Proposal of the European Ombudsman for a friendly solution in the inquiry into complaint 25/2013/ANA against the European Commission

Solution - 21/01/2013
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(5) of the Statute of the European Ombudsman [1]
The background to the complaint
1. The complainant is a Greek company which imports and distributes medical devices. It complains about the manner in which the Commission handled a complaint (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. In its infringement complaint, the complainant provided a brief overview of the sutures market in Greece and 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 call for tenders in order to circumvent the CJEU's rulings to favour their preferred supplier, a 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 government kept increasing the fees for filing an injunction.

4. In its infringement complaint, the complainant specifically contended that (a) all 'special specifications' are copied from the multinational's advertising material; (b) the multinational

is fighting all injunctions against calls for tenders; (c) the multinational attempts to establish a precedent in Greek courts that the rejection of CE certified products on the ground of not meeting these 'special specifications' is compatible with EU law; (d) the multinational markets its products, in particular, its sutures, as 'European products', although they have been manufactured in India or China, thereby taking advantage of a gap in the EU legislation on rules of origin; (e) in 2007, the multinational admitted to bribing Greek physicians and hospital authorities.

5. 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 tenders in court using public funds. The complainant stated that it is a " *rather peculiar sense of justice and law enforcement where the innocent and law abiding citizen must suffer to force the government to issue* [lawful] *tenders* ."

6. In conclusion, the complainant argued that Greek hospitals infringe the Public Contracts Directive, the Medical Devices Directive and the CJEU's judgment on a daily basis because they add " *meaningless, illegal and totally subjective 'specifications'* ". The complainant enclosed a sample of tenders with 'special specifications', Greek court decisions and the opinion of the EOF (the Greek Medicines Agency) on 'special specifications'.

7. On 10 September 2012, the Commission informed the complainant that, subsequent to the CJEU's judgment in *Commission v Greece* , the Commission 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 [8] .

8. In its reply of the same day, the complainant argued that Law 3897/2010 deals with road safety and that Article 21, which concerns hospital procurement, was inserted with the sole aim of showing the Commission that the Greek Minister of Health was doing something about the issue. However, the provision in question requires a joint decision by the Minister of Health and the Minister of the Economy as well as the opinion of the SEYYP (the Health Services Inspectors Body) before any penalty is imposed on hospitals. Although there have been hundreds of infringements since the entry into force of this law, no penalty has ever been enforced.

9. The complainant supported its assertion by stating that its offers of CE certified medical products were rejected on four occasions in 2012 on dubious grounds (" *medical gloves were too thin and not strong enough* ", " *the packing of sutures was not practical* " etc.). The complainant filed injunctions in court in respect of these rejections and won two cases, while the other two were pending (total cost of the injunctions: EUR 20 000). No penalty was imposed on anyone involved in the rejection of its bids in any of these cases. On this basis, the complainant questioned the effectiveness of Article 21 of Law 3897/2010 and requested the Commission to ask the Greek authorities to inform it about the number of cases in which the law had been enforced. The complainant expressed its certainty that there has been no such case.

10. The complainant also criticised the Commission's acceptance of the role of the EPY (the Greek Health Procurement Authority) in monitoring compliance. In fact, according to the complainant, the EPY accepted 'special specifications' in tenders in spite of the Greek courts' decisions finding an infringement of the Medical Devices Directive. The complainant added that it could not " *accept EPY as the stronghold of law and order in public procurement* ".

11. The complainant concluded that if the Commission thinks that " *an unenforceable law is the solution to the massive abuse of EC Directives and European Court decisions, by Greek contract awarding authorities, and an unenforceable law is the best that can be done, so be it. We obviously do not agree with you. We would want to see a law that is quite clear and simple. If a violation occurs and is reversed by a court decision, even a temporary court order, the violators should be immediately sanctioned.* "

12. On 31 December 2012, the complainant lodged this complaint with the European Ombudsman.

The inquiry

13. 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* .

14. In the course of the inquiry, the Ombudsman received the opinion of the Commission on the complaint and, subsequently, the comments of the complainant in response to the Commission's opinion. The Ombudsman's friendly solution proposal takes into account the arguments and opinions put forward by the parties.

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

Arguments presented to the Ombudsman

15. In its complaint, the complainant presented the following arguments in support of its allegation:

(a) When issuing calls for tenders for medical devices, Greek hospitals regularly infringe the Medical Devices and Public Contracts Directives and disregard the CJEU's judgment.

(b) Affected tenderers do not enjoy effective judicial protection (i) because the Greek hospitals persist in issuing non-compliant calls for tenders in spite of the CJEU's judgment and the national courts' injunctions, and (ii) because of the non-recoverable fee of a minimum of EUR 1 000 imposed by law on an affected tenderer wishing to file an injunction against a call.

