European Ombudsman

Decision on how the European Commission addressed concerns about violation of fundamental rights of the Polish- and Russian-speaking population in Lithuania due to non-availability of the leaflets on medicinal products in the respective languages (case 1185/2022/KT)

Decision
Case 1185/2022/KT - **Opened on** 15/07/2022 - **Decision on** 15/07/2022 - **Institution concerned** European Commission (No maladministration found) |

Dear Ms X,

You recently submitted a complaint to the European Ombudsman against the European Commission about how it dealt with your complaint against Lithuania.

In your complaint to the Commission, you claimed that Lithuania breaches EU law because the leaflets accompanying the medicinal products placed on the market in that country are available, besides Lithuanian, only in Estonian and Latvian. You contended that there are many elderly people in Lithuania, members of the Polish- and Russian-speaking communities, who hardly understand Lithuanian and who do not understand Estonian and Latvian. You argued that this situation amounts to discrimination against those people and is in breach of various articles of the Charter of Fundamental Rights of the European Union [1] .

In your complaint to the Ombudsman, you are dissatisfied with how the Commission addressed your concerns. You believe that the Commission should have assigned your complaint to a department responsible for dealing with violations of fundamental rights, rather than to its Directorate-General for Health and Food Safety (DG SANTE), Unit B5, 'Medicines: Policy, authorisation and monitoring'. You also doubt whether the replies that you received from the Commission represent its official position on the matter.

After careful analysis of all the information you provided with your complaint, we have decided to close the inquiry with the following conclusion:

There was no maladministration by the European Commission. [2]

On the language used in the package leaflets of the medicinal products

The Commission said that, according to the applicable EU legislation [3] , the package leaflet accompanying the medicinal products *"must be clearly legible in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified [...] by that Member State* ". As the leaflets of the medicinal products placed on the market in Lithuania are available in the official language of the country (Lithuanian), Lithuania complies with the language requirements under EU law.

The Commission also said that Member States are free to use additional, non-official languages in the leaflets of the medicinal products placed on their markets; however, this is a matter falling within the Member States' responsibility.

The Ombudsman considers this explanation to be reasonable.

On the Commission department that dealt with your concerns

Given the subject matter of the concerns raised in your complaint to the Commission, the Commission's decision to assign your complaint to Unit B5 in DG SANTE appears to be reasonable.

In any case, please note that it is up to the Commission to decide which of its departments is best placed to reply to individuals or deal with complaints. The only way its decision could be challenged would be if it were to be demonstrated that it had manifestly misunderstood or misinterpreted the matter or complaint, but there is no indication that this has been the case.

On whether the replies represent the Commission's official position

There is no indication that the letters you received from the Commission do not represent its official position. The text " *[t]his message represents solely the views of its author and cannot be regarded as the official position of the Commission* ", found at the end of the cover emails in which the DG SANTE's secretariat forwarded to you these letters, is rather a standard disclaimer relating to the content of the cover email itself. The letters themselves were all electronically signed by the head of the relevant unit and were registered in the Commission's official document management system (Ares), as indicated by the reference number.

Based on the information provide in your complaint, there was no maladministration by the European Commission.

Yours sincerely,

Tina Nilsson

Head of the Case-handling Unit

Strasbourg, 15/07/2022

[1] Articles 20 (*Equality before the law*), 21 (*Non - discrimination*), 25 (*The rights of the elderly*) and 26 (*Integration of persons with disabilities*).

[2] Full information on the procedure and rights pertaining to complaints can be found at https://www.ombudsman.europa.eu/en/document/70707 [Link]

[3] Article 63(2) of Directive 2001/83/EC on the Community code relating to medicinal products for human use, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0083-20220101&from=EN [Link]