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

Press release to applicants Rev. 15.10.2020

In compliance with the internal Standard Operating Procedures of the Centralized Procedures Office approved by AIFA, the request for complete (immediate and outer labelling and package leaflet) or partial (immediate or outer labelling or package leaflet) exemption from the Italian translation [or German translation 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 centralized procedure according to Regulation 726/2004, shall be submitted according to the instructions given below.

For medicinal products with a new marketing authorization (MA)

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

For variations to MA of already authorized medicinal products

The request can be submitted after the CHMP has issued a positive opinion for the medicinal product, or after the EMA notification[2].
The approval/rejection letter will be issued only after the date of publication of the CTS decision on the AIFA website or of publication of the EMA's positive opinion (when the latter is directly applicable), except for special circumstances (e.g. public health risk situations).

The request:

- shall be sent by the Marketing Authorization Holder (MAH)/applicant to the Centralized Procedures Office in paper format, or electronically by certified e-mail (*PEC*) to the e-mail address: procedure.centralizzate@pec.aifa.gov.it[3]
- shall include the following[4]:
  1. revenue stamp (*marca da bollo opportunamente annullata*)
  2. name and contact information of the MAH's reference person or accredited attorney at AIFA
  3. name of the medicinal product/active substance, MA European/Italian numbers for the involved presentations
  4. 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[5]
  5. 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)
  6. labelling mock-up (coloured version) in Italian and in other language(s) to be used, package leaflet in Italian

1 "If the medicinal product is not intended to be supplied directly to the patient, AIFA may waive the obligation to include certain indications on the labelling and package leaflet and to draw up the package leaflet in Italian and, for medicinal products marketed in the Bolzano area, in German"
2 Timeline different from EMA document "Recommendation for the implementation of exemptions to labelling and package leaflet obligations in the Centralised procedure"
3 See document "Contact details of national competent authorities for requests of translation exemption falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages"
4 See also Annex 1 of EMA document "Recommendation for the implementation of exemptions to labelling and package leaflet obligations in the Centralised procedure"
5 When the exemption translation request involves the labelling of an orphan medicinal product, it is managed by the EMA's Quality Review of Documents Working Group (QRDWG), according to art. 63.1 of Directive 2001/83. In this case, if the package leaflet translation exemption request is also included, the entire request (labelling and package leaflet) is managed by the QRDWG. If the package leaflet translation exemption request of an orphan drug is submitted after the QRDWG evaluation of the labelling exemption request, the package leaflet exemption request falls under article 63.3 of Directive 2001/83 and is evaluated at national level.

7. 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
8. impact assessment on the safe use of the medicinal product without the package leaflet and/or labelling in Italian and German
9. 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)
10. description of optional information (mandatory and/or additional) that can be retrieved from the package leaflet and/or labelling through digital technologies.

The approval/rejection letter will be sent by the Centralized 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