Identification of manufacturers on medical devices
1 December 2011

In the case of complaints, vigilance incidents and investigations, users, distributors and the authorities should identify and contact the companies responsible without delay¹. For that reason, the full postal address of the manufacturer in question should be stated on the packaging and also on package leaflets and instructions for the use of medical devices². If the manufacturer's registered offices are not located in one of the contracting States³, it is also necessary to state the full address of the authorised representative with registered offices in a contracting State.

Against this background, the addresses stated on medical devices in Europe will be checked for completeness as of September 2012⁴. The competent authorities may then initiate surveillance procedures with regard to companies that do not fulfil this requirement.

Swissmedic therefore recommends that all manufacturers and their authorised representatives check the addresses to be stated on new packaging elements prior to their production. Incomplete details should be corrected.

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Further information by Swissmedic on medical devices is available at www.swissmedic.ch/md.asp.

References and comments:
¹ Medical Devices Ordinance (MepV, SR 812.213), Art. 7 MepV (Product information), Art. 14 MepV (Self controls), Annex 1 of the European Medical Devices Directives 90/385/EEC, 93/42/EEC, 98/79/EC.
² Central Management Committee (CMC) on Medical Devices, Document Reference N:3 "CMC Decision on information to be provided in relation to the address of the manufacturer".
³ International contracts for mutual recognition of conformity assessments and the registered offices of manufacturers and authorised representatives have been enacted with EU Member States (SR 0.946.526.81), EFTA States (SR 0.632.31), Turkey (Decision no. 3 2009 to SR 0.632.317.631).
⁴ The CMC was founded by the competent authorities for medical devices. It is intended to achieve greater consistency in the interpretation of European law on medical devices and thus to improve implementation and decision making between the National Regulatory Authorities in Europe. The implementation of the CMC's decisions by the authorities is co-ordinated in Europe by the Compliance and Enforcement Group (COEN).
Annex

Reference N:3

Central Management Committee
Decision

CMC Decision on information to be provided in relation to the address of the manufacturer

The CMC decided:

The 'address of the manufacturer' as required in the Essential Requirements on the labels and instruction for use, is the address of the registered place of business of the legally responsible manufacturer and shall include:

- street/road,
- number/house/floor,
- postal code
- city
- state/region and
- country

The decision is intended to achieve a common interpretation of the requirement the manufacturer has in relation to provision of his address on the label and instruction for use.

The same details have to be provided for the address of the authorised representative.

Background:

The essential requirements state that the manufacturer has to place his name and the address on the label and on the instruction for use. In practice wide variations in the information provided has been noted. This could impact adversely on post market surveillance activities.

In order to bring consistency and harmonisation to this issue the CMC decision was taken.

Date of Decision 23rd February 2011
Latest Revision: 7th June 2011