

## Decision of the European Ombudsman closing his inquiry into complaint 452/2010/BEH against the European Commission

Decision

**Case 452/2010/BEH - Opened on 10/03/2010 - Decision on 17/12/2010 - Institutions concerned** European Commission ( Settled by the institution ) | European Commission ( No further inquiries justified ) |

### The background to the complaint

1. The complainant is a public limited company incorporated under German law. In the early 1990s, it invented an inhaler for the treatment of asthma. In 1997, the competent German regional authority prohibited its sale in Germany. Subsequently, the German Federal Ministry of Health, acting under the safeguard clause procedure foreseen by Article 8 of Directive 93/42/EEC ('the Directive') [\[1\]](#) [\[Link\]](#), formally notified the Commission of that prohibition. According to the complainant, the Commission failed to start a safeguard clause procedure, even though it would have been required to do so under Article 8 of the Directive.

2. On 19 March 2008, the complainant sent a letter entitled "*supervisory complaint*" ("*Dienstaufsichtsbeschwerde*") to the European Anti-Fraud Office (OLAF). In that letter, it essentially alleged that a former Commissioner and two Commission staff members had knowingly infringed the Directive following notification of the marketing prohibition in Germany. The complainant denounced what he perceived to be corruption and mismanagement on the Commission's part.

3. On 1 April 2008, the complainant submitted a petition (Petition 473/2008) to the Committee on Petitions of the European Parliament ('the Committee on Petitions'). In that petition, it essentially asserted that it alerted the Commission to the above circumstances, but that the Commission failed to react adequately. According to the complainant, it emerged from a letter sent by a then Commissioner to a Member of the European Parliament (MEP) that the Commission acknowledged its infringement of Article 8 of the Directive. The Commission would have been required to hear the producer of the inhaler in order to clarify the matter rapidly. Instead, however, the safeguard clause procedure launched in 1997 was never concluded, and the producer of the inhaler was never heard. The complainant also pointed out that, in 2005, the competent German authority renewed the marketing prohibition, this time without notifying the



Commission. In the complainant's view, there were serious shortcomings in the EU system of legal protection, given that the complainant had effectively been deprived of a remedy. The complainant submitted that its ensuing economic ruin had knowingly been accepted.

4. On 4 February 2009, the complainant turned to the Ombudsman (complaint 309/2009(NM)BEH) and submitted that the subject-matter of its complaint could be derived from the petition it submitted to the Committee on Petitions, a copy of which it attached to its complaint. The complainant also submitted that the Commission had tried to mislead it, lied to it, and sought to avoid its responsibility. In its view, the Commission thus knowingly accepted the destruction of its economic existence. Referring to its letter to OLAF dated 19 March 2008, the complainant asserted that OLAF, for incomprehensible reasons, transferred the case to IDOC [\[2\]](#) [\[Link\]](#). The latter refused to give the complainant access to information about the outcome of its investigation. The complainant considered that this refusal was aimed at protecting the pharmaceutical industry. Article 228 of the Treaty on the Functioning of the EU empowers the Ombudsman to "conduct inquiries for which he finds grounds". By letter dated 11 March 2009, the Ombudsman informed the complainant that there were no grounds for an inquiry into its complaint, given that the Committee on Petitions was dealing with the grievances raised in its complaint. As regards the complainant's remarks on OLAF and IDOC, the Ombudsman stated that it was not clear whether the complainant also wished to complain about those bodies.

5. On 15 February 2010, the complainant again turned to the Ombudsman and submitted the present complaint.

6. On 4 May 2010, the complainant submitted a further complaint to the Ombudsman (complaint 1199/2010/BEH) in which it complained about OLAF's handling of its complaint. The complainant alleged that, by transferring the said complaint to IDOC, OLAF failed to handle it properly. In addition, the complainant claimed that OLAF should investigate the said complaint. The Ombudsman opened an inquiry into complaint 1199/2010/BEH on 29 June 2010.

## The subject matter of the inquiry

7. In its present complaint, the complainant submitted the following allegation and claim:

The Commission failed properly to handle its complaint, which OLAF transferred to IDOC.

The complainant should (i) be informed about the current state of the IDOC inquiry, and (ii) be granted access to the results of this inquiry in their entirety.

