JUDGMENT OF THE COURT (Fourth Chamber)

19 March 2009 *

In Case C-489/06,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 27 November 2006,

Commission of the European Communities, represented by M. Patakia and X. Lewis, acting as Agents, with an address for service in Luxembourg,

applicant,

v

Hellenic Republic, represented by D. Tsagkaraki and S. Chala, acting as Agents, with an address for service in Luxembourg,

defendant,

* Language of the case: Greek.

THE COURT (Fourth Chamber),

composed of K. Lenaerts, President of the Chamber, T. von Danwitz, R. Silva de Lapuerta, E. Juhász (Rapporteur) and G. Arestis, Judges,

Advocate General: J. Mazák,
Registrar: R. Grass,

after hearing the Opinion of the Advocate General at the sitting on 20 November 2008,

gives the following

Judgment

1 By its application, the Commission of the European Communities asks the Court to declare that, by rejecting tenders in respect of medical devices bearing the CE certification marking, without, in any event, the competent contracting authorities of Greek hospitals having complied with the procedure provided for in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ 2003 L 284, p. 1) ('Directive 93/42'), the Hellenic Republic has failed to fulfil its obligations under Article 8(2) of Council Directive 93/36/EEC of 14 June 1993 coordinating procedures for the award of public supply contracts (OJ 1993 L 199, p. 1), as amended by Commission Directive 2001/78/EC of 13 September 2001 (OJ 2001 L 285, p. 1) ('Directive 93/36'), and Articles 17 and 18 of Directive 93/42.

Legal context

Community legislation

2 Article 8(1) to (4) of Directive 93/36 provides:

'1. The technical specifications defined in Annex III shall be given in the general or contractual documents relating to each contract.

2. Without prejudice to the legally binding national technical rules, in so far as these are compatible with Community law, the technical specifications mentioned in paragraph 1 shall be defined by the contracting authorities by reference to national standards implementing European standards, or by reference to European technical approvals or by reference to common technical specifications.

3. A contracting authority may depart from paragraph 2 if:

(a) the standards, European technical approvals or common technical specifications do not include any provision for establishing conformity or technical means do not exist for establishing satisfactorily the conformity of a product to these standards, European technical approvals or common technical specifications;

(b) the application of paragraph 2 would prejudice the application of Council Directive 86/361/EEC of 24 July 1986 on the initial stage of the mutual recognition of type approval for telecommunications terminal equipment [(OJ 1986 L 217, p. 21)] or Council Decision 87/95/EEC of 22 December 1986 on standardisation in the field of information technology and telecommunications [(OJ 1987 L 36, p. 31)] or other Community instruments in specific service or product areas;

(c) use of these standards, European technical approvals or common technical specifications would oblige the contracting authority to acquire supplies incompatible with equipment already in use or would entail disproportionate costs or disproportionate technical difficulties, but only as part of a clearly defined and recorded strategy with a view to change-over, within a given period, to European standards, European technical approvals or common technical specifications;

(d) the project concerned is of a genuinely innovative nature for which use of existing European standards, European technical approvals or common technical specifications would not be appropriate.

4. Contracting authorities invoking paragraph 3 shall record, wherever possible, the reasons for doing so in the tender notice published in the *Official Journal of the European Communities* or in the contract documents and in all cases shall record these reasons in their internal documentation and shall supply such information on request to Member States and to the Commission.'

3 Annex III to Directive 93/36, entitled 'Definition of certain technical specifications', provides:

'For the purposes of this Directive the following terms shall be defined as follows:

1. Technical specifications: the totality of the technical prescriptions contained in particular in the tender documents, defining the characteristics required of a material, product or supply, which permits a material, a product or a supply to be described in a manner such that it fulfils the use for which it is intended by the contracting authority. These technical prescriptions shall include levels of quality, performance, safety or dimensions, including the requirements applicable to the material, the product or the supply as regards quality assurance, terminology, symbols, testing and test methods, packaging, marking or labelling.

2. Standard: a technical specification approved by a recognised standardising body for repeated and continuous application, compliance with which is in principle not compulsory.

3. European standard: a standard approved by the European Committee for standardisation (CEN) or by the European Committee for Electrotechnical Standardisation (Cenelec) as "European standard (EN)" or "Harmonisation documents (HD)" according to the common rules of these organisations.

4. European technical approval: a favourable technical assessment of the fitness for use of a product, based on fulfilment of the essential requirements for building works, by means of the inherent characteristics of the product and the defined

conditions of application and use. The European agreement shall be issued by an approval body designated for this purpose by the Member State.

