Draft recommendation of the European Ombudsman in the inquiry into complaint 25/2013/ANA against the European Commission

Recommendation
Case 25/2013/ANA - **Opened on** 21/01/2013 - **Recommendation on** 26/03/2015 - **Decision on** 21/03/2016 - **Institution concerned** European Commission (Draft recommendation accepted by the institution) |

Made in accordance with Article 3(6) of the Statute of the European Ombudsman [1]

The complainant alleges that the conduct of public procurement tenders for medical supplies in Greek hospitals is in breach of EU law. The complaint, made by a Greek firm dealing in hospital supplies, is that the European Commission has failed to ensure that Greece complies with EU law. The complainant rejected the Commission's position that, following a ruling by the Court of Justice of the EU, Greece had taken the steps necessary to ensure compliance with EU law.

In particular, the case concerned the rejection by Greek hospitals of the complainant's medical devices even though they carry the CE certification mark.

The Ombudsman proposed, as a solution to the complaint, that the Commission should re-examine its infringement complaint file against Greece. The Commission's response was that it had already looked carefully at all of the issues raised and that it saw no reason to doubt its conclusion that Greece now has adequate measures in place to ensure both compliance with EU law and redress for affected tenderers.

The Ombudsman's finding is that, in fact, the Commission has not examined with proper diligence the complainant's allegations. Accordingly, the Ombudsman has now recommended to the Commission that it carries out a proper examination of the information provided by the complainant in support of its allegation.

The background

1. The complainant is a Greek company which imports and distributes medical devices. It complains about the manner in which the Commission handled the infringement complaint it had submitted to it and in which it had expressed the view that the procedures followed by Greek

hospitals for the award of public supply contracts fail to comply with the judgment of the Court of Justice of the European Union (CJEU) in Case C-489/06 *Commission v Greece* [2] . In that judgment, the CJEU ruled that, by rejecting tenders in respect of medical devices bearing the CE certification marking [3] , Greece failed to fulfil its obligations under the Public Contracts Directive [4] and the Medical Devices Directive [5] .

2. The infringement complaint concerned the Greek market for the supply of sutures and the complainant argued that several hospitals had repeatedly turned down tenders for medical devices, including the complainant's sutures, as unfit and dangerous for public health, even though the relevant products bore the CE certification marking. Until the matter was referred to the CJEU [6] , national courts did not protect tenderers because they considered that the rejection of medical devices for public health reasons was compatible with the Medical Devices Directive.

3. The complainant argued that, in spite of the CJEU's judgment establishing the infringement, Greek hospitals did not change their practices. Moreover, according to the complainant, Greek hospitals had developed other practices, for instance, including 'special specifications' in the calls for tenders in order to circumvent the CJEU's rulings to favour their preferred supplier, a multinational ('the multinational') that used to enjoy a virtual monopoly in Greek hospital supplies. The complainant submitted that it successfully filed an injunction against calls for tenders containing these 'special specifications' many times. In turn, the Greek government kept increasing the fees for filing an injunction.

4. The complainant pointed out that, despite the fact that the Greek Supreme Administrative Court has set a clear precedent in respect of the unlawfulness of these 'special specifications' under both EU and Greek law, the practice of hospitals has not changed. Unless an affected tenderer is prepared to shoulder the legal fees (up to EUR 5 000 per injunction), an unlawful tendering process will go ahead as planned. Even if a tenderer is successful in court, the Greek hospitals then cancel the tendering process and continue buying from their " *preferred supplier* ". Therefore, while the complainant needs to pay a non-recoverable fee of EUR 5 000 per injunction, the hospitals keep defending unlawful calls for tenders in court using public funds.

5. In conclusion, the complainant argued that Greek hospitals infringe the Public Contracts Directive, the Medical Devices Directive and the CJEU's judgment. The complainant enclosed with its complaint a sample of calls for tenders with 'special specifications', Greek court decisions and the opinion of the EOF (the Greek Medicines Agency) on 'special specifications'.