(c) The monitoring of compliance with EU public procurement legislation by the EPY is inefficient.

(d) The requirements laid down in Article 21 of Law 3897/2010, which is intended to improve compliance with the Medical Devices and Public Contracts Directives, are so onerous that they have never been applied in practice in spite of widespread infringements.

(e) The Commission's reply about the issue of alleged bribery of Greek hospitals and doctors by a multinational company is inadequate.

16. In relation to its claim, the complainant argued that the Commission could ask Greece to:

(a) cancel the non-recoverable fee for filing an injunction against a call for tenders; (b) render the enforcement of Article 21 of Law 3897/2010 automatic; and (c) improve the monitoring of compliance of Greek hospitals with EU public procurement legislation either by requiring them to inform the Commission of every injunction filed against them or by asking affected tenderers filing an injunction to send a copy to the Commission.

17. In its **opinion** , the Commission submitted that in the case *Commission v Greece,* it based its claim on the argument that, by rejecting offers of medical devices bearing the CE certification marking, Greece had breached its obligations.

18. Following its decision to initiate sanctions proceedings against Greece for failing to take the necessary measures to comply with the CJEU's judgment, the national authorities notified the Commission of the measures they took in order to terminate the infringement. These measures were taken in late 2010 and included (a) a circular to the Greek hospitals explaining the reasoning of the CJEU's judgment and (b) Law 3897/2010.

19. In these circumstances, the Commission asked the Greek authorities for more information on these measures. In their reply, the Greek authorities explained that Article 21 of Law 3897/2010 provides for pecuniary, administrative and criminal penalties both for hospital administrations and evaluation committees in the event of an illegal rejection of

tenders.

20. On 31 November 2011, the Greek Ministry of Health issued a circular to all hospitals drawing their attention to the above provision and the fact that they should not reject medical devices bearing the CE marking for reasons allegedly linked to the protection of public health without informing the EOF and without following the procedure described in the Medical Devices Directive. In addition, the EPY was entrusted with the task of monitoring compliance with the Directives and the CJEU's judgment. On the basis of the EPY's findings of 4 November 2011, no infringement relating to the rejection of medical products bearing the CE marking had been detected. Furthermore, the SEYPP found that, by the end of October 2011, only two instances of hospitals illegally rejecting bids had been detected. The SEYPP took note of these two cases, declared that it was committed to investigate further and expressed its overall satisfaction with the application of the new framework.

21. In addition, on 18 December 2012, the Commission communicated the complainant's allegations concerning persistent violations to the Greek authorities. It informed the complainant that the newly created SPPA (Single Public Procurement Authority) was given the power to carry out checks on tendering procedures for the award of public contracts, and that this body had identified the health sector as one of its priority fields of intervention. The Commission also informed the complainant that, if there were to be further examples of tendering procedures where medical devices bearing the CE marking were nevertheless excluded, it should contact the SPPA directly to report these cases. It also noted that an overall reform of the Greek health system was underway and that centralisation of procurement, with safeguards in order to ensure that SMEs are not excluded from the market, was a key element of the modernisation process. Aggregated procurement and the subsequent centralised control over tendering procedures could help remedy the problems triggered by decisions of individual hospitals to exclude medical devices which comply with EU requirements.

22. On the basis of the information available, the Commission took the view that the national review system appeared to be working effectively. Therefore, if irregularities were to be detected by aggrieved tenderers, they could be pursued and remedied in the national courts. The Commission argued that the complainant did not express any doubts or suspicions concerning the effectiveness and impartiality of the Greek courts and supervisory authorities.

23. In addition, the Commission referred to an example (a tender at the Aretaieio Hospital) showing that the measures introduced at the national level are indeed working well. In particular, on 6 March 2013, the EPY informed the Commission that it had intervened swiftly to alert the hospital that a clause in the call for tenders it had published infringed the Medical Devices Directive, to remind it of the rules and to explain that it was necessary to review the relevant clause.

24. In light of these considerations, the Commission took the view that the Greek authorities had adopted adequate measures to prevent the repetition of the practices in question in the future.

25. Regarding the issue of the fee for filing an injunction, the Commission argued that this had never been brought to its attention and that the complainant first signalled it in its complaint to the Ombudsman.

26. In conclusion, the Commission argued that the complainant's allegation should be rejected. Finally, the Commission pointed out that, on 21 and 28 January 2013, after the closure of the case, the complainant reported further alleged infringements by Greek hospitals. The Commission, however, argued that it did not have sufficient information and evidence at its disposal to re-open the case. It added that should it become clear that further follow-up of the measures taken by Greece is necessary, it would not hesitate to proceed accordingly.