8. As regards the second aspect of the complainant's claim, the Ombudsman considered that it concerned a request for access to documents which was governed by Regulation 1049/2001 [\[3\]](#) [\[Link\]](#). Article 2(4) of his Statute requires complaints to the Ombudsman to be preceded by appropriate prior administrative approaches. In cases relating to requests for access to documents under Regulation 1049/2001, the requirement set out in Article 2(4) of the Ombudsman's Statute should be interpreted as meaning that, before complainants can submit a



complaint to the Ombudsman about refusal to grant access, they must submit an initial and a confirmatory application for access to the institution concerned, in line with Regulation 1049/2001. Given that the complainant had apparently not yet submitted an application for access to the Commission, the Ombudsman, therefore, considered the second aspect of the complainant's claim to be inadmissible. He advised the complainant to submit a relevant application for access to the Commission.

## **The inquiry**

9. The complaint was forwarded to the President of the Commission for an opinion. The Commission's opinion was forwarded to the complainant with an invitation to make observations. The complainant submitted observations on 3 and 11 August 2010.

## **The Ombudsman's analysis and conclusions**

### **Preliminary remarks**

10. In its observations, the complainant questioned the meaningfulness of inquiries conducted by IDOC and OLAF against Commission staff members in view of the fact that both bodies form part of the Commission's services. In the complainant's view, the only way in which these bodies could exercise their functions in an independent and impartial manner would be if their operations were to be supervised by Parliament, but not by the Commission. The complainant asked the Ombudsman to submit a special report to Parliament (see paragraph 17 below), and pointed out that this could be an opportunity for him to trigger a debate on whether both IDOC and OLAF should, in the future, operate under Parliament's supervision. The Ombudsman does not consider that the complainant's statements are intended to be a new claim. In any event, however, it appears useful to point out that the Ombudsman's mandate is limited to inquiring into instances of maladministration in the activities of the institutions, bodies, offices and agencies of the EU. The complainant's statements, however, even if understood as constituting a new claim, would appear to advocate a change of the current legal framework by the EU legislature. Such a claim would, therefore, not appear to relate to an instance of maladministration which could be reviewed by the Ombudsman.

### **A. Allegation of improper handling of complaint**

#### **Arguments presented to the Ombudsman**

11. In support of its allegation, the complainant submitted that there was a suspicion that IDOC had never seriously investigated its complaint, and that Commission officials had exerted influence on IDOC in order to protect other Commission staff. The complainant protested



against these perceived circumstances, which it considered to be unacceptable, and a potential threat to democracy. In the complainant's view, failure to disclose the outcome of the IDOC investigation amounted to an obstruction of justice. In so far as Commission officials had infringed EU law and lied to Parliament, this would give rise to the liability of the " *Community of EU Member States* ".

**12.** In its opinion, the Commission submitted that, following the complainant's complaint to OLAF, the latter finalised its initial assessment on 23 April 2008. OLAF considered that the file submitted by the complainant did not contain any substantive information supporting the latter's allegations of corruption. OLAF subsequently sent the file to IDOC for an assessment as to whether mismanagement had occurred. The complainant submitted further information to IDOC on 30 September 2008. The Commission submitted that IDOC carried out an assessment and, in view of the information submitted by both the complainant and OLAF, concluded that no wrongdoing by Commission staff could be established.

**13.** The Commission submitted that the case featured two main aspects, namely, (i) the safeguard clause notification from 1997, and (ii) the prohibition of 2005 (see paragraph 3 above). As regards the first aspect, the information submitted indicated that the Commission did not pursue the 1997 safeguard clause notification procedure because it considered that it had become obsolete. This was due to the fact that the inhaler had been withdrawn from the market [\[4\] \[Link\]](#). It was only when an up-dated model of the inhaler was later circulated, that the Commission had to take a position in relation to the German authorities' prohibition. The Commission pointed out that the complainant had repeatedly been informed of these considerations. As regards the second aspect, the Commission considered that, in view of the applicable legal framework, the German authorities were right to prohibit the marketing of the product, and they had followed the correct procedure. Again, the complainant had repeatedly been informed along these lines.

**14.** The Commission submitted that, given the above, IDOC's assessment was correctly terminated without any follow-up.

