

**Marketing Authorization Office**

**STATEMENT OF COMPLIANCE OF THE ITALIAN TRANSLATION**

**OF THE SPC, PL AND LABELLING APPROVED AT THE END OF DC/ MR PROCEDURE**

|  |  |
| --- | --- |
| **European procedure number:** | [To be completed] |
| **Name, strength, pharmaceutical form of the medicinal product** | [To be completed] |
| **SIS (C.I.S.) code** | [To be completed] |
| **Type of the application** | [Check as appropriate]  Initial MA  Line extension |
| **Date of approval by the RMS (eop date)** | [To be completed DD/MM/YYYY] |

I, the undersigned1: [To be completed]

In my capacity as[[1]](#footnote-1) : [To be completed]

Certify that the Italian translation of the Summary of Product Characteristics (SmPC), package leaflet and labelling for the above mentioned medicinal product is a true and accurate translation of the English texts approved following the above-referenced procedure. Any deletions, modifications or additions to the approved English texts must be duly justified in the area provided for this purpose.

Certify that the the Summary of Product Characteristics (SmPC), package leaflet and labelling for the above mentioned medicinal product are provided in full and are in the currently applicable “QRD template” form and in docx, in the style sheet format in force

Certify that the translations submitted to AIFA have been reviwed by a qualified person in order to ensure a strict quality check of the texts

Certify that the translations submitted to AIFA were produced in accordance with the recommendations of the “*Best Practice Guide on the submission of high quality national translations*” of the Coordination Group for Mutual Recognition and Decentralized Procedures (CMDh) and with the EMA recommendations *« Compilation of QRD decisions on stylistic matters in product information ».*

If applicable (in case of therapeutic indications covered by a patent), certify that proposals to remove information in the translated texts, thereby leading to a difference compared to the approved English texts, will be clearly indicated. If the Company wants to request the deletion of parts of the text of the Summary of Product Characteristics and of the Product Information Leaflet referring to therapeutic indications covered by a patent, it is necessary to proceed according to the provisions of the AIFA statement « *Richiesta di eliminazione delle parti coperte da brevetto dai testi degli stampati - Modalità operative »*

[Enter the information below for each paragraph affected by the request of deletion]

Section SmPC/PL: [To be completed]

Information to be removed [To be completed]

**The undersigned is responsible for the accuracy and truthfulness of this undertaking and for compliance with it.**

[surname and first name in capital letters, ]

[Title/position]

[Signature]

Date:

**List of european variation procedure, with impact on the MA annexes, approved after the end of procedure on the date of the submission of the italian translations and of the statement\***

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| --- | --- | --- | --- |
| **EU procedure number** | **Subject of the application** | **Date of submission of the application** | **Date of approval by the Reference Member State (RMS)** |
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In case of transfering of an holder to another holder, or change of the local representative/distributor, CESP number and date of submission should be comunicated.

\* The list should be only provided in the exceptional case of delayed and justified submission of the national translations over 7 calendar days after finalisation of the European procedure.

**Justification of any deletions, modifications or additions compared to the approved English texts:**

**Removal of information protected by intellectual property rights (in case of therapeutic indication covered by patent) for the reference medicinal product :**

[Check as appropriate]

YES  NO

**Other changes compared to the English text (to be specified):**

[Check as appropriate]

YES  NO

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1. The Applicant/MA holder, or the QPPV or the qualified personnel responsible of the proposed italian translation of PI on behalf of the MA holder. In the last case signature of the Applicant/MA holder should be also added. [↑](#footnote-ref-1)