European Ombudsman

Draft recommendation of the European Ombudsman in his inquiry into complaint 2493/2008/(BB)TS against the European Medicines Agency

Recommendation
Case 2493/2008/(BB)(TS)FOR - **Opened on** 14/11/2008 - **Recommendation on** 29/04/2010 - **Decision on** 23/03/2012

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

SUMMARY

The European Medicines Agency (EMA) plays an important role in the approval and the monitoring of medicines placed on the market in the EU, including the monitoring of adverse reactions to medicines. Its work has a direct impact on the health of European citizens. It is vitally important, therefore, that citizens should trust EMA and have confidence in its work.

Nearly two decades ago, in the Treaty of Maastricht, the European Union recognised that transparency (or openness) helps to build and maintain public trust in the institutions and strengthens their democratic nature. Subsequent developments include the recognition of public access to documents as a fundamental right of Union citizenship, guaranteed by the Charter of Fundamental Rights and by the Treaty on the Functioning of the Union. This right empowers citizens to monitor and scrutinise effectively the exercise of the powers vested in the institutions.

There are two ways of putting the principle of transparency into effect in relation to public access to documents and information. The first is to *react* to requests for access. The second is to be *proactive* in putting material into the public domain. The reactive and proactive approaches are complementary and reinforce each other. They are not alternatives, except in the sense that it is unnecessary to request access to something that is already in the public domain.

Regulation 1049/2001 [2] establishes rules on how the Union institutions must react to requests for access. It provides, in particular, that they must grant such requests unless one or more of the exceptions defined by the Regulation applies. The Regulation also establishes some obligations to be proactive; in particular, to make documents directly accessible to the public in electronic form.

The Regulation establishing EMA (Regulation 726/2004 [3]) provides that Regulation 1049/2001 shall apply to documents held by the Agency (Article 73). It also requires the Agency (i) to make data on reports of adverse reactions publicly accessible under certain conditions (Article 26) and (ii) to give the public appropriate levels of access to databases of information on adverse reactions (Article 57(1)(d)).

In the present case, EMA has basically argued that the two specific provisions mentioned above are intended to exclude requests under Regulation 1049/2001 for access to adverse reaction reports.

The Ombudsman does not believe that this was the intention of the legislator when adopting Regulation 726/2004. In the Ombudsman's view, the legislator clearly envisaged that Regulation 1049/2001 should apply to requests for *all* documents held by the Agency, including adverse reaction reports. The two specific provisions mentioned above require the Agency, in addition to dealing with possible requests for access, to be *proactive* in making accessible to the public data about adverse reactions.

This does not mean that requests for public access to adverse reaction reports must necessarily be granted. Rather, it means that such requests should be dealt with by applying Regulation 1049/2001 and the exceptions contained in that Regulation, which, if shown to apply, may justify withholding public access. The Ombudsman makes a draft recommendation in this sense to EMA.

The Ombudsman believes that, as well as according with the intention of the legislator, the approach he recommends would help ensure that European citizens trust EMA and have confidence in the important work it carries out on their behalf. The Ombudsman, therefore, hopes that EMA will respond positively to his draft recommendation.

THE BACKGROUND TO THE COMPLAINT

1. The European Medicines Agency (hereinafter, 'the Agency') has responsibility for the protection and promotion of public and animal health through the evaluation and supervision of medicines, including the collection, management and dissemination of information on adverse reactions to medicines (pharmacovigilance).

2. In order to carry out its pharmacovigilance tasks, the Agency receives information concerning suspected adverse reactions to medicines from the holders of marketing authorisations [4] and the competent authorities of the Member States. This information is stored, in encrypted form, in a central database known as EudraVigilance, which is administered by the Agency.

3. The complainant, a law firm based in Dublin, Ireland, complains on behalf of a client. On 22 April 2008, he submitted an application to the Agency for access to documents relating to Roaccutane [5] . Specifically, he requested access to (i) documents containing details of all

suspected serious adverse reactions [6] relating to Roaccutane which have been reported or made known to the Agency since 1982, including the date or year in which each suspected serious adverse reaction was experienced, when it was reported or made known to the Agency and the countries of origin, nature and sources of each relevant report and (ii) copies of all suspected serious adverse reaction reports received or made known to the Agency from 1982 until the time the application was submitted, which relate to certain central nervous system " *side effects* " [7] of Roaccutane.

4. On 19 May 2008, the Agency asked the complainant to clarify his application for access to documents. By letter of 23 May 2008, the complainant clarified that his request concerned, among others, documents containing anonymised details of suspected serious adverse reactions reported or made known to the Agency until the time the application was submitted. They included information on the date or year in which each suspected serious reaction was experienced, the date or year in which the relevant serious adverse reaction was reported to the Agency, the country in which the relevant adverse reaction occurred, the nature of the adverse reaction in each instance and the source of each relevant report, as well as the " *raw data* " held electronically in EudraVigilance concerning suspected serious adverse reaction reports received or made known to the Agency from 1982 onwards and which relate to side effects on the central nervous system.

5. By letter of 7 July 2008, the Agency refused these requests. On 9 July 2008, the complainant submitted a confirmatory application to the Agency. The confirmatory application was refused.

THE SUBJECT MATTER OF THE INQUIRY

6. The complainant submitted a complaint to the Ombudsman on 12 September 2008.

7. The Ombudsman opened an inquiry into the following allegations and claim:

Allegations :
- The Agency failed to give valid and adequate grounds for its refusal to grant the complainant's confirmatory request for access to the reports concerning suspected serious adverse reaction.
- In its reply to the complainant's confirmatory application, the Agency failed to inform the complainant of the relevant remedies available.

Claim :

The Agency should grant the complainant's access request.

THE INQUIRY

8. On 14 November 2008, the Ombudsman forwarded the complaint to the Agency. On 4 December 2008, the Ombudsman carried out an inspection at the Agency's premises. The

inspection report was subsequently forwarded to the complainant. The Agency then provided its opinion, which was also forwarded to the complainant with an invitation to make observations. The complainant sent his observations on 28 April 2009.

THE OMBUDSMAN'S ANALYSIS AND CONCLUSIONS

A. Allegation that the Agency failed to give valid and adequate grounds for its refusal to grant the complainant's confirmatory access request and corresponding claim

Arguments presented to the Ombudsman

9. The complainant argued in his complaint that the Agency failed to apply the provisions of Regulation 1049/2001 to his confirmatory access request. He also argued that the Agency wrongly handled his request by limiting its scope to reports held in electronic form in the EudraVigilance database.

10. In its opinion submitted to the Ombudsman, the Agency put forward the following three arguments in support of its decision to refuse the complainant's requests.

11. The Agency first argued that Regulation 1049/2001 should not be applied to the complainant's request for access to the Individual Case Safety Reports on suspected serious adverse reactions (hereinafter, 'suspected serious adverse reaction reports') which are stored electronically in the EudraVigilance database, because the right of access to suspected serious adverse reaction reports is exclusively regulated by Article 26 and Article 57(1)(d) of Regulation 726/2004. According to the Agency, these provisions constitute a law governing the specific subject matter (that is, a *lex specialis* [8]), which overrides the provisions on access to documents contained in Regulation 1049/2001.

12. In this regard, the Agency referred to the wording of Article 26(3) of Regulation 726/2004, which states that:

" *The Agency, in consultation with Member States and the Commission, shall set up a data-processing network for the rapid transmission of information to the competent Community authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding medicinal products authorised in accordance with Article 6 of Directive 2001/83/EC. Such data shall be made publicly accessible,* if relevant, after evaluation. " (emphasis added by the Agency)

13. The Agency also referred to the wording of Article 57(1)(d) of Regulation 726/2004:

" *The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety*

and efficacy of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Community legislation relating to medicinal products. To this end, the Agency, acting particularly through its committees, shall undertake the following tasks:

[…]

(d) ensuring the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database permanently accessible to all Member States; health-care professionals, marketing authorisation holders and the public shall have appropriate levels of access to these databases, with personal data protection being guaranteed.
"

14. The Agency underlined that the indiscriminate release of the raw data would not be of benefit to citizens since, most of the time, it would result in the circulation of unreliable and misleading data. The Agency stated that this was the reason why the legislator had only foreseen the possibility of granting the general public partial access to such data, and only following an evaluation by the Agency.