6. In response to the complainant's infringement complaint, the Commission stated that, subsequent to the CJEU's judgment in *Commission v Greece* , it received information that Greek hospitals continued to issue calls in a manner that failed to comply with the CJEU's judgment. In reaction to this information, the Commission initiated the proceedings envisaged by Article 260 TFEU (hereinafter, the 'sanctions proceedings') against Greece. In the context of those proceedings, it was established that Greece had not taken the necessary measures to conform to the CJEU's judgment and, consequently, on 24 November 2010, the Commission decided to bring the matter before the CJEU. However, in light of subsequent developments, notably, the

adoption of new Greek legislation on the subject (Article 21 of Law 3897/2010 [7]), the Commission decided to close the infringement file.

7. The complainant addressed the Commission again but did not succeed in convincing it to look into this matter again. As a result, on 31 December 2012, it lodged this complaint with the European Ombudsman.

8. The Ombudsman opened an inquiry into the complaint and identified the following allegation and claim:

1) The Commission failed to ensure that Greece complies with EU public procurement legislation concerning public tenders for medical devices as well as the CJEU's judgment in *Commission v Greece* .

2) The Commission should take appropriate action to ensure that Greece complies with EU public procurement legislation concerning public tenders for medical devices as well as the CJEU's judgment in *Commission v Greece* .

Allegation that the Commission failed to ensure that Greece complies with EU public procurement legislation concerning public tenders for medical devices as well as the CJEU's judgment in *Commission v Greece* and the related claim

The Ombudsman's friendly solution proposal

9. On 14 July 2014 the Ombudsman proposed a friendly solution with a view to resolving the issues in this complaint. In doing so, the Ombudsman took into account the arguments and opinions put forward by the parties [8] .

10. In her analysis the Ombudsman stated that, according to the rules governing public tenders for medical devices, a contracting authority may not reject an offer for medical devices bearing the CE marking on the ground of public health unless it follows a special procedure. The Ombudsman noted that in *Commission v Greece* , the CJEU found that the Greek hospitals had developed a repeated and persistent practice which was contrary to EU law and that the unlawful conduct of the Greek hospitals was not sufficiently reviewed and penalised by the competent Greek authorities [9] .

11. In order to analyse the complainant's allegation, the Ombudsman examined whether the Commission had acted with proper diligence in its examination of the infringement complaint at issue here.

12. In her reasoning, the Ombudsman took into account the complainant's arguments that Greek hospitals consistently issue unlawful calls for tenders for medical devices, and that both the monitoring of hospital practices and the remedies available to affected tenderers are insufficient, considering in particular the impact of the fee for filing an injunction. On the other hand, the Commission's main argument was that the legal and institutional framework governing the Greek hospitals' calls for tenders for medical devices had been strengthened as had the mechanisms for monitoring and ensuring compliance.

13. The Ombudsman took the view that the Commission did not assess the impact that the changes made by the Greek authorities may have had on tenderers such as the complainant. In fact, the complainant's arguments that 84% of calls for tenders continue to be unlawful and that Article 21 of Law 3897/2010 has never been applied, which, at first sight, appeared well-reasoned and substantiated, were not examined by the Commission. Likewise, the Ombudsman considered that the Commission's argument, that it did not have sufficient information and evidence at its disposal, did not appear convincing in the circumstances.

14. Moreover, the Ombudsman took the view that the issue of the fee for filing an injunction is linked to the national review procedures and remedies in national courts and that it remains relevant to affected tenderers when exercising their rights under EU public procurement law before the Greek courts. In this regard, the Ombudsman considered that the complainant made a sufficiently convincing case for considering that the fee is capable of undermining the effectiveness of the protection of its rights under EU law.

