

## SELF-CARE MEDICAL DEVICES – A NEW SELF-CARE CATEGORY

MIRANDA MOUSSA

Association of the European Self-Medication Industry (AESGP)

### ABSTRACT

**INTRODUCTION:** Through the wide availability of safe and effective products in the areas of non-prescription medicines, food supplements and self-care medical devices, people throughout the European Union can practise responsible self-care.

**DISCUSSION:** Understanding the particularities of self-care medical devices is a prerequisite to discussing and overcoming unnecessary regulatory delays while making sure that the most suitable regulatory framework is applied. This article provides background information on the self-care medical devices sector.

**CONCLUSION:** Aiding European consumers in the management of a healthy lifestyle is essential in years of economic constraints. Through a chemico-physical mode of action, self-care medical devices help in addressing minor ailments.

**Key words:** Self-care, medical devices, health, mode of action, classification rules.

### INTRODUCTION

Self-care is increasingly recognised by informed and empowered consumers as the first choice in treating illnesses and maintaining their health and well-being. Through the wide availability of safe and effective products in the areas of non-prescription medicines, food supplements and self-care medical devices, people throughout the European Union can practise responsible self-care<sup>1</sup>.

### DISCUSSION

#### Defining self-care medical devices

Self-care medical devices include products such as nasal sprays used for infants with colds and blocked noses, gels for vaginal discomfort, throat lozenges, dentifrices for sensitive teeth, verruca and wart removers, anti-snoring sprays, dental implants, flushing solutions, creams used to treat or prevent minor skin irritations or anti-flatulence products acting by a chemico-physical mode of action. These products are intended to be used for the purposes of monitoring, treating or alleviating a disease and are placed on the market in accordance with the Medical Devices Directive 93/42/EEC<sup>2</sup>. By treating minor ailments and/or relieving adverse events such as dryness of the eye, and skin irritation, self-care medical devices can help patients manage their well-being and

observe their treatment. For instance dry mouth, which is a side effect of more than 400 medicinal products, can be relieved by using artificial salivas (medical devices) as pointed out by the U.S. Food and Drug Administration in its Consumer Health Information paper entitled ‘Dry mouth? Don’t delay the treatment’<sup>3</sup>.

There are currently no specific criteria for defining a self-care medical device, in contrast to non-prescription medicines. Nonetheless the European Commission has introduced, in its proposed regulation<sup>4</sup>, several provisions on so-called ‘devices for use by lay persons’. These provisions state that these devices should be designed and manufactured in such a way so as to ensure that they are easy to use by the intended user at all stages of the procedure. Also, they should perform their intended purpose appropriately taking into account the skills and the means available to lay persons.

### **Mode of action versus function**

The mode of action is an important criterion when it comes to differentiating a medical device from a medicinal product. Whereas medicinal products act by a pharmacological, immunological or metabolic means, medical devices primarily have a chemico-physical mode of action that includes, amongst others, local pH changes, the modification or sequestering of a molecule and the formation of a physical barrier by chemical bonding or chemical reaction such as electrostatic van der Waals forces or H-bonding. In addition to Directives 2001/83/EC<sup>5</sup> and 93/42/EEC that define a medicinal product and a medical device, respectively, the amending directive 2007/47<sup>6</sup> states that ‘particular account shall be taken of the principal mode of action of the product, in deciding whether a product falls under the Medicinal Products Directive 2001/83/EEC or the Medical Devices Directive 93/42/EC’.

The United Kingdom’s authoritative body for medical devices – the Medicines and Healthcare products Regulatory Agency – in June 2013 published guidance on this legislation entitled ‘Borderlines between medical devices and medicinal products’<sup>7</sup>. This stipulates that the intended purpose of the product, taking into account the method by which the principal intended mode of action is achieved, should be taken into account when deciding whether a product is a medical device or a medicinal product. Additionally, it is important to make a distinction between the mode of action of a substance and its therapeutic effects or functions on the human body, as the same therapeutic effect or function can be reached by different modes of action, and these therefore make the difference in deciding whether the product is a medical device or a medicinal product.