15. The Agency then stated that, in order to pursue properly the interest of protecting public health and informing civil society in a focused way, the data held in EudraVigilance should not be indiscriminately released and the general public should not be granted direct access to the raw data hosted by the system.

16. In the context of its first argument, the Agency also stated that, in order to comply with Article 57(1)(d) and Article 26 of Regulation 726/2004 and with " *the principle of transparency* ", it had drafted a policy which would regulate access to the EudraVigilance database by the various stakeholders. This policy foresees, for the various stakeholders, three different levels of access to the system. In line with the relevant legal provisions, the following three categories of users would thus be granted appropriate rights of access: (i) the European Commission and Member States; (ii) pharmaceutical companies and sponsors of clinical trials; and (iii) the general public and healthcare professionals.

17. As a second argument, the Agency stated that Regulation 1049/2001 does not apply to the complainant's requests for access because the definition of " *document* " in Regulation 1049/2001 does not apply to the data stored in the EudraVigilance database. It stated that it had applied the definition provided by the European Commission, according to which a result of a normal search in the database constitutes a document. The Agency also pointed out that, according to the Commission's recent legislative proposal to amend the definition of " *document* " contained in Regulation 1049/2001, data contained in electronic storage, in a processing retrieval system, are only " *documents* " for the purposes of that Regulation if they can be extracted in the form of a printout or electronic-format copy using the available tools for the exploitation of the system. The Agency then argued that, under the currently applicable legislation, the suspected serious adverse reaction reports stored in the EudraVigilance database are not " *documents* ", because the retrieval of such information from the database is not immediate. Instead, a complicated procedure is necessary in order to obtain " *humanly*

readable data " from it. The Agency also stated that obtaining the requested reports from the EudraVigilance database would require a " *tailor made* " search of the database in accordance with the parameters the complainant set out in his application.

18. As a third argument, the Agency sought to justify its refusal to provide access to the requested suspected serious adverse reaction reports by referring to the principle of proportionality. The Agency stated that making available the requested " *ad hoc generated documents* " would result in a disproportionate administrative burden to it in terms of time and resources. It noted that the Agency did not have personnel available to deal with access to document requests on a full-time basis. In this regard, the Agency stated that generating and making available the requested reports in a readable format would take 67 working hours, excluding the time needed to redact personal data.

19. The Agency supported its third argument by referring to paragraph 102 of the judgment of the Court of the First Instance in Case T-2/03 [9] , according to which:

" *An institution must therefore retain the right, in particular cases where concrete, individual examination of the documents would entail an unreasonable amount of administrative work, to balance the interest in public access to the documents against the burden of work so caused, in order to safeguard, in those particular cases, the interests of good administration (see, by analogy, Hautala v Council, cited in paragraph 69 above, paragraph 86)* ".

20. The Agency stated that its third argument was supported and shared by the British Freedom of Information Act, which foresees the possibility for an institution to deny access whenever the cost of compliance exceeds appropriate limits [10] .

21. In his observations, the complainant first noted that the Agency had indeed acknowledged that it possessed the requested suspected serious adverse reaction reports. The complainant then pointed out that the Agency's arguments for refusing access to the reports relied principally upon the technical difficulties in making the reports available from the EudraVigilance database. He stated that the fundamental objective of the EudraVigilance database is to provide the regulatory bodies and other relevant stakeholders, such as market authorisation holders, with immediate access to the requested reports for the purposes of protecting public health and safety. The complainant then argued that, in light of this fundamental objective, the Agency's arguments relating to the difficulty in retrieving reports due to the nature and complexity of the EudraVigilance database were simply not convincing. Indeed, the Agency's assertions that " *human readable data* " could only be produced by a complicated procedure would (if true) indicate that the EudraVigilance database is completely unsuitable for its purpose, which according to the Agency is to ensure the dissemination of information on adverse reactions by means of a database permanently accessible to all Member States.

22. As regards the technical availability of the data from the EudraVigilance database, the complainant also stated that it follows from the Commission's guidelines entitled " *Detailed guidance on the European database on the Unexpected Serious Adverse Reactions (EudraVigilance - Clinical Trial Module - April 2004" (Guidance on SUSARs)* " [11] that any

competent database containing reports of the suspected adverse reactions must routinely allow for the search and retrieval of reports concerning a particular drug and concerning a particular side effect or adverse reaction. The complainant stated that what was entirely missing from the description of the EudraVigilance database provided in the Ombudsman's report of the inspection and, subsequently, from the Agency's opinion, was an identification of the search parameters and functions of the database which must be used on a daily basis by the staff of the Agency, by competent authorities of the Member States and by drug companies. However, the Commission's descriptions of the functions of the EudraVigilance database in the Guidance on SUSAR's clarify that the relevant search parameters must exist for given products and for types of reactions.

23. The complainant then stated that, for the purposes of his access request, the only relevant questions were the following:
- Are adverse reactions transmitted to the Agency in the form of reports?
- Are such reports held or stored by the Agency?
- Can the Agency produce those reports or the information contained within them?

According to the complainant, the only credible answer to each of the above questions was " *yes* ". This would imply that there is no proper basis for the Agency not to provide access to the requested reports.

24. The complainant also challenged the Agency's argument concerning the *lex specialis* status of Regulation 726/2004. He noted that the Agency's Implementation Rules for Regulation 1049/2001 state that their scope is intended to ensure the widest possible access to the documents the Agency produces or receives and has in its possession. Moreover, the Agency's assertions must be assessed in the context of the importance of the rights which are at stake. In this regard, he pointed out that the right of access to documents and to information held by the European institutions was recognised as a fundamental right in the established case-law of the Community courts [12] .

25. The complainant stated that the provisions of Regulation 726/2004, namely, Articles 26 and 57(1)(d), do not show a clear and manifest intention not to apply Regulation 1049/2001 or the fundamental right of access to documents established under Community law. He noted that neither Article 26(3) nor Article 57(1)(d) make any reference to Regulation 1049/2001. They do not expressly amend Regulation 1049/2001 nor override the rights it establishes. Furthermore, neither of these Articles is so repugnant to Regulation 1049/2001 that the two regulations concerned would be incapable of standing together.

26. Moreover, the complainant stated that Articles 26(3) and 57(1)(d) of Regulation 726/2004 only represent an intention to comply with Article 12 of Regulation 1049/2001, according to which "[i] *nstitutions shall as far as possible make documents directly accessible in electronic form ... in accordance with the rules of the institution concerned* ". In addition, the Agency's future EudraVigilance access policy would be irrelevant to an individual’s right to apply for access to documents held by the European institutions because the provisions of Regulation 1049/2001 are intended to ensure that access is provided, to the greatest extent possible, to

documents which are not already publicly accessible or available. The complainant stated that the above was confirmed in Article 5(1) of the Agency's Implementation Rules for Regulation 1049/2001: " *Applications for access to Agency documents,* which are not publicly available *, shall be made in writing including electronic form …*" (emphasis added by the complainant)

27. The complainant stated that, as there is no conflict between the two Regulations, the *lex specialis* doctrine could have no application in the present case, because it could only be applied where it is not possible to harmonise or to interpret consistently two pieces of legislation which deal with the same subject matter. Moreover, should the *lex specialis* doctrine apply, the *lex specialis* that determines public access to documents is obviously Regulation 1049/2001 and not the much broader Regulation 726/2004.

