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(Resolutions, recommendations and opinions)

OPINIONS

EUROPEAN COMMISSION

COMMISSION OPINION

of 22 July 2015

on the measure adopted by the Netherlands prohibiting the use of permanent dermal fillers for aesthetic purposes

(2015/C 241/01)

This opinion is based on Article 14b, fourth subparagraph, of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1].

By letter of 11 July 2014, the Dutch authorities notified the Commission of the draft decree amending the Medical Devices Decree (Besluit Medische Hulpmiddelen), which aims at prohibiting the use of permanent dermal fillers for other than reconstructive purposes, under Article 14b of Directive 93/42/EEC. As justification for the measure, the Netherlands invoked the risk of severe disfigurement that can be caused by the use of permanent dermal fillers. The Dutch authorities consider that the risks of such implications are not outweighed by the benefits of using permanent dermal fillers solely for aesthetic purposes.

Moreover, the Dutch authorities informed that the Dutch Association for Plastic Surgery has published a field standard stating that permanent dermal fillers must be used with restraint and only under strict conditions. In practice, this field standard has already led to a minimisation in the use of these products. It is expected, therefore, that the abovementioned ban will have little effect on the sale of these products in the Netherlands.

In the view of the Commission, the products that the draft decree aims to ban are those intended by the manufacturer for medical purposes only (i.e. reconstructive purposes) and which may be used 'off label' for aesthetic purposes, as well as those intended by the manufacturer to be used for both a medical purpose and an aesthetic purpose and which would also qualify as medical devices and would, by consequence, be covered by the medical devices legislation. Therefore, the Commission considers that although the ban only concerns the aesthetic use of permanent dermal fillers, it could restrict the placing on the market of products which do qualify as medical devices.

Products presented as intended only for aesthetic use may fall outside the scope of the national medical devices legislation. Therefore, the Commission invites the Dutch authorities to consider whether the ban should only be included in the medical devices decree or also in other national legislation under the scope of which would fall products that are only intended for an aesthetic purpose.

A consultation in accordance with Article 14b on the envisaged ban took place on 17 November 2014 at the occasion of the meeting of the Medical Devices Expert Group. It gave the opportunity to both Member States and other stakeholder representatives to express their views on the proposed measure.

In the course of the discussions, the justification invoked by the Netherlands following the risk assessment done at national level was not put into question — neither by other Member States, nor by the stakeholders. Nevertheless, Member States did not consider it necessary to extend the ban to the territory of the Union, in particular, due to the different approaches to the qualification of such products.

Given the rationale presented by the Netherlands and the outcome of the consultations, the Commission considers that the risks associated with the use of permanent dermal fillers justify their ban for purely aesthetic purposes.

[1] OJ L 169, 12.7.1993, p. 1.

Based on the above, the Commission considers that the Dutch decree amending the Medical Devices Decree banning the use of permanent dermal fillers for aesthetic purposes is justified.

Done at Brussels, 22 July 2015.

For the Commission

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Member of the Commission