15. In light of the above considerations, the Ombudsman made the following proposal for a friendly solution to the Commission:

" *Taking into account the above findings, the Ombudsman proposes that the Commission re-examine the infringement complaint file concerning Greece's compliance with EU public procurement legislation in respect of public tenders for medical devices and the CJEU's judgment in Commission v Greece.*

In doing so, the Commission could address the complainant's arguments that (a) the Greek hospitals consistently issue unlawful calls for tenders for medical devices, and (b) the monitoring of hospital practices and the remedies available to affected tenderers are insufficient.

If the Commission considers the complainant's arguments that Greece has not yet taken the necessary measures to comply with the CJEU's judgment in Commission v Greece to be meritorious, it could examine whether it would be appropriate to re-open the sanctions proceedings against Greece ."

16. In its reply to the Ombudsman's proposal, the Commission identified the following two main preliminary findings in the Ombudsman's analysis: (i) the Commission failed to handle the complainant's infringement complaint with diligence; and (ii) the mandatory fee for filing an admissible injunction application under Greek law raises concerns under EU law.

17. As regards point (i), the Commission disagreed with that finding and outlined its actions and the information received from the Greek authorities, on the basis of which it decided to close the case. The Commission argued that there was no evidence that the national redress system and the Greek administration would not be able to ensure both adequate enforcement of the applicable rules in Greece and compliance with the CJEU judgment in the future.

18. The Commission further contended that it cannot monitor the application of EU law by national authorities in each and every case. Nor can it keep complaint cases open for an indefinite period in order to continuously assess the performance of national bodies or monitor the compliance of the national authorities with EU law. In light of the above, the Commission stressed that the complaint submitted by the complainant " *is and will remain closed* ".

19. Nevertheless, the Commission stated that, in carrying out its duty of vigilance, it " *remains prepared to open an infringement case based on evidence that the Member State's systems are not functioning in accordance with EU law. Indeed, the Commission would open an infringement procedure in case it had evidence showing that a Member State did not comply with the EU Court case law in a specific situation. Such evidence could be brought to the attention of the Commission by means of complaints, or the Commission would become aware of this by its own means* ". The Commission added that it has already made it clear in its correspondence with the Ombudsman that, should it become clear that further follow-up of the measures taken by the Greek State become necessary, it would not hesitate to proceed accordingly. In this regard, the Commission stated that it " *is willing to further investigate the compliance by the Greek authorities with the EU Court judgment by opening an own initiative investigation procedure* ".

20. As regards point (ii), the Commission stated that the relevant Greek law (Article 5(1) of Law 3886/2010) envisages the payment of a mandatory fee as a pre-condition for filing an admissible application for an injunction before the Greek courts in respect of a possible breach of public procurement law by the contracting authority. In the Commission's view, this fee has been considered to be in conformity with the Greek Constitution by the Greek courts and with EU law by the Commission. In the context of investigations, the Commission considered that EU law does not prevent national legislation from imposing a mandatory fee and, in fact, such fees can be found in many Member States. In particular, the Commission took the view that the fee stipulated in Greek law (that is, 1% percent of the value of the contract, up to a limit of EUR 50,000) was compatible with the principle of proportionality, as its amount and the procedure for payment do not render the exercise of the rights conferred upon the economic operators under EU law impossible or excessively difficult. The Commission considered the fee reasonable, in light of the fact that its aim is to avoid abusive injunction procedures likely to overburden the courts and result in the suspension, without solid legal grounds, of procurement procedures. Moreover, the Commission argued that, under Greek law (see Article 5(5) of Law 3886/2010), it appears that the total amount of the fees must be refunded to the claimant if the application is fully or partially upheld by the courts. Finally, the Commission pointed out that because the deadlines for the hearing and the delivery of the courts' decisions in an injunction procedure are short under Greek law, in the event of a successful application, the fee is refunded to the claimant within a short period of time. In view of these arguments, the Commission came to the

conclusion that the fee in question does not violate EU public procurement rules and that, therefore, at this stage, the Commission does not intend to open an investigation procedure on this matter, unless the complainant provides it with substantial evidence showing a breach of EU law.

