

Barcode For Medical Products – Japan Report 2006

The need for implementation of global ISO and JIS standards for product packaging

Learning about the Barcode situation in Japan

Initiated by European suppliers for medical and dental products, health care associations and corresponding Japanese companies, a delegation went to the International Modern Hospital Show (IMHS) in Tokyo to learn about the Barcode situation, the requirements, the degree and the practice of use.

Legal obligations

It was widely understood that legal requirements for Tracking and Tracing have been established following the agreements with other nations in the world for preventive anti-disease systems. Barcode has become an important factor for practical fulfillment, patient safety, and efficient business communication.

Barcode trials and standards

In 2000, the EAN numbering system was considered to be appropriate in Japan. Following worldwide trends, ISO Barcode application standards have been developed in 2004 for product marking as the global base for fulfilling the requirements of error free data capture. The Japanese Ministry of Economy, Trade & Industry (METI) contributed to building this ISO standardization process. The Japanese Standards Association (JSA) published the ISO 22742 norm for marking product packages in January 2005 as an open, non-restrictive but interoperable solution. Manufacturers in Europe, as well as in America, Australia, etc. are committing time and efforts in marking their products uniquely so that they comply with the considerations which were developed under the protection of the governments.

The mission

Indications from several Japanese and foreign companies have shown us that Japan's 2000 approach for one single marking system did not work well for the members in the supply chain, so the delegation was asked to find out reasons. For analyzing it, it was planned to meet specific experts from different areas and to speak with visitors of the IMHS in Tokyo. The information event on July 14 motivated to discuss the opportunities to share expertise on the subject.

The Barcode situation in Japan: "Need for revision"

About 60 persons attended the J-HIBC barcode seminar on IMHS, about 90 contacts were made in total between July 11 and 14, addressing the issues of Health Care Barcode. The interest in the subject was great. Open and fruitful discussions have been undertaken, much input and understanding for the need of our mission has been registered.

Nevertheless it was found that older interpretations of worldwide standards are still common, deviating from world level. Older manuals for Barcoding have been seen not being updated yet. So the globally accepted standard for product package marking published by JSA was rather unknown in Japan. Assumptions that EAN would be the only standard possible, are still widespread. Therefore decision makers in Health Care and standardization may have a lot to do to inform the public about state of the art, the achievements and the full scope of the standards and how to use them for open trade and for gaining the benefit involved. (Details see appendix.)

Chances for ISO standards with EAN, HIBC, ADC

Due to the fact that Japan was one of the key developers of the global standards and that the standards enable most efficient communication (no re-labeling, no restriction on numbers nor symbologies), health care business will share the benefits with the international partners. It avoids trade barriers and breaking the traceability chain. It was a pleasure to learn that engaged experts in Japan are willing to support the standards promoted by METI, JSA, JIPDEC, JEITA, JAISA and others, and to assist in implementing them.

Solution: Scanning the given code – if ISO standard compliant

The discussions around the solution satisfying all parties (manufacturer, distributor, hospital & administration) involved 3 considerations leading to a conclusion:

1. Are 5 digits enough/efficient for identifying all kinds of products?
2. Is over-labeling an efficient practice for tracking & tracing quality products in health care?
3. Should international technical standards of ISO be applied in Japan for open trade?

It was found that the answers are pretty simple. Since the ISO standards shared by Japan are non-restrictive to length of product codes, there is no need for demanding EAN/JAN nor for over-labeling or spending time and cost for forcing the reference into a limited space. The most efficient solution for practicing interoperability, is reading the code as it is printed under ISO rules: EAN for typical 5-digit product codes, HIBC for up to 13 alpha numerics, and for more digits ASC data identifiers apply.



Q & A:

What does it need to implement global standards

Not more than information about the common standards and understanding about the benefits. Scanners can read everything; computers understand all languages and data structures.

Who supplies support

JSA supplies the specifications, JAISA and its members supply integration, branch associations as J-HIBC in Tokyo supply hot line support and guidance backed by the international support.

