OPINION OF ADVOCATE GENERAL SHARPSTON

delivered on 21 November 2006 [1]

1. The questions referred in this preliminary reference from the Greek Symvoulio tis Epikratias (Council of State) require the Court to consider how the EC rules on public procurement — in particular, the Public Supply Contracts Directive [2] — relate to the Medical Devices Directive. [3] The fundamental rules of the EC Treaty underlie that assessment.

2. In the main proceedings, a public hospital issued, ostensibly in accordance with procedures laid down in the Public Supply Contracts Directive, an invitation to tender for the supply of surgical sutures bearing the CE marking provided for in the Medical Devices Directive, but then excluded as technically unsuitable a particular tender for sutures bearing that marking.

3. The national court wishes to know to what extent and in what circumstances such conduct may be permissible under the combined provisions of the two directives, and what verification procedures must be observed.

4. The Austrian Government has raised a question as to admissibility. It points out that the value of the supply contract concerned is such that the contract would appear to fall outwith the scope of the Public Supply Contracts Directive.

1 — Original language: English.

2 — 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 in particular by European Parliament and Council Directive 97/52/EC of 13 October 1997 (OJ 1997 L 328, p. 1) and Commission Directive 2001/78/EC of 13 September 2001 (OJ 2001 L 285, p. 1).

3 — Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), as amended in particular by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 (OJ 1998 L 331, p. 1), Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 (OJ 2000 L 313, p. 22), Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 (OJ 2002 L 6, p. 50) and Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ 2003 L 284, p. 1). A consolidated version is available at http://eur-lex.europa.eu/.

Relevant legislation

The Medical Devices Directive

5. The Medical Devices Directive was adopted on the basis of Article 100a of the EEC Treaty (now Article 95 EC), under which the Council is to adopt measures for the approximation of provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. It constitutes an example of a directive implementing the so-called 'New Approach' to harmonisation.

6. The New Approach, introduced in 1985, [4] represents a regulatory technique intended to overcome the shortcomings encountered in the decision-making procedures for the adoption of harmonisation directives. The New Approach was considered to be a key instrument for the full realisation of the 1992 single market programme.

7. The preamble to the Medical Devices Directive makes it clear that the aim is, in essence, to create a single market in medical devices, free from internal frontiers. To achieve that aim, the directive lays down the essential requirements (ensuring a high level of protection for patients, users and others) which medical devices must meet in order to benefit from free movement. The directive harmonises applicable certification and inspection procedures. Devices that are considered, after being subject to a conformity assessment procedure, to meet the essential requirements of the directive are granted a CE marking. The directive also provides for the voluntary use of harmonised European standards to demonstrate conformity with the essential requirements. [5]

8. In accordance with Article 1(1), the Medical Devices Directive applies to medical devices, as defined in Article 1(2)(a), and their accessories, both of which are thereafter termed 'devices'.

4 — See Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards, OJ 1985 No C 136, p. 1.

5 — See in particular the 1st, 2nd, 3rd, 5th, 12th, 13th and 17th recitals. CE marking carries with it the presumption that products so marked fulfil the 'essential requirements' laid down in terms of results to be attained or hazards to be dealt with in the annexes to 'New Approach' directives and may thus benefit from free movement throughout the Community. Those essential requirements define the results to be attained or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so. In contrast, harmonised European standards lay down the technical solutions which, if complied with, ensure the fulfilment of the essential requirements contained in the various New Approach directives. Compliance with those standards remains voluntary and manufacturers may prove that their products comply with the essential requirements laid down in the 'New Approach' directives, and therefore obtain a CE marking, by any other means of their choice. See further, EC Commission, 'Guide to the implementation of the directives based on the New Approach and the Global Approach', 2000, at pp. 27 et seq.

9. Under Article 2, 'Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose'.

10. Article 3 provides that, 'The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned'.

11. The first of those requirements is: '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.' To a large extent, that requirement encapsulates the more detailed requirements that follow.

12. Article 4(1) provides that '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'.

13. Article 5 is entitled 'Reference to standards'. It provides:

'1. Member States shall presume compliance with the essential requirements referred to in Article 3 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 Communities*; Member States shall publish the references of such national standards.

2. For the purposes of this Directive, 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.*

...'

14. Article 8 is entitled 'Safeguard clause'. It provides as follows:

'1. Where a Member State ascertains that the devices referred to in Article 4(1) ..., 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.'

15. Article 9 provides for the classification of devices into Classes I, IIa, IIb or III, in accordance with rules set out in Annex IX. According to those rules, [6] surgical sutures appear to fall within Class IIa, as 'surgically invasive devices intended for short-term use'.

16. Article 10 is entitled 'Information on incidents occurring following placing of devices on the market' and contains detailed provisions aimed at ensuring that information regarding any serious public health incident relating to a device or its labelling is recorded and evaluated centrally. It requires Member States to notify the problem to the manufacturer (or his authorised representative); and, after appropriate consultation and without prejudice to Article 8, to inform the Commission and other Member States of any 'relevant measures' that have been taken or that are contemplated.

17. Article 11 lays down conformity assessment procedures. In order to qualify for CE marking, devices in Class IIa must be subjected either to one of three 'EC declaration of conformity' procedures ('full quality assurance', 'production quality assurance' or 'product quality assurance') [7] or to the 'EC verification' procedure. [8]

18. Article 17 lays down detailed provisions concerning the affixing of the CE marking of conformity to devices meeting the essential requirements referred to in Article 3 that are placed on the market.

19. Article 18 concerns wrongly affixed CE marking. It requires a Member State to oblige the manufacturer responsible for the wrongly affixed CE marking, or his authorised representative, to end the infringement (under conditions imposed by the Member State); and, where non-compliance continues, to 'take all appropriate

6 — See in particular the definitions in Points I.1.1 and I.1.2, and Rule 7 in point III.2.3.

7 — Set out in Annexes II, V and VI respectively.

8 — Set out in Annex IV.

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.'

20. Like Article 10, the application of the Article 18 procedure is 'without prejudice' to the possible use of the Article 8 procedure (the safeguard clause).

21. According to the order for reference, the Medical Devices Directive was implemented in Greek law by Joint Decree DI7/ik.2480 of 19 August 1994 of the Minister for Economic Affairs, the Minister for Health, Welfare and Social Security and the Minister for Industry, Energy and Technology. [9]

The Public Supply Contracts Directive

22. The Public Supply Contracts Directive coordinates procedures for the award of public supply contracts. In accordance with Article 1(a), such contracts include in particular contracts for the purchase of products from a supplier by a contracting authority. Contracting authorities are defined in Article 1(b) as the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or bodies governed by public law.