28. The complainant also contested the Agency's argument that the definition of document contained in Regulation 1049/2001 does not apply to information contained in databases. The complainant argued that the current wide definition of " *document* " does cover electronically saved information in databases. Indeed, Regulation 1049/2001 has been interpreted in this way for many years. In its decision refusing his confirmatory application, the Agency relied significantly on the Commission's 2004 report on the implementation of Regulation 1049/2001 [13] (the Commission's 2004 Implementation Report). The complainant recalled that the Commission's Implementation Report stated the following:

"[R] *egulation* [1049/2001] *provides a very broad definition of the concept of "document" under Article 3a. Hence all sets of information preserved in any form whatsoever constitute a document within the meaning of the Regulation. Bearing in mind the principle of partial access, as it was first defined in judicial decisions and then incorporated in* [R] *egulation 1049/2001, the right conferred by this regulation is in fact the right of access to the content of any existing document …*

The definition given by the Regulation also covers documents kept exclusively in electronic form (Word, PDF and HTML, for instance). The question is, however, whether to apply this definition to data bases … Normal practice at the Commission is to regard as a document any report extracted from such systems which corresponds to normal use of them. "

29. The complainant stated that the Commission's recent proposal to revise the definition of " *document* " in relation to databases simply intended to make clear what the intention of the Regulation always was and what the normal practice at the Commission has been for many years. Therefore, that proposal could not be used to limit or restrict the scope of the current definition of " *document* ".

30. The complainant noted that the quotation of the Commission's argument in the Ombudsman's decision on complaint 1693/2005/PB could not provide any legal authority in relation to the issues raised by the complainant. Indeed, in that case, the Ombudsman had rejected the Commission's argument as not satisfactory.

31. The complainant also rejected the Agency's assumption that the suspected serious adverse

reaction reports are not " *existing documents* ", because they cannot be retrieved by a " *normal search* " in the database. The complainant noted that once the Individual Case Safety Reports are transmitted electronically to the Agency, they are allocated a EudraVigilance Report number and are then stored in the EudraVigilance database. The Agency regularly provides copies of these reports to the originating sponsor/market authorisation holder. Therefore, they are " *documents* " received by it and " *in its possession* " within the meaning of Article 2(3) of Regulation 1049/2001. There could, therefore, be no doubt that the search functions available to the Agency must allow for the retrieval of specific suspected serious adverse reaction reports in respect of a particular drug and in respect of particular types of side effects. The relevant reports in respect of Roaccutane can be retrieved as part of a " *normal search function* " of the EudraVigilance database by making use of their EudraVigilance report numbers. The complainant recalled, in this respect, that the purpose of the database is to allow Member States and other relevant stakeholders to access the adverse reaction reports about specific drugs and about specific side effects in order to identify potential safety concerns.

32. The complainant also contested the Agency's distinction between " *documents* " and " *information* ". When doing so, he made reference to paragraphs 92 to 94 of the opinion of Advocate-General Léger [14] in Case C-353/99P *Council* v *Hautala* . These paragraphs read as follows:

" *92. The distinction between documents and information seems to me to be purely formal. The right of access to a document concerns the content of the document and not its physical form. No one can claim that when making a request for access to documents he is seeking the document itself and not the information it contains. When applying for the disclosure of a document, the applicant implies that he is seeking all of the information contained in the document, which leaves him free to ascertain the information which is of particular interest to him.*

93. The nuance introduced by the Council imposes a somewhat artificial distinction between the container and the content or between the medium and the information. So far as the applicant is concerned, it is only the substance of the document which is relevant. We request access to a document solely because it contains data which is likely to be of interest to us. It is therefore always ultimately a case of a request for information.

94. This understanding of the right of access to documents is, moreover, in accordance with the broad interpretation which should be used in such matters. It is necessary, therefore, to interpret the concept of the right of access to 'documents' as meaning a right of access to the 'information' contained in the documents. "

33. The complainant concluded that the suspected serious adverse reaction reports are clearly " *documents* " falling within the scope of Regulation 1049/2001. The fact that they are stored in an encrypted form in its EudraVigilance database did not have any relevance as regards their classification as " *documents* ".

34. Finally, the complainant contested the Agency's argument that access to the suspected

serious adverse reaction reports could be refused on the grounds that complying with the complainant's access request would cause a disproportionate burden to it in terms of time and resources. The complainant pointed out that it follows from Article 5(3) of the Agency's Implementation Rules for Regulation 1049/2001 that the Agency is obliged to confer with the applicant informally where an application relates to a large number of documents, with a view to finding a fair solution. The complainant stated that no attempt had ever been made on the behalf of the Agency to limit the scope of the complainant's request on the grounds of proportionality. The complainant also pointed out that, prior to the complaint to the Ombudsman, the Agency did not rely on the administrative burden argument as the basis for refusing the access request.

35. The complainant stated that the Agency's reference to Case T-2/03 [15] only relied on paragraph 102 of that judgment. The Agency ignored paragraphs 103, [16] 112 [17] and 113 [18] , where it is stated that a refusal to grant access can only be justified on the basis of proportionality in exceptional cases. The complainant stated that the present case was not an " *exceptional case* ".

36. As an example of the application of the principle of proportionality, the complainant stated that, in complaint 2350/2005/GG, the Ombudsman considered that it had not been established that it would be disproportionate to require the European Anti-Fraud Office to draw up a list of up to 8 000 documents in response to a request under Regulation 1049/2001.

37. As regards the Agency's estimate of the amount of administrative work required to comply with the complainant's access request, the complainant stated that the Agency had misinterpreted his request as covering all suspected serious adverse reaction reports in respect of Roaccutane. In contrast, the request was expressly limited to suspected serious adverse reaction reports relating to central nervous system side effects [19] . The complainant concluded that the Agency's estimate of 67 working hours was based on the erroneous assumption that it was required to provide all suspected serious adverse reaction reports relating to Roaccutane. Given that suspected serious adverse reaction reports relating to central nervous system side effects would probably average about 15% of all the reports involving Roaccutane, the Agency's estimate suggested that only 10 hours would be needed to produce the suspected serious adverse reaction reports sought. In any case, searching for, printing and reproducing the requested ADR reports should not require any significant amount of time or administrative effort. The complainant also underlined that comparable administrative entities have had no apparent difficulties in producing database records of the same type of reports [20] .

The Ombudsman's assessment

Preliminary remarks

38. The Ombudsman's assessment of the complainant's first allegation and the corresponding claim (paragraphs 39-48) begins with an analysis of the general principle of transparency, or openness, and the distinction between reactive and proactive methods of providing public access to documents and information. It then considers, successively, four arguments put

forward by the Agency: *lex specialis* (paragraphs 49-76); the definition of document (paragraphs 77-84); administrative burden (paragraphs 85-96); and the danger arising from the circulation of misleading and unreliable data (paragraphs 97-100). Paragraphs 101-104 consider the scope of the request for access and paragraph 105 concludes the assessment of the complainant's first allegation and the corresponding claim.

The principle of transparency or openness

39. The principle that EU institutions, bodies, offices and agencies (hereafter, 'EU institutions') must conduct their work and take decisions as openly as possible is enshrined in the Treaty on European Union [21] and the Treaty on the Functioning of the European Union [22] . Openness enables citizens to participate more closely in the EU decision-making process and contributes to strengthening the principles of democracy and respect for fundamental rights as laid down in the Treaties and in the Charter of Fundamental Rights of the European Union [23] . Respect of the principle of openness also guarantees that the administration will enjoy greater legitimacy amongst citizens.

40. Openness of the EU public administration, and the resulting strengthening of the legitimacy of the EU public administration, are especially important in those policy areas where the actions of the EU public authorities impact directly on the interests of citizens.

41. The Ombudsman underlines that citizens are directly affected by the Agency's decisions relating to the authorisation and supervision of medicinal products, including the continuous monitoring and assessment of the safety of medicines that are already on the market. It is therefore of vital importance that the Agency's decision-making be as open as possible.

