



Decision of the European Ombudsman closing the inquiry into complaint 364/2013/(EIS)PMC against the European Medicines Agency (EMA)

Available languages: [en](#)



Contents

- The background to the complaint
- The inquiry
- Alleged procedural failures and manifest errors of assessment when formulating the EMA's position on the application for a marketing authorisation
 - Arguments presented to the Ombudsman
 - (i) The EMA failed to take into account the bioequivalence study the complainant referred to and it therefore did not satisfy the legitimate

[Lodge a complaint](#)

[Request for information](#)

Closing summaries of cases

- [Failure to proactively disseminate environmental information \(Added on: 30 Jun 2014 13:01 CEST\)](#)
- [Access to documents regarding four aircraft maintenance service providers \(Added on: 30 Jun 2014 10:01 CEST\)](#)

[All summaries...](#)

Press releases

- [28 May 2014 Ombudsman: Commission releases internal documents on Common Fisheries Policy](#)
- [21 May 2014 EU "cohesion" policy: Ombudsman investigates protection of fundamental rights](#)

[All press releases...](#)

expectations of the complainant

- (ii) The EMA failed to take into account that the complainant's application included a restriction to the effect that the medicine was indicated only for patients "previously diagnosed" with migraine
- (iii) The EMA failed to take into account that there is no increased risk of cardiovascular or cerebrovascular events associated with the use of the medicine
- (iv) The EMA ignored evidence submitted by the complainant with regard to risk minimisation measures contained in the information leaflet
- (v) The EMA wrongly took the view that triptans constitute second-line treatment for migraines and not first-line treatment as shown in the European Guidelines for the self-management of migraine
- (vi) The EMA failed properly to address the complainant's concerns about alleged conflicts of interest when dealing with its case
- (vii) The EMA failed to take into account that the active substance in the medicine has been granted a marketing authorisation in at least four Member States
- The Ombudsman's assessment
 - (i) The EMA failed to take into account the bioequivalence study the complainant referred to and it therefore did not satisfy the legitimate expectations of the complainant
 - (ii) The EMA failed to take into account that the complainant's application included a restriction to the effect that the medicine was indicated only for patients "previously diagnosed" with migraine
 - (iii) The EMA failed to take into account that there is no increased risk of cardiovascular or cerebrovascular events associated with the use of the medicine
 - (iv) The EMA ignored evidence submitted by the complainant with regard to risk minimisation measures contained in the information leaflet
 - (v) The EMA wrongly took the view that triptans constitute second-line treatment for migraines and not first-line treatment as shown in the European Guidelines for the self-management of migraine
 - (vi) The EMA failed properly to address the complainant's concerns about alleged conflicts of interest when dealing with its case
 - (vii) The EMA failed to take into account that the

Upcoming events

- **09 Jul 2014** Meeting with US Ambassador to the EU Mission, Mr Anthony L. Gardner
- **14 Jul 2014** Meeting with the President of the European Investment Bank, Mr Hoyer, followed by a meeting with the staff of the complaints mechanism and the Chief Executive of the European Investment Fund

[More upcoming events...](#)

Past events

- **30 Jun 2014** Opening ceremony of the 8th Legislature of the European Parliament
- **26 Jun 2014** Meeting with Mr Morten Kjaerum, Director of the Fundamental Rights Agency

[All past events...](#)



Public consultation
Composition of
EC expert groups



active substance in the medicine has been granted a marketing authorisation in at least four Member States

- Conclusion
- Further remark

Case: 0364/2013/(EIS)PMC

Opened on **19 Mar 2013** - Decision on **30 Jun 2014**

- Institution(s) concerned: **European Medicines Agency**
- Field(s) of law: **Environment, consumers and health protection**
- Types of maladministration alleged – (i) breach of, or (ii) breach of duties relating to: **Lawfulness (incorrect application of substantive and/or procedural rules) [Article 4 ECGAB]**
- Subject matter(s): **Competition and selection procedures (including trainees)**

This complaint was made by a UK-based pharmaceutical company. It concerned an application to the EMA for a marketing authorisation for non-prescription medicine intended for the relief of migraine attacks. The marketing authorisation was refused for a number of reasons including concerns about a high risk of cerebrovascular (brain) and cardiovascular (heart) side effects as well as potential misuse and overuse. The complainant consequently complained about the conduct of the EMA, alleging that in formulating its position, the EMA had made procedural errors and manifest errors of assessment. The Ombudsman inquired into the issue and found no maladministration in the conduct of the EMA.

