France Simplifies Regulations for Implantable and Class III Devices

Decision of the Council of State: The RCD decree concerning the need to send to ANSM, the French NCA, a summary of the characteristics for Class 2b implantable and 3 devices, has no legal basis and can only be canceled

Seized by the SNITEM and MEDTECH, the French Supreme Court (Conseil d'Etat) has, in a judgment rendered on April 26, 2018, cancelled the decree n ° 2016-1716 of December 13, 2016 relating to the summary of the characteristics of the medical device (RCD) requesting a large information on clinicals for Class 2b implantable and Class 3.

The ruling came in response to a challenge by SNITEM, the French medical device syndicate, which argued successfully that the industry should comply with the summary of safety and clinical performance required under the EU's 2017 Medical Device Regulation.

Facts:

We remember that the law of January 26, 2016 to modernize our health system has inserted in the Public Health Code (CSP) an article L 5211-4-1 which provides that during the commissioning in the national territory of medical devices whose list is fixed by ministerial decree, the manufacturers or their agents transmit to the ANSM a summary of the characteristics of their device. The decree implementing this new provision was adopted on December 13, 2016 and entered into force on July 1, 2017. Article 1 of the decree provides that the devices subject to the transmission obligation set by law are implantable devices and class III devices. The II of this article fixes the composition of the file to be notified to the Agency.

Decision:

The Conseil d'état considers in turn that the legislative provision in question is incompatible with the objectives of the directives on medical devices, whether it is Directive 90/385 / EEC on active implantable medical devices or Directive 93 / / 42 relating to other devices, so that the decree cannot find its legal basis in the article of law (1). Having thus rejected the contrary law, the Council then directly confronts the decree with the two directives DM (2a), then with the future European regulation (2b), to conclude that neither one of these texts of law "derived "Cannot serve as a legal basis for the decree (2). Noting that the decree has no legal basis, neither in domestic law nor in European law, it declares its annulment (3).

1) **Article L 5211-4-1 of the CPMP is not compatible with the objectives of Directives 90/385 and 93/42 / EEC:**

In order to arrive at this first conclusion, which is necessary for it to decide whether the decree whose annulment is sought from it finds its legal basis in the legislative article, the Conseil d'état points out that clearly (...) the general scheme of the directives that these are intended to ensure full harmonization of national provisions relating to the placing on the market and putting into service of active implantable medical devices and other medical

devices, in order to guarantee, in compliance with the rules they lay down, the free movement of these devices. Consequently, a Member State could not, without disregarding the objectives of those directives, impose an additional obligation relating to the placing on the market or the putting into service of these devices accompanied by sanctions, in particular criminal sanctions, in case of ignorance of this obligation This leads logically the Council to dismiss the legislative article which cannot therefore serve as a legal basis for the decree, from the moment it does not comply with European law, which takes precedence over it (see point 6).

2) The decree cannot find its legal basis either in the harmonization directives (a) or in the future European regulation (b):

a) In the absence of a legislative basis, can the decree directly find its legal basis in the directives? The visas of the Decree refer to Article 14b of Directive 93/42 on health surveillance measures. But the High Court finds that, contrary to the Ministry's contention, this article "is not intended to authorize the introduction of transitional provisions in the event of a change in the applicable standards, but only to allow a Member State to which considers that it is necessary (...) to prohibit or subject to particular requirements the placing on the market and putting into service of a given product or group of products, to take all necessary and justified transitional measures, pending that the Commission gives its opinion on the justification of the national measures". This leads to the finding that neither Article 14b nor any other Article of Directive 93/42 or Directive 90/385 can serve as a legal basis for the contested decree (paragraph 5 of the judgment).

b) In the absence of a legislative basis, can the Decree directly find its legal basis in Article 32 of the new European Regulation? This is probably the most interesting part of the judgment since the Council of State is, quite unusually, led to decide on the scope of a provision that had not yet entered into force on 13 December 2016, date of the signing of the decree. The judge is led to this quite unusual solution if he wants to respond to the argument developed by the Ministry and that France has only anticipated the entry into force on May 26, 2020, the new regulation Article 32 provides for an obligation for implantable devices and Class III devices to notify the notified body of a dossier the content of which is substantially identical to that provided for by the contested decree. However, the answer to this argument circumscribes the operators' room for maneuver during the transitional period, during which the Regulation entered into force without being yet applicable.

The Council considers that the transitional period between the date of entry into force of the new Regulation (25 May 2017) and the date of its effective application (26 May 2020) only allows "by way of derogation from the Directives, the placing on the market of market for medical devices complying with the Regulation, in particular in order to enable economic operators to adapt to the amendments introduced by the 'Regulation' and does not authorize Member States to derogate from 'the Directives in order to impose the early application in their territory of the Regulation"

This is therefore a recital in principle which goes far beyond the sole case of the RCD decree and which sets the operators' margin of maneuver, the only ones being able to derogate from the directives, which are still applicable, by applying the regulation in advance, which the public authorities are not allowed to do. In other words, the transitional period is granted to the exclusive advantage of the industrialists, who are the only ones allowed to anticipate its application. Article 32 of the new regulation, relied on in defense, cannot, in turn, serve as a legal basis for the contested decree, which thus has no legal basis and can only be annulled

3) Without a legal basis, the contested decree can only be annulled:

This finding inevitably leads the High Authority to annul the decree referred to it. This outright cancellation is retroactive. It therefore takes effect on 1 July 2017, the date fixed by the decree for its entry into force, so that the annulled decree is deemed never to have existed.

It follows that companies that have executed and notified to ANSM an RCD of their products and who would be able to justify the additional cost representing the cost of the performance of this obligation can therefore obtain compensation within the framework of a litigation of State responsibility. If companies have been sanctioned for non-execution of the decree, they can similarly request the restitution of the fine imposed.

26.04.2018, Council of State, SNITEM, req. 407982