42. Public access to documents and information held by the EU institutions is an essential component of openness. It empowers citizens to monitor and scrutinise effectively the exercise of the powers vested in the EU institutions.

43. There are two ways of putting public access into effect. The first is to *react* to requests for access. The second is to be *proactive* in putting material into the public domain. The reactive and proactive approaches are complementary and reinforce each other. They are not alternatives, except in the sense that, if public access to documents is provided proactively, the public is spared the task of making *requests* for access to such documents and the institutions are equally spared the task of processing requests for access to such documents.

44. Public access to documents is a fundamental right of citizenship guaranteed by the Treaty. The right of access is governed by Regulation 1049/2001, which provides for the public to have access to documents in the possession of the EU institutions, subject to certain objective exceptions which are based on the need to protect defined public and private interests.

45. Regulation 1049/2001 establishes rules on how the EU institutions must *react* to requests for access to documents. In particular, it provides that the institutions must grant such requests unless one or more of the exceptions defined by the Regulation applies. The Regulation also

establishes certain obligations to be *proactive* . In particular, Article 12 requires that, as far as possible, documents be made directly accessible to the public. This is in line with the main principle of openness and the purpose of Regulation 1049/2001 of providing the widest possible access to documents.

46. More generally, the principle of transparency, or openness, implies that the EU institutions should *proactively* identify what information the public needs and then disseminate that information in a manner that the public can easily understand. When the EU institutions are working in areas which are technically complex, it is especially important that information be presented using language that can be easily understood by the public.

47. The *proactive* efforts of the EU institutions to provide information will normally, therefore, involve the preparation and publication of new material, as well as the provision of access to existing documents. In deciding what, when and how to publish proactively, the institutions necessarily have to exercise judgment based on their knowledge of the specific characteristics of their field of work.

48. However, the fact that the EU institutions should be proactive in disseminating information to the public is not a reason for imposing limitations on the right of members of the public to *request* access to *any* documents which have not been made directly accessible to them [24] . *Requests* for access to documents can only be refused if certain objective exceptions which are based on the need to protect defined public and private interests are shown to apply [25] .

The Agency's first argument: lex specialis

49. Against this background, the Ombudsman will now consider the first argument the Agency uses to refuse the complainant access to the suspected serious adverse reaction reports. The Agency argues that Regulation 726/2004 contains *lex specialis* rules concerning requests for public access to certain documents in its possession and that these rules apply *to the exclusion of Regulation 1049/2001* .

50. In the Agency's view, the last sentence of Article 26(3) of Regulation 726/2004 empowers the Agency to refuse public access to data in the EudraVigilance database unless that data is " *relevant* " for the public. The Agency considers that only part of the content of the EudraVigilance database could be " *relevant* " for the public because the EudraVigilance database also contains " *raw data* " which would " *not be of benefit for citizens* ".

51. The Ombudsman first recalls that Article 73(1) of Regulation 726/2004 provides that:

" *Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents shall apply to documents held by the Agency.* "

52. Article 26(3) of Regulation 726/2004 reads as follows:

" *The Agency, in consultation with Member States and the Commission, shall set up a data-processing network for the rapid transmission of information to the competent Community authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding medicinal products authorised in accordance with Article 6 of Directive 2001/83/EC.* Such data shall be made publicly accessible, if relevant, after evaluation . " (emphasis added)

53. The Ombudsman notes, as a first observation, that if the legislator had wished to derogate from the *explicit* requirement set out in Article 73(1) of Regulation 726/2004 to apply Regulation 1049/2001 to documents held by the Agency, it could have done so expressly. He notes, in this respect, that neither Article 73(1), nor any other provision of Regulation 726/2004, contain a derogation from the explicit requirement set out in Article 73(1) of Regulation 726/2004 to apply Regulation 1049/2001 to documents held by the Agency [26] .

54. The Ombudsman also notes that the Court of Justice has consistently held that, where it is necessary to interpret a provision of secondary Community law, preference should, as far as possible, be given to the interpretation which renders the provision consistent with the Treaty and the general principles of Community law [27] . It is a general principle of EU law that the EU institutions must act openly [28] . The Court of Justice has also consistently held that, in interpreting a provision of EU law, it is necessary to consider not only its wording, but also the context in which it occurs and the objects of the rules of which it is part [29] . When interpreting specific provisions, such as Article 26(3), account should always be taken of the general provisions of Regulation 726/2004, including Article 73(1), which is one of the general provisions of Regulation 726/2004.

55. The Ombudsman now considers it useful, in order to understand Article 26(3) of Regulation 726/2004, to study the legislative history of Regulation 726/2004.

56. The Commission's proposal for a Regulation governing the Agency did not contain any references to a right of public access to documents. Once it received the Commission's proposal, the legislator sought to ensure the transparency of the Agency's decision-making by incorporating several amendments to the proposal. In particular, the legislator introduced Article 73(1), according to which Regulation 1049/2001 applies to documents held by the Agency. The legislator also sought to make those specific articles, which referred to specific documents or sets of documents, consistent with that general rule.

57. As regards Article 26(3), the Commission's proposal contained the following formulation for what is now Article 26(3):

" *The Agency, in consultation with the Member States and the Commission, shall set up a data-processing network for the rapid transmission of data between the competent Community authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding medicinal products authorised in accordance with Article 6 of Directive 2001/83/EC.* "

That original formulation of Article 26(3) made no reference to public access to documents.

58. The European Parliament, which was the co-legislator, took the view, however, that warnings about faulty manufacture or serious adverse reactions should be made accessible to all interested parties. In its report, formulated in the course of the second reading, Parliament included in Article 26(3) an amendment which would allow the " *public* " to access to such data. This amendment was justified by the following statement:

"*… Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with Article 41 of the Charter of Fundamental Rights of the European Union and* Regulation 1049/2001 on access to documents of the EU institutions . " (emphasis added)

The wording suggested by Parliament formed the basis for the eventual wording of Article 26(3) of Regulation 726/2004.

59. In light of the above, it is clear that the legislator intended Article 26(3) of Regulation 726/2004 to be consistent with the general requirement set out in Regulation 726/2004 to apply Regulation 1049/2001 to documents held by the Agency.

60. Since Article 26(3) of Regulation 726/2004 must be interpreted *consistently* with Regulation 1049/2001, it is useful to recall that Regulation 1049/2001 *only* allows requests for public access to documents to be refused in accordance with Article 4 and Article 9 of that Regulation [30] . As the documents held by the Agency do not fall within the types of documents referred to in Article 9 of Regulation 1049/2001, the Agency can only refuse requests for access to the documents it holds *if* it can *demonstrate* that an exception set out in Articles 4(1) to 4(3) of Regulation 1049/2001 applies [31] .

61. Articles 4(1) of Regulation 1049/2001 reads as follows:

" *The institutions shall refuse access to a document where disclosure would undermine the protection of:*

(a) the public interest as regards:

— public security,

— defence and military matters,

— international relations,

— the financial, monetary or economic policy of the Community or a Member State;

(b) privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data. "

Article 4(2) of Regulation 1049/2001 reads as follows:

" *The institutions shall refuse access to a document where disclosure would undermine the protection of:*

— commercial interests of a natural or legal person, including intellectual property,

— court proceedings and legal advice,

— the purpose of inspections, investigations and audits,

unless there is an overriding public interest in disclosure. "

Article 4(3) of Regulation 1049/2001 reads as follows:

" *Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure.*

Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure. "

62. In line with the established case-law of the EU courts, these exceptions to the right of public access to documents must be interpreted and applied narrowly. Furthermore, the institution is obliged to identify the protected interest relevant to applying an exception; to justify the application of the exception by assessing whether access to the document would concretely and effectively undermine the protected interest; to examine whether the exception applies to all parts of the document; and to base its assessment on the concrete and individual examination of the content of the document. Furthermore, this examination should be visible from the institution's statement of reasons to refuse access [32] .

