

SUBSTANCE-BASED MEDICAL DEVICES AT THE CROSSROADS?

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BACKGROUND

Self-care medical devices are composed of substances or combination of substances. They include, amongst others, products such as saline solution nasal sprays primarily used for sufferers, often infants, with cold symptoms and blocked noses, lozenges to relieve throat discomfort, dentifrices for sensitive teeth, verruca and wart removers, gels for vaginal discomfort, cough syrups, products used for the reduction of bloating, denture cleansers and adhesives, creams to treat or prevent minor skin irritations or anti-flatulence products.

These are classified as devices in light of their mode of action which is not pharmacological, immunological or metabolic but relies on chemico-physical processes such as local pH changes, sequestering actions of molecules, and physical barrier formation.

Accordingly, these products are placed on the market in accordance with the essential requirements of Medical Devices Directive 93/42/EC, and are classified in class I (low risk), class IIa (medium-low risk), class IIb (medium-high risk) or class III (high risk) according to criteria such as duration of use or degree of invasiveness; this follows the New Approach legislative principles introduced and harmonised in the 1990's.

In September 2012, the European Commission proposed 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 (ie. high risk). The European Commission's Proposal for a Regulation on medical devices also suggested that these devices should comply with the relevant requirements of Annex I to Directive 2001/83/EC relating to medicinal products.

The first reading position of the European Parliament was adopted at the plenary session of 2 April 2014, and it opposed severe restrictions to substance-based medical devices. On 19 June 2015, the Council agreed the substance of its negotiating stance on the proposed regulation on medical devices. The discussions between these institutions are expected to start in October 2015.

GENERAL REMARKS

It is often stated that these regulatory changes are necessary because of a limited number of products that are causing concerns. However, the approaches being proposed by the European Commission and by the EU Member States will have far reaching consequences for many products. This is because the broadening of provisions related to substance-based medical devices will apply to 'all devices composed of substances that are introduced into the human body via a body orifice or applied on skin'.

Should the provisions remain as currently proposed by the European Commission and the EU Member States, developing and producing self-care medical devices will become too expensive for at least some of the manufacturers, particularly those of small and medium-sized capacity. This will not only have consequences for the innovation and competitiveness of EU manufacturers, but also result in potential losses in terms of jobs and growth.

Evident additional and significant costs will include the increased cost of a new contract with the notified body approving medical devices, and costs related to a more complex clinical evaluation including additional clinical studies that would have to be performed rather than on published literature evidence as is currently an option. Moreover, companies will have to invest significantly in new equipment in order to comply with requirements such as those related to the Unique Device Identification system.

In that regard, AESGP believes that an impact assessment should be performed so as to ensure that provisions remain well-designed, proportionate and fit for purpose to the self-care medical device sector, and particularly to the micro-, small or medium-sized enterprises which comprise 80% of medical devices manufacturers and employ a significant number of citizens in Europe. This percentage does not include the small and medium-sized suppliers and contractors who work with multinational companies.

While AESGP recognises that some technical aspects could be clarified in order to improve the evaluation of 'substance-based medical devices', it should be kept in mind that these have been successfully classified as medical devices, over the last decade, without any substantive safety issues related to their use. On the contrary, these products have contributed to an empowerment of consumers when maintaining their health and well-being.

Lastly, the term 'substances' used in all provisions related to self-care medical devices concerned by Rule 21 may encompass a wide range of molecules from small to large molecules including polymers, when consideration of existing EU definitions is taken into account. For that reason, further clarification as to the scope of 'device composed of substances or combination of substances' should be included in these recitals.

KEY POINTS

In the context of the upcoming discussions between the European co-legislators, AESGP would like to bring attention to the following main points of the proposed regulation on medical

devices, which would have a significant impact on the self-care medical devices sector in Europe:

- CLASSIFICATION OF SUBSTANCE-BASED MEDICAL DEVICES AND RULE 21: The classification of ‘devices that are composed of substances or combination of substances’ is a pivotal factor in determining the set of requirements pertaining to a device. Rule 21 should thus be proportionate and risk-based. Accordingly, the up-classification to class III is only justified in cases where devices are systemically absorbed in order to achieve their intended purpose.
- COMPLIANCE OF SUBSTANCE-BASED MEDICAL DEVICES TO THE MEDICINAL PRODUCTS DIRECTIVE (2001/83/EC): Requesting compliance of substance-based medical devices with Annex I to Directive 2001/83/EC is based on the presumption that the principal intended mode of action of substance-based medical devices is achieved by pharmacological, immunological or metabolic means; this is not the case. In addition, this is against the ‘principle of non-cumulation’ of regulatory requirements in the sense that the medical device and medicinal product legislative texts should not both apply to the same products.
- THE TRANSITIONAL PERIOD (ARTICLE 94): The transitional period should provide sufficient time for industry and notified bodies to comply with new requirements related to the foreseen up-classification of devices. These provisions should ensure that substance-based medical devices remain on the European market in the interim.

Other important points concern:

- The regulatory status of products (Article 3): The Commission will have the possibility of determining, by means of implementing acts, after consulting the Medical Device Coordination Group or at its own initiative, whether a specific product or category of product is a medical device or not. Prior to the launch of the examination procedure, a proper call for data on a category of products or a specific product should be published on the European Commission website.
- Inclusion of biological substances in the scope of the regulation (Article 1(2)): Viable biological substances that do not achieve their intended purpose by pharmacological, immunological or metabolic means should remain within the scope of the medical devices regulation; these include enzymes and *lactobacilli* which have been widely used in medical devices such as cleansing preparations/denture cleansers and vaginal capsules without safety issues arising.
- Classification of medical devices containing nanomaterials (Rule 19): Medical devices containing nanomaterials should only be in class III when nanomaterials are deliberately intended to be released into the human body, unless risk assessments on specific nanomaterials were performed by an EU agency or scientific body in which case Rule 19 should not apply.

- Provisions related to the Unique Device Identification system should be adapted to the category of self-care medical devices.
- For all classifications of device, including class III, there should be the possibility to use data, obtained via a search of published literature, from a demonstrated equivalent device from another manufacturer (Article 49) – no contract should be required when using literature or other data in the public domain.

CONCLUSIONS AND TIMING

The negotiations between the European Parliament and the Council are expected to come to a conclusion in early 2016. The outcome of these negotiations could have far-reaching implications for a significant sector of consumer self-care. Depending on these decisions, some substance-based medical devices successfully used by consumers for many years may cease to be available. At the very least, it is to be hoped that there will be adequate transitional arrangements, in particular for those products which are put into a higher class. Substance-based medical devices are indeed at the crossroads, and their future is far from certain.

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.

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