



## Reports of Cases

OPINION OF ADVOCATE GENERAL  
CAMPOS SÁNCHEZ-BORDONA  
delivered on 28 June 2017<sup>1</sup>

**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**

(Request for a preliminary ruling from the Conseil d'État (Council of State, France))

(Directive 93/42/EEC — Definition of medical device — CE marking — Drug prescription assistance software)

1. The Conseil d'Etat (Council of State, France) has referred a question to the Court of Justice for a preliminary ruling, the answer to which will enable it to establish whether, for the purposes of Directive 93/42/EEC,<sup>2</sup> particular prescription assistance software must be classified as a medical device.<sup>3</sup>
2. The interpretation which the Court provides of Directive 93/42 will have immediate consequences, as the placing on the market in each Member State of software which is not classified as a medical device is usually subject to less stringent conditions than the placing on the market of software which is classified as such.
3. Software is becoming increasingly important in the health sector, to which it can provide great benefits, including assistance with drug prescription. It is logical that an activity with a high technological profile should be involved in that sector, which requires ever more sophisticated and safe products and services.
4. However, it is also inevitable that the public authorities, which are ultimately responsible for that sector, should take precautions in the face of the rapid development of the technology and computer systems used in it. That concern led Member States to adopt national provisions on health protection, which may, and in fact do, differ considerably from each other. Directive 93/42 sought to harmonise those provisions and to remove any omissions or uncertainties so as to ensure the free movement of medical devices in the internal market.

<sup>1</sup> Original language: Spanish.

<sup>2</sup> Council Directive of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1).

<sup>3</sup> The Spanish version of Directive 93/42 uses the word 'productos' [products] whilst other versions use 'devices'. The German version ('Medizinprodukte') is like the Spanish, whereas the French ('dispositifs'), Italian ('dispositivi'), Portuguese ('dispositivos'), English ('devices') and Romanian ('dispozitivele') versions opt for 'devices'. However, I do not believe that those terminological differences affect the software at issue in these proceedings.

5. Therefore, it is undoubtedly important to specify the criteria which software must fulfil in order to qualify as a ‘medical device’ and fall within the scope of Directive 93/42, since its performance characteristics must meet high levels of safety and health protection.

## **I. Legal framework**

### **A. EU law**

#### *1. Directive 93/42*

6. The second, third and fourth recitals state:

... the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community;

... the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonised in order to guarantee the free movement of such devices within the internal market;

... the harmonised provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;

...’

7. Article 1, entitled ‘Definitions, scope’, states:

‘1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

2. For the purpose of this Directive, the following definitions shall apply:

- (a) “medical device” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - investigation, replacement or modification of the anatomy or of a physiological process,
  - control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

...

- (g) “intended purpose” means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional material;

...’

8. Article 4, entitled ‘Free movement, devices intended for special purposes’, provides:

‘1. Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11.’

9. Article 5(1), entitled ‘Reference to standards’, provides:

‘Member States shall presume compliance with the essential requirements ... in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the *Official Journal of the European Union*; Member States shall publish the references of such national standards.’

10. Article 8, entitled ‘Safeguard clause’, provides in paragraph 1:

‘Where a Member State ascertains that the devices referred to in Article 4(1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall 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. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

- (a) failure to meet the essential requirements referred to in Article 3;
- (b) incorrect application of the standards referred to in Article 5, in so far as it is claimed that the standards have been applied;
- (c) shortcomings in the standards themselves.’

11. Article 9, entitled ‘Classification’, provides in paragraph 1:

‘Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX.’

12. Annex IX, which is entitled ‘Classification criteria’, includes the following under ‘Definitions’:

‘ ...

*1.4. Active medical device Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other*

*elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand-alone software is considered to be an active medical device. ...*

*1.6. Active device for diagnosis Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.'*

## *2. Directive 2007/47/EC<sup>4</sup>*

13. Recital 6 of that directive is worded as follows:

'It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device.'

## ***B. National law***

### *1. Code de la sécurité sociale (Social Security Code)*

14. Pursuant to the second heading of Article L. 161-38 of the Social Security Code, the Haute Autorité de santé (National Health Authority, France) must determine:

'the certification procedure for drug prescription assistance software complying with a body of rules of good practice. It shall ensure that the rules of good practice are to specify that the software is to incorporate the medical and economic recommendations and opinions identified by the National Health Authority, enable direct prescription under international non-proprietary names, the display of product prices at the time of prescription and the total amount of the prescription, and the indication whether the product is included in the repertoire of generic drugs, as well as provide information concerning their designer and the nature of their funding.

