European Ombudsman

Decision in case 25/2018/CEC on how the European Commission handled correspondence about EU rules concerning breast implants

Decision
Case 25/2018/CEC - **Opened on** 01/02/2018 - **Decision on** 19/09/2018 - **Institutions concerned** European Commission (No maladministration found) | European Commission (Settled by the institution) |

The case concerned how the European Commission dealt with correspondence concerning EU rules on breast implants. The complainant felt the Commission had failed (a) to reply to concerns it raised about the Scientific Committee on Health and Environment and Emerging Risks (which provides scientific advice to the Commission) and its advice concerning breast implants. The complainant also believed that the Commission, in considering the risks related to breast implants, had failed (b) to take into account information demonstrating a causal link between breast implants and anaplastic large-cell lymphoma. The complainant wanted the Commission (c) to request that EU Member States (temporarily) place a moratorium on textured breast implants.

The Ombudsman inquired into the issue and found that the Commission had replied to the complainant. Regarding aspects (b) and (c) of the complaint, the Ombudsman found that there was no maladministration by the Commission.

The Ombudsman therefore closed the inquiry.

Background to the complaint

1. The complainant is a support centre for complaints concerning silicone breast implants in the Netherlands. It represents more than 4 700 women who have contacted it via a hotline it runs.

2. On 14 June 2016, on the request of the Commission, the Scientific Committee on Health and Environment and Emerging Risks (SCHEER) [1] launched 'calls for information' [2] on the safety of Poly Implant Prothèse (PIP) silicone breast implants [3] and on a possible association between breast implants and anaplastic large-cell lymphoma ('ALCL') [4] . In the context of these calls for information, the complainant submitted a literature review on general issues related to silicone breast implants [5] .

3. On 2 January 2017, the complainant sent an e-mail to the Commission requesting it to recall all textured breast implants (not just PIP implants) and introduce a moratorium, pending the review, in accordance with the 'safeguard clause' provided for in the EU Medical Devices Directive [6] .

4. Having received no reply from the Commission, the complainant turned to the Ombudsman (complaint 149/2017/CEC). During the course of the Ombudsman's inquiry, the Commission replied to the complainant. Amongst other things, it informed the complainant that the safeguard clause could be triggered only by a Member State, and not by the Commission. Since the Commission had replied, the Ombudsman closed the case as settled [7] .

5. On 7 April 2017, SCHEER's scientific advice on PIP implants and on Breast Implant Associated-ALCL (BIA-ALCL) was published and interested parties were invited to submit comments.

6. On 14 June 2017, the complainant submitted its comments, including an abstract of a study from 2017.

7. In September and October 2017, SCHEER adopted its scientific advice on PIP implants [8] and on BIA-ALCL [9] respectively. The scientific advice on BIA-ALCL concluded, amongst other things, that "[t] *he available information suggests that breast implants may be associated with an increased risk for ALCL. Although the very low incidence of ALCL and the methodological limitations of the available information/studies do not currently allow for a robust risk assessment, the SCHEER recommends that a more in-depth evaluation be conducted on the possible association of breast implants with the development of ALCL* ".

8. On 30 October 2017, the complainant sent an e-mail to the Commission. It expressed its dissatisfaction with SCHEER's scientific advice, in particular in relation to whether there is a possible link between breast implants and ALCL. According to the complainant, SCHEER put economic interests ahead of the interests of women's health. It argued that SCHEER had considered an older report from 2016 in the context of the call for information instead of the literature review it had submitted in June 2017. It stated that the scientific advice mentioned that a review of the published scientific literature and of " *any other source of relevant data available* " would be carried out. Against this background, it asked why its submission (notably the abstract of a study referred to above) had been excluded and whether this would have changed the outcome of the scientific advice. It further complained about the lack of communication between scientific organisations, health authorities and SCHEER.

9. Not having received a reply, the complainant turned to the European Ombudsman on 8 January 2018.

The inquiry

10. The Ombudsman opened an inquiry into the complainant's claims that:

(a) the Commission had not responded to the e-mail of 30 October 2017, expressing concerns about SCHEER's work on breast implants;

(b) the Commission had failed to consider, in the context of SCHEER's scientific advice, information demonstrating a causal link between breast implants and ALCL; and

(c) the Commission should request Member States to (temporarily) place a moratorium on textured breast implants.

11. In the course of the inquiry, the Commission forwarded to the Ombudsman its reply to the complainant's e-mail of 30 October 2017, which it had sent on 14 November 2017, that is, before the complainant contacted the Ombudsman. As this reply addressed the concerns raised by the complainant regarding SCHEER, the Ombudsman considered this matter (a) to be settled.

12. The Ombudsman subsequently received the comments of the complainant in response to the Commission's reply, and a further reply by the Commission.