63. Articles 4(1) to 4(3) of Regulation 1049/2001 do not contain any exception which would justify a refusal to grant access based only on the argument that the institution holding the document considers that the document is not " *relevant* " for the public. As such, a member of the public should not have to demonstrate that the documents were " *relevant* " for him/her in order to obtain access. Indeed, the Ombudsman notes that the rules on public access to documents do not require that members of the public must put forward *any* reasons for seeking access to requested documents [33] .

64. In sum, an interpretation of the last sentence of Article 26(3), which would allow for a refusal to grant a *request* for access to a document based on the " *relevance* " of the document, would clearly result in a failure to apply Article 4 of Regulation 1049/2001, in contravention of Article 73(1) of Regulation 726/2004, and in contravention of the legislator's intentions.

65. While the wording of Article 26(3) of Regulation 726/2004 cannot be read in conjunction with Article 4 of Regulation 1049/2001, it can, however, be easily and naturally understood as making more precise (for the Agency) the obligation contained in Article 12 of Regulation 1049/2001 to make documents *directly* accessible to the public. Article 12 of Regulation 1049/2001 reads as follows:

" *1. The institutions shall* as far as possible *make documents directly accessible to the public in electronic form or through a register* in accordance with the rules of the institution concerned .

2. In particular, legislative documents, that is to say, documents drawn up or received in the course of procedures for the adoption of acts which are legally binding in or for the Member States, should, subject to Articles 4 and 9, be made directly accessible.

3. Where possible , *other documents, notably documents relating to the development of policy or strategy, should be made directly accessible.*

4. Where direct access is not given through the register, the register shall as far as possible indicate where the document is located. " (emphasis added)

The last sentence of Article 26(3) of Regulation 726/2004, when understood in conjunction with Article 12 of Regulation 1049/2001, would require the Agency to make *directly* accessible any document in its possession which would be " *relevant* " [34] to an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data once these documents have been evaluated by the Agency [35] .

66. It is important, however, to understand that a decision not to make a document directly accessible to the public, pursuant to Article 12 of Regulation 1049/2001, has no bearing on the issue of whether or not the institution can validly refuse a request, made pursuant to Article 2(4) of Regulation 10419/2001 for public access, to an unpublished document it holds. Any refusal to grant a request for public access to a document, which the institution has not (yet) chosen to make directly accessible to the public pursuant to Article 12 of Regulation 1049/2001, must be dealt with in accordance with Article 4 of Regulation 1049/2001.

67. The Agency also made reference to Article 57(1)(d) of Regulation 726/2004 in its opinion to the Ombudsman. Article 57(1)(d) reads as follows:

" *The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it in*

accordance with the provisions of Community legislation relating to medicinal products. To this end, the Agency, acting particularly through its committees, shall undertake the following tasks:

[...]

(d) ensuring the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database permanently accessible to all Member States; health-care professionals, marketing authorisation holders and the public shall have appropriate levels of access to these databases, with personal data protection being guaranteed.
"

68. The Ombudsman also disagrees with the position taken by the Agency that Article 57(1)(d) of Regulation 726/2004 is a *lex specialis* rule concerning *requests* for public access to documents in its possession which applies to the exclusion of Regulation 1049/2001.

69. Article 57(1)(d) of Regulation 726/2004 primarily relates to access to information (for this reason it refers to the *dissemination* of information). However, insofar as the information referred to in Article 57(1)(d) of Regulation 726/2004 may be *already* contained in documents, Article 57(1)(d) of Regulation 726/2004 is also potentially relevant to access to documents.

70. Article 57(1)(d) of Regulation 726/2004 also only relates to *direct* access to information (and potentially documents). For this reason, it refers to the *dissemination* of information and refers to the fact that the database will be *permanently* accessible. Article 57(1)(d) of Regulation 726/2004 is not, however, applicable to *requests* for public access to documents (which, as explained above, are governed by Article 2(4) and Article 4 of Regulation 1049/2001).

71. As regards the " *appropriate* " level of direct public access to information and, potentially, documents referred to in Article 57(1)(d), it is useful to refer to the legislative history of Article 57(1)(d).

72. The Commission's legislative proposal contained the following formulations for the current Article 57(1)(d):

" *The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, the safety, and the efficacy of medicinal products for human or veterinary use ... To this end, the agency, acting particularly through its Committees, shall undertake the following tasks* :

[...]

d) assuring the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database permanently accessible to all Member States ... "

The Commission's legislative proposal for Article 57(1)(d) did not contain any reference to public access to information or documents.

73. The European Parliament, as the co-legislator, considered, at the end of first reading, that Article 57(1)(d) should read:

" *(d) ensuring the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database permanently accessible to all Member States; health care professionals, manufacturers and the general public shall have appropriate levels of access to that database, with business secrecy and personal data protection being guaranteed; ...* " (Amendment 88 of Parliament)

Parliament justified the above amendment by stating that:

" *(public) authorities should have access to all data. Manufacturers should be entitled to access to data concerning their own products. Heath-care professionals should have access to information expressed in expert terminology while patients require easily comprehensible information in layman's terms. Accordingly, access to the database should be graduated according to the* need . " (emphasis added)

74. It light of the above justification, it would be correct to understand that the level of *direct* access to information and documents held in databases, as referred to in Article 57(1)(d), should be determined by the needs of the public. Moreover, the information should be provided to different stakeholders in a form which best serves their interests and which is most comprehensible to them. As noted above, the obligation to make documents *directly* accessible should be interpreted as broadly as possible. As such, the references to the *needs* of the public (in the documents relating to the legislative history of the Regulation) should be interpreted broadly so as to encompass *as many documents as possible* .

75. It is important, however, again to understand that a decision not to make a document *directly* accessible to the public has no bearing on the issue of whether or not the institution can validly refuse a *request* , made pursuant to Article 2(4) of Regulation 1049/2001, for public access to an unpublished document it holds. Any refusal to grant a request for public access to a document which the institution has not (yet) chosen to make directly accessible to the public pursuant to Article 12 of Regulation 1049/2001 must be dealt with in accordance with Article 4 of Regulation 1049/2001.

76. In light of the above, the Agency's view that the last sentence of Article 26(3) of Regulation 726/2004 and Article 57(1)(d) of Regulation 726/2004 apply to " *requests* " for public access to the contents of the EudraVigilance database and, as such, only foresee the possibility of granting the public " *partial* " access to the contents of the EudraVigilance database [36] , is clearly not correct. In sum, a request for public access to a document in the EudraVigilance database, such as a suspected serious adverse reaction report, must be dealt with pursuant to Article 4 of Regulation 1049/2001.

The Agency's second argument: Definition of "document"

77. The Agency argues, as a second argument, that the suspected serious adverse reaction reports stored in the EudraVigilance database do not even fall within the scope of Regulation 1049/2001 because they are not covered by the definition of " *document* " in Regulation 1049/2001.

78. The Ombudsman notes, however, that Regulation 1049/2001 applies to requests for public access to " *documents* ", as defined by Article 3 of Regulation 1049/2001. Article 3 of Regulation 1049/2001 defines " *document* " as " *any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) concerning a matter relating to the policies, activities and decisions falling within the institution's sphere of responsibility.* "

79. Article 3 of Regulation 1049/2001 states that the term " *document* " refers to " *any content whatever its medium* ". The term " *document* " expressly includes " *content stored in electronic form* ". The data stored in the database is clearly " *content stored in electronic form* ".

