Decision in own-initiative inquiry OI/5/2013/PMC concerning the European Medicines Agency's web interface as well as the related guidance documents available in English only used by small-and-medium sized enterprises in order to carry out the registration of certain information about the medicines they sell in the EU

Decision

Case OI/5/2013/PMC - **Opened on** 27/09/2013 - **Decision on** 26/09/2016 - **Institution concerned** European Medicines Agency (No maladministration found) |

Pharmaceutical companies are obliged to register certain information about the medicines they sell in the EU with the European Medicines Agency (EMA), including information on suspected adverse drug reactions. The registration is done through a web-based interface. Two small German pharmaceutical companies complained that the web interface and the guidance documents on how to carry out this registration are available in English only. They added that they sell their medicines in Germany only and that they work exclusively in German.

The Ombudsman opened an own-initiative inquiry into this systemic matter. The Ombudsman found that the choice of language used in the web interface can in itself be a factor in determining EMA's performance in protecting the health of EU citizens. She pointed out that a differentiation in the use of languages can in certain circumstances be objectively justified, so long as it is proportionate in the context of the outcome sought. The Ombudsman found that EMA's reliance on one language only (English) in its web interface is objectively justifiable and proportionate. At the same time, she recognised the negative consequences for other EU languages where one language is given a privileged position in a particular domain and urged EU institutions to keep to an absolute minimum those situations where such differentiation occurs.

She also stated that it is unlikely that, in today's globalised world, a pharmaceutical company, no matter how small, can operate satisfactorily without relying on information from sources outside its own country. It is the case, for instance, that most academic and research papers in the pharmaceutical field are published first, and sometimes exclusively, in English.

She added that EMA had taken certain steps to become more user-friendly from a linguistic perspective. In particular, it has established a SME Office to address the special needs of SMEs and which replies, in any of the official EU languages, to any query on the submission of

information via the web interface or on any of the related documents.

Against this background, the Ombudsman closed the case with a finding of no maladministration. She nonetheless invited EMA to consider ways to improve further the information and training provided by its SME Office to pharmaceutical companies which need language support.

Background

1. Pharmaceutical companies must submit [1] , through a web interface, certain information to the European Medicines Agency (EMA) about the medicines they sell in the EU, including information on suspected adverse drug reactions. Small to medium sized enterprises (SMEs) operating in the pharmaceutical sector are also covered by this requirement. EMA stores this information in a database called 'EudraVigilance' [2] . EMA, national regulators, researchers and doctors can then use the information in the database to evaluate if medicines are safe for human use.

2. In April and October 2012, the Ombudsman received complaints [3] from two relatively small German pharmaceutical companies about the conditions for submitting such information; they complained that EMA's relevant web interface, as well as the guidance documents on how to carry out this registration, are available in English only. They added that they sell their medicines in Germany only and that they work exclusively in German. It is relevant to note here that, while the language of the web interface is English, companies are free to provide their replies in any one of the official languages of the EU. [4]

3. The Ombudsman decided to close the individual complaints she had received and to pursue the issues raised in the context of an own-initiative inquiry instead. This is because it appeared that the linguistic policy of EMA as to the registration of medicinal products by SMEs raised a systemic issue.

The inquiry

4. The Ombudsman opened her own-initiative inquiry into the following allegation:

Whilst SMEs from EU Member States have a legal obligation to register their medicinal products with EMA, the latter has failed to ensure that the relevant web interface as well as the information on how to carry out this registration is available in official languages of the EU other than English. By doing so, EMA may discriminate against those SMEs that do not operate in English and that are active only in their (non-English speaking) national market.

5. In the letter to EMA opening her inquiry, the Ombudsman noted that the Agency had argued [5] that providing translations in all languages would be " *excessive and disproportionate* ". EMA

had referred to an " *evident limitation of resources for translation* " and " *budgetary constraints in using external translation services* ". However, EMA had not provided any detailed information supporting its arguments.

6. Against this background, the Ombudsman asked EMA to provide, in particular, detailed information in support of its argument that translation into other EU languages would be excessive and disproportionate.

7. In the course of the inquiry, the Ombudsman received EMA's reply in December 2013 and, subsequently, the complainants' comments on that reply. The Ombudsman's inquiry team also carried out an inspection at EMA in September 2014. The complainants submitted comments on the inspection report. Upon request of the Ombudsman's inquiry team, EMA submitted additional information in October 2014 and February 2016. In conducting her inquiry, the Ombudsman has taken into account the arguments and points put forward by the parties.