23. Pursuant to the first indent of Article 5(1)(a), the substantive harmonising provisions of the directive (Articles 6 to 27) are applicable only to public supply contracts awarded by contracting authorities referred to in Article 1(b) 'where the estimated value net of value added tax (VAT) is not less than the equivalent in [euro] of 200 000 special drawing rights (SDRs)'. With effect from 1 January 2002, and at the material time in the present case, that equivalent was EUR 249 681. [10] Below that threshold, Member States are under no obligation to apply the rules in the directive, although they may of course choose to do so as a matter of national law.

24. Pursuant to Article 8(1) 'the technical specifications defined in Annex III shall be given in the general or contractual documents to each contract'. Article 8(2) provides that 'without prejudice to the legally binding national technical rules, in so far as these are compatible with Community law, the tech-

9 — FEK B' (Greek Official Journal) 679.

10 — See OJ 2001 C 332, p. 21.

nical 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'. A contracting authority may depart from that obligation only in the cases specified under Article 8(3). These derogations are not relevant to the main proceedings.

25. Article 26(1) specifies the criteria on the basis of which the contract is to be awarded. They are to be either (a) the lowest price only or (b) the most economically advantageous tender, on the basis of 'various criteria according to the contract in question: e.g. price, delivery date, running costs, cost-effectiveness, quality, aesthetic and functional characteristics, technical merit, after-sales service and technical assistance'.

26. Finally, insofar as relevant, Annex III, referred to in Article 8(1), contains the following definitions:

'(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.'

The main proceedings and the questions referred

27. In December 2003 the Venizelio-Pananio General Hospital of Heraklion ('the hospital') issued an invitation to tender, on the basis of lowest price as the award criterion, for the supply of various surgical sutures with an estimated value of EUR 131 500 including VAT. It was specified that the sutures had to be certified (by CE marking) in accordance with the European Pharmacopoeia and to possess certain technical characteristics concerning their size, diameter, length and type of needle.

28. Bids were submitted by nine companies, including Medipac — Th. Kazantzidis AE ('Medipac'). It is common ground that the sutures proposed by Medipac were duly certified by CE marking.

29. In an opinion to the committee conducting the tender procedure, the hospital's surgeons listed problems presented by certain of the sutures ('PGA type sutures') being offered by Medipac and requested their exclusion from the tender process. The committee accepted the surgeons' suggestion, and recommended that the sutures in question be rejected. It is common ground that those concerns were not reflected in the earlier tender notice.

30. The problems listed were that knots slipped easily and closed prematurely, that needles frequently twisted or broke and that the sutures did not retain adequate strength for sufficiently long.

31. On that basis, the hospital's Administrative Board ruled in March 2004 that the PGA type sutures fell outside the technical specifications for the tender and accordingly Medipac's tender was excluded from the procurement procedure.

32. It also appears from the case-file, in particular from the observations of the hospital, of Medipac and the oral observations presented by the Greek Government at the hearing, that in May 2004, in accordance with the national rules implementing the Medical Devices Directive, the hospital informed the Ethnikou Organismos Farmakon (the Greek authority responsible for ensuring the implementation of the Community directives on medical devices: 'EOF') of the objections raised by its surgeons regarding the suitability of Medipac's surgical sutures. In August 2004, the EOF, after carrying out laboratory tests, confirmed to the hospital that the surgical sutures provided by Medipac were in compliance with applicable rules and were thus safe to be used for their intended purpose. Despite those findings, Medipac's tender remained excluded from the tender procedure.

33. In April 2004 Medipac submitted an administrative appeal against the hospital's decision rejecting its tender, arguing, inter alia, that technical specifications not set out in the invitation to tender had been applied.

34. The administrative appeal was dismissed as unfounded, on the basis of the surgeons' complaints. Medipac is now appealing against that dismissal before the national court.

35. The national court expresses the view that, since 'the Medical Devices Directive does not preclude the administration from deciding, on the supply of a certain article for which a recognised specification standard exists and which bears the CE marking, that the article is not acceptable, provided that it argues and proves that there are special grounds therefore as stated above, it was permissible for the Administrative Board of the hospital to decide, when assessing the technical bids, that the sutures offered by the applicant were not acceptable, invoking the aforementioned public-interest grounds, which refer to the protection of public health and human life; furthermore, it would, in the view of this Court, be lawful to exclude the applicant's technical bid regarding those sutures. A corresponding term — that is to say that the articles to be supplied are entirely suitable for the use for which they are intended — even if not expressly mentioned in the invitation to tender, is implicit in every instance and therefore also when the award criterion is the lowest price. Therefore, the relevant ground for annulment to the contrary, by which it is submitted that the contracting authority was obliged to consider the applicant's bid regarding the sutures to be technically acceptable since, as the invitation to tender demands, they bear the CE marking, would have to be rejected as unfounded.'

36. The national court seeks a preliminary ruling from the Court on the following questions:

'(1) Whenever tender procedures governed by Council Directive 93/36/EEC for the supply of medical devices under Directive 93/42/EEC are conducted under the lowest-price system, is the contracting authority as the purchaser of the relevant goods able, in accordance with the Medical Devices Directive, interpreted in conjunction with Public Supply Contracts Directive, to reject a tender for medical devices which bear the CE marking and have been the subject of a quality check by the competent certification body, as technically unacceptable at the stage of the technical assessment, in reliance upon sound objections relating to their adequacy in terms of quality which are connected with the protection of public health and the specific form of use for which those devices are intended and in view of which objections the devices are considered inappropriate and unfit for that use (with the self-evident precondition that those objections are subject to review of their validity by the court having jurisdiction if there is a dispute as to whether they pertain)?

(2) If the preceding question is answered in the affirmative, is the contracting authority as the purchaser of the relevant goods able, for the foregoing reason, directly to consider medical devices which bear the CE marking unsuitable for the form of use for which they are intended, or must the safeguard clauses first be applied which are contained in the Medical Devices Directive and the abovementioned Joint Ministerial Decree DI7/ik.2480/1994 and which enable the relevant competent authority — which in Greece is the Ministry of Health, Welfare and Social Security acting through the Directorate for Biomedical Technology — to take measures either in accordance with the procedure in Article 8 of the directive, if correctly installed and maintained medical devices may jeopardise the life or safety of patients or users, or under Article 18 of the directive, if it is established that the CE marking has been affixed unduly?

