Ufficio Procedure Centralizzate

Request for translation exemption in Italian or German language of labelling and/or package leaflet (art. 63.3 Directive 2001/83 implemented by 80.4 of Italian Legislative Decree 219/2006)

Press release to applicants Rev. 17.10.2025

In compliance with the internal Standard Operating Procedures of the Centralized Procedures Office approved by AIFA, the request for complete (labelling and package leaflet) or partial (labelling or package leaflet) exemption from the Italian translation [or German for packages marketed in the Bolzano area, according to art. 80.1 of Italian Legislative Decree 219/2006] falling under art. 63.3 of Directive 2001/83 (implemented by art. 80.4[1] of Italian Legislative Decree 219/2006 as amended) for medicinal products authorized through the centralised procedure according to Regulation 726/2004, shall be submitted according to the instructions given below.

The request can be submitted after the CHMP has issued a positive opinion for the medicinal product[2], or after the EMA notification[2].
The approval/rejection letter will be issued only after the date of publication of the Scientific and Economic Committee (CSE) decision on the AIFA website, except for special circumstances (e.g. public health threat situations).

In accordance with Presidential Decree No. 642 of October 26, 1972, the request must include a revenue stamp marked for the start of the procedure, or payment of a tax of € 16.00 made using form F23 of the Italian Revenue Office. The request shall be sent to the Centralised Procedures Office in paper format or electronically by certified e-mail (PEC) to protocollo@pec.aifa.gov.it and must include a single attachment in zip format containing:

1. Proof of payment of revenue stamp

2. Application signed digitally by the legal representative of the MAH or by another person with powers of representation, or by an attorney with special power of attorney, including a copy of the signatory's document, name of the medicinal product/active substance, European/Italian MA numbers for the involved presentations

[1] "If the medicinal product is not intended to be supplied directly to the patient, AIFA may waive the obligation to include certain information on the labeling and package leaflet and to draft the package leaflet in Italian and, for medicinal products marketed in the province of Bolzano, also in German."

[2] Different timing from that indicated in the EMA document "Recommendation for the implementation of exemptions to labeling and package leaflet obligations in the Centralised procedure."

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3. If the medicinal product has obtained the orphan designation, in cases where the translation exemption request is under the responsibility of the national competent authority[3]

4. Type of exemption requested, whether complete or partial (package leaflet and/or labelling, specifying if primary and/or secondary labelling), the final language(s) to be used (in case of multilingual labelling)

5. Labelling mock-up (coloured version) in Italian and in other language(s) to be used, package leaflet in Italian

6. Description of reasons why the medicinal product will not be marketed with the Italian and German labelling and /or package leaflet, estimate of sales volumes in Italy based on the prevalence of the disease in Italy

7. Impact assessment on the safe use of the medicinal product without the package leaflet and/or labelling in Italian and German

8. Description of risk minimization measures approved by EMA (e.g. educational material, video) and further *ad hoc* measures (e.g. copy of Italian package leaflet distributed with the medicinal product)

9. Description of optional information (mandatory and/or additional) that can be retrieved from the package leaflet and/or labelling through digital technologies.

The acronym "UPC" must always be included in the 'Subject' of the certified email, both for the submission of the application and for any supplementary documentation, followed by "-" and then the specific subject, without inserting punctuation/characters between the words, as in the example below:

- UPC - exemption from the translation in Italian/German of primary and/or secondary labeling and/or package leaflet (Art. 63.3 Directive 2001/83 as implemented by Art. 80.4 of Legislative Decree 219/2006).

It is recommended to compress the application documentation to a total of 30 MB, by taking the following technical measures:

- Scanned documents must be in PDF format and must have a resolution of 200 dpi for all black/white or colour combinations; where possible, they should not exceed 10 MB
- All scanned documents may be sent in black and white in order to limit their size (labelling mock-up excluded)
- Each scanned document should be checked against image quality, specifically framing, text integrity, and content readability
- In case of defects of any kind, the document must be rescanned. Before sending the file, the quality of the digital image should be ensured.

[3] If the request for exemption from translation concerns the labeling of a designated orphan medicinal product, it is handled by the EMA's Quality Review of Documents Working Group (QRDWG), in accordance with Article 63.1 of Directive 2001/83: in this case, if the request for exemption from translation of the labeling is submitted at the same time as the request for exemption from translation of the package leaflet, the latter is also handled by the QRDWG. If the request for exemption from translation of the package leaflet for an orphan medicinal product is submitted after the assessment by the QRDWG, this request falls within the scope of Article 63.3 of Directive 2001/83 and is assessed at national level.

The approval/rejection letter will be sent by the Centralised Procedures Office to the MAH/applicant electronically (by certified e-mail, PEC) or in paper format: in the latter case, an e-mail containing a scanned copy of said letter will be sent via the e-mail address legge189.uae@aifa.gov.it.

Data: 17.10.2025

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