

WHEN DOES STAND-ALONE SOFTWARE QUALIFY AS A MEDICAL DEVICE IN THE EUROPEAN UNION?

- *THE CJEU'S DECISION IN SNITEM AND WHAT IT IMPLIES FOR THE NEXT GENERATION OF MEDICAL DEVICES*

Case:

Judgment in Case C-329/16 *Syndicat national de l'industrie des technologies médicales (SNITEM), Philips France v Premier ministre, Ministre des Affaires sociales et de la Santé Confédération paysanne and Others v Premier ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt* [2017]
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ABSTRACT:

This contribution analyses the first decision by the Court of Justice of the European Union (CJEU) on the qualification and regulation of stand-alone software as medical devices. Referring to the facts of the case and the applicable EU regulatory framework, the Court specifically found that prescription support software may constitute a medical device. This would even be the case where the software does not act directly in or on the human body. Yet, according to the CJEU it is necessary that the intended purpose falls within one or more of the 'medical purpose' categories of the regulatory definition of 'medical device'. The case has important implications, not only for specific legal debates. It also signifies a paradigm shift with a rapidly increasing digitalization of the health and life sciences. This highlights the demand for continuous debates over the necessary evolution of the regulatory framework applying to the interface of medical AI and Big Data.

Keywords:

Software, Medical Devices Directive, medical devices, healthcare, eHealth

I. INTRODUCTION AND BACKGROUND TO THE DECISION

The growing scope of software- applications is becoming increasingly important for the evolution of biomedical AI, as well as big data driven healthcare. This naturally leads to the question how to regulate it to safeguard the safety of patients, users and third parties. The European Union has been active in regulating medical devices and has issued Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC (Medical Devices Directive), which sought to harmonise national laws in the context of medical devices. The Directive seeks to create a presumption of conformity for medical devices through CE marking¹ necessary for the

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¹ Article 4, Medical Devices Directive.

unrestricted circulation and trade of such devices within the territory of the Union. More recently, the European legislator has issued the Medical Devices Regulation (EU) 2017/745 in May 2017 which replaces the Directive 93/42 and will become fully applicable in May 2020.²

This change in legislation has been mooted due to technological change which the legislators could not foresee at the time of its enactment in the 1990ies. The Regulation seeks “to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation”.³ The discussed decision by the CJEU already appears to cast some shadows on the reach of the incumbent Regulation which seeks to clarify the nature of software in the context of medical devices.⁴ While the decision in question is not the Court’s first on the definition of software in the context of Article 1(2) (a) of Directive 93/42, it is its first decision in this context of standalone software and was based on a preliminary reference by the French *Conseil d’État* (Administrative Supreme Court). The decision is of particular relevance since software used in this context would have to abide by more stringent conditions than software not classified as medical device.

II. FACTS

The *Syndicat national de l’industrie des technologies médicales* (‘SNITEM’) is a professional organization which represents companies in the medical devices sector. Philips France is one of the companies which manufactured and placed on the market a prescription assistance software called ‘Intellispace Critical Care and Anesthesia’ (‘ICCA’) which is used for resuscitation and anaesthesia. By inputting patient data and the intended prescribed medicine into the software, the software provides doctors and anaesthesiologists with any potential contraindications, interaction between different drugs and validates the correct dosage for the patient. It is also worth noting that the ICCA software contains the CE marking, which means that it conforms with the requirements of Directive 93/42. Software containing this CE marking should be able to enter the market in any EU Member State without any further constraints.

However, in France, the *Haute Autorité de santé* (High Health Authority) is required to determine whether certain software, including those bearing the CE marking, complies to their rules of good practice. Decree No 2014-1359 requires CE marked devices to be certified again by a national authority. If the software is found to be compliant, a certificate is then issued. According to the Decree, the purpose of the certification procedure is to improve prescription practice for medical products. SNITEM and Philips France brought an action before the *Conseil d’État* that Article 1(3) and Article 2 of Decree No 2014-1359 should be annulled. They maintained that the decree required software bearing a CE mark to have to be certified again by the national authority, which is incompatible with EU law. This additional requirement to the certification of medical devices is in breach of Article 4(1) of Directive 93/42, which requires Member States not to create any obstacles to medical devices with a CE mark entering the market in EU Member States. In the

² Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L117/1 (Medical Devices Regulation). See also: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2017] OJ L117/176, which becomes applicable in 2022.

