Application Form A for Transfer of an Authorised (Parallel) or Dual Pack Import Registration (DPR) Product

*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 Marketing authorisation/parallel import/dpr licence holder after transfer   Name and address  Name and address of the applicant acting on behalf of the proposed MA holder, if different |
| 1. Details of the current Marketing authorisation/parallel import/dpr licence holder   Name and address |
| 1. Details of the product(s)   \*For bulk transfer applications, only one application is required. If necessary, provide an annex listing of the (P)PA/DPR numbers, full product names and strengths. |
| Current (P)PA/DPR number  Full name of product(s)  Strength of product(s) |

STATEMENT TO BE SIGNED BY THE EXISTING MA/LICENCE HOLDER

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| Reason for transfer application:   1. I hereby notify the Health Products Regulatory Authority that **<insert product name(s)>** **<insert (P)PA number>** is to be transferred to **<insert name of the proposed MA holder>**.   I request that an amended authorisation, reflecting this transfer and based on the **<insert the word 'dossier' for PAs, or 'application file' for PPAs and DPRs>**\* and any ongoing or subsequent data submitted by me/us, be issued to **<insert name of the proposed MA/Licence holder>**.   1. Transfer application directly related to the UK’s decision to exit the EU, i.e. the transfer is required because the current MAH is located within the UK.   I agree that no new stock of this/these product(s) bearing the current (P)PA/DPR number will be QP-certified once six months have elapsed from the time the transferred authorisation has been granted.  or  Transfer application for other reason.  I agree that no new stock of this/these product(s) bearing the current (P)PA/DPR number will be QP-certified once the transferred authorisation has been granted.   1. I confirm that the entire dossier/application file for the product(s) has been transferred to **<insert name of the proposed MA/Licence holder>**.   For PAs, this dossier includes all of the data in support of the original application together with all correspondence with the Health Products Regulatory Authority (and its predecessors) and the Department of Health concerning the product(s) and all pharmacovigilance data both before and after the issue of the original PA(s).  For PPAs and DPRs, this application file includes all of the data in support of the original application together with all correspondence with the Health Products Regulatory Authority (and its predecessors) and the Department of Health concerning the product(s) both before and after the issue of the original (P)PA(s).   1. For PAs only: I acknowledge our responsibilities in respect of pharmacovigilance obligations or in the event of any quality defect associated with any remaining product(s) bearing our name, address and PA number. 2. I declare, where there is no manufacturer specified in the licence being transferred, that I am aware of the conditions of the licence in respect of the manufacturing site and the requirement to submit a variation application to add the manufacturing site in order to market the product(s).   Signed: Date:  Job title of signatory  Telephone  Email  **\*** Dossier for PAs. Application file for PPAs and DPRs. |

STATEMENT TO BE SIGNED BY THE PROPOSED MA/LICENCE HOLDER

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| Reason for transfer application:   1. I will have the sole responsibility for the product(s) including obtaining approval for any changes subsequent to the grant of this/these product authorisation(s). 2. I have received the entire **<insert the word 'dossier' for PAs, or 'application file' for PPAs and DPRs>**\* for **<insert name(s) of product(s)>** from **<insert name of the existing licence holder>**.   For PAs, this dossier includes all of the data in support of the original marketing authorisation/parallel import licence application together with all correspondence with the Health Products Regulatory Authority (and its predecessors) and the Department of Health concerning the product(s) and all pharmacovigilance data both before and after the issue of the original authorisation(s)/licence(s).  For PPAs and DPRs, this application file includes all of the data in support of the original marketing authorisation/parallel import licence application together with all correspondence with the Health Products Regulatory Authority (and its predecessors) and the Department of Health concerning the product(s) both before and after the issue of the original authorisation(s)/licence(s).   1. I have been assured by the current MA/licence holder/applicant that, apart from the change of name and address of the holder and the (P)PA/DPR number, the dossier/ application file 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(s) from the Irish market. 3. For PAs only: 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 applicants who do not hold a marketing authorisation/parallel import licence/DPR in Ireland:   1. I confirm that I/we are established in the European Union 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(s) within the meaning of Article 98 of Directive 2001/83/EC.   Signed: Date:  Job title of signatory  Telephone  Email  **\*** Dossier for PAs. Application file for PPAs and DPRs. |

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