The background to the complaint △



- 1.** The complainant is a UK-based pharmaceutical company. On 31 March 2010, it submitted an application to the European Medicines Agency (EMA) for a marketing authorisation for a non-prescription anti-migraine medicine (hereinafter 'the medicine'), intended for the relief of migraine attacks in people who have been diagnosed with migraine.
- 2.** On 21 July 2011, the EMA's Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion with regard to the granting of a marketing authorisation for the medicine. The EMA's negative opinion reflected a concern that, as a non-prescription drug, used without medical supervision and monitoring, there would be an increased risk for patients of cerebrovascular (brain) and cardiovascular (heart) side effects, as well as the potential for misuse and overuse. In addition, the CHMP argued that migraine as a condition changes over time, as does a patient's cardiovascular and cerebrovascular status, and monitoring is therefore essential. The measures proposed by the complainant to reduce these risks were considered insufficient.
- 3.** The complainant subsequently challenged the CHMP's opinion. However, following a re-examination of its opinion, the CHMP was still concerned about the safety of the medicine and confirmed its initial negative opinion in a second opinion issued on 17 November 2011.
- 4.** On 9 February 2012, based on the findings of the CHMP, the European Commission adopted a decision not to grant a marketing authorisation for the medicine.
- 5.** On 7 December 2012, the complainant contacted the EMA again, arguing that its position was vitiated by a number of errors and shortcomings.
- 6.** On 17 December 2012, the EMA replied to the complainant, explaining that it had been given an opportunity, including an oral hearing, to defend its rights at each stage of the procedure. It also stated that, in the re-examination procedure, a new rapporteur was appointed in order to ensure an impartial review of the disputed opinion. It added that its position was definite.
- 7.** Since it was dissatisfied with the EMA's position, the complainant turned to the European Ombudsman on

19 February 2013.

The inquiry

8. The complainant alleged that, in formulating its position on the application for a marketing authorisation, the EMA made (i) procedural errors and (ii) manifest errors of assessment. It claimed that the EMA should acknowledge its errors and inform the Commission accordingly.

9. The Ombudsman opened an inquiry into the above allegation and claim. In the course of the inquiry, the Ombudsman received the opinion of the Agency on the complaint and, subsequently, the complainant's observations in response to the Agency's opinion. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties.

Alleged procedural failures and manifest errors of assessment when formulating the EMA's position on the application for a marketing authorisation

Arguments presented to the Ombudsman

10. In support of its allegation, the complainant put forward seven arguments (marked (i)-(vii) below).

(i) The EMA failed to take into account the bioequivalence study the complainant referred to and it therefore did not satisfy the legitimate expectations of the complainant 

11. The complainant argued that the EMA failed to ensure due process and to uphold the highest standards of administration in accordance with the law. It contended that the validity of its application was called into question after the application fee had been

accepted and its application had been validated. Despite constant pressure to withdraw the application because of the CHMP's opinion regarding the bioequivalence study and the refusal of an extension of time so as to enable it to repeat the study, the complainant stated that it repeated the study at its own cost, while also drawing up an Expert report to justify granting it a biowaiver, that is, a waiver of the requirement to conduct an *in vivo* bioequivalence study.

12. In its opinion, the EMA argued that it followed the assessment procedure laid down in Regulation 726/2004[1] and that it considered all clinical studies submitted by the complainant. Moreover, the EMA contended that the CHMP could not accept the bioequivalence study, which was the only study the complainant submitted in support of its application, since an inspection of the site where the study had been conducted revealed that it had not been conducted in compliance with Good Clinical Practice (GCP), as explained in the CHMP's assessment report (hereinafter the 'assessment report')[2]. The EMA noted that the complainant itself suggested repeating the bioequivalence study, which implied that the complainant knowingly submitted data which were not in compliance with EU standards.