³ Recital 1, Medical Devices Regulation.

⁴ Recital 19, Medical Devices Regulation.

French Administrative Supreme Court, the judges were unclear as to whether the ICCA software was classified as a medical device according to Article 1(2)(a) of Directive 93/42.

The question by the *Conseil d'État* were as follows:

“Must ... Directive [93/42] be interpreted as meaning that software, the purpose of which is to offer to prescribers practising in towns, a health establishment or a medico-social establishment support for determining a drug prescription, in order to improve the safety of prescription, facilitate the work of the prescriber, encourage conformity of the prescription with national regulatory requirements and reduce the cost of treatment at the same quality, constitutes a medical device within the meaning of that directive, 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?”

III. THE ADVOCATE GENERAL'S OPINION

The Advocate General (AG) Campos Sanchez-Bordona delivered his opinion on 28 June 2017. He first outlined the purpose of Directive 93/42: First, it seeks to harmonise legislative, administrative and regulatory divergences in relation to Medical devices between the Member States of the European Union in order to enable the free movement of such devices. Secondly, it would aim at protecting the health and safety of users and patients, which would be established through certification of such devices by the CE mark. This would provide the device with a presumption of freedom of movement and Member States could not require the product to go through more onerous scrutiny in the form of further conformity assessment procedures. The AG added that Member States could only diverge from this assumption and create obstacles for marketing such a CE marked device “where they establish that it is liable to compromise the health or safety of intended users”.⁵ Article 8 of Directive 93/42 would authorise Member States to “take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service”, while obliging the Member State to immediately inform the European Commission. Conversely, this means that Member States are entitled to regulate devices not bearing a CE sign without restriction provided that this does not amount to a measure having equivalent effect violating the fundamental freedom of free movement of goods.

The AG then summarised previous case law on Article 1(2)(a) of Directive 93/42 which provides the legal definition of a medical device in the context of said Directive. He observed that none of the decisions related directly to software. Within the *Brain Products* decision, the Court incidentally found that for software to fall within the scope of Directive 93/42 “it is not sufficient that it be used in a medical context, but that it is also necessary that the intended purpose, defined by the manufacturer, is specifically medical”.⁶ Based on the decisions in *Oliver Medical*⁷ where the Court found that the CE marking would imply that the product is for medical use and *James Elliott Construction*⁸ where the Court held that where a product entail CE marking it would benefit of the presumption of conformity with Directive 93/42, the AG found that since the ICCA software in question would bear the CE mark, it would benefit of the presumption of conformity stipulated

⁵ Case C-329/16 *SNITEM*, Opinion of AG Campos Sánchez-Bordona, 28 June 2017, para 34.

⁶ Case C-219/11 *Brain Products* Judgment of the Court (Third Chamber) of 22 November 2012, para 17.

⁷ Case C-547/13 *Oliver Medical* Judgment of the Court (Tenth Chamber) of 4 March 2015, para 50 et seq.

⁸ Case C-613/14 *James Elliott Construction* Judgment of the Court (Third Chamber) of 27 October 2016, paras 38 and 39.

in Directive 93/42. Consequently, this would require the French authority to rebut this presumption.

Next, the AG turned on the question whether the software in question would qualify as a medical device pursuant to Directive 93/42. He restates the French Government's position which declares that the software in question did not amount to a medical device. It would therefore not benefit of the presumption of free movement and be subject to national authorisation. The French Government argued that the software's prescription assistance function would not pursue one of the functions within the meaning of Article 1(2)(a) of the Directive since "(a) it is not used for diagnostic or therapeutic purposes; and (b) it is not intended for investigation, replacement or modification of the anatomy or of a physiological process or for the control of conception".⁹

In order to rebut the French Government's points, the AG outlined the functions of the ICCA software. He states that its function lies in supporting the determination of drug prescriptions, "in order to improve the safety of prescription".¹⁰ As such, it would aid drug prescriptions within anaesthesia services and intensive care units and would provide doctors and health professionals with the ability to calculate the prescription of drugs and the duration of the treatment. This, according to the AG, would render the ICCA software - contrary to the opinion of the French Government - as "intended ... to be used specifically for diagnostic and/or therapeutic purposes 'in the meaning of Article 1(2) (a) of the Directive."¹¹ This point was supported by the reading of the definitions of "active medical Device" and "active device for diagnosis "within Annex IX of the Directive."¹² The latter would specifically include stand-alone software "which, alone or in combination with other medical devices, supply 'information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities".¹³ Contrary to the French government's view, it would not merely be software applied once the health practitioner has decided upon the appropriate treatment but would rather assist in determining the correct prescription. It would therefore fulfil the objective of "prevention, monitoring, treatment or alleviation of disease" pursuant to Article 1(2)(a) of the Directive.¹⁴