That certification procedure shall contribute to the improvement of drug prescription practice. It shall ensure that the software complies with the minimum requirements of security, conformity and efficiency of prescriptions.'

15. In accordance with the fourth heading of that article:

'The certifications provided for in I to III shall be implemented and issued by certification bodies accredited by the French Accreditation Committee or by the competent body of another Member State of the European Union certifying compliance with the rules of good practice enacted by the National Health Authority.

Those certifications are made compulsory for any software, of which at least one of the functions is to offer assistance in the prescription or dispensing of medicines under the conditions laid down by decree of the Conseil d'État (Council of State) and at the latest on 1 January 2015.'

<sup>4</sup> Directive of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ 2007 L 247, p. 21).

## 2. Decree 2014-1359<sup>5</sup>

16. This decree amends the Social Security Code. The third heading of Article 1 inserts into the regulatory part of the Code a subsection headed ‘Provisions relating to the certification obligation for drug prescription assistance software’.

17. In accordance with Article R. 161-76-1:

‘All software whose purpose is to offer support for carrying out drug prescription to prescribers practising in towns, a health establishment or a medico-social establishment, is subject to the certification obligation laid down in Article L. 161-38, without prejudice to the provisions of Article R. 5211-1 et seq. of the code de la santé publique (Public Health Code).<sup>6</sup> Software integrating functions other than supporting drug prescription is only subject to certification for that function.’

18. Article R. 161-76-3 states:

‘Drug prescription assistance software shall be certified by reference to a scheme established by the National Health Authority which provides for:

- (1) minimum requirements of security, relating in particular to the absence of any information extraneous to prescription or advertising of any kind, and to its ergonomic quality;
- (2) minimum requirements of conformity of the prescription with regulatory provisions and with the rules of good medical prescription practice;
- (3) minimum requirements of efficiency ensuring the reduction of the cost of treatment, for the same quality;
- (4) prescription under international non-proprietary names, as defined in the fifth paragraph of Article R. 5121-1 of the Public Health Code;
- (5) information on the drug taken from a database on drugs which satisfies a quality charter developed by the National Health Authority;
- (6) information on the software developer and the funding of the development of that software.’

19. Lastly, Article R. 161-76-4 stipulates that ‘certification of drug prescription assistance software shall be carried out by a certification body accredited by the French Accreditation Committee or by bodies which are members of the European Co-operation for Accreditation and have concluded multilateral mutual recognition agreements covering the entirety of the activity concerned.’

## II. The national proceedings and the question referred for a preliminary ruling

20. The Syndicat national de l’industrie des technologies médicales (‘Snitem’) represents undertakings in the medical devices sector in France.

21. One of those undertakings, Philips France (‘Philips’), manufactures and places on the market the drug prescription assistance software ‘Intellispace Critical Care and Anesthesia’ (‘ICCA’).

<sup>5</sup> Décret No 2014-1359, du 14 novembre 2014, relatif à l’obligation de certification des logiciels d’aide à la prescription médicale et des logiciels d’aide à la dispensation prévue à l’article L. 161-38 du code de la sécurité sociale (Decree No 2014-1359 of 14 November 2014 regarding the certification obligation for drug prescription assistance software and dispensation assistance software laid down in Article L. 161-38 of the Social Security Code (JORF of 15 November 2014, p. 19255).

<sup>6</sup> The Public Health Code brought French law into line with Directive 93/42.

22. According to the functional and technical document for the ICCA software, submitted by Philips,<sup>7</sup> that software, which is used for resuscitation and anaesthesia, provides a doctor with the necessary information for the correct prescription of drugs, relating, in particular, to possible contraindications, interaction between different drugs and excessive doses.

23. It is apparent from the documents in the case file that the ICCA software bears the CE marking,<sup>8</sup> attesting to the fact that it has undergone assessment of its conformity with the requirements of Directive 93/42.

24. By two actions brought before the Conseil d'État (Council of State), Snitem and Philips sought the annulment of the third heading of Article 1 and Article 2 of Decree 2014-1359. The referring court joined the actions.

