Public Law Remark

Analysis of the Judgment of the ECJ of 7 December 2017 (Case C-329/16), which clarifies when a computer program is a medical device

22nd december 2018

What was discussed:

The French National Union of the Medical Technology Industry questioned whether the submission to a certification obligation for certain software which, being within the scope of Directive 93/42/EEC, is in conformity with the provisions of that directive or whether, on the contrary, that obligation, as laid down in its internal rules, is contrary to the objectives set out in Article 4 thereof, which prohibits the restriction of marketing or placing on the market or putting on the market of certain software products.

The finding of the Court of Justice:

To resolve the case, the ECJ decided on the basis of Article 1 (2)(a) of the Directive, as amended by Article 2 of Directive 2007/47, which states in recital 6 that a computer program is a medical device when it is specifically intended for one or more of the medical purposes set out in the legal definition of those products by its manufacturer.

It follows from that provision that, for a computer program to be regarded as a medical device, it must satisfy two conditions cumulatively:

On the one hand, **the intended purpose**: the purpose of medical devices must be to be used in human beings for the diagnosis, prevention, control, treatment or alleviation of a disease or, where appropriate, the diagnosis, control, treatment, alleviation or compensation of an injury or deficiency. In other words, it is not enough for a computer program to be capable of being used in a health context, but it is necessary for its purpose to be specifically medical.

And it makes it clear: *"A computer programme which compares the patient's own data with the medicinal products which the doctor intends to prescribe, thereby being capable of automatically providing the patient with an analysis to detect, in particular, possible side-effects, drug interactions and excessive doses, is used for the purposes of prevention, control, treatment or alleviation of a disease and therefore pursues a specifically medical purpose, which makes it a medical device within the meaning of Article 1, paragraph 2 (a) of Directive 93/42/EEC. It is not the same thing, he continues, with a computer program that, "although it is also called upon to be used in a health context, its sole purpose is to archive, recompile and transmit data, such as a computer program for storing the patient's medical data..."*.

On the other hand, **the action taken**: i.e. whether a computer program, which does not act on its own within or on the surface of the human body, may constitute a medical device within the meaning of Directive 93/47.

In this respect, the Court of Justice of the European Union replied that the Directive requires that action inside or on the surface of the human body should not be obtained exclusively by pharmacological, immunological or metabolic means, but does not necessarily require that the product must be used directly inside or on the surface of the human body. In addition, it was specifically intended by the legislator to introduce the consideration of certain software as a medical device, as Directive 2007/47 was in line with this. To understand something else *"would in practice be to exclude from the scope of Directive 93/42 software which is specifically intended by the manufacturer to be used for one or more of the medical purposes listed in the definition of medical device, whereas the Union legislature wished, by Directive 2007/47, that such software should be covered by that definition, whether or not it acted directly within or on the surface of the human body."*

The judgment therefore concludes that, for a computer program to be classified as a medical device, it does not matter whether it acts directly on the human body or not, since the essential thing is that its purpose corresponds to those of a medical device. In support of his thesis, he cites the Commission's guidelines on the qualification and classification of stand-alone software used in the health sector within the regulatory framework for medical devices, which provide similar criteria.

What was concluded:

In short, the CJEU concludes that a software programme, such as the case under trial, with a functionality that allows the exploitation of patient data to detect side-effects, drug interactions and excessive doses, constitutes, as far as this functionality is concerned, a medical device, even if it does not act directly within the human body. When they are placed on the market, they must therefore carry the CE standard of conformity and, in accordance with Article 17 (1) of Directive 93/42/EEC, may be marketed and circulated freely throughout the Union without any additional certification procedure.

It should be stressed that the Court refers to this functionality in particular, since if a medical programme simultaneously includes modules which respond to the concept of a medical device with modules which are not ancillary to the medical device, in the sense of the Directive, only those modules fall within its scope and must be marked with an CE standard, the manufacturer being obliged to identify which modules constitute medical devices for that purpose.

The Commission guidelines on the qualification and classification of stand-alone software used in the health sector within the regulatory framework for medical devices can be found at the following link

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