**15.** In its observations, the complainant, referred to the German translation of the Commission's opinion, and submitted that the Commission's reference to a marketing prohibition concerning the inhaler, which was adopted in 1997, constituted an entirely new argumentation which was misleading. The complainant further submitted that the Commission sought to justify, by slanderous means, the fact that the safeguard clause procedure had not been concluded. According to the complainant, this was impertinent, ridiculous and absurd, given that it had submitted evidence which proved that the safeguard clause procedure had not become obsolete. The complainant also pointed out that an opinion of Parliament's Legal Affairs Committee dated 1 June 2010, concerning its petition, provided an entirely different assessment. The complainant attached a copy of that opinion to its complaint. Against this background, the complainant questioned whether there was any purpose in the Ombudsman conducting further inquiries into this case, given that the Commission operated on the basis of untrue and misleading facts in order to cover up manifest instances of maladministration. The complainant considered that the Commission's opinion was proof of this assertion. The



complainant further asserted that IDOC's investigation did not appear to have been conducted in an independent and impartial manner, and it suspected that other Commission services and/or Members of the Commission had influenced its work. In the given context, the complainant referred to two mutually contradictory statements made by a Director-General of the Commission, which suggested a clear case of abuse of position by that person.

16. The complainant stated that he would like to know the reasons why not one single document incriminating the Commission was referred to in the IDOC report. In the complainant's view, this again clearly confirmed the existence of a case of corruption.

17. The complainant took the view that a credible and serious assessment of why the Commission did not comply with EU law for many years could only be carried out by a parliamentary committee of inquiry. He asked the Ombudsman to send a special report to Parliament in order to make public, and denounce the instances of maladministration he had highlighted, so that Parliament could take action to remedy them. He also asked the Ombudsman to call on Parliament, in a special report, to set up a parliamentary committee of inquiry.

## The Ombudsman's assessment

18. The Ombudsman's long-established practice is to consider that there are no grounds for him to inquire into a complaint if the complainant has addressed a petition to Parliament on the **same subject-matter**, and if the Committee on Petitions has dealt with, or is dealing with it [\[5\]](#) [\[Link\]](#). The Ombudsman applies the same reasoning in cases in which an allegation or claim **relates to the subject-matter** of a petition [\[6\]](#) [\[Link\]](#).

19. The Ombudsman opened his present inquiry on the understanding that the complaint submitted to him has a different subject-matter to that of the complainant's petition to the Committee on Petitions. The complainant's petition 473/2008, which was declared admissible by the Committee on Petitions, and which the latter is currently examining, essentially concerns the Commission's alleged failure to conclude the safeguard clause procedure. In its complaint to the Ombudsman, however, the complainant alleged that IDOC failed properly to handle its complaint in which it alerted the Commission to the alleged misconduct of certain Commission staff members in connection with the safeguard clause procedure.

20. In the course of the Ombudsman's inquiry it became clear, however, that the subject-matter of the present allegation, although not identical to that of petition 473/2008, is closely related to it. Thus, in order to assess whether IDOC's investigation into alleged mismanagement by certain Commission staff members satisfies the requirements of a proper investigation, the Ombudsman would necessarily also have to evaluate the Commission's conduct in relation to the safeguard clause procedure. It is, however, precisely that issue which is currently being considered by the Committee on Petitions. Having, in the course of his inquiry, reviewed both the complainant's and the Commission's submissions, the Ombudsman is of the opinion that that the subject-matter of the complainant's allegation here under review, and of its petition to



Parliament, appear to be inextricably linked. It is true that, in these circumstances, the Ombudsman could decide to limit his inquiry to the procedural aspects of the IDOC investigation alone, thereby merely ascertaining whether IDOC made proper use of the powers at its disposal in order to investigate the complainant's complaint. Taking such an approach would not require the Ombudsman to assess IDOC's substantive assessment of the case. However, the complainant repeatedly submitted that it suffered damage as a result of the Commission's alleged infringement of the Directive. It, therefore, emerges from its submissions that the complainant is interested in a substantive evaluation of its case. In these circumstances, it would not serve a useful purpose to focus on the procedural aspects of the IDOC investigation alone.

**21.** The Ombudsman further notes that, in its observations, the complainant requested him to send a special report to Parliament, but, at the same time, it expressed the view that further inquiries by the Ombudsman would not serve any useful purpose. Article 3(7) of his Statute empowers the Ombudsman to send a special report to Parliament after submitting a relevant draft recommendation to the institution concerned. Therefore, even if he finds an instance of maladministration in a given case, the Ombudsman could not decide to send a special report to Parliament before making a relevant draft recommendation to the institution concerned. In order to assess whether there has been an instance of maladministration, and whether it is appropriate to send a draft recommendation to an institution, he would, in turn, have to pursue his inquiry, the usefulness of which the complainant has called into doubt in the present case. What clearly emerges from the complainant's submissions is that it wishes Parliament to deal with its case. However, given that the Committee on Petitions is currently assessing the complainant's case, it follows that, in effect, Parliament is already dealing with the said case.

**22.** In view of the above, the Ombudsman considers that there are no grounds for further inquiries at this point in time. However, he would like to emphasise that this finding does not preclude the complainant from submitting a new complaint concerning IDOC's inquiry, once the Committee on Petitions has finalised its assessment of the Commission's conduct, and closed the petition.

## **B. Claim to be informed of the results of the IDOC investigation**

### **Arguments presented to the Ombudsman**

**23.** On 30 September 2008, the complainant asked IDOC to inform it about the current state of its investigation. In its reply dated 13 October 2008, IDOC pointed out that the outcome of an internal investigation could not be disclosed to third parties outside the Commission. It would, therefore, not divulge any further information to the complainant regarding this matter. In its complaint to the Ombudsman, the complainant pointed out that the EU institutions should act in line with the principle of transparency. It also stated that the results of the IDOC investigation were of crucial importance to it. This was due to the fact that it had initiated court proceedings



against various national authorities, as well as the Commission, after suffering damage as a result of alleged infringements of EU law. The complainant also expressed the hope that, on the basis of IDOC's findings, Parliament would bring an action against the Commission. It, moreover, stated that it intended to sue the Commission for damages before the Court of Justice.

24. In its opinion, the Commission submitted that the reason IDOC declined to inform the complainant of its internal investigation was that its assessment had not been completed at that stage. IDOC's assessment of the case was finalised on 13 February 2009. The Commission pointed out that it informed the complainant thereof by means of the opinion it submitted in the course of the Ombudsman's inquiry. It also pointed out that, on 15 March 2010, the complainant submitted a request for access to the results of IDOC's assessment, in their entirety, and that it would deal with that request separately.

25. In its observations, the complainant did not specifically comment on its claim. However, it pointed out that it holds a copy of the results of IDOC's assessment, and it commented on their substance.

## **The Ombudsman's assessment**

26. The Ombudsman notes that, in its correspondence with the complainant, the Commission considered that the outcome of an internal investigation could not be disclosed. By contrast, in the course of the inquiry, it submitted that the reason for refusing to inform the complainant was that, at the time of the complainant's request, it had not yet concluded its assessment. While, at first sight, these two reasons are inconsistent, the Ombudsman notes that the Commission provided the complainant with information on the outcome of the IDOC investigation in the course of the present inquiry. Although this aspect is not covered by his inquiry, the Ombudsman, moreover, observes that the Commission appears to have granted the complainant access to the results of IDOC's assessment, given that, in its observations, the complainant explained that it was in possession of the relevant document, and referred to it in substance. The Ombudsman, therefore, considers that, following his intervention, the Commission has settled the complainant's claim.

## **C. Conclusions**

On the basis of his inquiry into this complaint, the Ombudsman closes it with the following conclusion:

**There are no grounds for further inquiries on the Ombudsman's part into the complainant's allegation.**

**Following the Ombudsman's intervention, the Commission has settled the complainant's claim.**





The complainant and the Commission will be informed of this decision.

P. Nikiforos Diamandouros

Done in Strasbourg on 17 December 2010

[1] [\[Link\]](#) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1). Article 8 of the Directive essentially provides that, once notified under that procedure, the Commission shall enter into consultation with the parties concerned as soon as possible. It shall subsequently inform the notifying Member State and certain other interested parties whether the measures taken, such as, for instance, a Member State's prohibition of placing a device on the market, are justified.

[2] [\[Link\]](#) IDOC is the Commission's Investigation and Disciplinary Office.

[3] [\[Link\]](#) Regulation (EC) No 1049/2001/EC of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43).

[4] [\[Link\]](#) The German translation of the relevant passage from the Commission's opinion reads as follows: "*Im Hinblick auf die Schutzklauselmeldung wurde darauf hingewiesen, dass die Kommissionsdienststellen dieses Verfahren nicht weiterverfolgt hätten, da es infolge des Vertriebsverbots für den Inhaler gegenstandslos geworden sei.*"

[5] [\[Link\]](#) See, for instance, the Ombudsman's decisions on complaint 646/97/IJH; complaint 880/2005/TN, paragraph 1.2; complaint 830/2005/JMA, paragraphs 1.4-1.6; complaint 431/2008/ELB, paragraphs 13-14; and complaint 2036/2008/(CD)BEH, paragraph 5.

[6] [\[Link\]](#) See the Ombudsman's decision on complaint 880/2005/TN, paragraph 1.4.