25. The applicants submit that, since Decree 2014-1359 requires certain software, including that bearing the CE marking, to be certified by the national authority, it is incompatible with EU law.

26. In particular, the applicants contend that that provision is a measure having an equivalent effect to a quantitative restriction on imports. In imposing an additional requirement to the certification of medical devices provided for in Directive 93/42, the decree is in breach of Article 4(1) of that directive, pursuant to which Member States must not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking.

27. The applicants further argue that the contested provision is not covered by Article 8 of Directive 93/42, for the national certification obligation, which is additional to that accredited by the CE marking, is not a safeguard measure included in that article.

28. The Conseil d'État (Council of State) is uncertain whether software such as the ICCA software must be classified as a medical device within the meaning of Article 1(2)(a) of Directive 93/42. It therefore seeks an interpretation of that provision from the Court, for which purpose it stayed the proceedings and then referred the following question for a preliminary ruling:

'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?'

29. Written observations were lodged in the present case by Snitem, the French and Italian Governments and the Commission. At the hearing, held on 26 March 2017, oral argument was presented by Snitem, the French Government and the Commission.

<sup>7</sup> Annex 2 to its written observations.

<sup>8</sup> Footnote not relevant to the English translation.

### III. Examination of the question

#### A. General considerations concerning the CE marking of medical devices

30. Directive 93/42, which is a harmonisation measure adopted under Article 100 A of the EC Treaty (Article 114 TFEU), is intended to promote the free movement of medical devices which comply with the requirements of that directive. It therefore prevents the creation of obstacles to intra-Community trade which might result from differences between the legislative, regulatory and administrative measures in force in the Member States.<sup>9</sup>

31. Furthermore, as a result of the framework created by Directive 93/42, the proper functioning of the internal market in that sector makes it necessary to ensure the safety and health protection of patients and users.<sup>10</sup>

32. The legislative harmonisation carried out by Directive 93/42 was achieved by establishing a number of essential conditions, fulfilment of which is accredited by the affixing of the CE marking. That marking indicates that the products on which it is affixed have passed an assessment in accordance with Article 11 of Directive 93/42.

33. Once the CE marking has been applied, Member States may not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking (Article 4 of Directive 93/42). Those devices therefore benefit from the presumption of freedom of movement without any Member State being able to require that product to undergo a further conformity assessment procedure and without it being possible for any other measure having an equivalent effect to a quantitative restriction on imports being able to undermine that freedom (Article 34 TFEU).<sup>11</sup>

34. Member States are entitled to create obstacles to the placing on the market of a medical device bearing the CE marking only where they establish that it is liable to compromise the health or safety of intended users. The protection of the general interest justifies that type of safeguard measure, based on an overriding requirement such as the requirement relating to health protection. Article 8 of Directive 93/42 authorises Member States to rely on that safeguard clause, in accordance with the conditions laid down therein (inter alia, that they must immediately inform the Commission).

35. Conversely, where a product does not fall within the scope of a harmonisation directive, it will not be eligible to bear the CE marking and the Member States will be entitled to regulate the placing on the market of that product, provided they do not create a restriction that can be classified as a measure having equivalent effect.<sup>12</sup>

36. The Court has ruled a number of times on the interpretation of Article 1(2)(a) of Directive 93/42, although not *directly* in connection with software.

<sup>9</sup> Judgment of 24 November 2016, *Lohmann & Rauscher International* (C-662/15, EU:C:2016:903, paragraph 27 and the case-law cited therein).

<sup>10</sup> Proposal for a Council Directive concerning medical devices of 23 August 1991, COM(91) 287 final, explanatory memorandum, p. 3.

<sup>11</sup> According to the case-law of the Court, it 'follows from those provisions that medical devices the conformity of which with the essential requirements of Directive 93/42 has been evaluated according to one of the procedures laid down in Article 11 of that directive and which bear a CE marking must be allowed to move freely throughout the European Union, and no Member State can require that such a product must undergo a further conformity assessment procedure ... That is the reason why Directive 93/42 does not provide for any compliance review mechanism to be added to or supplement those provided for in Article 11 of that directive' (judgments of 24 November 2016, *Lohmann & Rauscher International*, C-662/15, EU:C:2016:903, paragraph 30, and of 14 June 2007, *Medipac-Kazantzidis*, C-6/05, EU:C:2007:337, paragraph 42).