(3) In light of the answer to the second question, and in the event that the abovementioned safeguard clauses must first be applied, is the contracting authority obliged to await the outcome of the procedure initiated either under Article 8 or under Article 18 of the Medical Devices Directive and, further, is it bound by that outcome in the sense that it is obliged to procure the article in question even though its use demonstrably gives rise to risks for public health and generally it is unsuitable for the use for which the contracting authority intends it?'

37. Written observations have been submitted by Medipac, the hospital, the Greek and Austrian Governments and the Commission. At the hearing held on 22 June 2006 the Greek Government and the Commission presented oral observations.

The parallel infringement proceedings initiated by the Commission under Article 226 EC

38. It appears from the Commission's written and oral observations that Greek hospitals regularly refuse medical devices bearing CE marking, invoking health and safety grounds. Following contacts with the Commission, the EOF issued Circular No 19384/2004 to address this issue. In that circular, which the Commission summarises in its written observations, the EOF reminds hospitals that they may refer only to national and/or European technical specifications and should avoid referring to arbitrary technical specifications. If hospitals have doubts about the suitability of specific medical devices bearing CE marking, they are required to send them to the EOF for checking.

39. According to the Commission, Greek hospitals continue to ignore the instructions contained in that circular. The Commission has therefore initiated infringement proceedings against Greece under Article 226 EC for breach of Article 8(2) of the Public Supply Contracts Directive.

Admissibility

40. The Austrian Government raises doubts as to the admissibility of the reference. It is uncertain as to how an answer to the questions posed may assist the referring court in deciding the case before it. First, the questions relate explicitly to the interpretation of the Public Supply Contracts Directive, but the estimated value of the contract in issue falls below the threshold for the application of that directive. Second, it is not clear from the order for reference whether the surgical sutures concerned represented a real risk to health, or merely failed to meet the surgeons' expectations. That consideration is of particular relevance when determining the adjudicating authority's rights and obligations.

41. In the light of the Austrian Government's doubts as to the applicability of the Public Supply Contracts Directive, the Court decided, pursuant to Article 104(5) of the Rules of Procedure, to ask the referring court to clarify why it considered that that directive applied to the circumstances of the present case. However, the referring court indicated that, apparently for procedural reasons, it was unable to reply to the question.

Assessment

42. The tender documents annexed to Medipac's observations indicate that the total estimated value of invitation to tender No 146/2003 was indeed EUR 131 500 inclusive of VAT. Pursuant to Article 5(1)(a) of the Public Supply Contracts Directive, Articles 6 to 27 of the directive therefore do not apply to such a procedure. Nor do the remaining provisions of the directive lay down any rules which appear capable of being relevant to the determination of the case before the national court.

43. At the hearing the Greek Government confirmed that the value of the contract in the main proceedings was below the threshold triggering the application of the Public Supply Contracts Directive. However, it argued that the questions should not be treated as inadmissible. Although they also

refer to the Public Supply Contracts Directive, the preliminary questions in reality seek an interpretation of the Medical Devices Directive, which is indeed relevant for the resolution of the case before the national court. The Commission has argued along similar lines.

44. In my view, the Court should not declare the questions referred inadmissible.

45. First, although Member States are not required to apply the Public Supply Contracts Directive rules to procedures which fall below its threshold of applicability, they are clearly entitled to do so. It is possible that such a situation may prevail in Greece, although the referring court has been prevented for procedural reasons from confirming that hypothesis.

46. If that is so, it is clearly desirable for the national rules to be interpreted in the same way regardless of whether the tendering procedures in question fall above or below the threshold; and the proper interpretation of the Public Supply Contracts Directive thus becomes relevant.

47. That was the approach taken by the Court in *Dzodzi* and subsequent case-law. [11] In *Leur-Bloem* the Court ruled that it 'has jurisdiction under Article [234] of the Treaty to interpret Community law where the situation in question is not governed directly by Community law but the national legislature, in transposing the provisions of a directive into domestic law, has chosen to apply the same treatment to purely internal situations and to those governed by the directive, so that it has aligned its domestic legislation to Community law'. [12]

48. I therefore consider that the Court should provide a reply to the first question, which refers to the Public Supply Contracts Directive as well as to the Medical Devices Directive, even if the former is not applicable to the main proceedings by virtue of Community law alone.

49. Second, it is well established that, where contracts are excluded from the scope of the procurement directives, contracting authorities are nevertheless bound to comply with the fundamental rules of the EC Treaty during the tendering procedure for awarding

11 — Joined Cases C-297/88 and C-197/89 *Dzodzi* [1990] ECR I-3763. See also Case C-28/95 *Leur-Bloem* [1997] ECR I-4161, at paragraphs 27 to 29, and the case-law cited therein.

12 — See also *Leur Bloem*, paragraph 34.

such contracts, in particular the principles of non discrimination on ground of nationality and equal treatment between tenderers. According to the case-law, those principles also impose an obligation of transparency on contracting authorities. [13]

50. The national court has not referred to the fundamental rules of the EC Treaty in its order for reference. However, the Court, in assisting it to decide the case in the main proceedings, may 'consider provisions of Community law to which the national court has not referred in the text of its question'. [14] In my view, the Court can and indeed should examine the issues raised in the main proceedings in the light of the fundamental rules of the EC Treaty. As will become apparent, those rules are central to the dispute before the national court.

51. Third, as both the Greek Government and the Commission have noted, some three quarters of the order for reference consists of quotations from the Medical Devices Directive and of an account of the national provisions implementing that directive. The Public Supply Contracts Directive is mentioned only in the first question, whilst all three questions enquire about the proper interpretation of the Medical Devices Directive. It is thus clear that the national court's principal concern is with the interpretation of the latter.

52. In those circumstances, it seems to me that the correct approach is for the Court to rule on the proper interpretation of the Medical Devices Directive in the light of the fundamental Treaty rules applicable to all tendering procedures whatever their value, and then to add any appropriate additional indications concerning the interpretation of the Public Supply Contracts Directive.

