Application Form B for Transfer before Authorisation of a Marketing Authorisation for Human Medicines

*For details of the requirements, please see the Guide to Transfers of Marketing Authorisations, Parallel Import Licences and Dual Pack Import Registrations for Human Medicines.*

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| 1. Details of the proposed authorisation holder after transfer

Name and address Name and address of the applicant acting on behalf of the proposed holder, if different  |
| 1. Details of the company currently proposed as authorisation holder

Name and address  |
| 1. Details of the product

Current PA number  |
| Name of product       |
| Pharmaceutical form       |
| Name of active substance(s)      Strength(s)       |

STATEMENT TO BE SIGNED BY THE COMPANY CURRENTLY PROPOSED AS MA HOLDER

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| Reason for transfer application: 1. I hereby notify the Health Products Regulatory Authority that the application for **<Insert product name>** **<Insert PA number>** is to be transferred to **<Insert name of the proposed MA holder>**.
2. I confirm that the entire dossier for the product has been transferred to **<Insert name of the proposed MA holder>**.

 This dossier includes all of the data in support of the original application together with all correspondence with the National Drugs Advisory Board/Irish Medicines Board/Health Products Regulatory Authority (and Department of Health) concerning the product and all pharmacovigilance data.Signed: Date:      Job title of signatory      Telephone      Email       |

STATEMENT TO BE SIGNED BY THE PROPOSED MA HOLDER AFTER TRANSFER

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| Reason for transfer application: 1. I will have the sole responsibility for the product including obtaining approval for any changes subsequent to the granting of this marketing authorisation.
2. I have received the entire dossier for **<Insert product name>** from **<Insert name of the current MA holder>**.

This dossier includes all of the data in support of the original marketing authorisation application together with all correspondence with the National Drugs Advisory Board/Irish Medicines Board/Health Products Regulatory Authority (and the Department of Health) concerning the product and all pharmacovigilance data.1. I have been assured by the current holder/applicant that, apart from the change of name and address of the authorisation holder and the authorisation number, the dossier on which the transfer is based is identical in every respect to that submitted by the original holder.
2. I confirm that I/we have adequate procedures in place to recall the medicinal product from the Irish market.
3. I confirm that I/we have adequate procedures in place to meet pharmacovigilance obligations in accordance with current national and EU legislation and regulatory guidelines and will act in compliance with them.

Additional statements for proposed holders who do not hold a marketing authorisation in Ireland:1. I confirm that I/we are established in the European Community and evidence of establishment in the EU has been provided with this application.
2. I confirm that I/we have established within my/our undertaking a scientific service in charge of information about the medicinal product within the meaning of Article 98 of Directive 2001/83/EC as amended.

Signed: Date:      Job title of signatory      Telephone      Email       |

Please send application via CESP or by email to submissions@hpra.ie.