Failure to consider information demonstrating a causal link between breast implants and ALCL

Arguments presented to the Ombudsman

13. In its reply to the complainant, the Commission stated that SCHEER's role is to provide the Commission with scientific advice and risk assessments for its policy-making in the fields of health, the environment and relevant emerging risks [10] . SCHEER produces scientific advice based on specific mandates, as stipulated in the Rules of Procedure of the Scientific Committees (RoP) [11] . This advice must be based on scientific evidence, and address the tasks in the mandate. Consequently, SCHEER's work should not be confused with the stakeholders' consultation process [12] or with expert groups [13] , where the different views of various parties should be represented.

14. The Commission stated that it had forwarded to SCHEER, for its consideration, the complainant's contribution to the call for information in 2016 and its comments on SCHEER's scientific advice from 2017. It referred the complainant to the scientific advice on PIP and on BIA-ALCL for the results [14] and the evaluation [15] of the papers submitted in the context of the calls for information, and for details on the comments received on this advice [16] .

15. It stated that according to the RoP, the objectives of calls for information, public consultations and periods for receiving comments are to ensure that all relevant scientific information is available to Scientific Committees, to enhance the quality of their work. Regarding

the abstract to which the complainant referred, it stated that, according to the RoP, any document referred to in a response should be attached and that the Commission does not research documents or websites referred to in a submission [17] . It stated that, to the best of its knowledge, the study at issue had not yet been published in a scientific journal. As such, it was not possible to include this limited abstract information in the referenced literature for the scientific advice. However, the Commission pointed out that the scientific advice had recommended making a further in-depth evaluation of the link between breast implants and ALCL.

16. On 8 February 2018, in reply to a subsequent email from the complainant (see below, paragraph 23), the Commission reiterated that, in its scientific advice on BIA-ALCL, SCHEER had taken into account all the scientific information it had gathered. It added that the complainant's contributions had been carefully considered, as reported in the scientific advice.

17. The complainant replied, stating that its email did not concern SCHEER's advice on BIA-ALCL, but concerned a substance present in breast implants, which had never been investigated.

The Ombudsman's assessment

18. The Ombudsman notes at the outset that her mandate is to deal with complaints about *administrative* activities, and that her office cannot examine the merits of scientific evaluations carried out by a specialised scientific committee such as SCHEER.

19. The Ombudsman considers that the Commission provided reasonable explanations as to how SCHEER considered the complainant's submission to the calls for information and its comments on the scientific advice. The Ombudsman notes that, in accordance with the applicable rules, SCHEER does not have to take into account abstracts of studies that have not been attached in full [18] . Although the complainant may be disappointed about the evaluation of the available literature in the scientific advice, the Ombudsman does not find that there is any indication that it ignored or disregarded the submissions of the complainant.

20. In light of the above, the Ombudsman considers that **there was no maladministration by the Commission regarding this part of the complaint** .

Whether the Commission should request that Member States introduce a moratorium on textured breast implants

Arguments presented to the Ombudsman

21. In the course of the Ombudsman's earlier inquiry 149/2017/CEC, the Commission stated

that only Member States can initiate the safeguard procedure provided for under the Medical Devices Directive, and request a moratorium on medical devices. It informed the complainant that no Member State had done so with respect to textured breast implants.

22. In response, the complainant argued that this situation was unsatisfactory and meant no action had been taken as a result. It alleged that the Member States and the Commission are essentially putting manufacturers ahead of women's health, and that the women affected are not compensated for the damage they suffer due to textured silicone breast implants.

23. On 26 January 2018, the complainant sent an e-mail to the Commission and the Dutch National Institute for Public Health and the Environment (RIVM), claiming that complaints concerning breast implants had been ignored for years by governments. It argued that the authorities were not properly assessing the causes of BIA-ALCL. It referred to specific research regarding a particular substance in breast implants that had never been previously investigated [19] .

24. On 26 April 2018, the Commission sent a further reply to the complainant, stating that the structural components and properties of medical devices placed on the EU market are assessed for safety by the 'notified bodies' responsible for certifying their conformity [20] . In order to strengthen the regulatory framework, the EU had adopted new legislation aimed at regulating the lifecycle of medical devices [21] . This new legislation includes more stringent safeguards for medical devices, has strengthened surveillance after market approval and has enhanced supervision of the notified bodies [22] . Since the market surveillance activities were carried out at Member State level, it advised the complainant to contact the relevant Dutch authorities if it suspected that improper substances were present in breast implants [23] .

The Ombudsman's assessment

25. The Ombudsman notes that silicone breast implants within the EU are currently regulated by the Medical Devices Directive. Article 8 of the Medical Devices Directive states "[w] *here a Member State ascertains that the devices (…) 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 (…)* ". The Ombudsman notes that there is at present no legal provision granting the Commission the direct power to itself withdraw or restrict the placement on the market of silicone breast implants.