27. In its **observations** , the complainant argued that that the Commission did not adequately address the issues brought to its attention.

28. Specifically, the complainant argued that it demonstrated in its complaint that 84% of all calls for tenders continue to infringe the Directives and the judgment of the CJEU. At the same time, in practice, the EUR 1 000 fee for filing an injunction against an illegal call for tenders helps the multinational to eliminate competition. Against this background, the complainant questioned the Commission's decision to close the case. The complainant juxtaposed this case with one in which the Commission's action was swift, forcing the Greek government to withdraw the offending law within days. The complainant argued that that case involved " *oiling agents* ", whereas the present case involves small independently-owned companies which are a problem for multinationals. It added that " *the bribery concerning the multinational involved in hospital procurement in Greece and, in fact, the complainant's competitor, is not an allegation as the Commission appears to treat it but a well-documented fact* ".

29. In general terms, the complainant expressed the view that the Commission has not taken " *effective action* " in that it has done very little to enforce the Directives and the CJEU judgment.

30. Specifically, the complainant reiterated that Article 21 of Law 3897/2010, a law concerning road safety, is unenforceable because it requires agreement between two government Ministers for penalties to be imposed. The complainant contended that " *there has yet to be a single case in which the provisions of Article 21 were enforced* " despite the years that have passed since its enactment and the hundreds of infringements that took place during this period.

31. The complainant expressed its disappointment at the Greek Ministry of Health's circular of 31 November 2011. In fact, the hospitals were familiar with the provisions of the Medical Devices Directive and needed no reminder. The complainant added that, in a case brought by the complainant itself in 2008, that is, three years earlier, the Greek Supreme Administrative Court rendered a judgment that had already covered the content of the circular in full detail. In the complainant's view, the " *problem was, and is, neither the Court*

Decisions nor the Ministry circulars! The problem is the Commission's refusal to have the Greek government and its agencies abide by the Directive, without the need to run to the courthouse for almost every tender! "

32. As regards the SEYPP, the SPPA, " *and the rest of the acronyms* ", the complainant said that it did not need the Commission's advice to contact them. It argued that it had done so in the past and that they always denied any responsibility over the matter or any authority to act.

33. Concerning the Commission's argument that the EPY did not report any infringement, the complainant expressed its concern " *about the quality of people at the Commission who review these complaints* ". The complainant argued that the Commission should not expect the EPY to admit that Greek hospitals disregard both the Directives and the CJEU judgment.

34. In addition, the complainant expressed its disappointment at the Commission's opinion, given that, in its complaint, it presented a chart with 50 calls for tenders, 84% of which were illegal. The complainant added that it had also provided the reasons for the alleged illegality. Notwithstanding all this evidence, the Commission's response was that " *at this time the Commission services do not have at their disposal sufficient elements to re-open the case* ". The complainant declared itself ready to send any additional information and evidence the Commission might need but expressed its surprise at the fact that the figure of 84% of illegal calls for tenders was not sufficient for the Commission.

35. Regarding the example of the Aretaieio Hospital, the complainant pointed out that what in fact happened in that case was that after it sent the relevant information to the Commission, the EPY contacted the complainant. The complainant had to explain once again what the infringements were and subsequently, as a corrective action, the hospital removed one sentence which said " *that regardless of what the law is all about, the hospital doctors will determine which products will be acceptable* ". In other words, the hospital agreed not to ignore the CJEU's judgment. The complainant argued that this is not something that the Commission should be proud of.

36. Next, the complainant wondered if the Commission would adopt the same attitude if the infringement complaint came from a multinational or a company with proper lobbying activities in Brussels. It added that, because it is not represented by a lobbyist and has limited financial resources, it depends on the Commission's services. In the complainant's view, when 84% of the calls for tenders are illegal, this means that the Directives and the CJEU's judgment are being ignored. The complainant pointed out that, to its credit, the Greek judicial system had stood by it. However, the complainant added that national courts' judgments had no effect on those who infringe the Medical Devices Directive. Concerning the non-refundable fee of EUR 1 000, the complainant stated that it was only recently declared unconstitutional by the Greek Supreme Administrative Court. The complainant submitted that until then, it had sustained losses of hundreds of thousands of Euros.

The Ombudsman's preliminary assessment leading to the friendly solution proposal

37. 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. 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] .

38. The complainant's allegation is that the Commission has failed to ensure that Greece complies with these rules and with the CJEU's judgment. The issue for the Ombudsman therefore is whether the Commission has acted with proper diligence in its examination of the infringement complaint submitted to it. In this respect, the question whether the Commission handled the infringement complaint with diligence needs to be addressed with reference to the level of care that the Commission is expected to exercise in its role as the guardian of the Treaties. The Ombudsman takes the view that a diligent examination of a complaint requires the Commission carefully to analyse the arguments and evidence submitted to it.