53. Finally, as regards the adequacy of the factual detail provided in the order for reference, it is true that the order itself is not particularly forthcoming as to the precise reason(s) why Medipac's tender was rejected. In my view, the deficiency is sufficiently cured by the material in the case file lodged by the national court and by the observations submitted by Medipac and by the hospital, which concur in indicating that the tender was rejected on the basis of the objections raised by the hospital's surgeons to the quality of the PGA type sutures proposed

13 — See Case C-324/98 *Telaustria and Telefonadress* [2000] ECR I-10745, paragraph 60 and subsequent case-law. See also Case C-231/03 *Coname* [2005] ECR I-7287, at paragraphs 16 and 17; Case C-458/03 *Parking Brixen* [2005] ECR I-8585, at paragraphs 48 and 49; Case C-410/04 *ANAV* [2006] ECR I-3303, at paragraphs 20 and 21.

14 — Case 35/85 *Tissier* [1986] ECR 1207, paragraph 9.

by Medipac. In any event, in view of the specific circumstances of the case, whether the precise nature of the reasons underlying the hospital surgeons' objections is relevant in determining the obligations of the contracting authority under Community law can only be resolved by examining the substance.

54. I therefore conclude that the request for a preliminary ruling should be declared admissible in its totality.

Substance

55. In essence, the three questions seek to clarify the scope of the obligations arising from Community law for a contracting authority which has issued a tender notice for the supply of medical devices covered by the Medical Devices Directive specifying that the supplies must bear CE marking by virtue of that directive, in accordance with the European Pharmacopoeia, if that authority becomes aware that there may be public health grounds for regarding the medical devices offered by one of the tenderers as unsuitable even though they bear CE marking.

The EC Treaty rules and the Medical Devices Directive

The first and second questions

56. The first two questions address the issue of whether under the EC rules applicable to public procurement, read in combination with the Medical Devices Directive, a contracting authority is entitled directly to reject on public health grounds a tender consisting of supplies bearing CE marking as required by the tender notice, or whether in order to do so it must first engage the procedures in Article 8 and/or Article 18 of the Medical Devices Directive. Since those questions involve two interlinked aspects of the same issue, it is convenient to examine them together.

57. Article 18 of the Medical Devices Directive specifies the measures Member States are to adopt if they establish that CE marking has been affixed unduly to a device. In short, they must oblige the manufacturer to end the infringement in accordance with national law. If non-compliance continues, Member States should use the procedure in Article 8 to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market. Since Article 18 expressly refers to, and

thereby renders applicable, the Article 8 procedure, the analysis that follows is relevant to both provisions.

Submissions to the Court

58. Medipac argues first that, where there is a European system laying down technical standards and certification procedures for products, contracting authorities may only judge the technical suitability of those products by reference to those standards.

59. Second, in rejecting Medipac's tender on the basis that the sutures were not technically satisfactory, the hospital changed the original criteria specified in the notice to tender, thereby contravening the principles of transparency, equal treatment, legitimate expectations and open competition.

60. Third, Member States are not entitled to restrict or prevent the marketing of products which bear CE marking. Articles 3 and 17 of the Medical Devices Directive create a presumption that products bearing CE marking fulfil the essential requirements for such products. That presumption can be overridden only in accordance with the procedures laid down in Articles 8 and 18 of that directive.

61. Fourth, where the contract is to be awarded on the basis of the lowest price, the contracting authority has no discretion to take additional qualitative and technical criteria into account.

62. Fifth, if the hospital realised that it should have given different or more detailed specifications, it should have withdrawn the original invitation to tender and issued a new one enabling it to award the contract on the basis of the most economically advantageous tender, used the negotiated procurement procedure or invoked Article 8 or Article 18 of the Medical Devices Directive in accordance with the national rules implementing that directive.

63. The hospital stresses that, in its surgeons' professional opinion, Medipac's sutures were technically inadequate for the delicate operations for which they were required. Patients' health must be given priority.

64. The Commission argues that it is not permissible for a contracting authority to reject goods with CE marking in the way that the hospital did. Article 8(2) of the Public Supply Contracts Directive requires contracting authorities to use European approved references (such as CE marking) as the technical criteria in invitations to tender unless one of the derogations in

Article 8(3) applies, which was not the case here. The Medical Devices Directive creates a presumption that products marked CE fulfil the requirements to display that mark. If a contracting authority believes that a particular product does not fulfil those criteria, it must notify the competent national body, which can follow the procedures laid down in Articles 8 and 18 of the Medical Devices Directive — the only procedures for derogating from the presumption of compliance with the essential requirements conferred by CE marking. Only then may a contracting authority reject the goods in question.

65. In the Greek Government's view, CE marking is merely a minimum standard. The fact that a product bears CE marking creates a rebuttable presumption that it fulfils the relevant criteria. A contracting authority is therefore free to reject products which bear this marking, provided that it can show reasons for doing so based either on the need to protect public health or on the particular use for which the products are required.

66. The Greek Government stresses that the Medical Devices Directive aims to ensure that medical devices guarantee a high level of protection to patients, users and others. Moreover, Article 152 EC provides that the aim of guaranteeing a high level of protection of human health should be taken into account in all areas of the Community's activities. Community law thus implies into every invitation to tender the additional technical requirement that the use of the products tendered should not endanger health.

67. It would be absurd to require a contracting authority to buy a medical device which was clearly unsafe just because the device bore CE marking. If there is reason for concern, the contracting authority has a duty to investigate the product more closely, as long as the investigation is objective and its decision is susceptible to judicial review.

68. On that basis, the contracting authority may also reject the offer immediately, without waiting for the procedures specified in Articles 8 or 18 of the Medical Devices Directive to be commenced. Those procedures impose obligations only on the Member State concerned, not on the prospective purchaser.

69. At the hearing, the Greek Government initially contended that when acquiring

medical devices the hospital acted like any private purchaser, although it subsequently accepted that the hospital was a public law entity subject to the provisions of the Public Supply Contracts Directive. Nevertheless, it maintained that Articles 8 and 18 of the Medical Devices Directive do not affect the hospital's tendering process for an individual contract. Rather, they lay down generally applicable procedures designed to facilitate the free movement of products within the internal market and to ensure cooperation between Member States.

70. The Austrian Government argues that a contracting authority may reject a tender involving the supply of devices bearing CE marking under the Medical Devices Directive on legitimate public health grounds at the stage of technical assessment of the tenders. The contracting authority is however obliged to inform the competent national body under Article 8 of the Medical Devices Directive, so that the formal procedure provided under that provision can be followed.

Preliminary remarks

71. Four preliminary observations should be made.

72. First, the order for reference indicates that the tender notice issued by the hospital specified that the sutures had to be certified by CE marking in accordance with the European Pharmacopoeia. Although CE markings and European standards (or harmonised standards as they are referred to in New Approach directives) do not have the same meaning in law, [15] in the case of surgical sutures, Article 5(2) of the Medical Supplies Directive provides that the monographs of the European Pharmacopoeia act as European harmonised standards. As a consequence, for the purposes of the present case, CE marking and compliance with harmonised standards may indeed be used interchangeably.