The AG then outlined the differences between software for medical purposes and software for general purposes used in a healthcare setting as elaborated within the Court's *Brain Products* decision. The latter would not constitute a medical device pursuant to Directive 93/42. The AG highlighted that a similar but more detailed guidance is given within the new Regulation 2017/745. In addition, the same distinction could be found within the Commission's MEDDEV 2.1/6 guidance document. While the latter document would not be legally binding, it would impact on the systematic interpretation of the relevant legal framework. The Document provides manufacturers with guidance on the application of Directive 93/42. According to the guidelines a software does not classify as a medical device where it "does not perform an action on data or that action is limited to storage, archival, communication, simple search or lossless compression".¹⁵ However, where it creates and modifies medical information, and through this, assists medical professionals in using the information it may constitute a medical device. The French Government, however, sees the ICCA software as merely performing administrative functions by

⁹ Case C-329/16 *SNITEM*, Opinion of AG Campos Sánchez-Bordona, 28 June 2017, para 46.

¹⁰ *ibid* at para 48.

¹¹ *ibid* at para 49.

¹² *ibid* at para 50.

¹³ *ibid* at para 50.

¹⁴ *ibid* at para 53.

¹⁵ *ibid* at para 57.

archiving patient data as well as information in relation to the price, the international non-proprietary name and the existence of generic version of the drugs in question. Hence, the software would rather amount to a database which assists health practitioners.¹⁶ The French Government, however, contends that some features of the software may be considered as a medical device, such as the processing of patient's data for therapeutic and diagnostic purposes or medical imaging. But it added that the preliminary ruling in question would only relate to the software's prescription function.

The AG disagreed with this narrow view on the order for reference and found that the referring court sought to assess whether the ICCA software is a medical device. Further, he stated that the Commission's guidelines would require the software to go beyond the mere storing and archiving of data. The AG found that this would be exactly what the software was doing since its applications went beyond mere administrative functions.¹⁷ He added that software similar to the ICCA software had already been classified as a medical device by other competent national healthcare authorities.¹⁸ Based on this analysis, the AG concluded that "[s]ubject to the final assessment concerning its functions, which falls to the referring court, prescription assistance software of the kind at issue in the proceedings may be classified as a medical device, within the meaning of Article 1(2)(a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, in so far as it provides the doctor with the relevant information for identifying contraindications, drug interactions and excessive doses".¹⁹

IV. THE JUDGEMENT

The Court agreed with the AG's opinion and answer to the *Conseil d'État's* question, ruling that:

Article 1(1) and Article 1(2) (a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, must be interpreted as meaning 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 those provisions, even if that software does not act directly in or on the human body.²⁰

The Court maintained that there are two cumulative conditions which must be satisfied in order for a software to be considered a medical device. The first condition is related to the objective pursued, which is that the medical device must be intended by the manufacturer for use in humans for the purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease, as stated from Article 1(2)(a) of Directive 93/42. The Court stated that the software is a medical device when the manufacturer has specifically defined the device's purpose medical.²¹

In deciding whether the ICCA software met this first condition, the court found that software which cross references patient data with the drugs that the doctor is considering prescribing (which automatically provides the doctor with the information to detect possible contraindications, drug interactions and excessive dosages) is used for the purpose of prevention, monitoring, treatment

¹⁶ *ibid* at para 58.

¹⁷ *ibid* at paras 63 – 64.

¹⁸ *ibid* at para 67.

¹⁹ *ibid* at para 72.

²⁰ Case C-329/16 *SNITEM*, Judgment of the Court (Fourth Chamber), para 39.

²¹ The court referred to *Brain Products* (Case C-219/11 *Brain Products* Judgment of the Court (Third Chamber) of 22 November 2012), paras 16 and 17.

or alleviation of a disease. It would therefore pursue a specifically medical objective making it a medical device within the meaning of Article 1(2)(a) of Directive 93/42. The court contrasted this with a software that may be intended for use in a medical context, but whose sole purpose is to archive, collect and transmit data, such as patient medical data storage software, would not fall within the definition of a medical device within the meaning of Article 1(2)(a) of Directive 93/42.