13. The EMA also argued that the complainant could not have had any legitimate expectations that the CHMP would follow the decisions of other authorities on the marketing of the medicine in question, even if these decisions had been taken on the basis of the same bioequivalence study. In this regard, the EMA put forward that the CHMP is not bound by the decisions of competent national authorities, particularly when such decisions were rendered at different times and in response to different marketing authorisation holders. The EMA pointed out that the CHMP takes into account all available evidence, including scientific developments and the experience acquired in respect of the proposed treatment/indication. The fact that no further action has been taken against medicinal products authorised at the national level on the basis of the relevant bioequivalence study is due to Directive 2001/83[3] and Regulation 726/2004, according to which, the EMA and the CHMP are not competent to take any action against medicinal products which have been authorised by the competent national authorities.

14. Additionally, in response to the complainant's

argument that the EMA did not challenge the bioequivalence study from the start of the procedure and that therefore the complainant had to pay the relevant fee, the EMA said that, in line with its guidelines and the case-law of the Court of Justice, the validity of a study is subject to assessment by the CHMP and is not assessed during the administrative checks performed by the EMA at the time of validation of the application.

15. In its observations, the complainant pointed out that the EMA misrepresented its actions. It emphasised that it did not knowingly submit initial data that were not in compliance with EU standards, as the EMA argued, but it selected the relevant bioequivalence study for inclusion in its application because that study had already been relied on by regulatory authorities in more than one Member State for the purpose of granting a marketing authorisation for the medicine in question. It thus maintained its view that it could legitimately expect that the study in question would be taken into account.

16. Furthermore, the complainant contended that it was not given the opportunity to address the issue of the bioequivalence study at the oral hearing before the CHMP because it was instructed to remove the relevant slides containing information about the study from its presentation. In addition, during the hearing, the complainant was instructed to move to the next point of the presentation once it reached the slide containing information about the study.

17. Moreover, the complainant objected to the EMA's statement that marketing authorisations were granted at different times and in response to different marketing authorisation holders. It argued that the identity of the authorisation holder cannot be relevant for deciding whether or not an independently carried out bioequivalence study may be relied upon.

18. Finally, the complainant acknowledged that the EMA is not bound by the decisions of competent national authorities, but argued that it cannot be considered correct that, acting under the same regulatory system as that governing the EMA's decisions, national authorities continue to accept the very same published safety data in support of existing and new non-prescription licenses for the same medicine as the data submitted by the complainant to the EMA.

(ii) The EMA failed to take into account that the complainant's application included a restriction to the effect that the medicine was indicated only for patients "previously diagnosed" with migraine 

19. The EMA pointed out that, according to the CHMP's assessment report, the 'non-prescription' status of the medicine implies that the absence of clinical supervision can be compensated for by consultation with pharmacists or by patients themselves. The assessment report noted that the complainant proposed a restriction to the effect that the medicine be indicated for migraine patients who have previously been prescribed 50 mg tablets of the medicine in question. However, the CHMP argued that neither this nor any other measures proposed by the complainant, which included a patients questionnaire, would satisfactorily reduce the risk of inappropriate use of the product in a non-prescription setting. The assessment report also explained that patients' conditions may change over time and that the detection of misuse and overuse and corrective action would be delayed if doctors would no longer have to be consulted. Consequently, the CHMP advised against a 'non-prescription' status for the medicine. On the basis of the above, the EMA argued that the CHMP carefully took into account the complainant's application on this particular point and rejected it on the basis of the need for the protection of public health and of patients. Relying on settled case-law, the EMA also submitted that taking into account the complex technical assessment to be performed by the CHMP, the latter must be considered to enjoy broad discretionary powers.

20. In its observations, the complainant rejected the EMA's statements as unsubstantiated and argued that they contradict data provided in its application for a marketing authorisation. In this respect, the complainant submitted (a) that the medicine was first approved in Sweden in 2008 on the basis of the same data as that proposed by the complainant and under the same regulatory system, (b) that eight over-the-counter ('OTC') licenses for the medicine in question have since been approved in Sweden by the competent national authority, on the basis of the same data and under the same regulatory system, and (c) that after the EMA's negative opinion on the complainant's application in 2011, the Swedish authorities continued to approve OTC licenses for the

same medicine. Moreover, this medicine and other triptans^[4] continue to be available in Germany, Hungary, Romania and the UK, on the basis of the same information as that provided in the application in question.

(iii) The EMA failed to take into account that there is no increased risk of cardiovascular or cerebrovascular events associated with the use of the medicine Δ

21. The EMA stated that the CHMP considered the evidence provided by the complainant in writing and during the oral hearing, as well as the advice from the Safety Advisory Group (SAG), which was consulted by the CHMP in conformity with Article 56(2) of Regulation 726/2004. However, according to the EMA, this evidence failed to address the CHMP's concerns about the requirement of a medical diagnosis and follow-up of patients.