73. Second, it appears that the tender notice contained no reference to other specifications or conditions, such as might have reflected the hospital surgeons' concerns [16] regarding the performance in theatre of the sutures bearing CE marking offered by Medipac. These concerns, which provided the basis for rejecting Medipac's bid, were only introduced and given weight subsequently, during the technical examination of the tenders. The case-file also reveals that the hospital refused to accept Medipac's tender, despite the fact that the EOF had, at

15 — See footnote 5 above.
16 — See points 29 and 30 above.

the request of the hospital, confirmed the suitability of Medipac's surgical sutures for their intended purpose. [17]

74. Third, it is common ground that Greece initiated neither the safeguard procedure under Article 8 nor the procedure for dealing with wrongly affixed marking under Article 18 of the Medical Devices Directive. [18] As a result, the Commission was never informed of any complaint relating to Medipac's surgical sutures.

75. Fourth, the case-law on the notion of 'the State' for the purposes of the application of EC directives indicates that all entities assimilated to the State are under an obligation to respect the provisions of EC directives or at least not to act in a way which may hinder the attainment of their objectives. [19] At the hearing, the Greek Government confirmed that the hospital is indeed such an entity. [20] It follows that the provisions of the Medical Devices Directive are also binding on the hospital, regardless of whether the national rules implementing that directive impose any specific obligation on Greek public hospitals. The hospital was thus under a duty not to act in a manner that might jeopardise the application of the Medical Devices Directive in Greece, or to restrict the free circulation of devices bearing CE marking as provided for by that directive. [21]

Assessment

76. In my view the hospital's rejection of a tender proposing to supply products bearing CE marking as required by the tender notice on the basis of concerns subsequently expressed by the hospital's surgeons infringes the fundamental rules of the EC Treaty.

77. Those rules include the principles of non-discrimination on the ground of nationality and, more importantly in the present case, of equal treatment of tenderers, from which, as the Court has held, an obligation of transparency also arises. [22] Clearly those principles must be complied with at every

17 — See point 32 above.

18 — For the sake of completeness, I add that no mention was made either of any recourse to Article 10 of the Medical Devices Directive.

19 — Case C-198/01 *CIF* [2003] ECR I-8055, paragraph 49 and case-law cited therein. See also the order of the Court in Case C-297/03 *Sozialhilfeverband Rohrbach* [2005] ECR I-4305.

20 — Somewhat inconsistently, it also maintained that when acquiring supplies the hospital acted as a private purchaser. See point 69 above.

21 — See case-law cited in footnote 19 above.

22 — See case-law cited in footnote 13 above.

stage of the award procedure so as to afford equality of opportunity to all tenderers throughout the process. [23] In order to be effective, they must therefore cover not only the initial definition of technical specifications and award criteria by contracting authorities, but also the way in which those specifications and criteria are interpreted and applied during an award procedure.

78. Technical specifications identify the object of the contract in precise terms, enable interested undertakings to assess whether to present a bid and provide contracting authorities with the technical parameters to assess, in relation to their needs, the various bids presented. They play an essential role in the selection of suitable bids and they must, by their very nature, be laid down in advance. [24] In principle, any tender complying with the technical specifications referred to in the tender notice must be accepted as suitable to fulfil the object of the contract by the contracting authority, which must then proceed to apply the chosen award criteria — in the present case the lowest price — in order to select the successful bidder amongst those whose bids satisfy the technical specifications.

79. A contracting authority which defines the technical specifications of the supplies it seeks by reference to CE marking, but then rejects a tender offering products bearing CE marking on grounds which had not been previously defined in the tender notice or contract documents, which were not made known to the bidders and which were identified and relied upon for the first time during the technical examination of bids, infringes the very essence of the principles of equal treatment and transparency. [25] Such conduct represents arbitrary modification of the original conditions of the tender that is incompatible with the concept of the 'level playing field' to which tenderers are entitled under the EC Treaty.

80. That conclusion does not answer the question, however, of how contracting authorities are then meant to conduct an

23 — See *Parking Brixen*, cited in footnote 13 above, at paragraph 48 and the case-law cited therein, in particular Case C-87/94 *Commission* v *Belgium* [1996] ECR I-2043, at paragraph 54. That judgment in fact confirms that the general principle of equal treatment applies in the same manner to all contract award procedures irrespective of whether they fall within or outwith the procurement directives.

24 — See the Opinion of Advocate General Jacobs, delivered on 21 April 2005, in Case C-174/03 *Impresa Portuale di Cagliari*, at point 77.

25 — See, by analogy, *Commission* v *Belgium*, cited in footnote 23 above, at paragraphs 88 and 89. As mentioned above, even though that case was concerned with the application of the principle of equal treatment in the framework of the public procurement directives, the Court's considerations are also applicable to contracts award procedures falling outside the procurement directives. See in this respect, *Parking Brixen*, cited in footnote 23 above.

award procedure under the applicable rules when concerns arise relating to the health and safety of patients.

81. I agree with the Greek Government and the hospital to this extent: where serious public health and safety concerns are raised as regards particular supplies, it would be perverse to oblige contracting authorities to disregard those concerns altogether on the basis of a rigorous interpretation of the applicable rules.

82. However, contrary to the national court's suggestion in its order for reference, that proposition does not necessarily lead to the conclusion that contracting authorities are entitled without further ado to reject at any stage of the award procedure, on public health and safety grounds, tenders which comply with the original technical specifications as defined in the tender notice. The legitimate desire — indeed, the duty — of a hospital that is a contracting authority to protect public health must find expression in a way that does not cut right across the principles of free movement, equality of tenders, transparency and proportionality arising from the EC Treaty.

83. Here, two situations may be distinguished. In the first situation, no New Approach directive providing for the CE marking of (or establishing harmonised standards for) the supplies in question is applicable. Hence, the goods are not defined in the tender notice by reference to CE marking, but by reference to tailor-made technical specifications. In the second situation, there is a New Approach directive in place and the tender notice thus specifies that the goods being proposed should be certified by CE marking.

