**FORM FOR BRAILLE FORMAT ON PACKAGING**

Applicant/Marketing authorization holder:

MA procedure (NP/MRP/DCP):

Name of the medicinal product:

Active substance:

Strength:

Pharmaceutical Form:

Packaging (state all packaging which will be labelled with proposed Braille format):

1. **Proposed information in Braille format**

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1. **Braille format (state also the type of Braille format if it is different than "Marburg medium")**

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**An explanation of the applicant/marketing authorisation holder, if the proposed information in Braille format is not in accordance with “Guidance concerning the Braille requirements for labelling and the package leaflet« implemented in bylaw Rules on labelling of medicinal products and on patient information leaflet (Official Gazette of the Republic of Slovenia, No. 57/14)**

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Braille format was checked by:

 ZDSSS (Union of Blind and Partially Sighted of Slovenia)

ZDSSS confirms that the information mentioned in point one of this form is written in Braille format on labelling.

Signature of responsible person of ZDSSS

 Applicant/Marketing authorization holder

An Applicant/Marketing authorization holder confirms that the information mentioned in point one of this form is written in Braille format on labelling (the evidence that responsible person is capable to assure Braille format in Slovene should be provided).

 Signature of responsible person of

Applicant/MAH

**Fulfilled by Agency for Medicinal Products and Medical Devices of the Republic of Slovenia**

Form for Braille format on packaging was checked by:

Date: