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Draft Decree relating to the restoration of certain medical devices to good working order

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I. Context

On 24 March 2023, France notified the TRIS portal of a draft decree relating to the restoration of certain medical devices to good working order (hereinafter the "**Draft Decree**").

This is a text implementing Articles L. 5212-1-1 of the Public Health Code and L. 165-1-8 of the Social Security Code, resulting from Article 39 of Law No. 2019-1446 of 24 December 2019 on the financing of social security for 2020 ("**LFSS for 2020**").

Article 39 of the LFSS for 2020 provides in substance that:

- certain medical devices for individual use, whether or not they are reimbursed, may be subject to a *"restoration to good working order"* ("**RGWO**") with a view to reuse by patients other than those who initially used them. The implementation of RGWO is subject (i) to compliance with criteria guaranteeing the quality and safety of the device and (ii) to an approval procedure for centres or professionals authorised for this activity[1];

- furthermore, some products restored to good working order may be reimbursed by social security if they are registered on the list of reimbursable products and services. It is specified that

[1] Article L. 5212-1-1 of the Public Health Code.

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reimbursement may be conditional (i) on the one hand, on the commitment of the insured person to return to an approved centre the product that have been or may be restored to good working order and (ii) on the other hand, on the identification of the product by means of a code specific to it and on the transmission of information relating to its release, to the identification of the patient benefiting from it and to the repair and maintenance operations[2].

The LFSS for 2020 specifies that the modalities of application of these provisions will be set by a Council of State decree. This is the purpose of the Draft Decree notified by France.

The Draft Decree defines in particular the notion of RGWO, the regulatory framework for this activity, the rules for the distribution of products restored to good working order, the modalities for identifying products restored to good working order and the functioning of the "ECO-DM" database.

Snitem welcomes measures to encourage and regulate the reuse of medical devices by patients different from those who initially used them. However, such measures must necessarily take into account:

- on the one hand, secondary Union legislation, and in particular Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("**Regulation 2017/745**"), which sets out measures to ensure product safety and establishes the responsibilities of the various operators;

- on the other hand, the four freedoms and in particular the free movement of goods and the freedom to provide services.

Nonetheless, Snitem wishes to draw the Commission's attention to the fact that the Draft Decree, as written, would be in contradiction with Regulation 2017/745 and the principles of free movement of goods and services.

II. Issues related to the conformity of the the Draft Decree with Regulation 2017/745

1. On the definition of RGWO and its consequences

- **Provisions contained in the Draft Decree (Article 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"*.

[2] Article L. 165-1-8 of the Social Security Code.

France thus considers that the RGWO would not correspond to "fully refurbishing" within the meaning of Regulation 2017/745 and would therefore not fall within the scope of the areas harmonised by Regulation 2017/745, as is clear from the impact study of the LFSS for 2020 and the notification of the Draft Decree to the Commission[3].

- **As defined by the Draft Decree, the RGWO corresponds to the notion of "fully refurbishing" within the meaning of Regulation 2017/745**

Regulation 2017/745 defines fully refurbishing as, *"the complete rebuilding [in French "restauration"] 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"*.

Fully refurbishing is therefore characterised by the combination of two elements: (i) on the one hand, the restoration of a medical device already placed on the market or put into service and (ii) on the other hand, the assignment of a new lifetime to this device.

However, these two elements are precisely those that characterise the RGWO according to the Draft Decree. The latter is in fact defined as:

- *"all maintenance and servicing operations carried out on that device [corresponding to a restoration of the device[4]] for the purpose of a new distribution [...] when it has already been put into service"*;

- *"enabl[ing] to extend the duration of use of the medical device beyond the service life provided for by the EC marking".*

All in all, **despite some differences in terminology, RGWO as defined by the Draft Decree is indeed a fully refurbishing operation within the meaning of Regulation 2017/745**.

Moreover, it must be noted that the RGWO does not fall within the activities covered by the third recital of Regulation 2017/745, which states that *"this Regulation does not seek to harmonise rules relating to the further making available on the market of medical devices after they have already been put into service such as in the context of second-hand sales"*. Indeed:

- it is clear from the wording of this provision that it refers to cases of transfer of second-hand medical devices for reuse by another patient, without any intention of extending the lifetime of the device;

- these operations are already regulated at national level by Articles R. 5212-35-1 to R. 5212-35-6 of the Public Health Code, relating to the resale of second-hand medical devices. As stated in Article R. 5212-35-1, *"resale of a second-hand medical device is understood to mean any transfer of a medical*

[3] In the impact study of the LFSS for 2020, the French Government stated that *"the measure [RGWO] falls within the sole competence of France"*. France was careful to specify in the notification of the Draft Decree that *"Regulation (EU) 2017/745 of 5 April 2017 on medical devices does not harmonise the provisions governing the making available on the market of medical devices after they have already been put into service, in particular in the context of second-hand sales (recital 3)"*.

[4] The impact study of the LFSS for 2020 specifies that *"The measure [the RGWO] also allows for the reimbursement of restored medical devices, provided that this reuse is relevant".*

device that is neither new nor fully refurbished". However, the Draft Decree neither modifies nor removes the provisions governing the resale of second-hand devices. The concepts of second-hand devices and devices restored to good working order are therefore perfectly distinct under national law. Thus, France cannot rely on the third recital of Regulation 2017/745, which is already "translated" into national law by the provisions governing the resale of second-hand medical devices, to justify the new framework of the RGWO.

From all the above, it is clear that **the RGWO, as defined by the Draft Decree, falls within the scope of the areas harmonised by Regulation 2017/745**.

- **However, the Draft Decree is in contradiction with the requirements of Regulation 2017/745 for fully refurbished devices**

Fully refurbished medical devices are considered by Regulation 2017/745 as devices leaving the manufacturing process. The operator carrying out this activity must therefore comply with all the requirements imposed on the legal manufacturer. In particular, he must affix a new EC marking to the fully refurbished device attesting to the conformity of the device with the essential safety and clinical benefit requirements laid down by Regulation 2017/745.

However, Snitem notes in particular that, in the current wording of the Draft Decree:

- the operator carrying out the RGWO does not become the legal manufacturer of the device. Indeed, Article R. 5212-46 of the Public Health Code merely provides that this activity is carried out by approved centres or professionals, without giving them the status of legal manufacturer within the meaning of Regulation 2017/745;

- no new EC marking is affixed to devices restored to good working order. Indeed, Article R. 5212-46 of the Public Health Code only provides that the ministers responsible for health and social security shall set a standard defining the conditions under which the RGWO is performed. Moreover, the Draft Decree does not provide for the standard to be notified under the TRIS procedure, even though it is a technical regulation within the meaning of Directive (EU) 2015/1535.

All in all, **insofar as it allows, without having to comply with the requirements of fully refurbishment, the distribution of restored devices to which a new lifetime has been assigned, the Draft Decree is contrary to Regulation 2017/745**.

Beyond the contradiction of the Draft Decree with Regulation 2017/745, Snitem wishes to draw the Commission's attention to the significant risks that this text creates in terms of health safety.

On the one hand, the Draft Decree allows an operator who is not the legal manufacturer of the device to extend the lifetime of the device without a full EC marking assessment procedure.

According to Article R. 5212-46, it will be sufficient for an operator to obtain a certificate attesting to the compliance of his practices with a standard to be defined by the ministers - the content of which is not known - for him to be able to extend the lifetime of the device.

On the other hand, the Draft Decree seems to allow the RGWO - and lifetime extension - of non-reusable products (such as implantable medical devices for example).

Indeed, Article R. 165-4 of the Social Security Code, as amended by the Draft Decree, reads as follows *"The following may not be included on the list [of reimbursable products and services] [..] (6) Medical devices included in the [of products that may be subject to a RGWO] which are not declared as reusable in the EC marking"*.

It is therefore understood that the list of products eligible for a RGWO would include products declared as reusable in the EC marking but also non-reusable products (and that only the former would be eligible for reimbursment).

Finally, Snitem is alarmed by the total absence of effective protection relating to the certification of operators carrying out the RGWO for a period likely to be more than five years following the entry into force of the decree.

Indeed, as an exception to Article R. 5212-46, which requires these operators to be certified by a body specially authorised for this purpose, Article 3 of the Draft Decree provides that, for a period of up to 18 months following the entry into force of the Decree, operators carrying out the RGWO will be approved simply by sending the Director General of the National Agency for Medicinal and Health Products their commitment to ensure that their practice complies with the above-mentioned standard.

However, it can be deduced from the V of Article R. 5212-46 that this approval is valid for a period of up to four years!

For these reasons, **Snitem considers that the Draft Decree does not ensure a sufficient level of health safety and that it therefore creates serious risks for the users of devices that would be restored to good working order**.

2. On the affixing of the UDI

- **Provisions contained in the Draft Decree (Article 2)**

Pursuant to II of Article L. 165-1-8 of the Social Security Code, the ministers may issue an order to include medical devices that have been restored to good working order or that may be the subject of a RGWO on the list of reimbursable products and services.

In this case, the Draft Decree provides that the ministerial order may make the reimbursement of medical devices conditional on their identification in the information system known as "ECO-DM" (Article R. 165-106 of the Social Security Code).

Article R. 165-107 that the Draft Decree plans to introduce into the Social Security Code specifies that this identification in the ECO-DM system consists of *"the affixing to the product, by an authorised operator, of the unique device identifier (UDI) provided for in Article 27 of Regulation (EU) 2017/745 of 5 April 2017 on medical devices"* and specifies that *" The application for affixing [the UDI] shall be made by the operator ["exploitant"] of the product before the first commissioning of the product".* No exception is made for devices

for which a UDI would not be affixed and which would be put into service or taken in charge after the entry into force of the decree[5].

It should be noted that:

- *"identification operators meeting the conditions of solvency, competence and reliability defined by order of the ministers"* may be approved to affix the UDI (Article R. 165-109);

- the "exploitant" of the product is, within the meaning of Article L. 165-1-1-1 of the Social Security Code, *"the manufacturer, the latter's representative or a distributor operating the product"*.

In total, Articles R. 165-107 to R. 165-109 allow a non-manufacturer (the distributor) to ask another non-manufacturer (the authorised operator) to affix an UDI to the device, whether or not the device already has an UDI.

- **Contradiction of the UDI provisions with Regulation 2017/745**

Insofar as they allow a non-manufacturing operator to request another non-manufacturing operator to affix a UDI to the device, the above provisions are contrary to Regulation 2017/45, and in particular to the legal manufacturer's monopoly to affix an UDI created in accordance with the rules laid down by the issuing entity designated by the Commission to the device and, where applicable, to the higher packaging levels[6].

Furthermore, Article R. 165-107 refers to medical devices that have not yet been put into service, i.e. new medical devices. Regardless of how one defines the RGWO, this provision therefore leads to medical devices to which an UDI is already affixed by the manufacturer pursuant to Regulation 2017/745 - on a mandatory or on a voluntary and early basis depending on the class of the device - being assigned an additional UDI affixed at the request of the distributor.

In total, **the provisions of the Draft Decree relating to the identification of devices that have been or may be restored to good working order (Articles R. 165-106 to R. 165-110) are contrary to Regulation 2017/745 insofar as they relate to the affixing of the UDI**.

- **Early application of Regulation 2017/745 for Class I, IIa and IIb devices**

As indicated above, the Draft Decree provides that the reimbursment of devices that may be restored to good working order may be subject to their identification in the "ECO-DM" system, which requires the affixing of the UDI provided for in Article 27 of Regulation 2017/745 to the device.

However, the affixing of the UDI required by Article 27(4) of Regulation 2017/745 will only apply to reusable devices from 26 May 2025 for Class IIa and IIb devices and from 26 May 2027 for Class I devices[7].

[5] Article 3 II of the Draft Decree only provides for transitional provisions for devices that do not have an UDI if they were put into service and reimbursed before the entry into force of the decree.
[6] Article 27(3) of Regulation 2017/745 and point 2.3 of Part C of Annex VI
[7] Article 123(3)(g) of Regulation 2017/745.

The Draft Decree would therefore require reusable devices falling under Classes I, IIa and IIb - so in practice the devices it is primarily aimed at[8] - to apply Regulation 2017/745 in advance, in violation of Article 123 thereof.

For this reason again, **the provisions of the Draft Decree relating to the identification of devices that are or may be restored to good working order are contrary to Regulation 2017/745 insofar as they apply to Class I, IIa and IIb devices.**

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For all the above reasons, Snitem considers that the Draft Decree is contrary to Regulation 2017/745.

III. Issues related to the compatibility of the Draft Decree with principles of free movement of goods and services

3. The Draft Decree imposes a double certification obligation on manufacturers carrying out a RGWO activity

Article R. 5212-46, which the Draft Decree proposes to introduce into the Public Health Code, provides that the *" approval is mandatory for carrying out any activity related to restoration to good working order regardless of the operator"*. Operators carrying out these activities must therefore obtain certification attesting to the compliance of their practices with the requirements defined by a ministerial standard.

As stated in Article R. 5212-45, the purpose of the standard is to guarantee the quality and safety of use of medical devices.

In total, therefore, when the RGWO is carried out by the legal manufacturer of the medical device, it is obliged to obtain a certification attesting to the conformity of its practices with a French standard relating to the quality and safety of use of medical devices.

However, the assessment of the manufacturer's quality management system is already carried out at the stage of obtaining the EC marking.

The Draft Decree would therefore subject manufacturers carrying out a RGWO activity to a double obligation of certification of their practices.

Insofar as it duplicates the control carried out in the context of EC marking, **the control thus imposed by the French authorities on legal manufacturers constitutes a disproportionate obstacle to the free movement of goods and services**.

[8] The impact study of the LFSS for 2020 states that *"This measure [the RGWO] will facilitate access to certain medical devices for which there are currently significant remaining costs for the patient, such as wheelchairs"*.