<sup>12</sup> Judgments of 11 July 1974, *Dassonville* (8/74, EU:C:1974:82, paragraph 5); of 20 February 1979, *Rewe-Zentral* (120/78, EU:C:1979:42 ('*Cassis de Dijon*')); of 22 September 2016, *Commission v Czech Republic* (C-525/14, EU:C:2016:714, paragraphs 34 and 25); and of 23 December 2015, *Scotch Whisky Association* (C-333/14, EU:C:2015:845, paragraph 31).

37. In the judgment in *Brain Products*,<sup>13</sup> the Court observed, in relation to the third indent of the provision, that a device (in that case, a system which enabled human brain activity to be recorded) was a medical device for the purposes of that article only where it was intended for a medical purpose.

38. In its analysis, the Court referred *incidentally* to software, holding that, in the light of recital 6 of Directive 2007/47, Article 2 of which amended Article 1(2)(a) of Directive 93/42, ‘as regards software, the legislature ... made unequivocally clear that in order for it 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’.<sup>14</sup>

39. Similarly, in *Oliver Medical*,<sup>15</sup> the Court, giving judgment on the customs classification of the devices (for the treatment of dermovascular and dermatological problems) at issue in that reference for a preliminary ruling, took account of the fact that those devices had a medical purpose and held that ‘it is necessary to assess the use for which the product is intended by the manufacturer and the methods and place of its use’.<sup>16</sup>

40. In that judgment, the Court considered the fact that a product bears the CE marking to be an additional factor for establishing whether that product is intended for medical use.<sup>17</sup> The inclusion of CE marking is particularly significant since, as the judgment in *James Elliott Construction* held, its function is to confer on the product which bears the marking the benefit of the presumption of conformity with the basic requirements of the harmonisation directive.<sup>18</sup>

41. In view of the fact that, as stated above, the ICCA software bears the CE marking (as a result of which it is freely placed on the market in 16 Member States),<sup>19</sup> that software benefits from the presumption of conformity with Directive 93/42. Accordingly, it is for the French Government to rebut that presumption, which, in accordance with my analysis below, it has not succeeded in doing.

### ***B. Legal classification of the ICCA software in the light of Article 1(2)(a) of Directive 93/42***

42. In order to provide the referring court with an answer, it is necessary to ascertain, at the outset, whether or not, when the CE marking was affixed to the ICCA software, that software was correctly classified as a ‘medical device’ within the meaning of Article 1(2)(a) of Directive 93/42.

43. The application of Article 1(2)(a) of Directive 93/42 to the instant case in order to determine whether the functions performed by the ICCA software match any of the four functions referred to therein and to decide in that way whether it has a medical purpose, logically calls for an analysis of the specific characteristics of the software.

<sup>13</sup> Judgment of 22 November 2012, *Brain Products* (C-219/11, EU:C:2012:742).

<sup>14</sup> *Ibid.*, paragraph 17.

<sup>15</sup> Judgment of 4 March 2015, *Oliver Medical* (C-547/13, EU:C:2015:139, paragraph 50 et seq.).

<sup>16</sup> *Ibid.*, paragraph 52.

<sup>17</sup> *Ibid.*, paragraph 53.

<sup>18</sup> Judgment of 27 October 2016, *James Elliott Construction* (C-613/14, EU:C:2016:821, paragraphs 38 and 39). In the judgment of 16 October 2014, *Commission v Germany* (C-100/13, not published, EU:C:2014:2293, paragraph 63), the Court held that a Member State cannot require construction products which use and are correctly affixed with the CE marking to bear an additional national marking on the pretext that the harmonised provisions are incomplete.

<sup>19</sup> Point 83 of the applicants’ observations.

44. The French Government maintains that the ICCA software does not fall within the scope of Directive 93/42 as it is not a medical device within the meaning of Article 1(2)(a) of that directive. On that basis, the French Government submits that the placing on the market of the software must be subject to authorisation by the national authorities (the National Health Authority) and rejects the view that it can be sold freely as a result of the CE marking.