80. Any " *meaningful* " set of " *content* " recoverable from a database constitutes an individual " *document* ".

81. The Agency has provided the Ombudsman with an explanation as regards how the suspected serious adverse reaction reports are stored in EudraVigilance and how they are accessed. Suspected serious adverse reaction reports are received by the Agency in encrypted form from the national authorities and licence holders. The suspected serious adverse reaction reports are then stored in EudraVigilance in the form of recoverable sets of information, which are permanently available for consultation by authorised users of the database. All authorised users of the database, the Ombudsman understands, have access to EudraVigilance. The authorised users are thus able to consult the suspected serious adverse reaction reports by routinely using the normal search tools available for this purpose. Thus, in the present case, data concerning suspected serious adverse reaction reports submitted to the Agency by the license holders and Member State authorities are both " *available* " and " *recoverable* " in the EudraVigilance database.

82. The Ombudsman does not consider that the fact that the data stored in the EudraVigilance database may be made more secure through encryption (a printout of content from the EudraVigilance database is unintelligible if the content has not undergone decryption) alters the fact that the contents of the database are " *documents* " within the meaning of Article 3 of Regulation 1049/2001. The Ombudsman has consistently stated that " *content stored in electronic form* " covers identified and re-identifiable sets of information contained in a database. Encrypted data will be " *a re-identifiable set of information* " provided the Agency can retrieve those data using the information technology tools at its disposable [37] . The Ombudsman also agrees that if the purpose of the database is to allow Member States and other relevant stakeholders to access the adverse reaction reports about specific drugs and about specific side effects, in order to identify potential safety concerns, such reports can

obviously also be retrieved for the purpose of granting a request for public access [38] .

83. On 4 December 2008, the services of the Ombudsman carried out an inspection at the Agency's premises. In the course of the inspection, the Agency provided the Ombudsman's services with a presentation on the functioning of the EudraVigilance database. The Agency did not show the Ombudsman services an example of how a search could be made in the case of suspected serious adverse reaction reports relating to the use of Roaccutane. It did, however, provide information on the search functions which may be used for the purpose of collecting information from these reports in the context of the alert situations referred to in Regulation 726/2004. Subsequent to the inspection, the Agency sent the Ombudsman a printout copy of one Individual Case Safety Report. The Ombudsman has no doubt that this report clearly constitutes a " *document* " within the meaning of Article 3 of Regulation 1049/2001. The Agency also explained how such a report can be generated and printed.

84. In light of the above, the suspected serious adverse reaction reports stored in the EudraVigilance database are clearly " *documents* " within the meaning of Article 3 of Regulation 1049/2001.

The Agency's third argument: Administrative burden

85. The Agency has argued that, even if the requested serious adverse reaction reports were considered as " *documents* " under Regulation 1049/2001, access to them could nevertheless be refused on the basis of the principle of proportionality. It argued, in sum, that compliance with the applicant's request would cause a disproportionate administrative burden on the Agency. It stated that the Agency does not have the personnel to deal with access to document requests on a full time basis. Therefore, to comply with the request, the Agency would need to take personnel away from their normal activities relating to the Agency's core business. The Agency stated that generating and making available the requested reports in a readable format would take at least 67 working hours, excluding the time required to redact personal data.

86. In support of its third argument, the Agency relied on paragraph 102 of Case T-2/03 *Verein für Konsumenteninformation v Commission* , which states that:

" *An institution must therefore retain the right, in particular cases where concrete, individual examination of the documents would entail an unreasonable amount of administrative work, to balance the interest in public access to the documents against the burden of work so caused, in order to safeguard, in those particular cases, the interests of good administration* " [39] .

87. The Ombudsman notes that the Agency appears to be of the view that the principle of proportionality on its own constitutes a separate justification for a refusal to provide access to the requested reports. As will be clear from the analysis set out below, this view is clearly incorrect.

88. First of all, the Ombudsman recalls that Regulation 1049/2001 does not contain any exception, according to which the amount of administrative work would justify a refusal of

access to documents.

89. As regards the case-law referred to by the Agency, the issue which the Court dealt with in *Verein für Konsumenteninformation v Commission* was not whether the principle of proportionality constituted, as such, a justification for not providing access to the requested documents, but whether it was permissible, on the basis of the principle of proportionality, for the Commission to refrain from *carrying out a concrete, individual examination of each of the documents* in response to a request for access. This issue arose because the Commission had, in relation to a request for access to a very large number of documents (the file in question contained over 47 000 pages), refused to carry out a concrete and individual examination of each of the documents. Rather, it provided justifications, based on the exceptions set out in Regulation 1049/2001, for four categories of documents " *en bloc* ".

90. The Agency does not, however, invoke the volume of work required to deal with the request for access *as a reason for refraining from carrying out a concrete, individual examination of each of the documents* . Rather, it wishes to invoke the volume of work required as a justification, *in itself* , for not agreeing to the request for access. In sum, the Agency relies on an " *administrative burden* ", as such, as *an additional exception to the right of access to documents* . This is clearly not in line with the *Verein für Konsumenteninformation v Commission* case law. The principle of proportionality cannot, *on its own* , stand as a reason to refuse a request for access to documents. The reasons for a refusal of access to documents must exclusively be based on the exceptions of Regulation 1049/2001. *At most* , if it were proven to apply, the principle of proportionality would only explain why justifications based on a concrete and individual examination of each of the documents could be replaced by justifications relating to a *series* of documents.

91. It is also recalled that the 67 hours of work referred to by the Agency only concerns the work of recovering and printing the requested suspected serious adverse reaction reports. This 67 hours of work does not relate to the analysis of whether a justification under Article 4 of Regulation 1049/2001 applies to the documents (indeed, the Agency has provided no justifications based on Article 4 of Regulation 1049/2001). As such, this 67 hours of work is not the work envisaged by the exception set out in the *Verein für Konsumenteninformation v Commission* case law [40] .

92. The Ombudsman does not consider, in any case, that the complainant's request relates to a " *manifestly unreasonable number of documents* " and that the Agency's compliance with the request could " *very substantially* " paralyse the proper working of the institution [41] .

93. Regulation 1049/2001 contains, in any case, a procedural provision which can be applied to reconcile a situation where the administrative work caused to the institution would be disproportionate (namely, Article 6(3) of Regulation 1049/2001). According to Article 6(3), in the event of an application relating to a very long document or to a very large number of documents, the institution concerned may confer with the applicant informally, with a view to finding a fair solution [42] . The Agency appears not to have used this procedure in the present case.

94. It must also be recalled that Regulation 726/2004 aims at, among other things, ensuring that serious adverse reaction reports are rapidly made available to national authorities and to the Commission in alert situations. This implies that providing access to the documents requested, either in electronic or paper form, should not take an unreasonable amount of time and should not be unreasonably resource-consuming for the Agency. The Ombudsman notes in this respect that the Agency could, using the procedure set out in Article 6(3) of Regulation 1049/2001, offer to send the documents to the complainant in electronic format (for example, on a DVD) rather than as a printout. Given that 65 of the 67 hours which the Agency estimates would be required to deal with the request for access concerns the printing out of the requested reports, such a solution would considerably reduce the workload of the Agency.

95. It follows from the above that the Agency's refusal of access by a simple reference to the principle of proportionality, without any reference to the exceptions contained in Regulation 1049/2001, does not constitute valid and adequate grounds for refusing access to the documents requested.

96. In addition, the Agency supported its argument concerning a disproportionate administrative burden by reference to the English Freedom of Information Act. With regard to this reference, it need only be recalled that the specific provisions contained in Member States' national legislation do not, as such, bear relevance in the context of applying the detailed Community legislation on access to documents. Therefore, it is not necessary to inquire into this aspect of the third argument.

The Agency's fourth argument: The danger arising from allowing misleading and unreliable data to circulate

97. When refusing the complainant's request for access, the Agency stated that " *the indiscriminate release of the raw data* " contained in the reports would result in the circulation of unreliable and misleading data.

98. The Ombudsman first notes that Regulation 1049/2001 does not contain an exception allowing public access to documents to be refused due to the *unreliable* or *misleading* character of the information contained in the requested documents. Such arguments are not, therefore, of relevance as regards an analysis of requests for access to documents under Regulation 1049/2001.