84. Where the first situation pertains, I agree with Medipac that the proper course would be to cancel the existing contract award procedure and to initiate a new procedure based on new technical specifications reflecting any additional (legitimate) public health concerns, rather than to reject a tender under the existing procedure which complies with the tender notice but is thought 'unsafe' by the contracting authority. A new tender procedure would enable all original tenderers, and any interested new bidders, to submit offers complying with the new specifications, thereby placing them on an equal footing and ensuring that the principles of transparency and proportionality are respected, whilst giving proper weight to the legitimate public health concerns of the contracting authorities.

85. The Court has accepted that a contracting authority which has commenced a procedure for the award of a contract under the Public Supply Contracts Directive on the basis of the lowest price may discontinue the procedure without awarding a contract when it discovers after examining and comparing the tenders that, because of errors it itself committed in its preliminary assessment, the content of the invitation to tender makes it impossible for it to accept the most economically advantageous tender. The Court added, however, that when it adopts such a decision, the contracting authority must nevertheless comply with the fundamental rules of Community law on public procurement, such as the principle of equal treatment. [26]

86. That reasoning balances responsible behaviour on the part of the contracting authority with the need to ensure that all tenderers are treated equally. I can see no good reason why it should not apply, *mutatis mutandis*, where the contract in question falls below the threshold of the relevant directive and the contracting authority, at the stage of assessing the technical merits of the tenders, entertains serious doubts about the safety of the supplies offered.

87. Where the second situation pertains, the line of analysis is necessarily different. By rejecting a tender for goods which are CE certified on grounds of public health, the contracting authority is questioning the validity of the presumption conferred upon the goods by their CE marking. It is thus contesting either the assessment of conformity made by the competent certification authority granting the CE marking, or, where harmonised European standards have been used by the supplier to show compliance with the essential requirements, the validity of the harmonised standard itself, or both. Specific procedures are laid down in 'New Approach' directives, designed to deal with such situations. Those procedures balance the protection of public health and safety against the requirements of free movement of goods. They are mandatory procedures, which Member States are required to follow.

88. Those are precisely the circumstances of the present case.

89. The principal objective of the Medical Devices Directive is to ensure the free movement of medical devices through, in particular, the operation of the CE marking procedure. Medical devices that have obtained CE marking in accordance with Article 11 are presumed to comply fully with the essential requirements laid down in the annexes to the directive. According to the directive's preamble, those essential requirements are designed to guarantee a high level of safety and protection to patients, users

26 — Order of the Court (Second Chamber) of 16 October 2003 in Case C-244/02 *Kauppatalo Hansel* [2003] ECR I-12139.

and others. Devices complying with the essential requirements are thus *not* expected to 'compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons'. In short, products marked CE are considered suitable for their intended purposes and, as a consequence, suitable for free circulation within the Community.

90. In the specific case of surgical sutures, compliance with the monographs of the European Pharmacopeia, as required by the tender notice in issue in the main proceedings, necessarily gives rise to the presumption that the essential requirements are complied with, in accordance with Article 5 of the Medical Devices Directive.

91. Member States are required by Article 2 of the directive to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in the directive. In parallel, they are prohibited under Article 4(1) from creating 'any obstacle to the placing on the market or the putting into service within their territory of devices bearing CE marking'. Those obligations also apply to the hospital as an emanation of the State.

92. Clearly, as the Greek Government contends, a presumption of compliance may be rebutted. CE marking does not make medical devices infallible. That is why Member States are required to organise and carry out market surveillance on a continuing basis to check that medical devices meet the essential requirements laid down in the Medical Devices Directive. Indeed, for obvious reasons relating to the protection of public health, such market surveillance is particularly important in the case of medical devices.

93. The Medical Devices Directive expressly provides two instruments of market surveillance.

94. First, Article 10 requires Member States to organise a system whereby any information on incidents which might lead to a public health hazard [27] following the placing of devices on the market is recorded and evaluated centrally. After assessing the incident, and without prejudice to the setting in motion of the 'safeguard clause' in Article 8,

27 — Article 10(1)(a) and (b) of the Medical Devices Directive.

Member States are required to inform the Commission and other Member States immediately of any incidents 'in relation to which relevant measures have been taken or are contemplated'. [28]

95. Second, and more importantly for present purposes, pursuant to the 'safeguard clause' in Article 8 Member States are entitled (and indeed obliged) to adopt interim measures to prevent medical devices bearing CE marking being placed on the market, or order them to be withdrawn from circulation, if they consider that the devices concerned compromise public health. In such circumstances Member States are obliged to inform the Commission 'immediately', indicating their detailed reasons for adopting interim measures. [29] The Commission then examines the concerns raised by the Member State and decides whether the interim measures adopted are justified or not. [30]

96. In broad terms, the same procedure applies where a Member State establishes that CE marking has been unduly affixed, a situation again expressly covered by the Medical Devices Directive. [31]

97. It follows that, read together, the fundamental rules of the EC Treaty applicable to public procurement and the provisions of the Medical Supplies Directive prohibit a State hospital acting as a contracting authority from rejecting a tender for the supply of medical devices bearing CE marking, in conformity with the original tender notice, if it becomes aware during the course of the award procedure that there may be grounds for considering that the CE-marked goods could jeopardise patients' health, without previously setting in motion the safeguard procedure provided by Article 8 of the Medical Devices Directive.

98. Instead, the hospital must suspend the award procedure and inform the competent national authority of its concerns. If the competent national authority rejects those concerns as unfounded, [32] the suspension of the award procedure must be lifted and the tender in question treated as technically acceptable. If the competent national authority decides, on the contrary, that the hospital's concerns are well founded, it must

28 — Article 10(3) of the Medical Devices Directive.

29 — Article 8(1).

30 — Article 8(2).

31 — Article 18 which refers back to the procedure in Article 8.

32 — As seems *prima facie* to have happened here: see point 32 above.

set in motion the safeguard procedure under Article 8 of the Medical Devices Directive. The Member State must then adopt 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' and inform the Commission immediately.

The third question

99. By its third question the national court asks whether, if the safeguard procedure in Article 8 of the Medical Devices Directive [33] must be applied, the contracting authority must wait for, and is bound by, the outcome of that procedure.

Submissions to the Court

100. Medipac and the Commission argue that the hospital may reject the tender only after the full safeguard procedure has been completed and the Commission has concluded definitively that the device should not bear CE marking. The contracting authority is bound by the outcome of that procedure. If the Member State considers that the delay could endanger public health, it must take any necessary interim measures.

101. The Greek and Austrian Governments consider, on the contrary, that the contracting authority may reject the tender without having to wait for the outcome of the safeguard procedure.