21. In its observations on the Commission's reply, the complainant insisted on the role of the above-mentioned multinational in the drafting of any call for tenders for the supply of surgical sutures in Greece. In the complainant's view, that multinational was the cause of both the cases that led to the CJEU judgments because of its involvement in decisions of hospital committees and tender specifications. However, the complainant highlighted the fact that, in the USA, unlike the EU, the multinational in question was condemned to pay a hefty fine for its practices.

22. Next, the complainant expressed its dissatisfaction with the Commission's response which focuses on the adequacy of the legislative framework in force and exalts the positive effect of Greek Law 3897/2010. However, the complainant argued that no one ever complained that there was any shortage of laws, directives and court decisions. For any public official, the Medical Devices Directive is more than adequate to ensure the free circulation of medical devices bearing the CE marking between EU Member States. In addition, the CJEU closed any potential loophole by ruling in *Commission v Greece* that, where it is claimed that a product bearing the CE marking threatens public health, the procedure described in the Directive must be followed before that product is rejected. Therefore, the complainant argued that there is no need for any additional legislation or rules.

23. However, in the complainant's view, the issue as to who enforces the law remains. In this regard, the complainant argued that the Commission referred to measures taken by the Greek authorities and information provided by them without disclosing anything specific. What is more, the complainant argued that Article 21of Law 3897/2010 to which the Commission assigns great importance has been in force for almost five years and that, during that period, it has been breached hundreds of times by Greek hospitals and doctors (on this issue, the complainant argued that, if the hospitals were to cooperate with it, it could prove that the Directive has been breached by hospitals thousands of times). Yet, the complainant argued that Article 21 of Law 3897/2010 has never been enforced. This is because the law was adopted solely to stop the Commission's investigation following the infringement complaint. In the complainant's view, the requirement that two government Ministers must agree before a fine is imposed renders this measure a sham. In view of this, the complainant contested the Commission's position that such law constitutes an adequate measure.

24. The complainant challenged the Commission's position that there is no evidence to support the conclusion that the national redress system and the Greek administration is unable to ensure both adequate enforcement of the applicable rules in Greece and compliance with the CJEU judgment. The complainant pointed out that, in its letter of 5 July 2013 and in the addendum thereto, it had shown that, since the enactment of Article 21 of Law 3897/2010, 84% of all calls for tenders for sutures contained illegal specifications that violate the Medical Devices Directive and the CJEU's judgment in *Commission v Greece* . Based on a survey it carried out, the complainant insists that, for 2014, the percentage of calls for tenders containing illegal

specifications increased to 87.8%. Among them, there are two calls for tenders with a value of more than EUR 8 million in sutures. It stated that the list of hospitals and calls for tenders could be made available to the Commission. The complainant wondered whether the Commission is waiting until this percentage reaches 100% to act, or whether it believes that EU law is adhered to by the Greek authorities, when nearly 88% of hospital calls for tenders infringe the Directive and the CJEU's judgment.

25. Against this backdrop, the complainant argued that it has provided tangible evidence of total disregard of the Directive and of the CJEU's judgment. In contrast, the Commission bases its conclusion on Article 21 of Law 3897/2010 that has never been - and will never be - enforced. In spite of the fact that Greek courts apply the law, 88% of the calls for tenders for sutures are illegal. The complainant insisted that the Commission should not be satisfied with its vigilance and diligence. Finally, the complainant wondered what level of evidence the Commission would need in order to be convinced that Greek hospitals do not comply with the Directive and the CJEU judgment. The complainant argued that the Commission should specify what it requires in order to be convinced that violations occur; it should specify how many calls for tenders or unlawful decisions it requires and it should explain what specific evidence it considers adequate.

