Braille Declaration Form

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| *FOR HPRA USE ONLY* |
| CRN:       |

*Marketing authorisation holder’s declaration of compliance with Article 56a of Directive 2001/83/EC, as amended. For details of the requirements, please see the Guide to Labels and Leaflets of Human Medicines.*

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| *Section 1a or 1b, and Section 2 must be completed. Please tick the box if applicable.*  |
| I **<insert name>**, being the person responsible for communication on behalf of **<insert applicant company name>**, hereby declare: |
| **Section 1a**[ ]  that **<insert product name and PA number>** is in compliance with Article 56a of Directive 2001/83/EC as amended by Directive 2004/27/EC, as interpreted in the European Commission guidance ‘Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended)’The following text appears in Braille on the labelling: **<add, in non-Braille text, the text which appears in Braille>**I furthermore declare that the text which appears in Braille is easily readable, clearly comprehensible and does not adversely affect the legibility of the non-Braille labelling text, and that the Braille used is in a format suitable for Irish patients. |
| **Section 1b**[ ]  that no Braille is required on the labelling for **<insert product name and PA number>**as per European Commission guidance ‘Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended)’ because the product is intended for administration by healthcare professionals only. |
| **Section 2**[ ]  that the package information leaflet for **<insert product name and PA number>** is made available in formats suitable for the blind and partially-sighted in accordance with Article 56a of Directive 2001/83/EC as amended by Directive 2004/27/EC. |
| Signature of applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Capacity in which signed:      Date:      Telephone no.:      E-mail address:       | Print/type name:      Fax no.:       |

Send to: Receipts and Validation, Health Products Regulatory Authority, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2.

Tel: +353 1 676 4971; Fax: +353 1 676 7836.