26. Based on this, the Ombudsman finds that the Commission was correct to state that it does not have the power to place a moratorium on breast implants. It is the role of the responsible authorities in Member States to ascertain whether devices pose a risk to public health and safety, and the Commission cannot request a Member State to (temporarily) introduce a moratorium on breast implants.

27. Furthermore, the Ombudsman notes that the Commission has taken steps to further strengthen the regulatory framework on medical devices, which will apply after a transitional period [24] .

28. The Ombudsman thus finds that there was **no maladministration by the Commission regarding this aspect of the complaint** .

Conclusions

Based on the inquiry, the Ombudsman closes this case with the following conclusions :

The European Commission has settled the issue of failure to reply.

There was no maladministration by the Commission regarding the other aspects of the complaint.

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

Emily O'Reilly

European Ombudsman

Strasbourg, 19/09/2018

[1] SCHEER is comprised of experts from the scientific community. It provides advice to the Commission on health and environmental risks.
https://ec.europa.eu/health/scientific_committees/scheer_en [Link]

[2] The calls for information sought data, which SCHEER would then review. More information https://ec.europa.eu/health/scientific_committees/consultations/calls/scheer_call_info_02_en [Link] and https://ec.europa.eu/health/scientific_committees/consultations/calls/scheer_call_info_03_en [Link].

[3] In 2010, it was discovered that a French medical devices company (PIP) had, since 2001, illegally made and sold breast implants made from industrial-grade silicone, instead of medical-grade silicone. The PIP scandal led to the banning of PIP implants and the imprisonment of a PIP executive. It is estimated that 400 000 women worldwide were victims of

the PIP scandal.

[4] ALCL is a type of lymphoma, a cancer involving cells of the immune system. Breast Implant Associated-ALCL (BIA-ALCL) is a specific type of ALCL.

[5] See number 50 “Literature review from a patient’s perspective” from the year 2016 on the list of papers received during the call for information: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_007_a2.pdf [Link]

[6] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ 1993, L 169, p. 1-43. Article 8 sets out a ‘safeguard clause’, which provides for the withdrawal from the market of medical devices that have been demonstrated to pose risks to the health or safety of patients or users.

[7] See the decision of the European Ombudsman in case 149/2017/CEC: https://www.ombudsman.europa.eu/en/cases/decision.faces/en/87859/html.bookmark [Link]

[8] Scientific advice on the evaluation of new scientific information on the safety of PIP breast implants, see: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_008.pdf [Link]

[9] Scientific advice on the state of scientific knowledge regarding a possible connection between breast implants and anaplastic large-cell lymphoma, see: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_007.pdf [Link]

[10] See Article 3 of the Commission Decision of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment: https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/rules_procedure_2016_en.pdf [Link].

[11] See Annex I, point 7 to the RoP: https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/rules_procedure_2016_en.pdf [Link].

[12] More information: http://ec.europa.eu/smart-regulation/guidelines/consultation_2014/stakeholder-consultation/index_en.htm [Link].

[13] More information: http://ec.europa.eu/transparency/regexpert/index.cfm?do=faq.faq&aide=2 [Link].

[14] See chapter 5.1.2 of its scientific advice on PIP and chapter 5.2 of its scientific advice on

BIA-ALCL

[15] See Annex II to both scientific advice papers: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_007_a2.pdf [Link].

[16] See chapter 5.1.3 of its scientific advice on PIP and chapter 5.2.1 on its scientific advice on BIA-ALCL.

[17] In accordance with the RoP, as well as the Guidelines for submission of contributions to the calls for information by the non-food Scientific Committees, https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/call_info_guidelines2016_en.pdf [Link].

[18] In accordance with points 4 and 5.2 of the RoP.

[19] https://www.clinmedjournals.org/articles/cmrcr/clinical-medical-reviews-and-case-reports-cmrcr-3-087.pdf [Link]

[20] It referred to Articles 2, 3 and 16 of the Medical Devices Directive and to Annex I, point 7 to this directive, which set out the obligations on Member States, the essential requirements to be met under the directive and the role of notified bodies. It also referred to the following link for more information: https://ec.europa.eu/growth/sectors/medical-devices/questions-answers_en [Link] (last question on the list).

[21] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1 and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176.

[22] The Commission referred to the following link: https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en [Link]

[23] The Commission referred the complainant to the following link: https://www.igj.nl/ [Link].

[24] Namely, 3 years after entry into force for Regulation (EU) 2017/745 on medical devices (spring 2020) and 5 years after entry into force (spring 2022) for Regulation (EU) 2017/746 on in vitro diagnostic medical devices.