Allegation that EMA's language policy regarding its web interface and the relevant guidance documents is discriminatory

EMA's position and the complainants' comments

8. EMA stated, in its reply to the Ombudsman, that English is its working language and that, due to the highly technical nature of the EU pharmaceutical regulatory and scientific guidelines, these are generally available in English only. Translating all such information would not be a simple exercise, and such translation work does not fall within EMA's remit. It would require specific skills for which EMA lacks human and financial resources.

9. EMA argued that it has already taken certain steps to become more user-friendly from a linguistic perspective, translating some guidance documents into all EU official languages. In particular, details about the information that Marketing Authorisation Holders have to submit electronically regarding medicines can be found in the " *Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004* ", which is also available in German [6] . Moreover, EMA has created a dedicated SME Office to address the particular needs of SMEs which replies to questions in any official EU language. EMA stated that the information leaflet on the SME Office has been published in all EU languages.

10. EMA said that its web interface, which is available in English only, is an interactive tool that generates a report with information about a particular medicine and its Market Authorisation Holder [7] . EMA created the web interface specifically for SMEs and non-commercial research facilities, so as to provide them with a secure means of electronic reporting to EMA and other competent authorities.

11. During the inspection, EMA's staff explained that the 'predefined entries' in the web interface

use keywords defined and updated by international organisations other than EMA, such as the World Health Organisation and the European Directorate for the Quality of Medicines of the Council of Europe.

12. EMA stated that the guidance documents explaining how the web-interface works are, due to their technical nature, available in English only. These documents require continuous technical updates. In view of their large volume, it would be too costly for EMA to translate them, continuously, into all official EU languages.

13. In their comments on EMA's reply, the complainants, whose cases prompted this own-initiative inquiry, put forward a number of arguments challenging EMA's position. They argued that EMA's decision to use English as its working language should be of relevance only for its own staff and should not determine the language of communication with third parties. They argued that it cannot be acceptable to pose questions in a language that the respondent does not understand (in this case, the material in question is available in English only). They argued that a scarcity of human and financial resources should not interfere with EMA's general policy objectives. They argued that the Agency needed to communicate with Marketing Authorisation Holders throughout the EU. Thus, the relevant financial resources to do so should be made available to it. They added that there are long delays in the SME Office replying to questions asked in any EU language other than English. They noted that the obligatory training on the use of the web interface is available in English only. They argued that the fact that the majority of SMEs did not raise any language concerns does not mean that they do not face any difficulties. Finally, they argued that the fact that information is available in English only reduces the safety of medicinal products, as misunderstandings and mistakes may occur.

Additional information submitted by EMA

14. In December 2015, the Ombudsman's inquiry team asked EMA whether it had made available additional guidance documents on the registration of medicinal products in languages other than English. EMA replied that it had published a fact sheet in all 24 official languages, on 17 December 2014 that explains what information has to be submitted and updated by Marketing Authorisation Holders [8] .

15. EMA further stated that it provides training to Marketing Authorisation Holders, through an e-learning course in English only, on the submission of the required pharmaceutical information. It does so to ensure the quality of data submitted to the *EurdraVigilance* database. The e-learning course provides self-paced learning activities. EMA also arranges two-day face-to-face training courses, providing the participants with an opportunity to discuss real-life scenarios and examples. Participants can ask for immediate advice during training courses. While tutorials are normally in English, EMA may from now on also organise training sessions in other EU languages on demand. [9]

The Ombudsman's assessment

16. It is important to be clear that this inquiry concerns only the language of EMA's **web interface** through which Marketing Authorisation Holders submit information about the medicine that they sell, as well as the language of the related **guidance documents.** It does not, therefore, concern the language in which Marketing Authorisation Holders must write or submit information to EMA. [10]

17. Languages play an important role in Europe's cultural heritage. [11] The right to communicate with the EU institutions in one's own language [12] is based not only on the general principle of non-discrimination [13] , but also on the consideration that, without such a possibility, decisions cannot be taken as closely as possible to citizens, thus excluding them from participation in the democratic life of the Union [14] . It is against this background that the Ombudsman held by analogy that resource and budgetary constraints cannot justify *systematically* putting the burden on citizens themselves to pay for documents to be translated into their respective language if they wish to participate in the democratic life of the Union. [15] It is thus part of the Ombudsman's mission to take appropriate action in those cases where the EU institutions, bodies, offices and agencies do not respect the Union's linguistic diversity and the principle of linguistic non-discrimination.