Preliminary remarks

102. First, the Commission stated at the hearing in answer to questions from the Court that the 'safeguard clause' procedure has been used rarely, if at all. As a result, the practical and legal aspects of the procedure remain largely untested.

103. Second, to some extent the answer to this question may be pre-empted by the answers I have suggested should be given to

33 — By implication, the question also covers the situation where a Member State establishes that the CE marking has been unduly affixed (Article 18, which then cross refers to Article 8 for the procedure to be followed).

the first and second questions. If I am right that the proper course of action is for the hospital to suspend the award procedure and immediately notify the competent national authority, it then falls to the latter to make the initial decision as to the validity or otherwise of the hospital's concerns.

104. If that authority decides that the concerns are ill founded, it will inform the hospital accordingly. The hospital will then have no lawful reason to reject the tender in question on grounds of technical unsuitability. Its only proper response will be to lift the suspension of the tender procedure and to apply its chosen award criteria (here, lowest price).

105. If, on the other hand, the competent national authority is satisfied that there is a genuine risk to public health, the Member State is under a duty to adopt 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'. It follows that, if the Member State decides to order the withdrawal, or to impose a prohibition on the marketing, of the device in question, the tenderer cannot lawfully offer to supply the devices in question and/or the hospital cannot lawfully agree to purchase them for the duration of those interim measures.

106. Third, I stress that the decision of the competent national authority is an *initial* decision, not the final decision which may validly be taken by the Commission alone. It is equally important to emphasise that 'interim measures' are meant to be precisely that: interim, rather than definitive. In that context, there is abundant case-law of the Court in other areas emphasising that interim relief should not pre-empt the outcome of the substantive claim. [34] In cases involving challenges to Community measures, the Court has emphasised the importance of safeguarding the Community interest when deciding whether or not interim relief should be granted by the national court pending the outcome of a reference under Article 234 EC to determine the validity of the contested Community measure. [35]

107. Fourth, there is an important general Community interest in promoting the free movement of goods, emphasised by the EC Treaty and by the Medical Devices Directive alike. Conversely, there is both a national interest and a general Community interest in

34 — See, for example, in the field of competition law, the order of the Court of 17 January 1980 in Case 792/79 R *Cameracare* [1980] ECR 119, at paragraph 19. As regards the granting of interim measures by the Court itself under Article 243 EC, see, for instance, the order of 26 March 1987 in Case 46/87 R *Hoechst* [1987] ECR 1549, paragraphs 29 to 31.

35 — Joined Cases C-143/88 and C-92/89 *Zuckerfabrik Süderdithmarschen* [1991] ECR I-415, at paragraphs 20 to 33; Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 *ABNA* [2005] ECR I-10423, at paragraphs 103 to 107, and case-law cited therein.

ensuring a high level of protection of public health.[36] The immediate obligation to act to protect public health falls squarely on the Member State. However, the final arbiter as to the suitability and/or validity of the CE marking is, under the applicable procedure, the Commission, not the Member State. The interim measures adopted by the Member State pending final determination by the Commission under the Article 8 procedure must reflect and respect these competing factors.

Assessment

108. Under Community law, the balance is achieved by applying the principle of proportionality. The nature and scope of any interim measures must be appropriate having regard to the actual public health hazard that the devices in question pose. The interim measures chosen must represent, amongst the possible alternatives, the least restrictive means of protecting public health in terms of the free movement of medical devices. It is of course for the Member State to justify the scope of the specific interim measures adopted by reference to that principle. Whether the measures are, or are not, proportionate can ultimately be determined only on a case by case basis. Thus, there may be situations where the ascertained risk is so grave that an immediate, full and unconditional withdrawal of the device in question from the market is the appropriate interim measure. Where the risk identified is not so extreme, less draconian restrictions on the marketing of the devices, such as subjecting their sale to prior authorisation or medical prescription, or limiting the full range of circumstances in which they are to be used, may be the appropriate (and hence proportionate) response.

109. Against that background, I turn to the third question posed by the national court.

110. In my view, requiring a contracting authority to wait for the final outcome of the Article 8 safeguard procedure provides for a better balance between free movement of goods and the need to protect public health, and is less restrictive of free movement than allowing a contracting authority to reject a

36 — See the Article 30 EC derogation from Article 28 EC; see also Article 152 EC.

tender definitively while the Article 8 procedure has yet to run its full course.

111. Such a solution also accords better with the rationale of the Medical Devices Directive and its safeguard procedure. Setting that procedure in motion must imply that the presumption of compliance conferred by CE marking is suspended but not (as yet) rebutted. It is only the final Commission decision under Article 8 of the Medical Devices Directive, subject of course to the review of this Court, which confirms or rebuts the presumption of compliance definitively, and in so doing rejects or endorses any interim measures adopted by the Member State. That being so, it follows that Member States, including their contracting authorities, may not reject a tender proposing medical devices bearing CE marking when the tender specified that CE certified goods were required so long as the final Commission decision concerning those devices is pending. To permit them to do so would be inconsistent with the aim of ensuring the free movement of medical devices, with the effectiveness of the CE marking system, and ultimately with the rationale of the safeguard clause procedure.

112. If the validity of the CE marking of the medical devices in question is confirmed by the Commission, the award procedure must be continued. All tenders complying with the original specifications and offering to supply devices bearing CE marking must accordingly be accepted as suitable and go forward to be assessed under the chosen award criteria. Conversely, if the Commission decides that the devices in question do *not* meet the essential requirements and ought not to bear CE marking, the contracting authority is then entitled to reject that particular tender.

113. I add that if the award procedure is not suspended, the tenderer's only remedy will be to bring an action for damages, which may be both difficult and cumbersome. Where a tenderer has taken the necessary steps to obtain CE marking for his products, the rights which he ought to derive from so doing, in terms of being able to market his goods throughout the Community, seem to me to be better protected by the solution I suggest.

114. I do of course realise that requiring a hospital to suspend procurement of medical devices for an unknown length of time may give rise to grave problems. If the acquisition

of essential medical devices is unduly delayed and no interim solution can be adopted, patients' well-being may be put at risk. My concerns in this respect are not allayed by the fact that at the hearing the Commission was unable to offer any real guidance as to how the safeguard procedure operates in practice and, in particular, what sort of time scale would be involved.

115. However, as Medipac and the Commission have correctly noted, in cases of real urgency, contracting authorities may purchase essential medical devices by means of direct negotiations with a supplier of their choice.