### **Definitions of pharmacological, immunological and metabolic mode of action**

When defining the borderline between the two categories, the definitions of a pharmacological, immunological and metabolic mode of action are important. Case C-308/11 (judgment of 6 September 2012)<sup>8</sup> concerned the classification of a mouthwash as a medicinal product considering its pharmacological mode of action. To this end, the Higher Regional Court of Frankfurt am Main relied on the definition of a pharmacological mode of action in part of the 2009 guidance document ‘Borderline products, drug-delivery products and medical devices incorporating as an integral part, an ancillary medicinal substance or an ancillary human blood derivative’<sup>9</sup>. These definitions are currently being considered at European level. The latest discussions noted that the metabolism

of a product does not imply that it achieves its principal intended action by a metabolic means. Updated definitions are expected to be published in 2014.

### **Borderline cases**

An interesting case study is the request for a preliminary ruling from the European Court of Justice on a vaginal capsule<sup>10</sup> used for correcting bacterial imbalances further to its classification by the Finnish Medicines Agency as a medicinal product and as a class III medical device in the European market. In May 2013, the Advocate General observed in his opinion that the principal function of a product or substance and its mode of action often determine which directive applies. He also noted that ‘a product containing a substance that has a physiological effect cannot automatically be classified as a medicinal product by virtue of its function’. Furthermore, the Advocate General acknowledged the difficulty of avoiding differences in the classification of products between the Member States due to an incomplete harmonisation in this field. This lack of harmonisation stems from the fact that the EU regulatory framework on medical devices is currently made up of three Directives<sup>11</sup>. On 3 October 2013, the European Court of Justice ruled that the classification of a product as a medical device in one Member State does not preclude the competent authorities of another Member State from classifying the same product as a medicinal product<sup>12</sup>. Several expert groups and taskforces have therefore been created by the European Commission to ensure greater harmonisation within EU Member States. Each expert group responsible for the establishment of guidance oversees particular areas of medical devices such as vigilance, notified bodies, clinical investigation, and classification and borderline issues. The last is of a certain interest as the expert group has a task to provide decisions on the classification of a product. In fact, together with experts from National Competent Authorities, Industry, Notified Bodies, and Standardisation Bodies, the European Commission is discussing the regulatory status and/or the classification of specific product or groups of products on a case-by-case basis. Any agreement among Member States on the classification or status of a product leads to its publication in the Manual on Borderline and Classification in the Community regulatory framework for medical devices<sup>13</sup>.

### **MEDICAL DEVICES**

Medical devices play a crucial supporting role in the diagnosis, prevention, monitoring and treatment of diseases, the safety of blood used in transfusions and improving the quality of life of people suffering from disabilities<sup>14</sup>. They include a wide range of products from contact lenses and stethoscopes for diagnosis to retinal implants, conductive gels for obstetric ultrasound, hemodialysis machines, neurostimulators and self-care medical devices.

### **New Approach**

For the last twenty years, the so-called ‘New Approach’ has allowed an extensive and broad range of safe and effective products to be placed on the market. The New Approach consists of ensuring the compliance of medical devices with the essential health and safety requirements set out in the Medical Devices Directives<sup>11</sup>. In this context, the role of the Notified Bodies is to assess compliance with the Directives, focusing on risk management and whether clinical benefits outweigh risks to

patients and users. Manufacturers can then choose to use the harmonised standard to help meet the Directives' requirements<sup>15</sup>. After obtaining a CE-mark, self-care medical devices can be placed on the market in all 28 EU Member States.

**STAKEHOLDERS**

**Notified Bodies**

A Notified Body is a certification organisation which the National Competent Authority of a member state designates to carry out one or more of the conformity assessment procedures described in the Medical Devices Directives. 75 European Notified Bodies are currently authorised under Directive 93/42/EEC. They are, on behalf of the National Competent Authorities, involved in the conformity assessment of medical devices other than class I medical devices without a measuring function or a sterile condition. In these latter cases, corresponding to low-risk medical devices, the manufacturer assesses the device himself.