22. Furthermore, the EMA argued that the relevant assessment report clearly shows that the CHMP took into account data from scientific literature focusing on the safety profile of the medicine, as submitted by the complainant. However, no reassurance regarding the CHMP's concerns about the need for a medical diagnosis and follow-up of patients was provided. Moreover, in the same report, the CHMP referred to a scientific study which emphasises the risk of adverse events in patients suffering from angina and listed three further studies revealing safety concerns in relation to the use of triptans in general.

23. The EMA added that the SAG was asked to comment on the cerebrovascular and cardiovascular safety of the medicine and the potential impact of its prescription or non-prescription status on these specific aspects, as well as on the safety of using this medicine in general. The EMA noted that while the SAG can provide guidance on particular issues, it does not provide a complete opinion on the product in question. Indeed, according to the SAG's Rules of Procedure, the CHMP takes into account the position expressed by the SAG, but remains responsible for its own opinion.

24. In its observations, the complainant argued that the EMA did not follow the advice given by the SAG, which found that there is no significant evidence of an increased risk of cardiovascular or cerebrovascular adverse events when using the medicine. The

complainant also asserted that if the SAG's advice had indeed formed the basis of the CHMP's opinion, as the EMA argued, the CHMP would have been bound to follow that advice. The CHMP's opinion therefore established that the CHMP in fact did not take into account the SAG's advice.

(iv) The EMA ignored evidence submitted by the complainant with regard to risk minimisation measures contained in the information leaflet

25. The EMA argued that the CHMP did take into account the evidence provided by a particular expert regarding the risk minimisation measure proposed by the complainant, as outlined in the CHMP's relevant joint assessment report (hereinafter 'the joint assessment report')[5]. The EMA pointed out that although this evidence was submitted for the first time during the re-examination procedure, it had been duly considered. However, it failed to allay the CHMP's concerns.

26. In its observations, the complainant reiterated its argument that the EMA had ignored evidence submitted in respect of the supply of non-prescription drugs in Sweden where there is no routine involvement of a pharmacist for non-prescription drugs. Instead, the information leaflet of a medicine makes it clear when a patient should speak to a pharmacist or a doctor. In the complainant's view, the Swedish example is thus "*the most challenging to meet*" because the risk minimisation measures have to be described in the information leaflet in such a way that they can easily be read and understood by the customer without the involvement of a pharmacist. The complainant argued that the EMA failed to consider this point and that the Swedish experience since 2008 clearly demonstrates that the medicine in question can safely be supplied to Europeans.

27. Furthermore, the complainant acknowledged that new evidence which it provided during the re-examination procedure was taken into account, but also argued that further evidence, produced during the oral hearing and addressing concerns about the risk minimisation measures contained in the information leaflet, were ignored.

(v) The EMA wrongly took the view that triptans constitute second-line treatment for migraines and not first-line treatment as

shown in the European Guidelines for the self-management of migraine

28. In its opinion, the EMA argued that the CHMP had carefully considered this point during the first assessment and the re-examination, as evidenced by the relevant assessment reports. It noted that the complainant referred to a specific publication in a scientific journal but not to the CHMP's Guidelines. The EMA added that the CHMP follows scientific developments and keeps abreast of the latest publications, but underlined that publications cannot be considered to constitute conclusive and binding guidelines for the CHMP and they therefore cannot form the basis of the CHMP's conclusion.

29. In its observations, the complainant stated that it nonetheless expected the EMA to substantiate any decision to discard current scientific evidence and to update its opinion when faced with new scientific evidence, even though it was not obliged to follow it.

(vi) The EMA failed properly to address the complainant's concerns about alleged conflicts of interest when dealing with its case

30. The complainant specifically argued that the CHMP failed to address concerns that physicians and pharmacists represented on that committee have a financial interest in ensuring that medicines can be dispensed by prescription only. The complainant argued that there is a risk that physicians see the increased availability of non-prescription medicines as a threat to their "*prescription franchise*" and income.