18. However, the purpose of the web interface, as well as the relevant guidance documents, provided by EMA mainly in English, is not that of cultural and linguistic diversity. Nor is their purpose to guarantee citizens the right to participate in the democratic life of the Union. The purpose of the web interface and its related guidance documents is to enable EMA to collect information from the Marketing Authorisation Holders to support its system for **reporting and evaluating suspected adverse drug reactions** during the development and marketing of medicines in the European Economic Area. This database is accessible to the Agency, national regulators, researchers and doctors to help evaluate if medicines are safe. It is on the basis of this information that EMA - whose fundamental purpose is to **provide the Member States and the EU institutions with the best possible scientific advice on any question relating to the quality, safety and efficacy of medicines** [16] - takes decisions affecting the health of millions of EU citizens. The language regime chosen by EMA must be fit for its important public health mission.

19. The Court of Justice has held that, even though EU legislation contains several references to the use of languages in the European Union, those references cannot be regarded as recognising a general principle of Union law that confers a right on *every* citizen to have a version of *anything* that might affect his or her interests drawn up in his or her language in *all circumstances* . [17] Likewise, the Court of Justice has ruled that a differentiation in use of languages can, in certain circumstances, be objectively justified, so long as it is proportionate to the aim sought. [18] The question here for the Ombudsman is whether, objectively, EMA's language regime enhances the protection of public health and, if so, is the operation of that regime proportionate in relation to that objective.

20. The Ombudsman pays particular attention to the argument that making information available to SMEs, mainly in English, reduces the safety of medicinal products, since misunderstandings

and mistakes may occur where the SME in question is not accustomed to working through English. Where a Marketing Authorisation Holder does not understand what information is required, and/or how it is to be provided, this could have serious consequences for public health.

21. However, this argument does not take account of three key considerations .

22. First, EMA has stated that it uses terminology defined by the World Health Organisation and by the European Directorate for the Quality of Medicines of the Council of Europe. This supports the argument that there is a harmonised pharmaceutical language in operation both at EU level and globally . The Ombudsman considers it reasonable for EMA, in setting out the data it requires to be provided, not to diverge from the practice of using this harmonised language. She also notes that it would constitute a significant administrative burden to translate guidelines and terminology which are being changed and adapted continuously by other organisations. Also, rather than helping to avoid misunderstandings, translating harmonised language could potentially lead to misunderstandings.

23. Second, it is unlikely that, in today's globalised world, a pharmaceutical company, no matter how small, can operate satisfactorily without relying on information from sources outside its own country. It is the case, for instance, that most academic and research papers in the pharmaceutical field are published first, and sometimes exclusively, in English. We may now have reached the point where some capacity to operate in English has become a necessity for any company operating in the pharmaceutical area. This conclusion arguably applies also to the two companies whose complaints prompted this inquiry. While they may sell their products exclusively in Germany, it is nonetheless highly doubtful that the production of their medicinal products was not somehow based on research from outside that country or at least published in English.

24. Third, EMA has taken certain steps to become more user-friendly from a linguistic perspective. In particular, it has established a SME Office to address the special needs of SMEs. EMA says that its SME Office helpdesk replies to any query on the submission of information via the web interface or on any document in *any official EU language* . EMA says also that it has now developed a general fact sheet *translated into all national languages* (including German), and that - since the Ombudsman's present inquiry - it organises two-day face-to-face training sessions *in national languages on demand* . Participants in these training sessions can thus ask questions *in their own language* . Therefore, if a small company has any doubts as to the meaning of any of the content in the EMA interface, it can obtain clarifications from the Agency either by email, telephone or in person.