45. The French Government contends that the prescription assistance function integrated into the software ‘does not pursue any of the four purposes listed in Article 1(2)(a) of Directive 93/42’.<sup>20</sup> After citing the Opinion of Advocate General Sharpston in *Laboratoires Lyocentre*,<sup>21</sup> the French Government acknowledges that, ‘as a result of its physical presentation and its intended use’, the ICCA software satisfies ‘the first two criteria of the definition of a device’ within the meaning of that provision.<sup>22</sup>

46. As regards the third criterion, the French Government refers to recital 6 of Directive 2007/47, pursuant to which software is a medical device if it is ‘specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device’. The French Government submits that the ICCA drug prescription assistance software does not serve any of those purposes because: (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.

47. The description of the functions of the ICCA software in the order for reference refers to ‘support for determining a drug prescription, in order to improve the safety of prescription’. The order for reference also states that the software facilitates the work of the prescriber by detecting contraindications, drug interactions and excessive doses.

48. According to the documents in the case file, the ICCA software assists drug prescription in anaesthesia services and intensive care units. In the case of the former, when the patient is admitted, the software incorporates pre-operative information and information available in the systems to which the software is connected; the software analyses and processes that data in order to provide the anaesthetist with information during the operation. As regards intensive care, resuscitation or continuing care units, the software is capable of handling the many details about the patient needed to make medical decisions. In both cases, the ICCA software has an engine which enables doctors and health professionals to calculate drug prescription, possible allergies and the duration of treatment.

49. In the light of those functions, contrary to the French Government’s assessment, I find it difficult to deny that the ICCA software is ‘intended ... to be used specifically for diagnostic and/or therapeutic purposes’, to use the wording with which Directive 2007/47 amended Article 1(2)(a) of Directive 93/42.

50. A reading of the definitions of ‘active medical device’ and ‘active device for diagnosis’ in Annex IX to Directive 93/42<sup>23</sup> bolsters that interpretation. The latter category includes active medical devices (which expressly include ‘stand-alone software’)<sup>24</sup> 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’.

<sup>20</sup> Point 21 of its written observations.

<sup>21</sup> Case C-109/12, EU:C:2013:353, point 38. In Advocate General Sharpston’s view, a medical device is defined by reference to its (i) physical presentation (it can be ‘any instrument, apparatus, appliance, material or other article’); (ii) use (‘for human beings’); (iii) purpose (the four categories of functions listed in Article 1(2)(a) of the Medical Devices Directive); and (iv) means of achieving its principal intended action or mode of action (which cannot be achieved ‘in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means’).

<sup>22</sup> Point 23 of its written observations.

<sup>23</sup> See point 11 of this Opinion.

<sup>24</sup> Although I believe that the ICCA is stand-alone software and not an accessory of another device, that factor will in all likelihood lose its importance in the immediate future. 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 (OJ 2017 L 117, p. 1) has deleted the term ‘stand-alone’ and classifies all software as an active device (Article 2(4)).

51. The ICCA software improves medical practice by assisting with the correct (and, to that same extent, preventing the incorrect) prescription of drugs. It is, therefore, a tool for supporting health professionals, whom it assists with their therapeutic tasks and with the monitoring of patients under anaesthesia or in intensive care. Once a doctor inputs the patient's details into the software, it will help the doctor to identify the appropriate treatment while warning the doctor of any problems which may result from inappropriate treatment.<sup>25</sup>

52. Contrary to the French Government's assertion at the hearing, 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. The medical purpose which Directive 93/42 requires of software for it to qualify as a medical device is clearly present in software with the features of the ICCA software.

53. The ICCA software provides assistance with particular information so that the doctor prescribes drugs more safely, thereby preventing incorrect prescription. It therefore fulfils instrumentally the objective of 'prevention, monitoring, treatment or alleviation of disease'.

***C. Distinction between software for a medical purpose and software for general purposes when used in a healthcare setting***

54. On the basis of recital 6 of Directive 2007/47, the Court set out, in the judgment in *Brain Products*,<sup>26</sup> the dual category of software for a medical purpose and 'software for general purposes when used in a healthcare setting'. Unlike the former, the latter 'is not a medical device' and must therefore be excluded from the scope of Directive 93/42. Identical guidance is maintained and given more detailed expression in the new Regulation 2017/745.<sup>27</sup>

55. That same distinction is found in the Commission guidance document Meddev 2.1/6<sup>28</sup> ('the guidelines'), relating to the classification of standalone software used in the health sector.