31. The EMA argued that there was no breach of any legislative or procedural requirement regarding conflicts of interest. It explained that the composition of the CHMP is governed by Article 61 of Regulation 726/2004 and Article 1 of the CHMP Rules of procedure and that this composition remains unchanged for the assessment of all medicinal products, regardless of the proposed means of dispensation.

32. Moreover, the EMA explained that it has its own Conflicts of Interest Policy according to which, the members of the CHMP have to declare any potential conflict of interest at the beginning of each meeting. The EMA therefore considered the complainant's view, that a conflict of interest would arise based on a specific category of professionals, to be groundless. It

added that a conflicting interest that could prejudice the independence of the CHMP would rather arise from the particular position held by individuals involved and would thus concern specific subjective circumstances affecting the work of the Committee.

33. In addition, the EMA argued that the complainant's view regarding potential conflicts of interest is unfounded as the CHMP has issued positive opinions for non-prescription medicines before, when it considered that they met the necessary quality, safety and efficacy standards.

34. Furthermore, the EMA noted that certain revisions of pharmaceutical legislation were made so as to allow non-prescription drugs to benefit, under certain circumstances, from the centralised procedure at the EU level. However, the CHMP would not engage in the assessment of non-prescription medicines already widely available at the national level.

35. In its observations, the complainant argued that the definition of 'conflict of interests' should not be limited by the EMA's Conflicts of Interest Policy and that under general principles of EU law, any conflict of interest should be relevant in determining whether or not an application was fairly dealt with.

(vii) The EMA failed to take into account that the active substance in the medicine has been granted a marketing authorisation in at least four Member States 

36. The EMA stated that the CHMP is not bound by the decisions of the national competent authorities and that the complainant's argument is therefore unfounded. The EMA also submitted that the CHMP takes into account all available evidence, including scientific developments and the experience acquired in respect of the proposed treatment. Furthermore, it explained that the Committee was aware of the authorisation status in four Member States. However, on the basis of scientific arguments and in view of scientific and public health concerns relating to the administration of the products, it decided not to adopt a positive opinion.

37. The complainant did not submit any observations in respect of this argument.

The Ombudsman's assessment 

38. This case concerns the evaluation of a scientific proposal which raises complex scientific questions. In examining cases of this kind, the Ombudsman takes the view that she should not substitute her own assessment for that of the scientific experts^[6]. Moreover, the CHMP enjoys wide discretionary powers to conduct scientific assessments regarding applications for marketing authorisations. The Ombudsman's review, therefore, is concerned with assessing whether a procedural error has occurred or whether there is a manifest error in the reasoning of the contested decision.

(i) The EMA failed to take into account the bioequivalence study the complainant referred to and it therefore did not satisfy the legitimate expectations of the complainant 

39. The Ombudsman considers that the EMA gave reasons to explain why the CHMP did not accept the relevant bioequivalence study. In particular, it submitted that the assessment report specified why the study was considered not to comply with GCP, and also argued that the CHMP is not bound by the decisions of competent national authorities. These reasons are borne out by the documentary evidence submitted to the Ombudsman. She therefore considers them to be plausible.

40. The complainant has submitted that it was not given the opportunity to address the issue of the bioequivalence study during the oral hearing before the CHMP. If this indeed occurred, the Ombudsman finds it most unusual for an applicant to be instructed not to comment on particular scientific data in support of its application during an oral hearing. In this case, however, she sees no need to pursue this aspect further since, in any event, the CHMP and the EMA addressed and took into account the arguments the complainant put forward in support of its application, including its position on the bioequivalence study.

41. The complainant also argued that it had legitimate expectations arising from the fact that competent national authorities had previously accepted the bioequivalence study which the complainant submitted to the EMA. It is not in dispute that certain national authorities have accepted the study. However, given that it is equally undisputed that the EMA is not bound by decisions of national authorities, the Ombudsman is not convinced that the decisions of national authorities could give rise to any legitimate expectation that the

EMA would adopt the same position. Nor could the fact that the EMA did not take any action regarding medicinal products authorised by certain Member States give rise to any legitimate expectations, since the EMA convincingly explained that it is not competent to do so. Lastly, in its observations, the complainant appeared to suggest that the fact that it had paid the relevant application fee and that its application had been validated could have given rise to legitimate expectations. However, the EMA's position, that the CHMP assesses the validity of a study only after an application has been validated, is fully convincing.

