

## Central Management Committee Decision



*PROTECTING PUBLIC HEALTH TOGETHER*

### **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 and thereby where applicable\*:

- 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.

\*Note: Not all of the above mentioned details may be part of the registered address in the country where the manufacturer or authorised representative has his registered place of business. For instance, a postal code may not exist in a particular Member State or a floor number may not be relevant and therefore cannot be included. On the other hand, a standard postal address which will identify the location of the manufacturer in that Member State is acceptable (a postal box/post office addresses are therefore not acceptable as it would not identify the specific location of the manufacturer).

#### **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 the updated Decision 16<sup>th</sup> July 2012

- Original Decision latest update 7<sup>th</sup> June 2011 -

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Date of Decision 23rd February 2011