical Software

Introduction and International Comparative Overview

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AHWP TC Training Workshop – Parallel session 2
Chinese Taipei
November 03, 2012
Summary

1. What is DITTA?
2. DITTA vision on medical software
3. An international comparison of regulations for medical software
4. What DITTA is doing on medical software?
5. Our workshop today...
TTA is the Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association

TTA is a global trade association representing medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical Industry.

TTA was officially incorporated in 2012 as a non-profit trade association in the United States after more than 12 years of existence.

TTA’s membership currently includes COCIR (Europe), JIRA (Japan), MEDEC (Canada), MITA (United States), THAIMED (Thailand), CAMDI (China) and IMEDA (Russia).

More on http://globalditta.org
What does DITTA do?

TTA Member Goals:
• Detect disease early
• Improve the quality of care
• Reduce the likelihood of medical errors
• Lower the long-term cost of health care

TTA Activities:
• Communicate, cooperate and coordinate between associations
• Identify topics and trends with global industry impact
• Develop and submit joint industry positions
• Promote ethical conduct and practices
• Leverage the benefits of international standards

• Build and improve public awareness and relevance of industry products in healthcare and its benefits for patients and users
• Advocate for efficient and appropriate regulation that promotes innovation
• Enhance the global competitiveness of member companies
• Identify unnecessary regulatory burdens
• Promote and pro-actively provide solutions to harmonize regulatory frameworks as much as possible (approved once, accepted everywhere)
• Expand market access for member companies
• Streamline clearance processes
2. DITTA vision on medical software

Differences across the globe challenging for manufacturers...

International harmonization is urgently needed...

- In the best interest of patient safety,
- To resolve different interpretations among different countries,
- Where possible, to reduce regulatory uncertainty and remove trade barriers,
- To resolve unfair competition at tender level

“Registered once, accepted everywhere”
### Europe

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<thead>
<tr>
<th>Stand Alone Software with medical purpose</th>
<th>communicates</th>
<th>stores</th>
<th>communicates, stores + changes or creates</th>
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<tr>
<td>Human entered information</td>
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<td>Medical device sent information</td>
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- It depends on whether the system is regulated by the authority.
- The system needs to be approved by the authority.
- The system needs to be audited by the authority.
- The system needs to be tested by the authority.
- The system needs to be monitored by the authority.
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<td>Human enters information</td>
<td>✗</td>
<td>✗</td>
<td>✅ MMH, drug dose calc</td>
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<tr>
<td>Medical device sends information</td>
<td>✓ MDDS, LMD</td>
<td>✓ MDDS, LMD, NNF</td>
<td>✓ LLZ</td>
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- Blood bank software (MMH, 864.9175)
- Medical Device Data Systems (MDDS, 880.6310)
- Calculator/data device processing module for clinical use, e.g. LIS (862.2100)
- Drug dose calculator (868.1890)
- Digital image storage devices PACS, opthalmic image storage devices (NNF), some RIS (LMB, 892.2010)
- Medical image communications device, e.g. MIMS (LMD, 892.2020)
- Image processing system, e.g. PACS (LLZ 892.2050)
Harmonisation still not there....

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<th>Countries known to regulate stand alone software with medical purposes</th>
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<td>1. Australia</td>
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<td>2. Brazil,</td>
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<td>3. Canada,</td>
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<td>4. China, EU,</td>
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<td>5. Morocco,</td>
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<td>6. Japan,</td>
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<td>7. Taiwan</td>
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<td>8. Singapore</td>
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**Legends:**

- ✓ regulated
- ✗ not regulate
- ❍ It depends
DITTA submitted a New Work Item Proposal on medical software to IMDRF in Feb. 2012
To achieve global regulatory convergence on medical software
To determine common key criteria to qualify whether software is a medical device or not

DITTA set up a dedicated Task Force on medical software
To develop DITTA position and strategy with respect to IMDRF NWIP on medical software
To develop concrete proposals that support a pragmatic implementation of relevant regulations for medical devices with respect to software in general and in particular for standalone software
To contribute to the development on harmonized Guidelines on qualification and classification of stand alone software as medical device
To monitor trends in regions (USA, Canada, Japan, China, etc.)
Two sessions and six presentations covering major geographies and main topics:

Session 1 on the Regulatory Framework in Key Countries

- **Europe**: Lauren Selles – DG SANCO, European Commission
- **USA and Canada**: John Abbott, MITA (replaced with Peter Linders)
- **Japan**: Susumu Takahashi, JIRA

Session 2 on Standards to Support Regulations

- **IEC and ISO**: Peter Linders, COCIR Standardisation Focus Group Deputy Chair, CENELEC TC 62 Chair
- **Notified Bodies**: VDE Testing & Certification Institute, Head of Medical Devices Testing
- **Industry**: Maurizio Andreano, COCIR Member
This workshop will give you **an opportunity** to learn more about regulations applicable to software used in medical practice in several geographies: ongoing discussions on regulatory framework especially in Europe, Canada, USA and Japan?

We hope this workshop will also enhance a **collaborative partnership** between regulators and regulated industry by strengthening our **mutual trust** and **structural collaboration**

DITTA is committed to strengthening its cooperation with AHWP and other stakeholders in the interest of patient safety and better patient access to advanced health IT technologies.
Thank you!

and have a good and fruitful workshop!