25. EMA's position is that choosing to operate its web interface in one language only, where that language is in effect the global language of the pharmaceutical industry, reduces the risks of mistakes and misunderstandings when compared to a situation in which the interface would operate in a multiplicity of languages. This position is the opposite of that taken by the two companies whose complaints prompted this inquiry. On balance, the Ombudsman accepts EMA's position and concludes that its reliance on one language for its web interface better

serves the interests of citizens' health than does an interface operating in a multiplicity of languages. Article 3(3) of the Treaty on European Union states that the Union " *shall respect its rich cultural and linguistic diversity, and shall ensure that Europe's cultural heritage is safeguarded and enhanced* ". This provision is mirrored in Article 22 of the Charter of Fundamental Rights of the European Union. The Ombudsman appreciates that giving effect to these provisions is not easy and, as described in Paragraph 19 above, differentiation as between EU languages can sometimes be justified on an objective basis. However, the Ombudsman also appreciates that, even where different treatment of languages is objectively justified, this can lead to at least indirect negative consequences for those languages which are excluded. The long-term exclusion of languages from certain domains - such as science and pharmaceuticals in this case - can lead ultimately to the diminution of the capacity of that language in relation to those domains. Any diminution of capacity of a language in a given domain is likely to result, ultimately, in a loss of overall capacity and status of that language. In order to respect the obligation to ensure that linguistic diversity is "safeguarded and enhanced", EU bodies should strive to confine to the absolute minimum those circumstances in which one EU language is given privileged status over other EU official languages.

26. The Ombudsman finds that, in the particular circumstances of this case, there is an objective justification for EMA's decision to use English as the sole language of its web interface and of its guidance documents. **Furthermore the Ombudsman finds that, in the context of best serving the health of citizens, EMA's action in relation to the web interface is proportionate** . Therefore, the Ombudsman finds that there is no maladministration on the part of EMA arising from its sole reliance on English for its web interface and related documentation.

Conclusion

Following her inquiry the Ombudsman closes it with the following conclusion:

There was no maladministration in this case.

Suggestion

The Ombudsman invites EMA to improve further the information and training provided by its SME Office to pharmaceutical companies which need language support. In particular, EMA should identify further guidance documents which could be translated into all official EU languages or translate at least summaries thereof. Moreover, EMA should commit to assigning additional human resources to the SME Office as soon as possible in order to guarantee that questions asked in various official EU languages other than English are answered with the minimum of delay.

The Ombudsman will inform EMA of this decision.

Emily O'Reilly

European Ombudsman

Strasbourg, 26/09/2016

[1] In accordance with Article 57(2) of Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, p. 1.

[2] For more information on the topic, visit: https://eudravigilance.ema.europa.eu/human/

[3] That is, cases 889/2012/(KM)VL and 2177/2012/VL.

[4] Other than in “closed fields” where the respondent must choose from a menu of options which are in English only.

[5] This was in EMA’s replies to the two companies which had complained on the matter.

[6] The English version can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/07/WC500108212.pdf.

[7] The Agency referred to the generation of " *a 'manual' medicinal product and acknowledgement report* ".

[8] This fact sheet is available on the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mi

[9] More information about EMA's training sessions can be found here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000596.jsp&mid=WC0b0

[10] In fact, Marketing Authorisation Holders are not obliged to write or submit information to EMA exclusively in English. For instance, SME declaration forms can be filled in and submitted in any EU language, and so can the annual accounts and the proof of establishment in the EU. Moreover, According to Recital 12 of the EMA Regulation, the Agency should adopt provisions to allow, among other things, taking over responsibility for translations in respect of those SMEs which market medicinal products authorised via the *centralised* procedure (that is, via EMA), in order to reduce their costs. Consequently, it is clear that, as regard information that needs to be transmitted to the Agency, the latter is required to provide assistance to the Marketing

Authorisation Holders in certain cases.

[11] See Article 3(3) of the Treaty on European Union and Article 22 of the Charter of Fundamental Rights of the European Union.

[12] Article 24 of the Treaty on the Functioning of the European Union ('TFEU'), Article 41(4) of the Charter and Article 2 of Regulation 1/1958 determining which documents and publications have to be drawn up in all official languages of the EU.

[13] Article 22 of the Charter states prohibits, among other things, language discrimination.

[14] Article 1 of the Treaty of the European Union states that " *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** ". Moreover, Article 10(3) of the same Treaty writes that " *every citizen shall have the right to participate in the democratic life of the Union. Decisions shall be taken as openly and as closely as possible to the citizen* ".

[15] See, for instance, the Ombudsman's decision in case 640/2011/AN, para. 69. The decision is available online: http://www.ombudsman.europa.eu/en/cases/decision.faces/en/12009/html.bookmark.

[16] See, in this respect, Article 57(1), as well as Recital 19 of the EMA Regulation.

[17] Case C-361/01 P, *Kik v OHIM,* paragraph 82.

[18] See, for example, the recent judgment in *Italy and Spain v Commission* , Joint Cases T-124/13 and T-191/13, from paragraph 101 onwards.