4. The Draft Decree does not allow the putting into service in France of devices that have been restored to good working order in another Member State

Article L. 5212-1-2 of the Public Health Code allows the RGWO of certain medical devices for reuse by patients different from those who initially used them, subject to compliance with the conditions, set by a Council of State decree, *"under which certain medical devices may be the subject of a [RGWO] as well as the conditions for carrying out the approval procedure"*.

In other words, it will only be possible to put into service in France devices that have been the subject of a RGWO if the conditions, at this stage set out in the Draft Decree, are met.

However, the Draft Decree implicitly requires that the RGWO activity takes place in France.

Indeed, Article R. 5212-46 that the Draft Decree plans to introduce into the Public Health Code specifies that *"the Director General of the Regional Health Agency or the Departmental Directorates for the Protection of Territorial Populations on the basis of the place where this activity of restoration to good working order is carried out"* receive the decision to certify the activity of the RGWO (paragraph IV), may request a copy of the audit reports used for certification (paragraph VI), may refer the matter to the certification body in order to organise a control audit (paragraph VIII), are informed of the failings of operators carrying out a RGWO activity (paragraph IX) and are informed of decisions to suspend or withdraw the certification of these operators (paragraph X).

Furthermore, the Draft Decree does not contain a "single market clause" which would allow the putting into service of devices from another Member State of the Union or party to the EEA Agreement if (i) these devices comply with a technical rule which is mandatory for the RGWO in one of these States and (ii) this technical rule makes it possible to ensure a level of health protection and safety equivalent to that sought by the Draft Decree.

All in all, **the Draft Decree prevents the putting into service in France of devices that have been restored to good working order in another Member State of the Union or party to the EEA Agreement, regardless of whether the RGWO was carried out in accordance with a technical rule ensuring an equivalent level of protection or whether it was carried out in accordance with the ministerial standard provided for by the Draft Decree.**

On this ground too, the Draft Decree creates disproportionate restrictions on the free movement of goods. The Commission also issued a detailed opinion on the draft decree on the resale of second-hand medical devices on the grounds that it did not ensure the recognition of any equivalent certificates already established in other Member States[9].

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It follows from the above that, if the Draft Decree were adopted as it stands, it would create a disproportionate obstacle to the free movement of goods and services within the Union or the EEA.

[9] TRIS notification 2006/0550/F.

IV. Conclusions

In accordance with the principle of primacy of Union law, France should refrain from adopting legislation which, as in the case of the current Draft Decree, would be manifestly contrary to Regulation 2017/745 and would create a disproportionate obstacle to the free movement of goods and services.

Snitem therefore asks the Commission to issue a detailed opinion concluding that the Draft Decree is not in conformity with Regulation 2017/745 and with the principles of free movement of goods and services, for the reasons set out in this contribution.

If France were to maintain the Draft Decree, it would appear necessary for Snitem to make at least the following changes:

- remove the possibility of extending the period of use of devices that have been restored to good working order[10];
- specify that the standard defining the conditions under which the RGWO is carried out, which will be set by ministerial order, must be notified in advance to the Commission under the TRIS procedure[11];
- remove the requirement for legal manufacturers of devices restored to good working order to be approved for the RGWO[12];
- clarify that inclusion in the list of devices that can be restored to good working order is not possible for non-reusable devices[13];
- remove the possibility for operators other than the device manufacturer to affix the UDI to the device[14];

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[10] Article R. 5212-44 of the Social Security Code could be rewritten as follows: "*The restoration of a medical device to good working order within the meaning of Article L. 5212-1-1 corresponds to 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. 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, or extending its lifetime. It differs from fully refurbishing within the meaning of Article 2(31) of Regulation (EU) 2017/745 of 5 April 2017.*"

[11] Addition of the sentence *"This standard constitutes a technical regulation subject to the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services"* at the end of II of Article R. 5212-45.

[12] Substitution of the sentence *" This approval is mandatory for carrying out any activity related to restoration to good working order regardless of the operator"* by the sentence *"This approval is mandatory for carrying out any activity related to restoration to good working order, except where the operator performing the restoration to good working order is the manufacturer of the medical device".*

[13] Addition of the sentence *"Devices which are not declared as reusable in the EC marking may not be included in this list"* at the end of Article R. 5212-45, I.

[14] Articles R. 165-107 to R. 165-109.

- remove the possibility for operators carrying out the RGWO to be certified simply by submitting their commitment to comply with the ministerial standard for up to 18 months following the entry into force of the decree[15];

- specify that the Draft Decree does not prevent the putting into service of devices that have been returned to good working order in a Member State of the Union or party to the EEA Agreement, if an equivalent level of protection is provided.

[15] Deletion of Article 3 I of the Draft Decree.