(ii) The EMA failed to take into account that the complainant's application included a restriction to the effect that the medicine was indicated only for patients "previously diagnosed" with migraine 

42. The complainant contended that the EMA did not take into account that the medicine was intended only for patients previously diagnosed with migraine. The Ombudsman is not convinced by this argument especially since the assessment report states that a patient's condition and headache/migraine conditions may change over time, and that this may affect the appropriateness of using the medicine. The assessment report moreover refers to the need to detect misuse and/or overuse. Therefore, the complainant's view that the restriction it proposed was not taken into account cannot be sustained. It is clear from the complainant's observations, in which it referred to the experience gained in Sweden and in other Member States that the complainant in fact disagrees with the outcome of the CHMP's assessment. However, this does not suffice to substantiate the argument that the CHMP failed to take into account the restriction proposed by the complainant.

(iii) The EMA failed to take into account that there is no increased risk of cardiovascular or cerebrovascular events associated with the use of the medicine 

43. It is clear from the assessment report that the CHMP considered the risk of cardiovascular or cerebrovascular events associated with the use of the medicine. The assessment report shows that the CHMP noted that the complainant presented data from literature focusing on the safety profile of the medicine, but that no reassurance was provided in relation to the CHMP's concerns about the need for a medical

diagnosis and follow-up of patients. The complainant disputed this finding, relying on the opinion of the SAG, a further study, as well as the experience in Sweden and, on this basis, argued that there is no increased risk of cardiovascular and cerebrovascular adverse events. It is clear from the assessment report that, in making its assessment, the CHMP relied on certain scientific studies suggesting an increased risk. It is not for the Ombudsman to take a view on the respective merits of the scientific studies referred to by the complainant and the EMA. However, since the CHMP explained how and, in particular, on the basis of which studies it reached its conclusion, the Ombudsman cannot find any procedural error or a manifest error in the CHMP's reasoning. Nor can she find any such errors in the CHMP's decision not to follow the SAG's opinion, since it is clear from the assessment report that the opinion was taken into account in the assessment and the CHMP was not bound to act in accordance with it.

(iv) The EMA ignored evidence submitted by the complainant with regard to risk minimisation measures contained in the information leaflet 

44. The Ombudsman considers that there is nothing to suggest that the EMA did not take into account the evidence submitted by the complainant, as shown by the relevant passages of the assessment report and the joint assessment report. In fact, the Ombudsman notes that the CHMP acknowledged the opinion of leading experts in support of the non-prescription status of the medicine, as emerges from page 20 of the joint assessment report, but nevertheless concluded that the measures proposed by the complainant were insufficient, and gave reasons in support of its view. While, in its observations, the complainant again referred to the example of Sweden, for the reasons set out above, this does not affect the finding that the CHMP considered the relevant evidence.

(v) The EMA wrongly took the view that triptans constitute second-line treatment for migraines and not first-line treatment as shown in the European Guidelines for the self-management of migraine 

45. The Ombudsman notes that the EMA specified that the CHMP relied on the applicable EU Guidelines. This is confirmed by the assessment report which, on page 18, states that in assessing whether the use of the medicine in a non-prescription setting would be safe, it

had to apply the criteria laid down in the relevant EU Guidelines. The complainant did not challenge the applicability and relevance of these Guidelines, but argued that the CHMP is required to update the Guidelines when confronted with new scientific evidence. While it would appear logical that the EMA would have to update the relevant Guidelines in the event that new scientific evidence seriously calls them into doubt, the complainant did not argue that this was the case. It follows that the EMA cannot be considered to have committed a manifest error by relying on the Guidelines in force.

(vi) The EMA failed properly to address the complainant's concerns about alleged conflicts of interest when dealing with its case 

46. The Ombudsman notes that the complainant argued that there was a conflict of interest because physicians and pharmacists sitting on the CHMP have a financial interest in ensuring that medicines can be dispensed only by prescription. The EMA argued that it had acted in accordance with the applicable rules on conflicts of interest as regards the composition of the Committee. It furthermore submitted that there was no evidence of a conflict of interest, considering that the CHMP has already approved other non-prescription drugs. While the complainant suggested that compliance with the EMA's Conflicts of Interest Policy in itself would not be sufficient, the Ombudsman considers that the EMA's position, in particular its reference to the fact that the CHMP has approved non-prescription drugs in the past, properly addresses the complainant's concerns, which the complainant did not substantiate further.