26. Regarding the injunction fee, the complainant explained that the fee required under Law 3886/2010 for an injunction to be filed is refundable, in the event that the court's judgment is favourable to the company seeking the injunction. However, the complainant argued that the fee it complains about is provided for under Article 15(6) of Presidential Decree 118/2007. The complainant explained that, in order to file an admissible court injunction, the affected tenderer must first pay a non-refundable fee of EUR 1 000 to lodge an administrative appeal against the hospital (the contracting authority). Unless that fee is paid, the injunction is rejected by the courts; the complainant pointed out that this has happened to it several times.

27. To support its contentions, the complainant summarised its position when tendering for the supply of sutures as follows: (a) the hospitals refuse sutures bearing the CE marking, (b) the complainant must lodge an administrative appeal after paying the EUR 1 000 non-refundable fee, (c) the complainant must then file an injunction, the fee for which is refundable if it is successful. The complainant mentioned three calls for tenders involving a single hospital (the General Hospital of Etoloakarnania) to which it responded in 2014 and in which its sutures bearing the CE marking were rejected. It had to pay EUR 3 000 in fees for the administrative appeal, EUR 2 000 in fees for the injunctions and EUR 6 000 in lawyers' fees. All three cases are pending before the Administrative Court of Appeal of Patras and, in the meantime, the hospital continues to buy from its preferred supplier (the same multinational) at three to thirty-five times the market price. When the Greek courts give judgment, the hospital will simply cancel the tendering process, keep the EUR 3 000 in fees, and issue a new call for tenders. Nothing will happen to the hospital and those taking decisions within it. The complainant contended that, because of the non-refundable fee, the end result is that it makes no economic sense for a small supplier to contest the hospital's illegal decisions rejecting its bids. In the complainant's view, the fee in question is there to serve the interests of the multinational.

28. The complainant argued that, except it is the case that the Commission finds nothing wrong " *with this whole mess* ", it should insist that the Greek government 1) make the fee in question refundable in the event of a favourable court judgment and 2) provide for automatic penalties against those involved in infringements of EU law. The latter provision would involve removing the requirement of a joint Ministerial Decree for the imposition of a penalty under Article 21 of Law 3897/2010. Moreover, the Greek government should provide for compensation to be paid to the company whose goods are illegally rejected. The complainant concluded its submissions by expressing its readiness to provide any additional data that the Commission might consider necessary to prove the statements made in its observations or in any of its previous submissions within this complaint.

The Ombudsman's assessment after the proposal for a friendly solution

29. The first issue to be considered is whether, in fact, dissatisfied tenderers have access to an effective remedy by way of court action. This involves looking at the issue of the injunction fee. After a careful examination of the relevant legislation and the parties' arguments, it is clear that the factual and legal framework governing public tenders for medical devices in Greece is as follows: a tenderer whose offer of sutures bearing the CE marking is rejected must, as a first step, lodge an administrative appeal against the hospital decision rejecting the tender and pay a non-refundable fee (the 'administrative appeal fee') of 0.1% of the value of the tender with a minimum of EUR 1 000 and a maximum of EUR 5 000 (Article 15(6) of Presidential Decree 118/2007). Within 10 days from the rejection of the administrative appeal or the expiry of the 15-day deadline for deciding on that appeal, a tenderer may file an injunction in a competent court. The fee (the 'injunction fee') for filing an admissible injunction is 1% of the value of the tender, with a limit of EUR 50 000 and is refundable if the injunction is granted. According to the Commission, the injunction fee is proportionate.

30. On the issue of the injunction fee, the Ombudsman thanks the Commission for responding positively to her suggestion in the friendly solution proposal that it address the complainant's arguments about the injunction fee although this aspect of the case was not brought to its attention before this complaint was submitted to the Ombudsman. As regards the substance of that reply, the Ombudsman considers that the Commission put forward valid arguments in support of the view that the injunction fee is in line with the principle of proportionality and does not render the exercise of rights under EU law and, more specifically, the pursuit of an effective remedy in the Greek courts for affected tenderers, excessively difficult.

