FURTHER GUIDANCE FROM THE CJEU ON E-HEALTH

By recently ruling that a drug prescription assistance software qualified as a medical device, the CJEU has indirectly sent a reminder to IT companies seeing new opportunities in health care that their technology may fall under EU regulation.

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As underlined in the opinion issued by the Advocate General in the important case ruled upon by the Court of Justice of the European Union (CJEU) on December 7, 2017 (Case C-329/16), since software *"is becoming increasingly important in the health sector"* and *"its characteristics must meet high levels of safety and health protection"*, *"it is undoubtedly important to specify the criteria which software must fulfil in order to classify as a medical device"* as per EU regulation.

This is what the CJEU endeavored to do in this case, when given its first opportunity – by a request for a preliminary ruling raised by the French Council of State *(Conseil d'Etat)* – to rule on the interpretation of Article 1(2)(a) of the European Medical Devices Directive 93/42/EEC as modified by Directive 2007/47 ("Directive 93/42") directly in connection with software.

BACKGROUND OF THE CASE

The software at issue, named "Intellispace Critical Care and Anesthesia" (ICCA), was developed by Philips France (Philips). It is a drug prescription assistance software used in anaesthesia services and intensive care units, which helps physicians determine the appropriate prescription of drugs by providing information relating to possible contraindications, drug interactions and excessive doses.

Philips has obtained CE marking for its ICCA software, which implies that it meets the requirements set out by Directive 93/42, and that pursuant to Article 4(1) of said Directive, Philips should therefore be able to place it on the market without any obstacle from the Member States.

However, France adopted in 2014 a new Decree (no.2014-1359) that required that *"all software whose purpose is to offer support for carrying out drug prescription"*, including that bearing the CE marking, be certified by the national authority.

THE FRENCH PROCEEDINGS AND THE REQUEST FOR A PRELIMINARY RULING

Philips, together with the professional organization SNITEM (which represents the French medical technologies industry) brought actions before the French Council of State in order to challenge the legality of this national certification requirement for drug prescription assistance software that already meets the requirements of Directive 93/42.

The Council of State was uncertain as to whether the ICCA software should actually be considered as a medical device within the meaning of Article 1(2)(a) of Directive 93/42. It therefore stayed the French proceedings and requested a preliminary ruling from the CJEU, asking whether drug assistance prescription software does constitute such a medical device *"where that software has at least one function that permits the use of data specific to a patient to help his doctor issue his prescription, in particular by detecting contraindications, drug interactions and excessive doses, even though it does not itself act in or on the human body"*.

THE DECISION ISSUED BY THE CJEU

The two cumulative criteria set forth by Article 1(2)(a) of Directive 93/42 for classification as a medical device pertain to (i) the objective pursued by the product (it must be intended *for use in humans for the purposes, in particular, of the diagnosis, prevention, monitoring, treatment or alleviation of a disease, and the diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap)*, and (ii) the action resulting in or on the human body from the objective pursued.

All software used in the health sector may not, therefore, qualify as a medical device, as confirmed by Recital 6 of Directive 2007/47 which distinguishes software that is *"specifically intended to be used for one or more of the medical purposes set out in the definition of a medical device"* from *"software for general purposes when used in a healthcare setting"*.

Before the CJEU, the French Government sustained that the ICCA software does not serve any of the medical purposes set forth by Directive 93/42 because: (i) it is not used for diagnostic or therapeutic purposes, and (ii) it is not intended for investigation, replacement or modification of the anatomy or of a physiological process or for the control of conception.

After a thorough analysis of the ICCA software's functionalities, the CJEU took the opposite view and, following the opinion issued by the Advocate General, ruled that Philips' software does meet the two cumulative criteria set forth by Article 1(2)(a) of Directive 93/42.

As far as the first criteria is concerned, the Court considered that *"software that cross-references patient-specific data with the drugs that the doctor is contemplating prescribing, and is thus able to provide the doctor, in an automated manner, with an analysis intended to detect, in particular, possible contraindications, drug interactions and excessive dosages, is used for the purpose of prevention, monitoring, treatment or alleviation of a disease"* – which the Advocate General had formulated as follows: *"it is not software which acts only after the practitioner has decided on the appropriate treatment, but rather it assists the practitioner to determine the correct prescription"*.

And, as far as the second criteria is concerned, the Court addressed the Council of State's concern that the ICCA software does not *"itself act in or on the human body"* by strongly affirming that Directive 93/42 does not require that the medical device acts "***directly*** *in or on the human body"*, and that in order to preserve the effectiveness of the Directive, the focus shall be *"on the purpose of use* [of the software] *and not the manner in which the effect it is capable of producing on or in the human body is likely to materialise"* (thereby expressly referring to fulfilment of the first criteria).

The CJEU thus concluded that ***"software, of which at least one of the functions makes it possible to use patient-specific data for the purposes, inter alia, of detecting contraindications, drug interactions and excessive doses, is, in respect of that function, a medical device within the meaning of [Directive 93/42], even if that software does not act directly in or on the human body".***

In practice, software used in the health sector that goes beyond the administrative functions of storing, archiving or transmitting medical data (which, as explained by the Advocate General, may assist practitioners in prescribing drugs but does not create or modify medical information) may classify as a medical device, with a twofold consequence: a mandatory CE marking, and its free circulation in the EU without additional conformity procedures imposed by Member States.

THE STAKES OF THIS DECISION

From a French law standpoint, the CJEU decision implies that the French certification procedure imposed by Decree no.2014-1359 amounts to unlawful restriction on free flow of goods, and the Council of State should likely, when the French proceedings resume, cancel it for incompliance with EU law. However, the French Parliament surprisingly seems to ignore the fall-out from this Court decision since it has, in its December 30, 2017 Law on the funding of social security for 2018, extended this certification mechanism to new functions of software with a medical purpose.

More generally, this CJEU decision is noteworthy in the framework of the evergrowing market of medical software apps and the integration in the health sector of major high-tech companies investing massive resources in developing new offerings supported by artificial intelligence – such as the AI-based software developed by Alphabet (that predicts possible deaths of hospitalized patients) or the Health Records feature of Apple's Health app (which brings together medical data from hospitals and iPhone users).

In this perspective, the clarification by the CJEU of the criteria that software aimed at the health sector must fulfil to qualify as a 'medical device' should also be seen by these IT companies as a reminder that this area is heavily subject to EU regulation – now complemented by the Medical Devices Regulation 2017/745 (fully effective in May 2020), which sets new uniform rules and further guidance as concerns new technologies but also introduces new medical purposes for "prediction" and "prognosis" of diseases, thereby further expanding the definition of a medical device.

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