56. Although not legally binding, those guidelines may be taken into account for the purposes of a systematic interpretation of the applicable legal framework. Through the guidelines, the Commission seeks to provide manufacturers with guidance on the application of Directive 93/42. Drawn up in collaboration with the authorities of the Member States, the Commission's services, the healthcare industry and accredited bodies in that sector, the guidelines reflect the interpretation of the legislation which is used in practice.<sup>29</sup>

<sup>25</sup> It is clear that the incorrect prescription of a drug, without taking into account its possible contraindications or interaction with other drugs, and without handling sufficient information about the suitable dose, may aggravate the patient's condition or create new health problems for that patient.

<sup>26</sup> Judgment of 22 November 2012 (C-219/11, EU:C:2012:742, paragraph 16).

<sup>27</sup> According to recital 19 of Regulation 2017/745: 'It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while 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. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.'

<sup>28</sup> '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 version of January 2012 has been amended by that of July 2016.

<sup>29</sup> See the Opinion of Advocate General Mengozzi in *Brain Products* (C-219/11, EU:C:2012:299, point 14).

57. According to the guidelines, if the software does not perform an action on data or that action is limited to storage, archival, communication, *simple search*<sup>30</sup> or lossless compression, it cannot be classified as a medical device. *A contrario*, if the software creates or modifies medical information to assist the healthcare professional with the use of that information, it might be a medical device.<sup>31</sup>

58. The French Government, which adopts that dual classification, maintains that the ICCA software performs purely administrative functions: it archives patient data and information relating to the price, the international non-proprietary name and the existence of generics of the drugs. It is, therefore, a type of database which assists practitioners to prescribe drugs but does not create or modify medical information. Accordingly, it does not fulfil any of the purposes set out in Article 1(2)(a) of Directive 93/42 and is excluded from its scope.

59. The French Government accepts that prescription assistance software may include modules or functions for a medical purpose, such as the processing of patients' data for therapeutic or diagnostic purposes or the improvement of medical images. In its written observations and at the hearing, the French Government agreed that software like the ICCA could be considered to be a medical device for the purposes of Directive 93/42, as far as those modules are concerned. However, the French Government argued that the question referred for a preliminary ruling is limited to that software's prescription assistance function (or module).

60. I do not agree with that reading of the order for reference and I believe that the referring court is asking whether or not, in the light of all its functions and modules, the ICCA software is a medical device. The question referred for a preliminary ruling is unambiguous in that respect, since it refers to both 'administrative or operational' elements<sup>32</sup> and 'medical' elements<sup>33</sup> of the software.

61. As is logical, it is ultimately for the referring court to decide, having regard to the documentary (and possibly expert) evidence adduced in the proceedings, the extent to which the software gathers, analyses and interprets the patient data which healthcare professionals input into it.

62. Subject to that qualification, it is possible to infer from the contents of the order for reference and the annexes to the observations lodged by Snitem and Philips a response favourable to the position of those parties and contrary to the position of the French Government. The collection, analysis and processing of patient data, operations through which the ICCA software assists with the identification of contraindications, interactions between drugs and excessive doses, distance that software tool from those of a merely administrative nature. On the contrary, all the indications are that, as a result of its specific features, it is more akin to software with strictly medical functions.

<sup>30</sup> According to the Meddev 2.1/6, p. 11, "simple search" refers to the retrieval of records by matching record metadata against record search criteria, e.g. library functions. Simple search does not include software which provides interpretative search results, e.g. to identify medical findings in health records or on medical images'.

<sup>31</sup> In accordance with the Meddev 2.1/6, p. 11, 'software which is intended to create or modify medical information might be qualified as a medical device. If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by the healthcare professionals when reviewing medical information, (e.g. when searching the image for findings that support a clinical hypothesis as to the diagnosis or evolution of therapy) the software could be a medical device'.

<sup>32</sup> '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.'

<sup>33</sup> '... 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 ...'

63. As stated above, the Commission guidelines stipulate that, in order to be classified as a medical device, the software must not be limited to the storage and archival of data<sup>34</sup> but must modify or interpret that data.