99. However, the Ombudsman fully understands the Agency's concerns as regards the circulation of unreliable and misleading information, or of incomplete information, which may result from the public disclosure of adverse reaction reports.

100. The Ombudsman takes the view that, when deciding on the extent, manner and timing of its *proactive* public information efforts, the Agency should take into consideration the fact that certain documents in its possession must be made publicly accessible in response to a request under Regulation 1049/2001. The Agency could thus provide, as part of its proactive information

policy, additional explanations to facilitate the understanding of such documents. This is particularly important in sensitive areas, such as in the area of public health, where it is extremely important that the public are well-informed [43] . If, due to the need to comply with the legally binding rules concerning access to documents, *unreliable* or even *misleading* information could make its way into the public domain, the Agency could tailor its information policy to take account of this eventuality [44] .

Scope of request for access

101. The complainant argues that the Agency wrongly handled his request by limiting its scope to reports held in electronic form in the EudraVigilance database.

102. The Ombudsman first notes that it is factually correct to state that the Agency limits the scope of the complainant's request to only those reports which are contained in the EudraVigilance database.

103. The Ombudsman observes that Regulation 1049/2001 applies to all documents in the possession of the institution concerned, including paper copies of such documents.

104. The limitation of the scope of the request would, of course, be justified if the Agency did not have in its possession any paper copies of the requested reports. However, the Ombudsman notes that the Agency has not responded, in its opinion to the Ombudsman, to the complainant's argument. In particular, it has not stated if it holds the requested reports in paper form. The Ombudsman will take this into consideration when making a draft recommendation.

Conclusion

105. On the basis of the foregoing, the Ombudsman finds that the Agency has failed to provide valid and adequate grounds for its refusal to grant access to the requested reports on serious adverse reactions contained in the EudraVigilance database. This constitutes an instance of maladministration. He therefore makes a draft recommendation in accordance with Article 3(6) of the Statute of the European Ombudsman (see below).

B. Allegation that, in its reply to the complainant's confirmatory application, the Agency failed to notify the complainant of the relevant remedies available.

Arguments presented to the Ombudsman

106. The complainant alleged that, in its reply to the confirmatory application, the Agency failed to notify him of the relevant remedies available, because it did not advise him to submit a complaint to the Ombudsman or take action before the Court of Justice.

107. The Agency did not address the complainant's second allegation in the opinion it submitted

to the Ombudsman. The complainant did not submit any observations on this matter.

The Ombudsman's assessment

108. According to Article 73(4) of Regulation 726/2004,

" *Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may give rise to the lodging of a complaint with the Ombudsman or form the subject of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.* "

109. Taking into account the Ombudsman's finding in the context of the complainant's first allegation, the Agency was, on the basis of Article 73(4) of Regulation 726/2004, obliged to inform the complainant that the relevant remedies available consisted of the possibilities to submit a complaint to the Ombudsman or to refer the matter to the Court of Justice. By not advising the complainant to turn to the Ombudsman or to submit a complaint to the Court of Justice, the Agency has clearly failed to act in accordance with the above-mentioned provision. However, given that the present inquiry into the complainant's first allegation is ongoing, and that the complainant found out by himself that it could turn to the Ombudsman, the Ombudsman considers that further inquiries are not justified into the second allegation.

C. The draft recommendation

On the basis of his inquiries into this complaint, the Ombudsman makes the following draft recommendation to the Agency:

The Agency should carry out a full analysis, under Regulation 1049/2001, of the possibilities to grant access to the reports on suspected serious adverse reactions requested by the complainant. The Agency's analysis should cover documents held by it in any form, such as paper form or electronic form. The Agency should also consider possibilities to provide public access to the requested reports in any form, including electronic form.

The Agency and the complainant will be informed of this draft recommendation. In accordance with Article 3(6) of the Statute of the European Ombudsman, the Agency shall send a detailed opinion by 31 July 2010. The detailed opinion could consist of the acceptance of the draft recommendation and a description of how it has been implemented.

P. Nikiforos DIAMANDOUROS

Done in Strasbourg on 29 April 2010

[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] Regulation (EC) No 1049/2001 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.

[3] 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.

[4] Medicinal products cannot be placed on the market of a Member State unless a marketing authorisation has been issued in relation thereto.

[5] Roaccutane is a medicine used to treat severe forms of acne.

[6] The concept of " *serious adverse reaction* " is defined as follows in 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, pp. 67–128)* : " *An adverse reaction which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect* ".

[7] By " *side effects* " the complainant referred to " *all suspected reactions concerning psychiatric disorders, adverse psychiatric effects, depression, psychosis, schizophrenia, aggressive behaviour, suicide ideation, suicide attempts, suicide, emotional instability, nervousness, malaise or lethargy* ".

[8] The legal term " *lex specialis* " is used to describe the principle whereby a law governing a specific subject matter (that is, a *lex specialis*) overrides a law which only governs general matters (that is, a *lex generalis*).

[9] Case T-2/03 *Verein für Konsumenteninformation v Commission* [2005] ECR II-1121.

[10] The Agency noted that, in particular, The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 (Statutory Instrument 2004 no 3244) provide for a limit of GBP 600 per request in the case of certain public bodies (including governmental departments) and GBP 450 in the case of other public authorities. The Statutory Instrument also foresees that the costs are to be estimated at a rate of GBP 25 per person per hour.

[11] SUSAR refers to 'Suspected Unexpected Serious Adverse Reactions'.

[12] In this regard, the complainant referred to the following statement contained in Case C-353/99 P *Council v Hautala* [2001] ECR I-9565: "[t] *he authorities responsible for applying it*

are under a strict requirement to give it the wide interpretation demanded by its nature ".

[13] Report on the Implementation of Principles in the EC Regulation No 1049/2001 regarding Public Access to European Parliament, Council and Commission documents (COM 2004/45 final).

[14] Opinion of Advocate-General Léger of 10 July 2001 in Case C-353/99 P *Council of the European Union v Heidi Hautala* .

[15] See Case T-2/03 *Verein für Konsumenteninformation v Commission* cited in footnote 9 above.

[16] Case T-2/03 *Verein für Konsumenteninformation v Commission* paragraph 103: " *However, that possibility* [to rely on the administrative burden as a basis for refusing an access request] *remains applicable only in exceptional cases.* "

[17] Case T-2/03 *Verein für Konsumenteninformation v Commission* , paragraph 112: " *Accordingly, it is only in exceptional cases and only where the administrative burden entailed by a concrete, individual examination of the documents proves to be particularly heavy, thereby exceeding the limits of what may reasonably be required, that a derogation from that obligation to examine the documents may be permissible.* "

[18] Case T-2/03 *Verein für Konsumenteninformation v Commission* , paragraph 113: " *In addition, in so far as the right of access to documents held by the institutions constitutes an approach to be adopted in principle, it is with the institution relying on an exception related to the unreasonableness of the task entailed by the request that the burden of proof of the scale of that task rests.* "

[19] According to the complainant, an estimate of the likely amount of such reports could be made on the basis of a report from the WHO database. It appeared from that report that, between 1982 and 1997, 724 worldwide individual Case Safety Reports on psychiatric side effects were made to the WHO in relation to Roaccutane. The vast majority of these were from the USA, whereas only 41 (5.7%) appeared to have come from European countries. Therefore, even a 100% increase would result only in some 120 European reports.

[20] The complainant submitted documentation evidencing that reports comparable to the ICSR's were provided by the World Health Organisation (WHO) between 1982-1997; the Medicines Control Agency (UK) between 1982-1997; Norwegian Medicines Agency between 1985-2005 and the Swedish Medical Products Agency between 1983-2008.

