International standard EN 15223-1 to replace EN 980 as EU's symbols standard

As of 31 January 2013, the familiar and well-used horizontal EU labelling standard for medical devices, EN 980 – which applies to medical devices and in vitro diagnostics across the board – is being replaced with a globally recognised standard: EN ISO 15223-1.

EN ISO 15223-1 – Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements – has been adopted and published, and is just starting to become available from European standards organisations.

This standard features internationally recognised symbols with precisely defined descriptions. These will be of considerable value to manufacturers marketing globally.

It will be harmonized under all three EU medical device directives. This means that compliance with its requirements will be considered as demonstrating compliance with the relevant essential requirements in the medical device directives.

Although compliance with harmonised standards is voluntary, using correct symbols avoids the need and costs for translation into the 23 languages spoken in Europe, demanded – in most cases – by national authorities on labels and instructions for use of products sold in their territory.

It is a key part of quality management and risk reduction and the decision over symbols use should be part of the risk assessment: Symbols address the practical issues surrounding having multiple languages on a single label and mitigate potential confusion and delays to those having to select the appropriate language when using the device.

No change to part 2 of EN 15223

EN ISO 15223-1 is the first part of a two-part series. EN 15223-2 is the second part and covers symbol development, selection and validation. But part 2 is to remain an international standard since it relates to standards being developed for the global market, Rob Turpin, healthcare sector content manager at BSI, the British Standards Institution, told *Clinica*.

BSI considers that EN ISO 15223-1 will be of particular interest to medical device manufacturers, and also not just to regulatory professionals, but also designers, production teams and consultants. Other interested parties are likely to include suppliers of safety signs and stickers, technical authors and regulators.

In the UK, BSI is due to publish a CD-ROM in early August 2012 containing each of the symbols in JPEG, TIF and EPS format, which can then be downloaded and reproduced easily by users. The CD-ROM will also contain the standard BS EN 15986:2011 – Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates – along with its symbols in JPEG, TIF and EPS formats.

BS EN ISO has also commented that 15223-1 will be a complementary standard useful to those already using BS EN ISO 13485:2012 – Medical devices. Quality Management Systems. Requirements for regulatory purposes – published earlier this year; and BS EN ISO 14971:2012 – Medical devices. Application of risk management to medical devices – the latter of which is likely to be published later this month.

Both standards are internationally recognised and recently updated and are being adopted as harmonised standards in the EU.

EU and Japan take a step closer to regulatory convergence

Medical device regulatory convergence between the EU and Japan may have once seemed an impossible goal, but with news of the European Commission's intention to seek a mandate from the Member States to negotiate a cross-sector free trade agreement (FTA) with Japan, there is now optimism that it might be within grasp.

The two markets have worked closely together on medical device regulatory convergence – along with the US, Australia and Canada – as founding members of the GHTF, but both have very different regulatory systems. For EU companies, the Japanese system is often described as difficult to negotiate and even impenetrable.

Commenting on the commission's intention to seek a mandate for a FTA with Japan, European medical device industry associations, EDMA and Eucomed, commented: "Regulatory convergence will help remove technical barriers to trade and reduce the 'device gap' and 'device lag' in Japan whereby significant kinds of medical devices well-established in Europe are either not available or available only after delays of as much as five years."

Closer integration of the two economies would promote more regulatory unity, the associations believe, by:

- facilitating international clinical investigations;
- encouraging wider use of international standards;
- and reducing compliance burdens.

All of this can be achieved, in their view, whilst maintaining public confidence in medical devices marketed under the two systems.

The European Commission's Directorate General for Enterprise and Industry commented that Japan is the EU's second biggest trading partner in Asia, after China. Together, the EU and Japan account for more than a third of world GDP. A trade deal with Japan could boost the EU's GDP by almost 1% and EU exports to Japan could increase by one third.

Further details at: www.clinica.co.uk