The second condition is in regards to the action resulting from the objective pursued by the device. The French court asked whether software that does not function automatically in or on the human body can be considered to be a medical device within the meaning of Article 1(2)(a) of Directive 93/42. The CJEU responded to this question by declaring that a medical device does not need to act directly on or in the human body to fall within the scope of the Medical Devices Directive.²² Referring to Directive 2007/47/EC which amended Article 1(2)(a) of Directive 93/42, and in particular its Recital 6, the Court maintained that the EU legislature intended to focus on the purpose of its use, rather than the effect it is capable of producing on or in the human body which is likely to materialise when classifying software as a medical device.²³

The Court found confirmation for its interpretation in the Commission Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices, MEDDEV 2.1/6. The Guidelines serve “to promote a uniform application of the provisions of the Medical Devices Directive within the European Union”.²⁴ They state that software would constitute a medical device “where it is specifically intended by the manufacturer to be used for one of the purposes set out in Article 1(2)(a) and where it is intended to create or modify information, in particular by means of calculation, quantification or comparison of the recorded data against certain references in order to provide information about a particular patient”.²⁵ Conversely, this would mean that software which “merely functions as a digital library performing actions limited to storage and archiving”²⁶ should not be considered a medical device. Based on this analysis, the Court maintained that the ICCA software constitutes a medical device and must, therefore, compulsorily bear a CE marking when it is placed on the market. Once the CE marking is obtained and the device is placed on the market, it should circulate freely in the European Union without having to go through any additional procedures, such as a new certification.

V. THE IMPACT

In essence, the decision of CJEU clarified that the *intended purpose of the manufacturer* remains the most important factor to be considered in the assessment of whether a product qualifies as a medical device. By incorporating the MEDDEV 2.1/6 guidelines into its findings, the court elevated these into binding case law. Moreover, by following the approach taken in its earlier decision in *Brain Products*²⁷ and confirming that stand-alone software having a relevant medical purpose may qualify as a medical device if the specific conditions are fulfilled (including the

²² Case C-329/16 *SNITEM*, Judgment of the Court (Fourth Chamber), para 28.

²³ *ibid* at para 29.

²⁴ *ibid* at para 33.

²⁵ *ibid* at para 33.

²⁶ *ibid* at para 33.

²⁷ See *Brain Products*, above, n 6.

requirement for an CE certification mark), the CJEU's judgment also gives valuable guidance with regard to the growing market for applications of support software in healthcare.²⁸

In that regard, it should further be pointed out that this decision should also be seen in context with the forthcoming Medical Device Regulation 2017/745 (MDR) which was adopted in May 2017 and will become fully effective in May 2020.²⁹ Notably, it seems that the definition of medical devices provided by the Court continues to be well aligned with the definitions in the MDD, in the MDR and in the evolving new guidelines. Although the MDR provides a new legislative basis, and now includes software for the “prediction” and “prognosis” of disease in the medical device definition in Art. 2 MDR, the essence of the CJEU’s findings basically affirms the definition set forth in the applicable legislative frameworks.

The inclusion of automated software-based decision making into the existing regulatory framework for medical devices also leads to additional issues that will have to be considered very carefully, such as the question of where exactly the boundary lines of liability between the healthcare professional and the medical device manufacturer should be drawn.³⁰ Another issue that will presumably remain relevant to legal and regulatory debates relates to the manufacturer’s intention as being decisive whether the device in question falls within the scrutiny of the MDD and soon, the MDR. Like the MDD, the MDR states in its Recital 19 that “software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device”. Considerable regulatory uncertainty will remain in relation to many wearable devices or virtual fitness and health apps and assistants, especially where manufacturers try to escape the scrutiny of the Medical Devices regulatory framework or where patients use medical devices in different ways than originally intended by the manufacturer.