**National Competent Authorities**

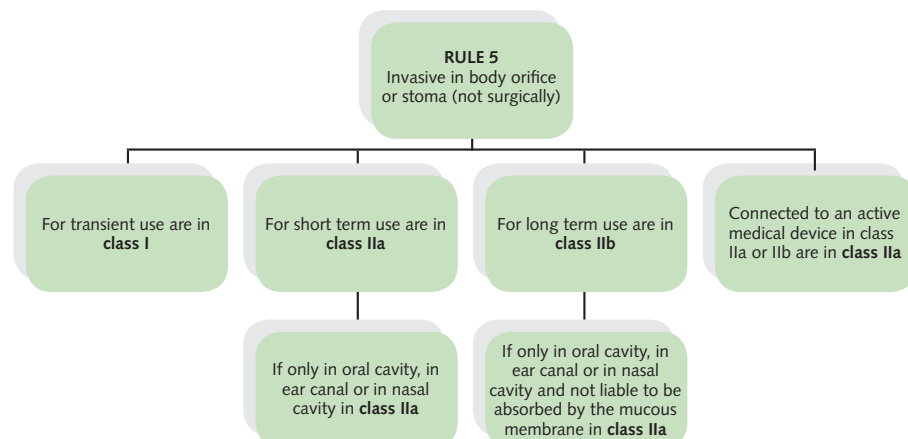
In addition to designating Notified Bodies, National Competent Authorities are mostly involved in post-marketing surveillance activities. This includes ensuring that manufacturers placing devices on the market comply with the Regulations and evaluating adverse incident reports received from manufacturers. Additionally, National Competent Authorities carry out a pre-clinical assessment of devices intended for clinical investigation and assess applications for the exceptional use of non-compliant medical devices<sup>16</sup>.

**CLASSIFICATION OF SELF-CARE MEDICAL DEVICES**

**Current classification rules**

Medical devices are classified in accordance with Annex IX 'Classification criteria' to Directive 93/42/EC, based on the vulnerability of the human body and taking account of the potential risks associated with the device in light of its invasiveness and duration of use. Most of the self-care medical devices are classified in accordance with Rule 5<sup>17</sup>. (Figure 1)

**Figure 1: Rule 5 of Annex IX 'Classification criteria' to directive 93/42/EC (reference: European Commission. MEDDEV Guidance document 2.4/1 Rev.9 'Classification of medical devices')**



In case of a capsule, it is more likely that the medical device will incorporate animal tissues or derivatives rendered non-viable, and is therefore categorised in class III according to Rule 17<sup>17</sup>.

### **New classification rules**

In September 2012, The European Commission proposed<sup>18</sup> a Rule 21 that would classify devices composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally in class III. This class involves different requirements and a more stringent conformity assessment procedure. In addition, appropriate technical specifications showing presumption of conformity (common technical specifications and harmonised standards) have to be adopted and a (new) competent designated Notified Body has to be selected to conduct the conformity assessment procedure.

The European Commission's Proposal for a Regulation on medical devices also suggests the compliance of these devices with the relevant requirements of Annex I to Directive 2001/83/EC relating to medicinal products. These new requirements could however endanger innovation in the self-care medical devices sector given that the development and production of self-care medical devices may become too expensive for the micro-, small or medium-sized enterprises making up 80% of medical devices manufacturers in Europe<sup>14</sup>. In addition, any classification as a class III medical device may require the involvement of Special Notified Bodies in the conduct of conformity assessments, as proposed by the European Parliament in its amendments adopted on 22 October 2013<sup>19</sup>. Special Notified Bodies are conformity assessment bodies designated by the European Medicines Agency.

The European Parliament has moreover proposed making the summaries of the safety and performance reports on high-risk medical devices publicly available via the European Databank on Medical Devices (Eudamed) in the same way the European Medicines Agency is publishing European Public Assessment Reports (EPARs) for centrally authorised medicinal products.

## **CONFORMITY ASSESSMENT PROCEDURES FOR SELF-CARE MEDICAL DEVICES**

For class III medical devices such as capsule-type devices (Rule 17), the manufacturer should ensure that the devices conform to the essential safety and performance requirements laid down in the Directive<sup>2</sup> via stringent conformity assessment procedures. The assessment will result in the issuance of a certificate needed to place a medical device on the European market. The conformity assessment is based on a full quality assurance system or on joint procedures.