31. In its observations, the complainant argued that its main grievance concerns the administrative appeal fee. The Ombudsman notes that the Commission did not address this issue in its reply. However, this is understandable given that, when the complainant raised the matter in its correspondence with the Commission, it always referred to it as the fee for filing an injunction. As regards the administrative appeal fee, it is clear that the amount of this fee is much smaller than the amount of the injunction fee (0.1% of the value of the tender, with a limit of EUR 5 000). However, the complainant correctly observed that, on the basis of the Greek

legislation in question, the administrative appeal fee is not refunded, regardless of whether or not the appeal is successful. The Ombudsman further notes that the complainant has pointed out that the number of cases in which Greek hospitals infringe EU law is very high. It is therefore necessary to consider the impact of the administrative appeal fee against that background, and not just its limited amount in individual cases. In these circumstances, the complainant's argument that the administrative fee calls into doubt the availability of an effective remedy to the affected tenderers in Greek hospital tenders appears reasonable at first sight. The Commission has not addressed this issue yet. The Ombudsman therefore considers that it is necessary to call upon the Commission to do so in its detailed opinion on the Ombudsman's draft recommendation below.

32. The principal aspect of the complainant's allegation is that, without incurring any cost, a Greek hospital may reject, time and again, offers for sutures bearing the CE marking in breach of the Medical Devices Directive and the CJEU's judgment in *Commission v Greece* . In fact, and according to the complainant, where a judicial appeal is successful, a Greek hospital is still able to cancel the tendering process and to continue dealing with its favoured supplier. This leads to the examination of whether it is true that, notwithstanding the enactment of Article 21 of Law 3897/2010, Greek hospitals have not abandoned their consistent practice, castigated by the CJEU in *Commission v Greece* , of rejecting medical devices bearing the CE marking. In other words, the question is whether the Commission handled the complainant's infringement complaint to this effect with the required standard of diligence. As emphasised by the Ombudsman in her proposal for a friendly solution (paragraph 38), a diligent examination of a complaint required the Commission carefully to analyse the arguments and evidence submitted to it. In the infringement complaint and subsequent submissions to the Commission, the complainant put forward that the percentage of decisions rejecting offers for sutures bearing the CE marking is overwhelmingly high and that the seemingly draconian provision in Article 21 of Law 3897/2010 [10] , that was enacted in order to deter Greek hospitals from breaking the law, has never been applied in practice.

33. The Ombudsman confirms the view she took in her proposal for a friendly solution (paragraph 44) that the complainant's arguments appear well-reasoned and substantiated at first sight. In order to meet the requirement of diligence in the handling of the infringement complaint in question, the Commission ought to have properly addressed the complainant's detailed and specific arguments in support of its grievance that Greece has not yet taken all the necessary measures to comply with the CJEU's judgment in *Commission v Greece* (notably, that (a) 84% of the calls for tenders for sutures are illegal and that (b) Article 21 of Law 3897/2010 has never been applied). If it considered that it did not have sufficient evidence at its disposal, it could have acted upon the complainant's offer and asked for clarifications and additional information. However, the Commission did not address the above issues at all, on the assumption that the mere enactment of Article 21 of Law 3897/2010 would suffice to discourage hospitals from infringing EU law governing public procurement of medical devices. However, this is unconvincing, at the very least as long as the Commission has not addressed the complainant's detailed submissions in support of its claim that the relevant provision is not applied in practice.