Finally, a few words on the concrete impact of the CJEU decision on the case at issue: Following the ruling of the CJEU, the *Conseil d’État* partially annulled Decree No. 2014-1359 on 12 July 2018. In line with the CJEU’s findings, the *Conseil d’État*, invalidated the additional obligation of a general certification obligation for medical prescription assistance software by the High Health Authority irrespective of its functionalities (Decision n. 387156).³¹ More specifically, the *Conseil d’État* struck down the particular stipulations in Articles 1, 3 and 2 of the decree that required such additional certification of medical prescription software for specific functionalities enabling the use of patient-specific data for medical purposes that are covered by Article 1(2) of the Medical Devices Directive. According to the Court this also applies to modules which are accessories to such functionalities within the meaning of the same provisions.³² The *Conseil d’État* also held that Article L.161-38 II of the French Social Security Code does not comply with the objectives of Article 4 of the Medical Devices Directive, since there is no justification for such an additional requirement

²⁸ E Friedel, T Goraya and M Kuhn, ‘CJEU rules on prescription support software as a medical device’ (Taylor Wessing Synapse, March 2018) <<https://united-kingdom.taylorwessing.com/synapse/march18.html>> accessed 10 November 2019.

²⁹ See supra n 2.

³⁰ See also E Friedel, T Goraya and M Kuhn, above n 28.

³¹ See: Conseil d’État, 1ère chambre, 12/07/2018, No. 387156, ECLI:FR:CECHS:2018:387156.20180712, Inédit au recueil Lebon, <<https://www.legifrance.gouv.fr/affichJuriAdmin.do?oldAction=rechJuriAdmin&idTexte=CETATEXT000037188972&fastReqId=112402314&fastPos=13>> accessed 29 November 2019.

³² See also: E Van Keymeulen, ‘French Administrative Supreme Court quashes mandatory certification of medical prescription assistance software’ (Allen & Overy Life Sciences Hub, 2 August 2018) <<http://www.aolifescienceshub.com/french-administrative-supreme-court-quashes-mandatory-certification-of-medical-prescription-assistance-software/#page=1>> accessed 29 November 2019. A prior version of this post was originally published by the same authors in Practical Law – Life Sciences, July 2018 Issue (Thomson Reuters). This post was originally co-authored by Patricia Carmona Botana (accessed 2 December 2019).

due to Article 8 of the Medical Devices Directive, which includes a safeguard clause, or Article 14b, providing for specific health surveillance measures.³³ Consequently, the *Conseil d'État* held that the contested stipulations of the decree lacked, in that regard, an adequate legal basis.³⁴

VI. CONCLUDING REMARKS

The CJEU decision in *SNITEM* has important implications for the interpretation on the emerging regulatory framework for medical devices, since it confirms its previous finding in *Brain Products* that stand-alone software may qualify as a medical device. While the decision related to the medical device directive, the CJEU (indirectly) endorsed fundamental provisions and definitions in the new medical device regulation (MDR). It will therefore improve coherency and support the harmonization of national procedures with regard to digital health apps in the EU. In that regard, it is also a signifier of the increasing digitalization of the health and life sciences. This is not only indicated by the ongoing discussions surrounding the emerging EU guidance³⁵ regarding the new medical devices, but also by recent developments in the US³⁶ and the evolution of national health & reimbursement systems for digital solutions³⁷. However, in light of recent advances in AI and machine learning, it might very well be that additional amendments to the regulatory framework may soon be necessary. This highlights the demand for continuous debates over the further development of regulatory frameworks and guidelines applying to the interface of medical AI, Big Data and machine learning.

³³ *ibid.*

³⁴ *ibid.* (adding that the Court also refused the Ministry of Health's request to limit the effects of the annulment in time, and the annulment therefore takes effect as of the date of the ruling (12 July 2018)).

³⁵ See e.g. the MDCG 2019-16 - Guidance on Cybersecurity for medical devices <<https://ec.europa.eu/docsroom/documents/38941>> accessed 15 January 2020.

³⁶ See e.g. U.S. Food & Drug Administration, 'Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback', <<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>> accessed 20 November 2019.

³⁷ See e.g. On 7 November 2019, the German parliament passed a new law enhancing digital healthcare provision for patients (Digital Health Service Act/Digitale-Versorgung-Gesetz). The new law inter alia entitles patients in statutory health insurance to reimbursement of digital health solutions by incorporating such provisions in the Social Security Code V (Sozialgesetzbuch V – SGB V), <<https://www.hlregulation.com/2019/11/15/digital-health-solutions-to-become-reimbursable-in-germany-milestone-for-patients-and-providers/>> accessed 3 December 2019. See also the official version in the Bundesgesetzblatt at:

<https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&start=%2F%2F%2A%5B%40attr_id%27bgbl119s2562.pdf%27%5D#_bgbl_%2F%2F%2A%5B%40attr_id%3D%27bgbl119s2562.pdf%27%5D_1580154363241> accessed 22 December 2019.