**Potvrda točnosti podataka navedenih Brailleovim pismom na pakiranju lijeka**

**Form for Braille Format on Packaging of Medicinal Product**

Podnositelj zahtjeva / Nositelj odobrenja:

(Applicant / Marketing authorisation holder)

Naziv lijeka / Name of the medicinal product:

Djelatna tvar / Active substance:

Jačina / Strength:

Farmaceutski oblik / Pharmaceutical form:

Broj odobrenja / Marketing authorisation number *[[1]](#footnote-1)*:

Broj procedure (u slučaju MRP/DCP) / MA procedure (in case of the MRP/DCP):

Vrsta i veličina pakiranja / Packaging*[[2]](#footnote-2)*:

**1. Prijedlog podataka koji će se navesti Brailleovim pismom na pakiranju**

**Proposed information in Braille format**

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| --- |
|  |

**2. Ispis podataka iz točke 1. na Brailleovom pismu**

**Information from point 1 in Braille format:**

|  |
| --- |
|  |

**3. Za ispis na Brailleovom pismu je korišten „Marburg medium“ font:**

**The “Marburg medium” font for Braille is used**

DA / YES [ ]

NE / NO [ ]  *ako nije, navesti koji font, u nastavku pod obrazloženje / please state under the explanation which font is used*

|  |
| --- |
| **Obrazloženje podnositelja zahtjeva/nositelja odobrenja**,ako podaci na Brailleovom pismu nisu u skladu sa smjernicom Europske komisije „[Guideline on the readability of the labelling and package leaflet of medicinal products](https://health.ec.europa.eu/system/files/2016-11/2009_01_12_readability_guideline_final_en_0.pdf)“ for human i normom **»**[HRN EN 17351:2014 Ambalaža — Pismo za slijepe na ambalaži za lijekove](http://31.45.242.218/HZN/todb.nsf/wFrameset2?OpenFrameSet&Frame=Down&Src=%2FHZN%2Ftodb.nsf%2FNormaSve%2F9370339631746eadc1257cd60036c910%3FOpenDocument%26AutoFramed)«: **An explanation of the applicant/marketing authorisation holder**, if the proposed information in Braille format is not in accordance with “[Guideline on the readability of the labelling and package leaflet of medicinal products](https://health.ec.europa.eu/system/files/2016-11/2009_01_12_readability_guideline_final_en_0.pdf)” and Norm **“**[HRN EN 17351:2014 Packaging – Braille on packaging for medicinal products](http://31.45.242.218/HZN/todb.nsf/wFrameset2?OpenFrameSet&Frame=Down&Src=%2FHZN%2Ftodb.nsf%2FNormaSve%2F9370339631746eadc1257cd60036c910%3FOpenDocument%26AutoFramed)”:       |

**4. Ispis na Brailleovom pismu iz točke 2. ove Potvrde pregledao/potvrdio**

 **Information in Braille format in the point 2 was checked by:**

      *(navesti naziv i adresu saveza/ili udruge/ili ustanove za slijepe i slabovidne osobe)* potvrđuje da su podaci iz točke 1. točno napisani Brailleovim pismom, kako je navedeno pod točkom 2. ove Potvrde.

      *(Name and address of an Union of Blind and Partially Sighted person)* confirms that the information from the point 1 of this form is written in Braille format correctly as stated in point 2 of this form.

Odgovorna osoba/Responsible person:

*(ime, prezime i potpis odgovorne osobe saveza/ili udruge/ili ustanove)*

*(name and signature of responsible person of Union of Blind and Partially Sighted person)*

      *(navesti naziv i adresu podnositelja zahtjeva/nositelja odobrenja)* potvrđuje da će podaci iz točke 2. biti ispravno otisnuti Brailleovim pismom na pakiranju lijeka.

      (*name and address of an Applicant / Marketing authorisation holder*) confirms that the information from the point 2 of this form will be printed in Braille format correctly on the packaging.

Odgovorna osoba/ Responsible person:

 *(navesti ime, prezime i potpis odgovorne osobe podnositelja zahtjeva/nositelja odobrenja)*

*(name and signature of the responsible person of Applicant/Marketing authorisation holder)*

1. *Navesti broj odobrenja kada se podnosi kao izmjena/ Marketing authorisation number in case of the variation application*  [↑](#footnote-ref-1)
2. Navesti sve vrste i/ili veličine pakiranja koje će biti označene s nazivom lijeka na Brailleovom pismu predloženim pod točkom 1. ove Potvrde/ state all packaging which will be labelled with proposed Braille format [↑](#footnote-ref-2)