COEN Guideline
"Implementation of the CMC Decision No. 3"

This guideline will support national authorities by a harmonised implementation of the CMC decision Nr.3.

Background of the CMC decision:

The CMC decision is an attempt to establish a harmonised interpretation of the European Medical Devices Regulation between the European Competent Authorities with regard to the specific labelling requirement set out in the Directives. To develop a harmonised market surveillance practice in Europe, it is vital that devices can be safely and uniquely identified in all member states. That requires harmonised rules on the labelling and a harmonised interpretation of those rules.

In the last few years Competent Authorities have organised and contributed to the COEN group and have discovered different interpretations of the legal requirement by manufacturers, distributors and others. Therefore, COEN asked the CMC to agree a harmonised interpretation of the regulation.

On June 7, 2011 CMC issued a decision to provide market surveillance authorities with a harmonised interpretation of what address a manufacturer (and when relevant an authorised representative) of medical devices shall present on the label and/or instructions for use. CMC asked COEN to implement this decision.

The CMC decision contains two principal statements:

- The address shall be the address of the registered place of business of the legally responsible manufacturer. Not of a sales office or a customer center located at a different address than the legal manufacturer.

- The address must be a complete street address. Not a URL, an e-mail address or post office box.

The decision does not affect other aspects of labelling, such as where the information shall be applied, its readability or what other information to be provided.

The CMC decision is very close to the text and to the purpose of the regulation. The regulation doesn’t offer a possibility to deviate from the labelling requirement of the address of the manufacturer. And as already mentioned in the Regulation (e.g. see annex I 13.1 of MDD) the information on the label (etc.) "must allow the identification of the manufacturer". In Europe the address is one of the essential elements which can be used for that identification and it is absolutely necessary that this address is the address of the registered place of business. This address shall also be used when notifying the competent authority for medical devices as a manufacturer or authorised representative and at the declaration of conformity and
in certificates when applicable. Otherwise a unique identification is not possible in Europe.

Other regions in the world are using centralised registration, approval and listing systems by which devices can be easily identified with e.g. registration codes which have to be provided on the device or on the label etc.

Through a letter, agreed by COEN, the Competent Authorities informed manufacturers, Authorised Representatives, Notified Bodies and national and European branch organisations of this decision. In this letter it was said that the decision will be applied by national market surveillance authorities as from 1\textsuperscript{st} September 2012 giving industry a transfer period of one year.

**How to enforce the decision?**

Starting from 1\textsuperscript{st} September 2012 national competent authorities shall consider market surveillance activities on the market. If breaches of the regulations are found the NCA shall use the following step-wise approach.

**Step 1**
- Under Article 18(a) MDD, 17(a) IVDD or 13(a) AIMDD, the market surveillance authority shall make the manufacturer aware of the breach and specify the terms for how it should be addressed. The terms should, when possible, be drawn up in dialogue with the responsible manufacturer and be specified with regard to the risks the breach may impose to the user / patient. The terms can when the risk assessment allows for this include an individually fixed period of transition.

- The manufacturer is obliged to remedy the breaches.

**Step 2**
- If the parties cannot find a consensus and the non-compliance continues the Authority shall take measures under Article 18(b) MDD, 17(b) IVDD or 13(b) AIMDD. These measures shall be proportional to the deviation, but should be sufficient to restrict or stop unduly CE marked devices to be put on the market.

**Step 3**
- If the breach is deemed to pose a risk to users / patients, the measure taken shall be taken in accordance with the procedure in Article 8(1) MDD and IVDD or Article 7(1) AIMDD.
- If the breach is not considered to represent a significant risk, the Authority shall inform the other Member States and the Commission of the decision taken under Article 8(3) MDD and IVDD or Article 7(3) AIMDD. For this information the COEN 2 form shall be used.

When enforcing the decision of CMC, which is a harmonised interpretation of the existing European regulation, the NCA may have difficulties to define and assess appropriate corrective measures and the necessary period of grace, which can be
used by the manufacturer to re-establish the conformity of their products with the provisions of the Medical Devices Directives, without stopping the placing on the market. The difficulties are maybe related to legal inaccuracies in the legal texts.

**Following incomplete Q and A list should assist NCA enforcing the CMC decision Nr 3:**

**Q1:** Question: For many companies, 01 September 2012 seems too short for full compliance. What will happen to the products not compliant with the requirements of CMC Decision No.3 requirements after that date?

The NCA will start with Step 1 and will require a corrective action by the manufacturer. Due to the fact that this specific incorrect labelling in most cases cannot be considered as a safety issue, the manufacturer should make the corrective action within an adequate time period, without stopping the placing on the market.

**Q2:** Question: Is it sufficient if the details of the manufacturer’s/authorised representative’s address as required by the CMC Decision are printed on the product, or the outer packaging, or the sales packaging, or in the instructions for use? Or is it rather mandatory to have a label with the address directly on the device itself.

The directives give the following directions:

AIMDD: The sterile pack, the sales pack and the instructions for use shall include the name and address of the manufacturer. When relevant the instructions for use and the sales pack shall also include the name and address of the authorised representative (annex 1 (14)).

MDD: The label and the instructions for use must bear the (trade) name and address of the manufacturer. When applicable the name and address of the authorised representative shall be given at the label or the outer package or in the instructions for use. (MDD Annex I (13.1, 13.3, 13.6))

IVDD: The label and the instructions for use must bear the (trade) name and address of the manufacturer. When applicable the name and address of the authorised representative shall be given at the label or the outer package or instructions for use. (IVDD Annex 1 (8.1, 8.4))

**Q3:** Question: What is to be done if one or several elements of the address as defined in the CMC decision are not applicable (e.g. no postal code in Ireland).

Some elements of the address given in the decision may not be relevant in all countries. Only elements applicable to the area where the company has its registered place of business must be given in the address.
Q4: Question: Must NCA utilize the safeguard clause or implement other barriers/alerts, if devices do not “comply” completely with the CMC Decision after September 2012?

To achieve a harmonised approach NCA shall consider Step 2 and 3 if manufacturers are not able to establish the necessary corrective actions within an appropriate time.

Q5: Question: What should manufacturers and authorised representatives do if they encounter difficulties to respect the 01 September 2012 deadline?

A company that cannot reach the 1st September deadline is expected to set up a letter giving the reason for the delay and a date when the labelling will be fully adapted to the decision. This letter, together with copies of the existing label and the sales package shall be sent to the NCA in the country where the manufacturer or when relevant the authorised representative has its registered place of business. The NCA will act according to the answers of Q1 and Q5.

Abbreviations used in this document
AIMDD Directive 90/385/EEC
CMC Central Management Committee
COEN Compliance and Enforcement Group
IVDD Directive 98/79/EC
MDD Directive 93/42/EEC
NCA National Competent Authority