European Ombudsman

P. Nikiforos Diamandouros
European Ombudsman

OI/5/2013/VL
S2013-181272

Mr Guido Rasi
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Strasbourg, 27 -09- 2013

Own-initiative inquiry OI/5/2013/VL

Dear Mr Rasi,

I am writing you concerning the European Medicine Agency's (EMA) linguistic policy with regard to the submission of information on medicinal products, pursuant to Article 57(2) of Regulation 726/2004[1].

The complainants in cases 889/2012/(KM)VL and 2177/2012/VL, two German SMEs, operating only within their national market, raised the issue that EMA's web interface as well as the supporting information were available only in English. An inquiry into the first of these cases was opened on 29 May 2012 and EMA sent its opinion on 31 August 2012. The second of the above cases was the subject of a telephone procedure, which resulted in EMA sending a reply to the complainant on 13 December 2012. The complainants in both cases have submitted observations.

After carefully considering the evidence gathered in the above inquiries, I concluded that the issue raised is systemic and could best be examined through an own-initiative inquiry. Furthermore, there seemed no realistic prospect of finding a solution to the specific situations of the complainants without dealing with the systemic issue.

I therefore decided to close the inquiries into cases 889/2012/(KM)VL and 2177/2012/VL and letters have been sent to EMA and to the complainants accordingly.

I also decided to open the present own-initiative inquiry, framed as follows:

Whilst SMEs from the EU's 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

[1] 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

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official languages of the EU other than English. By doing so, EMA may have discriminated against those SMEs that do not operate in English and that are active only on their (non-English speaking) national market.

As you may know, I have consistently taken the view that good administration requires that, as far as possible, the institutions, bodies, offices and agencies of the EU should provide information to citizens (as well as SMEs, for that matter) in their own languages.[2] Any limitations of the number of languages in which such information is available should therefore be justified.

I note that EMA has argued that providing translations in all languages would be "excessive and disproportionate" and cited an "evident limitation of resources for translation" and "budgetary constraints in using external translation services". However, no details have been provided that could support such an argument.

I would also very much appreciate it if, in its opinion on the own-initiative inquiry, EMA could address the following issue:

> *It appears to emerge from EMA's reply to the complainant in case 2177/2012/VL, that the Agency acknowledges that Regulation 726/2004 does not foresee a specific obligation for registrants to provide translations in English. Could EMA therefore please explain on what legal basis it requires such translations into English from SMEs?*

I should also be grateful if EMA could provide me with (i) background information on the web interface(s) used for registration, (ii) the supporting documents and tools available to the SMEs, and (iii) the EU official language versions available to SMEs for (i) and (ii).

I would very much appreciate if EMA could send its opinion by 31 December 2013 at the latest. I will forward your opinion to the complainants in cases 889/2012/(KM)VL and 2177/2012/VL for possible observations. I would, therefore, appreciate it if you could provide a translation of the opinion into German.

Enclosed, please find a copy of the complainants' observations in cases 889/2012/(KM)VL and 2177/2012/VL.

Yours sincerely,

P. Nikiforos Diamandouros

Enclosures:

- Observations from cases 889/2012/(KM)VL and 2177/2012/VL

[2] See for instance Ombudsman decisions in cases 1363/2012/BEH, 640/2011/AN, or 2413/2010/MHZ.