(vii) The EMA failed to take into account that the active substance in the medicine has been granted a marketing authorisation in at least four Member States 

47. The Ombudsman points out that the EMA acknowledged that the medicine was authorised in a non-prescription setting in certain Member States but repeatedly explained that the CHMP is not bound by decisions taken by national authorities. The EMA explained that the refusal to grant a marketing authorisation was based on scientific arguments and was due to scientific and public health concerns related to the administration of the medicine. This position is borne out by the assessment report and is in line with the legal framework governing the EMA's activities.

48. Consequently, there is nothing to suggest that the EMA committed a procedural or manifest error of assessment when formulating its position on the complainant's application for a marketing authorisation.

49. In view of the above, the Ombudsman concludes that the complainant's allegation cannot be sustained. Consequently, the related claim cannot succeed either.

50. Nevertheless, it is clear to the Ombudsman from the information provided that (i) marketing authorisations for medicines identical or similar to the one proposed by the complainant have been granted in some Member States, and (ii) the relevant decisions appear to have been based on the bioequivalence study that was submitted by the complainant. The Ombudsman understands that the EMA is not competent to take any binding action in relation to medicinal products that have been authorised by Member States. However, the EMA and the CHMP concluded that the relevant study was not conducted in compliance with Good Clinical Practice. In these circumstances, the Ombudsman takes the view that the EMA could consider informing the Member States concerned and/or the Commission of its findings as regards the relevant bioequivalence study, so that the authorities of these Member States will be able to take any action they may consider necessary in this respect.

Conclusion

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

There was no maladministration in the present case.

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

Further remark

The EMA could consider informing those Member States in which medicines identical or similar to the one at issue in the present case were granted marketing authorisations, based on the same bioequivalence study as the one submitted by the

complainant in support of its application, of its findings as regards that study. The EMA could consider also informing the European Commission of its findings as regards that study.

Emily O'Reilly

Done in Strasbourg on 30 June 2014

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 L 136, p. 1.

[2] Assessment Report of 23 November 2011, EMA/40740/2012, p. 11.

[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001 L 311, p. 67.

[4] Triptans are a class of drugs used to relieve migraine attacks and cluster headaches. They cause blood vessels to narrow, inhibit secretion of inflammatory neuropeptides and block neurotransmission of pain.

[5] Joint Assessment Report of the Grounds for the Re-examination Procedure, European Medicines Agency, London, 20 October 2011, EMA/CHMP/840720/2011, p. 20.

[6] See, for example, the Ombudsman's decision in cases 875/2012/(ER)PMC, 2111/2011/RA and 1458/2011/(BEH)JN, available at:
<http://www.ombudsman.europa.eu/en/cases/home.faces>

Related documents

Case: 0364/2013/(EIS)PMC

- Case opened: [Refusal of a marketing authorisation for an anti-migraine medicine](#)

At your service

European Ombudsman

- Who can help you?
- An information sheet for businesses and organisations
- Complaint form
- The Ombudsman's Team
- Recruitment / Traineeships
- Public access
- Dissatisfied with our service?

European Network of Ombudsmen

- Introduction
- Interactive guide
- National ombudsmen
- National ombudsmen in the applicant countries
- Regional ombudsmen
- Committee on Petitions of the European Parliament

Other

- Other means of redress

Activities

European Ombudsman

- Editorial
- Calendar of activities
- Speeches
- Annual reports
- Co-operation
- Visits to agencies
- Information visits

European Network of Ombudsmen

- The Network's activities

Press

European Ombudsman

- Introduction
- Press releases
- Selection of cases
- Statistics and surveys
- Photos and images
- Videos
- Visual Identity
- About Emily

Cases

European Ombudsman

- Search cases
- Cases opened
- Closing summaries
- Decisions
- Draft recommendations
- Special reports
- Own-initiative inquiries
- Follow-up
- Digest of cases
- Compilation of decisions

Resources

European Ombudsman

- Public register
- Statute
- Implementing provisions
- European Code of Good Administrative Behaviour
- Public Service Principles
- Guide to complaints
- Strategy
 - Strategy for the mandate
 - Annual Management Plan
 - Annual Activity Report
- Data protection
- Declaration of financial interests
- Public procurement
- Historical documents
- Other documents
- Elections

European Network of Ombudsmen

- Statement