5. Common technical specification: a technical specification laid down in accordance with a procedure recognised by the Member States to ensure uniform application in all Member States which has been published in the *Official Journal of the European Communities*.'

4 The third, fifth, eighth, thirteenth, seventeenth and twenty-first recitals in the preamble to Directive 93/42 state:

'Whereas 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;

…

Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;

…

Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonisation and standardisation [(OJ 1985 C 136, p. 1)], rules regarding the design and manufacture of medical devices must be confined to the provisions required to meet the essential requirements; whereas, because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements should be applied with discretion to take account of the technological level existing at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;

…

Whereas, for the purpose of this Directive, a harmonised standard is a technical specification (European standard or harmonisation document) adopted, on a mandate from the Commission, by either [the CEN or Cenelec] or both of these bodies in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations [(OJ 1983 L 109, p. 8)], and pursuant to the … general guidelines [on cooperation between the Commission and these two bodies signed on 13 November 1984]; … whereas, for specific fields, what already exists in the form of European *Pharmacopoeia* monographs should be incorporated within the framework of this Directive; whereas, therefore, several European *Pharmacopoeia* monographs may be considered equal to the abovementioned harmonised standards;

…

Whereas medical devices should, as a general rule, bear the CE mark to indicate their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose;

…

Whereas the protection of health and the associated controls may be made more effective by means of medical device vigilance systems which are integrated at Community level.'

5 According to Article 1(1) thereof, Directive 93/42 is to apply to medical devices and their accessories. For the purposes of that directive, accessories are to be treated as medical devices in their own right.

6 In accordance with Article 2 of Directive 93/42, Member States are required to take all necessary steps to ensure that medical devices may be placed on the market and/or put into service only if they comply with the requirements laid down in that directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.

7 Under Article 3 of that directive, the medical devices must meet the essential requirements set out in Annex I to the directive which apply to them, taking account of their intended purpose.

8 Article 4(1) of Directive 93/42 prohibits Member States from creating any obstacle to the placing on the market or the putting into service within their territory of medical devices bearing the CE marking provided for in Article 17 of that directive, which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11 thereof.

9 Pursuant to Article 5(1) of Directive 93/42, Member States are to presume compliance with the essential requirements referred to in Article 3 of that directive in respect of medical 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 Communities*.

10 Article 5(2) thereof states that, for the purposes of Directive 93/42, reference to harmonised standards also includes the monographs of the European *Pharmacopoeia* notably on surgical sutures, the references of which have been published in the *Official Journal of the European Communities*.

11 Article 5(3) of Directive 93/42 refers to Article 6(2) thereof with regard to the measures to be taken by the Member States if a Member State or the Commission considers that the harmonised standards do not entirely meet the essential requirements referred to in Article 3 of that directive.

12 Article 8 of that directive, entitled 'Safeguard clause', is worded as follows:

'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.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

— the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6,

— the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorised representative established within the Community.

3. Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.'

13 Article 10 of Directive 93/42 provides:

‘1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving a Class I, IIa, IIb or III device is recorded and evaluated centrally:

(a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

2. Where a Member State requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorised representative established in the Community, is also informed of the incident.

3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.’

14 Article 11 of Directive 93/42 regulates the procedure for assessing the compliance of medical devices with the requirements of that directive. For this purpose, as is stated in the 15th recital in the preamble to that directive, medical devices are grouped into four product classes and the checks to which they are subject are progressively stricter depending on the vulnerability of the human body and taking account of the potential risks associated with the technical design and manufacture of those devices.

15 Article 14b of that directive provides:

'Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Article [30 EC], the availability of such products should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures. It shall then inform the Commission and all the other Member States giving the reasons for its decision. The Commission shall, whenever possible, consult the interested parties and the Member States and, where the national measures are justified, adopt necessary Community measures in accordance with the procedure referred to in Article 7(2).'

16 Under Article 17(1) of Directive 93/42, medical devices, other than devices which are custom-made or intended for clinical investigations, which are considered to meet the essential requirements referred to in Article 3 thereof must bear the CE marking of conformity when they are placed on the market.

17 Article 18 of that directive states:

‘Without prejudice to Article 8:

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorised representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8.

….’

18 Annex I to that directive, entitled ‘Essential requirements’, states in Part I, entitled ‘General requirements’:

‘1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their

use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

— eliminate or reduce risks as far as possible (inherently safe design and construction),

— where appropriate[,] take adequate protection measures[,] including alarms if necessary, in relation to risks that cannot be eliminated,

— inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(2)(a), as specified by the manufacturer.

….'