34. In light of the above, the Ombudsman finds maladministration on the part of the Commission arising from its failure to examine with the required diligence the complainant's allegation that Greece has not yet taken all the necessary measures to comply with the CJEU's judgment in *Commission v Greece* . The Ombudsman considers that, for this instance of maladministration to be remedied, the Commission should carry out a proper examination of the information provided by the complainant in support of that allegation. If it considers that it does not have sufficient evidence at its disposal, it should act upon the complainant's offer to provide clarifications and additional information. If, on the basis of a diligent examination of the available information, it reaches the conclusion that the infringement of the Medical Devices Directive and the CJEU's judgment in *Commission v Greece* remains, it should examine whether it would be appropriate to re-open the sanctions proceedings against Greece. She therefore makes a corresponding draft recommendation below, in accordance with Article 3(6) of the Statute of the European Ombudsman.

The draft recommendation

On the basis of the inquiry into this complaint, the Ombudsman makes the following draft recommendation to the Commission:

The Commission should carry out a proper examination of the information provided by the complainant in support of its allegation that Greece has not yet taken all the necessary measures to comply with the CJEU's judgment in *Commission v Greece* **. If it considers that it does not have sufficient evidence at its disposal, it should act upon the complainant's offer to provide clarifications and additional information. If, on the basis of a diligent examination of the available information, it considers that the infringement of the Medical Devices Directive and the CJEU's judgment remains, it should examine whether it would be appropriate to re-open the sanctions proceedings against Greece.**

The Commission and the complainant will be informed of this draft recommendation. In accordance with Article 3(6) of the Statute of the European Ombudsman, the Commission shall send a detailed opinion by 30 June 2015. The detailed opinion could consist of the acceptance of the draft recommendation and a description of how it has been implemented.

Strasbourg, 26/03/2015

Emily O'Reilly

European Ombudsman

[1] Decision of the European Parliament of 9 March 1994 on the regulations and general

conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom), OJ 1994 L 113, p. 15.

[2] Case C-489/06 *Commission v Hellenic Republic* [2009] ECR I-1797. See also, Case C-6/05 *Medipac-Kazantzidis AE v Venizelio-Pananio (PE.S.Y. KRITIS)* [2007] ECR I-4557.

[3] The CE marking is a mark that medical devices should, as a general rule, bear in order to indicate their conformity with the provisions of the Medical Devices Directive, to enable them to move freely within the Union and to be put into service in accordance with their intended purpose.

[4] Council Directive 93/36/EEC of 14 June 1993 coordinating procedures for the award of public supply contracts, OJ 1993 L 199, p. 1, which has been replaced by Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, OJ 2004 L 134, p. 114.

[5] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ 1993 L 169, p. 1, as amended.

[6] The Court ruled in *Medipac-Kazantzidis* , cited above in footnote 2, that " *the principle of equal treatment and the obligation of transparency preclude a contracting authority, which has issued an invitation to tender for the supply of medical devices and specified that those devices must comply with the European Pharmacopoeia and bear the CE marking, from rejecting, directly and without following the safeguard procedure provided for in Articles 8 and 18 of Directive 93/42, on grounds of protection of public health, the materials proposed, if they comply with the stated technical requirement. If the contracting authority considers that those materials may jeopardise public health, it is required to inform the competent national authority with a view to setting that safeguard procedure in motion* ", paragraph 55.

[7] Article 21 of Law 3897/2010 imposes strict penalties on hospitals, members of the management bodies of hospitals and members of evaluation committees that reject offers of products bearing the CE marking.

[8] For more information and detail on the background to the complaint, the parties' arguments and the Ombudsman's preliminary assessment leading to a friendly solution proposal, please refer to the full text of the Ombudsman's friendly solution proposal available at: http://www.ombudsman.europa.eu/cases/correspondence.faces/en/59352/html.bookmark [Link]

[9] Case C-489/06 *Commission v Hellenic Republic* , cited above in footnote 2, paragraphs 53-55.

[10] It is worth reiterating that, according to Article 21 of Law 3897/2010, strict penalties are to be imposed on hospitals, members of the management bodies of hospitals and members of evaluation committees that reject offers of products bearing the CE marking.