Draft Decree relating to the restoration of certain medical devices to good working order - RGWO (Remise en Bon Etat d'Usage)

Contribution from Invacare France Operations

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Invacare France Operations manufactures and distributes Manual Wheelchairs in France, producing approximately one hundred thousand wheelchairs per year. Concerned about compliance with all applicable regulations, in particular French Laws (Code de la Santé Public) and EU Regulation 2017/745, and committing to ensure safety and performance of wheelchairs used by patients, we would like to bring to your attention some important points of the Draft Decree related to the Restoration of certain medical devices to Good Working Order (RGWO-Remise en Bon Etat d'Usage), that we think are in violation of some articles of EU Regulation 2017/745 and also in violation of EU Principle about Free Movement of Goods & Services.

Invacare France Operations is mainly concerned by 5 important points that are described in this Degree and we think are clearly in violation with the following 2 EU Regulations:

- EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices which describes requirements to ensure product safety & performances; and establishes Operators responsibilities
- Principle about Free Movement of Goods and Services.

Point 1:

Article R. 5212-44 that the Draft Decree plans to insert into the Public Health Code defines the RGWO as *"all maintenance and servicing operations carried out on that device for the purpose of a new distribution, in accordance with the manufacturer's instructions provided for in the instruction manual, when it has already been put into service, with the exception of products refurbished within the meaning of Article 2(31) of Regulation (EU) 2017/745 of 5 April 2017".*

The RGWO would not then correspond to "fully refurbishing" according the MDR 2017/745.

But the sentence:
"*The restoration to good working order enables to restore the function of the device in accordance with the intended purpose indicated by the manufacturer, covered by the EC marking, without altering the performance, technical and functional characteristics, in particular as regards hygiene and safety. It enables to extend the duration of use of the medical device beyond the service life provided for by the EC marking, within the limit of a period fixed by order of the Ministers responsible for health and social security, if necessary according to the category of device concerned.*"

Says exactly the opposite, means it falls in the meaning of what MDR 2017/745 about "Fully refurbishment: … rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device".

By extending the lifetime and doing full refurbishment, we consider that the Draft Decree is in contradiction with the requirements of Regulation 2017/745 for fully refurbished devices.

Point 2:

The aim of the RGWO to "enables to extend the duration of use of the medical device beyond the service life provided for by the EC marking" means that the person who is doing the RGWO give a new lifetime to the Medical Device which fall under the scope of the Manufacturer according to MDR 2017/745.

How the Legal Manufacturer according to MDR 2017/745 can be responsible for Safety and Performance of a medical device when a third-party operator carrying out the RGWO changed the device by extending its lifetime and becoming a new Manufacturer? Keeping on the device the original labelling where the Legal Manufacturer is stated.

By extending the lifetime of device already put into the Market, we consider that the Draft Decree is in contradiction with the requirements of Regulation 2017/745 for the Manufacturers' Responsibilities, and as a consequent limit the Principle about Free Movement of Goods and Services because the MDR 2017/745 defines Economical Operators

For these reasons, we consider that the Draft Decree does not ensure a sufficient level of health safety that required by the EU regulation 2017/745 and that it therefore creates serious risks for the users of devices that would be restored to good working order.

Point 3:

The Draft Decree introduces a new Device Identification by setting the database "ECO-DM" where only the entities carrying out the RGWO will have access to this database.

We consider that affixing a second "UDI" is in the violation of Article 27 of the MDR EU 2017/745. According to Article 27 of EU 2017/745 the UDI is in responsibility of the Manufacturer.

We also consider that affixing a second "UDI" and allowing access to ECO-DM only to French entities carrying out the RGWO is in violation of the Free Movement of Goods and Services in Europe, preventing Manufacturers from information on the Medical Devices they are responsible for according to EU 2017/745 and preventing Manufacturers from fulfilling their Legal obligations in terms of Post Market Surveillance and Vigilance.

Point 4:

According to the draft of the Decree:"approval is mandatory for carrying out any activity related to restoration to good working order regardless of the operator". As a consequent, the Operators carrying out these activities must therefore obtain certification attesting to the compliance of their practices with the requirements defined by a new French Standard.

As a consequent, when the RGWO is carried out by the Legal Manufacturer of the medical device, it is obliged to obtain a second Certification attesting to the conformity of its practices with the French Standard, obliging the Manufacturers carrying out the RGWO to implement a double Certification of their Quality Management

System, because they are already obliged by the MDR 2017/745 to implement a Certification for their Quality Management System for their CE Marking.

We consider that this second obligation by the French authorities on Legal Manufacturers constitutes a disproportionate obstacle to the free movement of goods and services.

Point 5:

According to the Draft Decree the devices that have been RGWO in France can only be put into service in French Market. And thus, a Legal Manufacturer or a Distributor based in Europe but out of France are not able to carry out any RGWO and distribute in French Market, which create a disproportionate restriction on the Free Movement of Goods.

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