National legislation

19 Directive 93/36 was transposed into Greek law, principally, by way of Presidential Decree 370 of 14 June 1993 (FEK A' 199/1995). Article 16 of that presidential decree essentially reproduces Article 8 of Directive 93/36.

20 Joint Ministerial Decree DY7/oik.2480, making Greek legislation consistent with Directive 93/42…, of 19 August 1994 (FEK B' 679), transposed that directive into Greek law. In addition, the Ethnikos Organismos Farmakon (the national authority for medicines, 'the EOF') was designated under Article 19(3) of Law 2889/2001 as the competent authority in respect of medical devices.

The pre-litigation procedure

21 The Commission received a complaint according to which certain hospitals in Greece, which organised calls for tenders in order to obtain medical devices, had acted in breach of the obligations under Directive 93/36 in conjunction with Directive 93/42.

22 According to that complaint, certain Greek hospitals rejected tenders in respect of medical devices on grounds of public health, despite the certification of those products with the CE marking and, in any event, without the safeguard procedure provided for by Directive 93/42 being applied.

23 On 20 April 2004, in the context of the investigation of the complaint in question, the Hellenic Republic forwarded to the Commission the EOF's Circular 19384 of 2 April 2004 ('Circular 19384'), which recognised, first, that certain committees responsible for procurement in hospitals had rejected on grounds of non-conformity tenders submitted by companies in respect of numerous medical devices bearing the CE marking, without prior examination by the EOF and noted, second, that in certain cases the non-conformity concerned specifications arbitrarily fixed by the hospitals. That circular served as a reminder of the exclusive legal procedure which those committees were bound to follow and the details of that procedure.

24 By letter of 8 November 2004, the complainant furnished further information indicating that, in spite of distributing Circular 19384, the competent committees of certain hospitals, such as the general hospitals of Komotiní, Messolonghi, Agios Nikolaos of Crete and Heraklion, continued to be in breach of the rules.

25 In the light of that information, the Commission opened infringement proceedings against the Hellenic Republic under Article 226 EC by sending it, on 21 March 2005, a letter of formal notice. In its response of 24 May 2005, that Member State did not contest the fact that certain Greek hospitals were not acting in conformity with relevant Community provisions, but stressed the exceptional nature of the cases referred to by

the Commission, which, according to that State, did not attest to the existence of a large-scale, horizontal infringement of Community law in that area.

26 On 19 December 2005, the Commission issued a reasoned opinion setting out the failure of the Hellenic Republic to fulfil its obligations under Article 8(2) of Directive 93/36 and Articles 17 and 18 of Directive 93/42 in relation to the award of public supply contracts for medical devices and calling on that Member State to comply with the opinion within two months of its receipt.

27 In its response of 9 February 2006 to that reasoned opinion, the Hellenic Republic claimed that it had taken the necessary measures to ensure the proper application of Community law and that the cases referred to in that reasoned opinion were exceptions to normal practice. As well as the adoption of Circular 19384, it also stated that systematic checks on the quality of hospital supplies were carried out by the EOF at the request of those hospitals. The Hellenic Republic stated that the national hospitals increasingly comply with the instructions of that body.

28 However, the Commission had knowledge of new information according to which the infringement at issue was still continuing. Moreover, it was apparent from the information received that the EOF was not competent to exercise any administrative control over the hospitals or to impose any penalty on them, and that so far no other body in the Greek legal order had exercised any powers in this area.

29 Taking the view that the Hellenic Republic had failed to fulfil its obligations under Article 8(2) of Directive 93/36 in conjunction with Articles 17 and 18 of Directive 93/42, the Commission brought the present action.

The action

Arguments of the parties

30 The Commission submits that Directive 93/36 establishes a precise framework concerning any contracting authority's definition of technical requirements imposed on devices included in a tender. According to Article 8(2) of that directive, reference to national standards implementing European standards, to European technical approvals or to common technical specifications is obligatory both in the tender notice and in the assessment of conformity of the products which are the subject of the tender. The Commission underlines the fact that derogations from the principle enshrined in Article 8(2) are set out exhaustively in Article 8(3).

31 The Commission maintains that the calls for tenders issued by the Greek hospitals refer, in accordance with Article 8(2) of Directive 93/36, to the requirement of a European technical approval particular to medical devices, that is, the CE marking, which is also laid down in Directive 93/42. Nonetheless, the contracting authorities proceeded to exclude tenders of certain medical devices bearing the CE marking, without such exclusion being covered by one of the categories of derogations provided for by Article 8(3) of Directive 93/36.