### **Full quality assurance system**

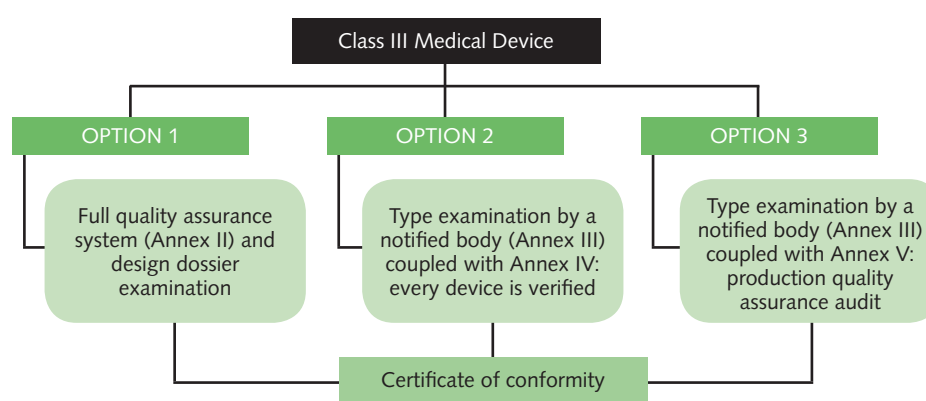
The manufacturer lodges an application for the assessment of his quality system with a Notified Body. This application aims at ensuring that the products conform, from design to final inspection, to the provisions of Directive 93/42/EC. The assessment includes an audit of the quality system to determine whether the essential safety and performance requirements are met. In addition, the Notified Body assesses and examines the design dossier relating to the product prior to issuing the EC-design examination certificate. Moreover, the Notified Body may require additional tests or evidence before issuing the certificate of conformity.

### Joint procedures

A representative sample of the production is assessed by the Notified Body through the examination of the technical documentation. If the sample is found to be manufactured in conformity with the documentation, the EC-type examination certificate is issued. In addition, the quality management system is assessed by the Notified Body, ultimately resulting in the issuance of an EC quality assurance certificate.

The manufacturer can also choose to undergo the assessment of a representative sample and ensure that the devices conform to the type described in the EC-type examination certificate. In this case, every device is examined individually and the appropriate tests carried out. Alternatively, a random sample can be taken and controlled from every batch. This will lead to the issuance of a certificate of conformity. (Figure 2)

**Figure 2: Conformity assessment procedure of class III medical devices (based on Directive 93/42/EEC)**



### TRACEABILITY OF MEDICAL DEVICES

A globally harmonised system for the traceability of medical devices – similar to the safety features for pharmaceutical products – has been under development in recent years. As a result, several pieces of legislation are being discussed in the United States and at international level. Currently, self-care medical devices sold at retail bear the Universal Product Code – a specific type of barcode on their packaging. In Europe, the European Commission in April 2013 published a Commission Recommendation on a common EU framework for a Unique Device Identification (UDI) system<sup>20</sup> aimed at providing Member States with guidance to achieve pan-European harmonisation. The Unique Device Identification system consists of: 1) a device identifier specific to a manufacturer and a device model; and 2) a production identifier related to the device production unit that determines the level of traceability to be achieved. Although it does not define specific types of products to be exempted from the UDI requirements, the Recommendation foresees possible exceptions and/or exemptions in accordance with international guidance<sup>21</sup>.

## CONCLUSION

Self-care medical devices are increasingly present in the European market. In the same manner as non-prescription medicines, these devices aim at supporting European citizens in the management of minor ailments through responsible self-medication while maintaining and protecting the health and well-being of European consumers. The overhaul of the medical devices regulation currently being discussed at European level will certainly play an important role in the evolution of the sector.

**Disclosure: The Association of the European Self-Medication Industry represents national trade associations and manufacturers of non-prescription medicines and consumer healthcare products in Europe.**

**Correspondence to: Miranda Moussa, Association of the European Self-Medication Industry, 7 avenue de Tervuren, B-1040 Brussels, Belgium, email: m.moussa@aesgp.eu**

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