[21] Article 1 of the TEU reads as follows:

" *This Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen.* "

[22] Article 15 of the TFEU (ex Article 255 EC) reads as follows:

" *1. In order to promote good governance and ensure the participation of civil society, the Union institutions, bodies, offices and agencies shall conduct their work as openly as possible.*

2. The European Parliament shall meet in public, as shall the Council when considering and voting on a draft legislative act.

3. Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to documents of the Union institutions, bodies, offices and agencies, whatever their medium, subject to the principles and the conditions to be defined in accordance with this paragraph.

General principles and limits on grounds of public or private interest governing this right of access to documents shall be determined by the European Parliament and the Council, by means of regulations, acting in accordance with the ordinary legislative procedure.

Each institution, body, office or agency shall ensure that its proceedings are transparent and shall elaborate in its own Rules of Procedure specific provisions regarding access to its documents, in accordance with the regulations referred to in the second subparagraph.

The Court of Justice of the European Union, the European Central Bank and the European Investment Bank shall be subject to this paragraph only when exercising their administrative tasks.

The European Parliament and the Council shall ensure publication of the documents relating to the legislative procedures under the terms laid down by the regulations referred to in the second subparagraph. "

[23] See Recitals (1) and (2) of Regulation 1049/2001. See also Article 42 of the Charter of Fundamental Rights of the European Union.

[24] Of course, if the documents requested have *already* been made directly accessible to the public, the person concerned should be informed where the documents (or documents containing that information) can be accessed.

[25] See Article 4 of Regulation 1049/2001.

[26] Indeed, given that the legislator included Article 73 (1) in Regulation 726/2004, it is not surprising to find that the various specific articles in Regulation 726/2004 which concern access to specific documents or sets of documents are, in fact, fully consistent with the general obligation to apply Regulation 1049/2001 to documents held by the Agency. In sum, if the Agency gives public access to documents in accordance with Regulation 1049/2001, it will also comply with the obligations concerning access to documents set out in specific articles of

Regulation 726/2004.

[27] See, for example, Joined Cases 201/85 and 202/85 *Klensch and Others* [1986] ECR 3477, paragraph 21, and Case C-314/89 *Rauh* [1991] ECR I-1647, paragraph 17.

[28] See Article 1 of the TEU and Article 15 of the TFEU.

[29] See Case 292/82 *Firma E. Merck v Hauptzollamt Hamburg-Jonas* [1983] ECR 3781, paragraph 12.

[30] Article 2(4) of Regulation 1049/2001 reads as follows: " *Without prejudice to Articles 4 and 9, documents shall be made accessible to the public either following a written application or directly in electronic form or through a register. In particular, documents drawn up or received in the course of a legislative procedure shall be made directly accessible in accordance with Article 12.* "

[31] Article 9 of Regulation 1049/2001 only applies to certain sensitive documents as defined in Article 9 of Regulation 1049/2001. In any case, if a document falls within the scope of Article 9 of Regulation 1049/2001, an institution must, if it wishes to refuse public access to that document, give reasons for its decision in a manner which does not harm the interests protected in Article 4. In any event, the documents in question in the present case clearly do fall within the scope of Article 9 of Regulation 1049/2001.

[32] See Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council* [2008] ECR I-4723, and Case C-64/05 P *Sweden v Commission* and others ECR [2007] I-11389. As regards compliance with the obligation to state reasons, see Case C-41/00 *Interporc v Commission* [2003] ECR I-2125, paragraph 55.

[33] *Svenska Journalistforbundet v Council* Case T-174/95 [1998] ECR II-2289.

[34] It is also worth noting that the term " *if relevant* " in the last sentence of Article 26(3) of Regulation 726/2004, is not present in every language version of the Regulation. The French language version of Regulation 726/2004, for example, reads as follows: " *Ces* données *sont mises à la disposition du public, le cas échéant après évaluation.* " The wording of the French version would seem to require that *all* " *such data* " be made directly accessible to the public once the evaluation of the Agency has been completed. The Ombudsman observes that the Court of Justice has held that, in the case of divergence between the language versions of a Community measure, the provision in question must be interpreted by reference to the purpose and general scheme of the rules of which is part (see Case C-36/98, *Spain v Council* [2001] ECR I-779, paragraph 49). As such, Article 26(3) of Regulation 726/2004 would have to be interpreted by referring to the purpose and general scheme of the rules of which is part. Separately, it should also be noted that the obligation to make documents *directly* accessible should be interpreted as broadly as possible. As such, the term " *if relevant* " (in the English version of the Regulation) should be interpreted broadly so as to encompass *as many documents as possible* .

[35] It is recalled, in this respect, that Article 26(3) concerns primarily the rapid transmission of data to Member States through " *a data-processing network* " in the event of an alert. As such, under Article 26(3), Member States can have direct access to the documents through a database. In this context, when it was deliberating on the addition of a final sentence to Article 26(3), it is entirely logical that the legislator did not conceive Article 26(3) as a mechanism for dealing with *requests* for public access to documents, but rather conceived it as a mechanism for making documents directly accessible (also) to the public. With specific reference to Roaccutane, the Ombudsman is not aware that Roaccutane has been the subject of an alert. As such, Article 26(3) would not apply to serious adverse reaction reports relating to Roaccutane.

[36] The Agency appeared simply to refer to its future policy on access to the information held in the EudraVigilance database, which foresees the possibility to grant public access to " *aggregated* " data concerning the reported suspected serious adverse reactions to medicinal products authorised in the EU.

[37] Indeed, the use of encryption to store documents is analogous to the use of a locked safe to store documents. As such, encryption is, in effect, a secure " *container* " in which content is stored. In the same way that an institution cannot refuse access to a document simply because the document is currently held in a locked safe (unless the institution had no key to that safe), the fact that content is encrypted cannot be used as a reason for an institution to refuse access to a document it holds (unless the institution is unable to decrypt the content using decryption tools at its disposal). In sum, if it has the key to the safe, or the decryption software/codes, it has the ability to provide public access to the documents contained in the safe or protected by encryption.

[38] The Ombudsman notes that the Agency website itself states that " *EudraVigilance supports in particular the electronic exchange of suspected adverse reaction reports (referred to as Individual Case Safety Reports) between the* Agency *, national Competent Authorities, marketing authorisation holders, and sponsors of clinical trials in the EEA* ".

[39] Case T-2/03 *Verein für Konsumenteninformation v Commission* [2005] ECR II-1121.

[40] The Agency has informed the Ombudsman that the time required to prepare and run the query to retrieve all the individual cases and the related safety reports for each medicinal product characterisation was approximately 2 hours. Once the individual cases and the related safety reports are retrieved, a document for each report had to be generated and printed. The time required for each document to be generated and printed was estimated to be a minimum of 45 seconds. The Agency concluded that the total time required to deal with the complainant's request would amount to 67 working hours. This would not include the time required for the redaction of personal data.

[41] See paragraphs 100 and 101 of *Verein für Konsumenteninformation v Commission* .

[42] A provision identical with Article 6(3) of Regulation (EC) 1049/2001 is contained in Article

5(3) of the Agency's Implementation Rules for Regulation (EC) 1049/2001.

[43] See European Governance: A White Paper, 25 July 2001, COM(2001)428 final.

[44] As regards the possibilities to give the fullest possible effect to the right of public access to documents at the European level, the Ombudsman considers it useful to refer to the standard practice of other comparable institutions. In this regard, it is noteworthy that, for instance, the standard practice of the US Food and Drug Administration is to make the information it receives on the adverse reactions of drugs regularly available online on its webpage. The information of adverse drug reactions is available at the following web address:

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193 [Link].

It is noteworthy that the webpage contains the following information about the reports contained therein: " *For any given report, there is no certainty that a suspected drug caused the reaction. This is because physicians are encouraged to report suspected reactions; however, the event may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or simply occurred by chance at that time* " and " *Accumulated reports cannot be used to calculate incidence (occurrence rates) or to estimate drug risk. Comparisons between drugs cannot be made from these data* ."