32 As regards Directive 93/42, the Commission states that it prescribes in detail the procedures for approving, certifying and placing medical devices on the market, but also for checking them, such as to leave no doubt as to the certified qualitative

characteristics and no discretion on the part of the national authorities beyond the framework established by the provisions of the directive.

33 The Commission states that the essential requirements of conformity and safety which apply to medical devices are specified in Annex I to Directive 93/42 and that products bearing the CE marking satisfy all those requirements. Article 3 of that directive, in conjunction with Article 17 thereof, sets out the basis on which the mark of conformity of those devices is legitimate and they may, therefore, circulate freely in the internal market.

34 The Commission maintains that it is possible that certain medical devices, despite bearing the CE marking, are considered by doctors to endanger the health or safety of patients. In that case, the Commission points out that such devices may be rejected by the contracting authorities, but only in the context of the safeguard procedure provided for in Directive 93/42 and described in Circular 19384.

35 The Commission states that instead of applying that safeguard procedure, the contracting authorities proceeded directly to reject the tenders of medical devices bearing the CE marking. The Commission submits that, in one case concerning Heraklion general hospital, the EOF was informed, but its ruling, according to which the medical devices in question had to be accepted, was not complied with.

36 However, according to the Commission, it follows from settled case-law that the existence of a directive approximating the laws of the Member States, such as Directives 93/36 and 93/42, and stating that the compliance of products included in tenders with

the technical prescriptions of that directive is necessarily certified by the CE marking, gives rise to the obligation on the part of the Member States to follow the special procedures of that directive where the validity of the certification is disputed.

37 The Commission maintains that, despite the adoption of Circular 19384 and the sending of a reminder on 19 January 2006, that is to say two years later, after the Commission's reasoned opinion, the unlawful conduct of the contracting authorities, as well as the Greek authorities' failure to review those authorities, persist. The Commission notes that the cases of which it is aware are characteristic examples of a practice which seems to be standard in Greek hospitals. The Hellenic Republic's argument based on the existence of national procedures to penalise any notified infringement of the rules on public contracts cannot in any way justify the infringement at issue.

38 The Hellenic Republic submits that hospitals, in their role as contracting authorities, do comply with the relevant provisions of Community law and national law in the area of supplies. It submits that the cases of certain hospitals not acting in accordance with the relevant Community provisions are purely and simply exceptions, from which it cannot be deduced that there is a large-scale horizontal infringement of Community law in the area at issue.

39 The Hellenic Republic maintains, moreover, that the EOF did issue Circular 19384, as well as a reminder on 19 January 2006, relating to the appropriate way of assessing medical devices for the purpose of their supply. Consequently, it took the measures necessary to ensure the proper application of Community law. That Member State explains, furthermore, that the reason why no penalties have yet been imposed on the hospitals which do not comply with the relevant Community provisions is that the body

of inspectors of health and welfare services (Soma Epitheoriton Ipiresion Igias kai Pronias) is still undertaking an inquiry into that question.

Findings of the Court

40 It is settled case-law that, where the Commission relies on detailed complaints revealing repeated failures to comply with the provisions of a directive, it is incumbent on the Member State concerned to contest specifically the facts alleged in those complaints (see, to that effect, Case 272/86 *Commission* v *Greece* [1988] ECR 4875, paragraph 19, and Case C-494/01 *Commission* v *Ireland* [2005] ECR I-3331, paragraph 46).

41 However, in the present case, the Hellenic Republic has neither provided specific evidence to contradict the allegations made by the Commission nor challenged in substance and in detail the Commission's assertions. That Member State simply acknowledged in its defence and in Circular 19384 that certain hospitals had acted in breach of the relevant Community provisions.

42 Consequently, the facts alleged by the Commission must be regarded as proven.

43 According to the Court's case-law, contracting authorities which have issued an invitation to tender for the supply of medical devices bearing the CE marking cannot

reject, on grounds of protection of public health, the tender in respect of such products, directly and without following the safeguard procedure provided for in Articles 8 and 18 of Directive 93/42. If a contracting authority considers that the tender in respect of medical devices bearing the CE marking may compromise public health, it is required to inform the competent authority with a view to setting that safeguard procedure in motion (Case C-6/05 *Medipac-Kazantzidis* [2007] ECR I-4557, paragraph 55).

44 It should be observed that the Hellenic Republic also does not dispute the failure of the contracting authorities of the Greek hospitals criticised by the Commission to comply with Article 8(2) of Directive 93/36 and Articles 17 and 18 of Directive 93/42, relating to the procedures for the award of public contracts concerning medical devices bearing the CE marking.