39. The Ombudsman notes that, in a nutshell, the complainant argued that the 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 complainant's effective judicial protection.

40. In its opinion, the Commission submitted that the legal and institutional framework governing the Greek hospitals' calls for tenders for medical devices had been strengthened and it focused on the mechanisms established for monitoring and ensuring compliance.

41. The Ombudsman notes, however, that, as the complainant argued in its observations, the admittedly strengthened legal and institutional framework does not appear to have led to sufficient improvements in the hospitals' practices. Specifically, the Commission did not address the complainant's submission that 84% of the calls for tenders issued by the Greek hospitals are still unlawful, thereby calling into question the practical effectiveness of the measures taken by the Greek authorities.

42. As regards the mechanisms to improve the monitoring of compliance by Greek hospitals (the EPY - and, subsequently, the SPPA - as well as the SEYPP), the complainant explained in its observations that they have not managed to achieve their intended goal of remedying illegality; the Aretaieio Hospital example merely constitutes an exception. The Ombudsman notes that, as regards this aspect of the case, the Commission merely seems to have taken note of the changes made by the Greek authorities, without assessing the impact that these changes may have had.

43. It appears, therefore, that the Commission did not sufficiently address the complainant's concerns that these mechanisms are ineffective. In particular, concerning Article 21 of Law 3897/2010, the Commission did not respond to the complainant's argument that, in the

three years since the adoption of that law, it has never been applied.

44. In view of the above findings, the Ombudsman considers that the complainant has put forward arguments which, at first sight, appear well-reasoned and substantiated. Moreover, taking into account that the thrust of the CJEU's judgment in *Commission v Greece* was not the legal and institutional framework itself but the Greek hospitals' consistent practice of rejecting medical devices bearing the CE marking, in order to meet the requirements of diligence in the handling of the infringement complaint in question, the Commission ought to have properly addressed the complainant's detailed arguments and to have carried out an examination of the evidence submitted by it. The Commission's argument that it did not have sufficient information and evidence at its disposal does not appear convincing in the circumstances.

45. The Ombudsman thus makes the preliminary finding that the Commission failed to handle the complainant's infringement complaint with diligence. Also taking into account that the Commission unequivocally stated in its opinion that, should further measures prove to be necessary, it would not hesitate to proceed accordingly, the Ombudsman makes a corresponding proposal for a friendly solution below, in accordance with Article 3(5) of the Statute of the European Ombudsman.

46. Regarding the fee for filing an injunction, the Ombudsman accepts the Commission's argument that it was not brought to its attention before the present complaint was submitted to the Ombudsman. However, this issue is closely linked to the other issues raised by the complainant. The Ombudsman therefore takes the view that it would be desirable and in the interest of procedural efficiency if the Commission were to take it into consideration when addressing her proposal for a friendly solution. In fact, the issue of the fee is very relevant to the Commission's argument that the national review procedures are working properly and that irregularities can be effectively pursued and remedied in the national courts.

47. In this connection, the complainant observed that the Greek Supreme Administrative Court found that the fee is contrary to the Greek Constitution. However, even though the Greek Constitution entrusts courts with the task of carrying out a constitutionality review and consider inapplicable any law that is found unconstitutional, it is only the Supreme Special Court that is entitled to strike down legislation that is not in conformity with the Constitution. Although the administration is obliged to take into account the Supreme Administrative Court's ruling and to take the initiative to change the law, until and unless that happens, this law will continue to apply.

48. Within the context of this case, it is therefore clear that the fee for filing an injunction remains relevant to affected tenderers when exercising their rights under EU public procurement law before the Greek courts. The Ombudsman notes that, where harmonised procedural rules for the enforcement of EU law do not exist, the national procedural rules to be applied must be *equivalent* to those that apply for the enforcement of national law and *effective* , that is, such as not to render the exercise of the right in question excessively difficult [10] . While the complainant did not adduce any evidence to show that the fee for

filing an injunction causes problems regarding equivalence, it made what appears to be a sufficiently convincing case that the fee is capable of undermining the effectiveness of the protection of its rights under EU law.

The proposal for a friendly solution

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.**

Emily O'Reilly

European Ombudsman

Strasbourg, 14 July 2014

[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 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] The Commission's arguments in support of this position are extensively analysed in the analysis part of this proposal and will therefore not be reproduced here.

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

[10] Case C-312/93 *Peterbroeck v Belgian State* [1995] ECR I-4599, paragraph 12.