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UK Opens Door To Re-Manufacturing Of Single-Use Devices

By Vibha Sharma, 14 July 2016

NEW GUIDANCE FROM THE UK MHRA sets out the conditions under which re-manufacturing of single-use devices is allowed; new CE mark needed and re-manufacturer assumes legal responsibility.

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The UK Medicines and Healthcare products Regulatory Agency has issued new guidelines that open the door to re-manufacturers of single-use devices (SUDs) by setting out the conditions under which the activity is allowed.

The final guidance clarifies that re-manufacturing is different from re-processing/refurbishment; the MHRA does not allow SUD re-processing. (Also see "UK MHRA consults on single-use device remanufacturing" - *Medtech Insight*, 23 Jul, 2015.)

The key difference between a re-processor and re-manufacturer is that the latter needs to have a CE mark to bring a product to the market. This point is made in the guideline. In addition, the guideline states that the re-manufacturer would assume the full legal responsibility and liability for the re-manufactured device.

The guideline clarifies that the intended use of the re-manufactured device must be the same as that of the device as originally produced, notes law firm Hogan Lovells. Also, re-manufactured devices are required to be supplied to health care institutions through closed loop contracts. "The health care facility is responsible for returning the devices to the original re-manufacturer, destroying or returning devices that have been re-manufactured the maximum number of times specified and reporting any issues with the device to the re-manufacturer," the law firm adds.

Gert Bos, executive director and partner at consultancy company Qserve Group, confirmed that the guideline appears to indicate that re-processing of SUDs is only permitted in cases where it can be classified as re-manufacturing. On first reflection, Bos said, the MHRA guidance appears to be compliant with the requirements of the new EU Medical Device Regulation. "Once [the] MDR kicks in, the UK interpretation, however, should not be in a guidance document, but rather in national law. As such, one could see the guidance as an attempt to test the system prior to writing a supporting national law on it," Bos told *Medtech Insight*.

The MHRA guidance appears to be compliant with the requirements of the new EU Medical Device Regulation, said Gert Bos, executive director and partner at consultancy company Qserve Group.

Bos believes that the concept of re-manufacturing SUDs – as explained by the MHRA in its final guideline – would be acceptable to other countries as well as it involves placing a newly introduced CE-marked product on the market. "The only difference being that some of the components [of the product] may have been used before, or at least their sterile packages [may] have been opened," he added.

According to Bos, re-manufacturing currently does not take place on a large scale in the EU. "A type of re-manufacturing that does happen is the refurbishing of capital equipment. Companies take back older products, repair and update the product in line with the maintenance that should have been done, and then sell it again, typically under another legal entity," he explained. Re-processing of SUDs, on the other

hand, is more widespread. While in some EU countries there are clear rules on this, in others it is controlled at the hospital level, but without any strict supervision. Bos said Germany has the clearest rules on SUDs reprocessing; there supervision is done through dedicated notified bodies.

The MHRA, for its part, said it was aware of a number of manufacturers who had a CE mark for a re-manufactured SUD and who wanted to put their products on the UK market. "These companies have been re-manufacturing SUDs for a number of years and such devices are widely used in some countries," the agency said.

To support its final guidance, the MHRA carried out a detailed review over the last three years of re-manufacturers, assessing their technical, regulatory and clinical processes.

Class I (low-risk) medical devices are excluded from the policy. The MHRA says it does not permit re-manufacturing of this class of device as there would be no external or independent assessment of CE mark compliance. Class I products are subject to self-assessment for CE mark compliance.

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