116. All the procurement directives expressly provide for that possibility. As regards supplies, Article 6(3)(d) of the Public Supply Contracts Directive provides that 'contracting authorities may award their supply contract by negotiated procedure without prior publication in so far as is strictly necessary when, for reasons of extreme urgency brought about by events unforeseeable by the contracting authorities in question, the time-limit laid down for the open, restricted or negotiated procedures referred to in paragraph 2 cannot be kept. The circumstances invoked to justify extreme urgency must not in any event be attributable to the contracting authorities'.

117. The same justification must *a fortiori* be possible when the contract in question falls outside the scope of the procurement directives. [37]

118. Furthermore, public health considerations constitute a legitimate mandatory requirement entitling Member States to derogate from the free movement principles of the Treaty provided that, in so doing, they respect the principle of proportionality. In appropriate circumstances, contracting authorities may thus in my view lawfully derogate (on a strictly limited basis and for a limited time) from the principles of transpar-

37 — See the Opinion of Advocate General Jacobs in Case C-525/03 *Commission* v *Italy* [2005] ECR I-9405, at point 47. In the same vein, see also the Opinion of Advocate General Stix-Hackl of 14 September 2006 in Case C-532/03 *Commission* v *Ireland*, at point 111.

ency and equal treatment in order to preserve public health. [38]

119. Urgency brought about by the fact that an award procedure for the acquisition of medical devices is suspended because the safeguard procedure under Article 8 of the Medical Devices Directive has been initiated would in principle justify the use of direct negotiations to procure a limited interim supply of essential medical devices by way of derogation from the EC Treaty rules applicable to public procurement.

120. As the case-law of the Court clearly shows, it is for the contracting authority to demonstrate the existence of the requisite conditions of urgency in order lawfully to derogate from the general principles of transparency and equal treatment. [39] If real urgency cannot be shown, and public health is thus not immediately compromised, contracting authorities are required to await the outcome of the safeguard procedure before awarding the contract.

38 — In that sense, see *Coname*, cited in footnote 13, at paragraph 19; or, by analogy, Case C-158/03 *Commission* v *Spain*, judgment of 27 October 2005, not published in the ECR, at paragraph 35. See also the Opinion of Advocate General Stix-Hackl in *Commission* v *Ireland*, cited in footnote 37 above, at points 94 and 95.

39 — See, for instance, Case C-340/02 *Commission* v *France* [2004] ECR I-9845, at paragraph 38.

The Public Supply Contracts Directive and the Medical Devices Directive

121. The observations that follow are based on the premiss that the Public Supplies Contracts Directive is relevant either directly or because national law applicable to contracts falling below the threshold incorporates the same rules.

122. By stating in the tender notice that the surgical sutures proposed by tenderers had to bear a CE marking in conformity with the European Pharmacopeia, the hospital complied (whether deliberately or unintentionally) with the obligation under Article 8(2) of the Public Supply Contracts Directive to define technical specifications by reference to European standards when these exist. The issue raised by the national court is whether the hospital could, under the applicable provisions of the Public Supply Contracts Directive and the Medical Devices Directive, subsequently depart from those standards and reject Medipac's tender on the basis of the concerns expressed by the hospital's surgeons.

123. In my view, the reasoning I have developed earlier when examining the com-

patibility of the hospital's rejection of Medipac's offer with the fundamental rules of the EC Treaty remains applicable. As the Court has held, the duty to treat tenderers equally 'lies at the heart' of the procurement directives [40] and must be complied with at every stage of the award procedure in order to afford all parties equality of opportunity in formulating their tenders. It follows from that case-law that any change during the course of the award procedure in the interpretation applied to, or any modification of, the technical specifications originally laid down in the tender notice, without restarting that procedure, would constitute a breach of the principle of equal treatment of tenderers. Since that principle underpins the Public Supply Contracts Directive, it follows that such conduct also constitutes a breach of that directive. [41]

124. Furthermore, the Public Supply Contracts Directive contains no provision entitling contracting authorities to reject an otherwise compliant tender on public health grounds such as might alter that conclusion.

125. To what extent, if at all, is that conclusion affected by the Medical Devices Directive?

126. I recall that the Medical Devices Directive not only entitles but requires Member States to adopt any 'appropriate interim measures' to withdraw from the market medical devices bearing a CE marking on grounds of public health. For the reasons I have already given, [42] I consider that in order to do so, they must follow the procedures established in Article 8 or Article 18, as the case may be, of that directive. They are not entitled simply to reject, within a procurement procedure, a bid that complies with the tender notice by proposing devices bearing CE marking.

127. Finally, the comments that I have made earlier [43] as regards the possibility for contracting authorities to derogate from the provisions of the Public Supply Contracts Directive and resort to direct negotiations on grounds of urgency under Article 6(3)(d) of the Public Supply Contracts Directive remain equally applicable.

40 — *Commission* v *Belgium*, cited in footnote 23 above, paragraphs 51 and 52. See also, *Commission* v *France*, cited in footnote 39, paragraph 34; Case C-513/99 *Concordia Bus* [2002] ECR I-7213, at paragraph 81.

41 — See, inter alia, Case C-448/01 *Wienstrom* [2003] ECR I-14527, at paragraph 56; Case C-470/99 *Universale-Bau* [2002] ECR I-11617, at paragraph 93; and the case-law cited in the preceding footnote.

42 — See points 87 to 98 above.

43 — See points 114 to 120 above.

Conclusion

128. Accordingly, I propose that the Court should answer the questions raised by the Greek Symvoulio tis Epikratias as follows:

Where a contracting authority has issued a tender notice for the supply of medical devices covered by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (the Medical Devices Directive) specifying that supplies must bear CE marking by virtue of that directive, in accordance with the European Pharmacopoeia, and subsequently becomes aware during the technical assessment of the tenders that there may be public health grounds for considering the medical devices offered by one of the tenderers to be technically unsuitable even though they bear CE marking, the general principle of equal treatment of tenderers, which underlies the Public Supply Contract Directive, read in conjunction with the provisions of the Medical Devices Directive, prohibit the contracting authority from rejecting that tender directly. Rather, the contracting authority must inform the national authority competent to set in motion the procedures provided for by Article 8 and/or Article 18 of the Medical Devices Directive.

If the competent national authority considers that the contracting authority's concerns are prima facie well founded and accordingly commences the procedure under Article 8 and/or Article 18 of the Medical Devices Directive, the contracting authority must suspend the award procedure pending final determination of the procedure engaged under that directive and is bound by the terms of the Commission's decision bringing that procedure to an end.