What are the differences between the year 2000 approach and today

In 2000 it was assumed that the same length of a Barcode is achievable for every product. That time no ISO application standard was available yet, so nations started making their own experiences. Practice showed that if codes become reduced to a Point Of Sales (POS) type, the products will not become better, costs of re-labeling increase and traceability chains break easily. Thus, the demands for a global standard rose up. Thanks to METI, JSA and associated bodies, the "one standard" ISO 22742 for unique product labeling was developed. Today this standard is available for the public targeting the best practice of processing original product codes from production to point of care. Two-dimensional symbologies entered in; QR-Code according to Japanese standard, and DATAMATRIX are choices according to norm.

Meanwhile EAN-13 was found as reliable to carry a 5-digit product code right after the 7 digit JAN member's code, and HIBC for up to 13 characters for the product code. It was experienced that both together would work perfectly in synergy, ready for extended use and quick implementation of world wide business solutions.



Akira Shibata, member of JIS and delegate to ISO and IEC



The interest at IMHS in practising ISO standards and JIS standards for efficiency was enormous

Appendix: Spots of situation found in July 2006

- Barcode and 2D (QR-Code, Datamatrix) are widely known as professional tools for automatic data capture (ADC).
- There is tremendous interest in optimizing Barcode systems, specifically in the HIBC and DIN solution, the "Unique Identification Mark" for smallest medical instruments and in RFID solutions.
- HIBC is known and understood in Japan - if at all - only for export use. Technical prerequisites to print and to read are available thanks to the numerous Japanese manufacturers of barcode equipment.
- The starting paper about introducing Barcode for Medical Devices published by JFMDA in 2000 based on the "EAN Intl. Operation Manual" was found as ready for revisionⁱ,ⁱⁱ.
- Endeavors to implement EAN numbers lead to unnecessary re-labeling of products and even to user-confusing "multiple code" solutionsⁱⁱⁱ.
- Re-labeling was found as time consuming, costly and as a potential break of the traceability chain.
- The Ministry of Health, Labor and Welfare (MHLW) requires printing the Japanese registration number (16 char.) on medical products.
- The "Billing Forms" of the Social Insurance accept the name of the product as plain text, EAN number or any other product code associated with the registration.
- The global ISO standard 22742^{iv} for product packages is not yet known widely in health care. There is still the need to emphasize that EAN became just part of it in conjunction with the Health Industry Barcode (HIBC) and Data Identifier structure (ASC).
- JIS X0510 QR Code is not used for medical products, but accepted for export and with HIBC.
- It cannot be expected that the RSS Composite stacked code would be competitive to QR or Datamatrix.
- Exhibited Hospital ERP software featured both EAN and HIBC as internal codes.

Date: 06-07-14, editors: Claudius Deckert, Dr. Olaf Messing, Heinrich Oehlmann

ⁱ The year 2000's EAN manual: It was not yet updated after the 5 years period for Japan so it is still applied with some wrong arguments and in fact misleading because it contains only one of the world's codification systems.

ⁱⁱ Note: The 2000 paper includes the following statement which is wrong: "In Europe, EAN Intl, EUROHCS and EUCOMED developed the UCC/EAN 128 as its standard, and now UCC/EAN-128 has become a global standard as ISO 15417 & 15418 approved." Correct is that EUCOMED never developed a standard for Barcode. Now EUCOMED recommends to use what fits best - EAN or HIBC covered by ISO. ISO/IEC 15417 is the Symbol specification for Code 128 for open use by all branches as ISO/IEC is lifting the lists of EAN Application Identifiers and ASC Data Identifiers (HIBC "+" is included) to ISO.

ⁱⁱⁱ Samples of "multi-code-labels have been seen applied with JAN13, HIBC128 and EAN128 on the same label.

^{iv} ISO 22742 Packaging – linear barcode and two-dimensional symbols for product packing (source JIS).