45 By contrast, the Hellenic Republic claims that the cases referred to by the Commission are exceptional and cannot, therefore, constitute an infringement.

46 According to the Court's established case-law, even if the applicable national legislation itself complies with Community law, a failure to fulfil obligations may arise due to the existence of an administrative practice which infringes that law (see, in particular, Case C-278/03 *Commission* v *Italy* [2005] ECR I-3747, paragraph 13 and Case C-441/02 *Commission* v *Germany* [2006] ECR I-3449, paragraph 47).

47 In the present case, as is apparent from the observations of the parties, this action for failure to fulfil obligations is not intended to call into question the compliance of the Hellenic Republic's transposition of Directives 93/36 and 93/42, but is confined to the question of the application of those provisions by the competent Greek authorities.

48 In order for a failure to fulfil obligations to be found on the basis of the administrative practice followed in a Member State, the Court has held that the failure to fulfil obligations can be established only by means of sufficiently documented and detailed proof of the alleged practice; that administrative practice must be, to some degree, of a consistent and general nature; and, in order to find that there has been a general and consistent practice, the Commission may not rely on any presumption (Case C-156/04 *Commission* v *Greece* [2007] ECR I-4129, paragraph 50 and the case-law cited).

49 It must be pointed out that, according to the information in the file before the Court, the products in question are products fulfilling the requirements of the European *Pharmacopoeia* technical standard and must, by their very nature, be purchased repeatedly and regularly by hospitals and, consequently, with an established degree of regularity.

50 Nonetheless, at least 16 hospital contracting authorities rejected the medical devices in question, during tendering procedures, including the hospitals of Komotiní, Messolonghi, Agios Nikolaos of Crete, Venizeleio-Pananeio of Heraklion, Attica, Agios Savvas, Elpis, Argos, Korgialenio-Benakio, Geniko Nosokomio of Kalamata, Nauplie, P. & A. Kyriakou, Sparta, Panakardiko of Tripoli, Elena Venizelou and Asklipiio Voula.

51 The list of the hospitals mentioned by the Commission shows a variety in the size of the establishments, since some of the largest Greek hospitals such as Agios Savvas, Kyriakou and Asklipiio Voula are referred to, as well as medium-sized hospitals such as Argos, Agios Nikolaos of Crete or Sparta.

52 Moreover, that list refers to establishments with a geographical coverage encompassing the entire country with, in particular, hospitals in Athens, in the Peloponnese and on

Crete, but concerns also a wide field of competence, including general hospitals, a children's hospital, a hospital treating cancer-related illnesses and a maternity hospital.

53 Therefore, it can be deduced that the administrative practice of the contracting authorities in question, contrary to Article 8(2) of Directive 93/36 and Articles 17 and 18 of Directive 93/42, demonstrates a certain degree of consistency and generality.

54 Where the Commission has adduced sufficient evidence to show that a Member State's authorities have developed a repeated and persistent practice which is contrary to the provisions of a directive, it is incumbent on that Member State to challenge in substance and in detail the information thus produced and the consequences flowing therefrom (*Commission* v *Ireland*, paragraph 47), which is not so in the present case.

55 Moreover, it is apparent from the file before the Court that the unlawful conduct of the Greek hospital contracting authorities was not sufficiently reviewed and penalised by the competent Greek authorities. The defendant Member State has merely justified the lack of intervention on the part of its services by referring to the fact that the body of inspectors of health and welfare services was, at the time of the proceedings, carrying out an inquiry into the question and that it had not completed its work.

56 In view of the above, it must be declared that, by rejecting tenders in respect of medical devices bearing the CE certification marking, without the competent contracting authorities of Greek hospitals having complied with the procedure provided for in Directive 93/42, the Hellenic Republic has failed to fulfil its obligations under Article 8(2) of Directive 93/36 and Articles 17 and 18 of Directive 93/42.

Costs

57 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission applied for costs against the Hellenic Republic and the latter has been unsuccessful, the Hellenic Republic must be ordered to pay the costs.

On those grounds, the Court (Fourth Chamber) hereby:

1. **Declares that, by rejecting tenders in respect of medical devices bearing the CE certification marking, without the competent contracting authorities of Greek hospitals having complied with the procedure provided for in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003, the Hellenic Republic has failed to fulfil its obligations under Article 8(2) of Council Directive 93/36/EEC of 14 June 1993 coordinating procedures for the award of public supply contracts, as amended by Commission Directive 2001/78/EC of 13 September 2001, and Articles 17 and 18 of Directive 93/42, as amended by Regulation No 1882/2003;**

2. **Orders the Hellenic Republic to pay the costs.**

[Signatures]