64. Unless I have misunderstood the technical explanations in the documents in the case file, that is exactly what the ICCA software does. Using data collected about the patient (which may come from other systems and appliances to which that patient is connected), and with the assistance of its calculation engines, the software automatically converts that data into useful information for the health professional while at the same time suggesting the correct doses of drugs.

65. As the Conseil d'État (Council of State) points out in the question which it has referred for a preliminary ruling, that function 'permits the *use* of data specific to a patient to help his doctor issue his prescription'.<sup>35</sup> The referring court appears to assume, therefore, that the ICCA software does more than store data. In that way, it specifically facilitates the work of the anaesthetist or intensive care professional so that they can decide, in real time and based on the references provided by the software, what treatment is suitable for the patient.<sup>36</sup>

66. In short and, I repeat, subject to the final examination which must be carried out by the referring court, the information in these preliminary ruling proceedings suggests that the functions of the ICCA software go beyond mere administrative functions, such as the storage and archival of data, and allow it to be classified as a medical device.

67. It is significant, in that regard (and the applicants in the proceedings point this out) that the guidelines of other competent national healthcare authorities lead to an identical outcome; those authorities, in the same way as the Commission, classify software similar to the ICCA software as a medical device.<sup>37</sup>

68. Lastly, the Agence nationale de sécurité du médicament et des produits de santé (French National Agency for the Safety of Drugs and Health Products) ('ANSM') states on its website<sup>38</sup> that 'with the exception of individual dose calculation functions, functions ... will not be considered as the defining element of a medical device'.

69. The fact, mentioned by the national court, that the ICCA software does not itself act in or on the human body does not preclude its classification as a medical device.

34 For example, a hospital management information system is not a medical device. That is indicated by the Meddev 2.1/6, p. 19: 'Hospital Information Systems mean, in this context, systems that support the process of patient management. Typically they are intended for patient admission, for scheduling patient appointments, for insurance and billing purposes. These Hospital Information Systems are not qualified as medical devices.'

35 No italics in the original.

36 Examples of software classified as a medical device which performs comparable functions to the ICCA software are referred to in the Meddev 2.1/6, p. 20, in the following terms: 'In general, they are computer based tools which combine medical knowledge databases and algorithms with patient specific data. They are intended to provide healthcare professionals and/or users with recommendations for diagnosis, prognosis, monitoring and treatment of individual patients. Based on steps 3, 4, and 5 of Figure 1, they are qualified as medical devices: — Radiotherapy treatment planning systems are intended to calculate the dosage of ionizing irradiation to be applied to a specific patient. They are considered to control, monitor or directly influence the source of ionizing radiation and are qualified as medical devices. — Drug (e.g.: Chemotherapy) planning systems are intended to calculate the drug dosage to be administered to a specific patient and therefore are qualified as medical devices ...'

37 The Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom, states in its guidelines, 'Medical device stand-alone software including apps' (2016), that decision support software is a medical device if it applies automated reasoning. The Danish Lægemiddelstyrelsen, in its 'Guidance for manufacturers on health apps and software as medical devices' (2015), states that the fact that software is equipped with a calculation function suggest that it is a medical device. A similar approach is taken by the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) of the Federal Republic of Germany, whose guidelines, 'Differentiation between apps and medical or other devices as well as on the subsequent risk classification according to the MPG' (2015), differentiate between software which calculates drugs doses (classifiable as a medical device) and software which only reproduces the information on the basis of which users can determine the dose themselves. Those guidelines also state that decision support software is generally a medical device.

38 <http://ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/Logiciels-et-applications-mobiles-en-sante/> %28offset %29/1.

70. As the Commission rightly observes, to the extent that software assists with drug prescription, the purpose of that software is to enable correct action on the human body, as in the case of taking medicines. Since Article 1(2)(a) of Directive 93/42 does not require direct action by the device but rather ‘assistance’ with the principal action, that fact does not preclude the classification of that software as a ‘medical device’.

71. The foregoing arguments lead me to believe that software with the features of the ICCA software performs functions of a medical nature — beyond those of a purely administrative nature — which fall within the scope of the purposes listed in Article 1(2)(a) of Directive 93/42. Therefore, such software may be defined as a ‘medical device’ within the meaning of that directive.

#### **IV. Conclusion**

72. In the light of the foregoing considerations, I propose that the Court reply as follows to the question referred for a preliminary ruling by the Conseil d’État (Council of State, France):

Subject 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.