

## China gets tough on labelling and packaging of medtech imports

Manufacturers need to prepare for changes likely to result from Chinese proposals on labelling and packaging of devices manufactured overseas, says *Katherine Wang*.

If the draft notice in which China's State Food and Drug Administration sets out its plans to strengthen the regulation of labelling and packaging of medical devices manufactured overseas<sup>1</sup> is implemented as written, devices that do not have Chinese labelling and packaging will not be allowed to enter the country.

To fully comply with the SFDA's requirement, foreign device manufacturers will have to affix Chinese labels to their products at manufacturing facilities that are registered with the SFDA before releasing the products for importation into China. Importantly, it may no longer be viable for manufacturers of imported medical devices to ship such devices to a Chinese free-trade zone and attach the Chinese labels there before importing them to the domestic market. In addition, foreign manufacturers may not be able to engage a contract manufacturer in China only for Chinese labelling or packaging of the completely assembled products lacking Chinese labels or packages.

In its draft notice (issued on 21 May with comments due by 15 June), the SFDA makes it clear that it considers labelling and packaging activities to be an important part of the medical device manufacturing process. The activities should therefore be covered by manufacturers' quality management system, with manufacturers expected to ensure that the labelling and packaging of products manufactured by them are in compliance with regulatory requirements and standards.

Medical devices distributed and used in China are already subject to labelling and packaging language requirements pursuant to the Medical Device Specification, Labeling and Packaging Rules issued by the SFDA on 8 July 2004. Under these rules, labelling and packaging must be in Chinese and may also be accompanied with other languages (where relevant). What is different is the requirement for the Chinese labelling and packaging to be in place prior to import.

### Tackling prevailing issues

The draft notice addresses some prevailing issues associated with imported medical devices. Currently, some imported devices – eg some dental devices or disposable tracheal cannulas – do not bear any Chinese labelling. Others bear inaccurate Chinese labelling, with product names appearing on Chinese labels that are inconsistent with those approved by the SFDA, for example. Furthermore, many imported medical devices have been imported

into China by local trading companies which act as the domestic agent and distributor for the foreign manufacturers. These imported devices have been initially shipped into a bonded zone in China where Chinese labels are affixed by the domestic agent before actual importation (ie custom clearance) into the domestic market. The Chinese labels would be produced by the domestic agent; different agencies produce different labels so there can be a change in format when a manufacturer moves from one domestic agent to another.

Waigaoqiao in Shanghai, Tianzhu in Beijing, Suzhou Industrial Park in Jiangsu and Tianjin Port in Tianjin are examples of free-trade zones.

There has been speculation that relabelling in bonded areas might be acceptable in Shanghai as an interim option (the facility would have to either comply with the quality management systems standard ISO 13485 or good manufacturing practices issued by the SFDA in December 2009). This interim option may be possible in light of enforcement reality. The SFDA has not inspected any registered overseas manufacturing facility of a foreign manufacturer when it has issued the marketing authorisation in China. Nor has it conducted any import inspection on medical devices manufactured overseas to ensure labelling and packaging compliance. Despite the upcoming requirement in the draft notice, the SFDA does not really have an opportunity at the time of importation to exercise in a timely fashion regulatory oversight on when and where Chinese labelling and packaging are completed. However, if a foreign manufacturer were to perform relabelling at a manufacturing facility in the bonded area with an effective quality management system, it is arguable as to whether the products in question could still be deemed as manufactured "overseas" because the bonded area, from the SFDA's regulatory perspective, is deemed as a domestic territory. In addition, if relabelling were arranged at a place different from the registered address of manufacturing facilities of the products in question, it may lead to an unapproved change in manufacturing site and the products in question may be deemed unapproved as well.

According to the draft notice, the Chinese labels shall include:

- product name;
- model number;
- specification;
- name and registered address of the manufacturer;
- address of manufacturing facilities;

- contact information of the manufacturer;
- product licence number;
- product standard number;
- date of manufacturing or lot number;
- conditions for electricity connectivity/watt (if applicable);
- product expiry date (if applicable); and
- other graphics or symbols required by the nature of the product.

It will no longer be possible for any domestic trading agent to carry out labelling and packaging activities at a free-trade zone in China because the domestic agent is not licensed to perform any manufacturing activities in China.

The SFDA intends to better control inherent risks associated with mislabelling of imported medical devices through the draft notice. However, this draft notice will potentially increase the manufacturing costs of imported medical devices in China and reduce their competitiveness in the market. For those multinational medical device manufacturers with internal manufacturing capabilities in China, it is worth considering transforming some low-end imported devices with higher pricing sensitivity into "made-in-China" products. For those small to mid-size companies leveraging contract manufacturers in China, Chinese labels and packaging materials should be produced by contract manufacturers together with other product components for final assembly to minimise incremental costs. Companies may also try to ask the SFDA for a longer grace period by applying this draft notice initially to selected high-risk product categories, eg implants and sterile products, or by asking for an explicit exemption for certain low-risk product categories.

In conclusion, the SFDA's draft notice will involve considerable change regarding the manufacture and logistics of imported medical devices, especially those produced by small or medium-size companies that rely mainly on domestic agents in China for packaging and labelling. Medical device manufacturers are encouraged to incorporate this upcoming regulatory requirement in their current manufacturing process to avoid any unnecessary disruption of product supply in China.

### References

1. *Draft Notice on Further Regulating Labeling and Packaging of Medical Devices Manufactured Overseas*, <http://bit.ly/MuHRXz>

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