Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Virtual Manufacturing replaces Own Brand Labelling for medical device manufacturers

Version 1.0
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Contents

Revision history	Date published	Changes
V1.0		n/a

1. Overview

This document replaces previous MHRA guidance on ‘Own Brand Labelling’ (OBL).

The European Commission’s Recommendation 2013/473/EU published in October 2013 significantly amended the expectation for manufacturers who don’t design or manufacture devices but place their names on the product as the manufacturer.

These manufacturers are now expected to have their Quality Management System (QMS) audited and technical documentation reviewed by notified bodies.

Annex II of Recommendation 2013/473/EU states:

> “Notified bodies should note that manufacturers:
>
> (a) have to fulfil their obligations themselves regardless of any partial or total outsourcing of the production via subcontractors or suppliers;
>
> (b) do not fulfil their obligation to have at their disposal the full technical documentation and/or of a quality system by referring to the technical documentation of a subcontractor or supplier and/or to their quality system;
>
> (c) should integrate the quality system of critical subcontractors and of crucial suppliers with their quality system;
>
> (d) need to control the quality of services provided and of components supplied and the quality of production thereof regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier”.

2. What is changing?

MHRA is replacing the term ‘Own Brand Labelling’ with ‘virtual manufacturing’.

Previously the UK accepted Summary Technical Documentation (STED) to be held and reviewed by notified bodies.

Now all virtual manufacturers must hold the **full technical documentation** for any product they place on the market under their name.

3. Timeframes

All parties will be required to hold full technical documentation by 1st September 2017.

4. What is a virtual manufacturer?

A virtual manufacturer is considered to be the natural or legal person who places a new or fully refurbished device on the market under his name despite not undertaking the design or manufacture of the medical device itself. Where a manufacturer has designed the product and subcontracts the manufacturing and other associated processes, he remains the manufacturer.

Where the virtual manufacturer does not design the product, but has an agreement to supply a medical device in their own name that has been designed by another manufacturer, he is considered to be the manufacturer because he is placing their own name on the medical device.

Where notified body certification is required, the virtual manufacturer is required to have a quality management system which will be audited by their notified body. In addition virtual manufacturers are expected to hold the full technical documentation which may be subject to review by a notified body. Virtual manufacturers for medical devices not requiring notified body approval are required to hold the technical documentation for their medical devices, which may be subject to scrutiny by the Competent Authority. Virtual manufacturers, where relevant, are also required to meet the registration requirements (e.g. for Class I devices, IVDs etc.).

As the manufacturer under the medical device legislation, the virtual manufacturer is also required to sign a Declaration of Conformity that the devices concerned meet the requirements of the Medical Devices Directives.

Note: All virtual manufacturers, including those manufacturing Class I medical devices, are required to comply with the revised requirements.

5. What are the expectations for the technical documentation to be held by a virtual manufacturer?

All manufacturers are expected to hold full technical documentation in order to demonstrate that the medical device that they place on the market under their own name meets the regulatory requirements. Detailed guidance has been issued on this topic in NB-MED/2.5.1/Rec5.

The technical documentation should be fully integrated into the manufacturer's quality management system where applicable and should contain data relevant to the manufacturer (e.g. labels, instructions for use, risk assessment etc.)

In the case of virtual manufacturing where the manufacturer does not hold the rights related to product design, the notified body and Competent Authorities may accept a technical file from the virtual manufacturer that has redacted proprietary information as long as the redacted information is not essential for the purposes of the notified body or Competent Authorities assessing whether the medical device complies with the regulatory requirements. Redactions should be as limited as possible.

In cases where the virtual manufacturer holds redacted technical documentation they must have contractual arrangements to ensure full disclosure of all applicable information by the Original Equipment Manufacturer (OEM) directly to the notified body of the virtual manufacturer (without the further need for agreements to be put in place between the notified body and the third party OEM).

The following may constitute proprietary information:

a. Unique material formulae or ingredients which are specific to the medical device and not in general use which are of high commercial and intellectual benefit to the OEM
b. Unique manufacturing processes which have been designed by the OEM and give them a competitive advantage in the market place
c. Technical drawings and technologies (applicable where a patent is also being applied for) but not yet granted
d. Software algorithms

Note: Full redaction of all formulas, ingredients, algorithms or manufacturing processes cannot be accepted. Where redactions are made then the justification for these redactions by the OEM must be documented and the top level information provided should be sufficient to understand the medical device and any associated risks.

Any technical documentation provided to a notified body should include a statement drawn up by the virtual manufacturer indicating they fully understand all the documentation provided and that they accept full legal responsibility.

6. What should the contractual agreement between both parties cover as a minimum?

Virtual manufacturers will need to ensure an appropriate contract is in place with the OEM. As a minimum, the contractual agreement should contain the following:

a. A direct link between the medical devices being placed on the market by the manufacturer that holds the rights to the product design and the virtual manufacturer they are supplying who does not hold the design rights (e.g. by name / part number).

b. Arrangements for post market surveillance and vigilance activities (i.e. details of who is responsible for what in relation to these requirements, including reporting of adverse incidents). All virtual manufacturers should ensure that incidents or potential incidents are reported and also brought to the attention of the manufacturer that holds the rights to the product design. Similarly, the manufacturer is responsible for notifying the virtual manufacturer to enable them to take appropriate action with regard to their own products.

c. Provisions for post-production follow-up, including ensuring that post market clinical follow up provisions are in place.

d. Arrangements for details of any changes to the medical devices to be notified to both parties.

e. Provisions for unannounced audits – i.e. the notified body of the virtual manufacturer will be required to have access to any critical suppliers (including the manufacturer who holds the rights to the design).

f. The contract should include the fact that the virtual manufacturer may not enter into another contract with another virtual manufacturer for the same device, i.e. a virtual manufacturer cannot be the OEM for another virtual manufacturer for the same medical device.

g. Provision for the OEM (including the manufacturer who holds the rights to the design) to provide fully un-redacted information upon request of the notified body of the virtual manufacturer, without the requirement for further contractual actions between the notified body and critical supplier such as non-disclosure agreements.

h. Provision for the OEM, where relevant, to maintain and provide to the virtual manufacturer notified body certification covering the products concerned.

i. Provision for the OEM, where relevant, to maintain and provide to the virtual manufacturer evidence of registration (e.g. for their Class I devices, IVDs etc.) with their Competent Authority.

7. How should disputes with UK notified bodies be handled?

If there is a dispute between a UK notified body and a virtual manufacturer regarding the regulatory requirements, this may be referred to MHRA for clarification (devices.regulatory@mhra.gsi.gov.uk).