Application for a Waiver from the Requirement to Supply Written Confirmation with Consignments of an Imported Active Substance

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| 1. details of third country manufacturing site   Name of active substance:  *(Note: only one active substance is permitted per waiver application. Use INN nomenclature.)*  **For internal use only**:  Authorised manufacturer’s authorisation no.: \_\_\_\_\_\_\_\_\_\_\_  CWS reference no.: \_\_\_\_\_\_\_\_\_\_  Name of active substance manufacturer:  Address of active substance manufacturer:  Eircode:  Country:  Third country Competent Authority site/facility reference no. (if known): |
| 1. reason for application for this waiver   The manufacturer or importer should attach a document explaining the reason for requesting this waiver. Note that if the active substance is being sourced from a third country where the authority is known to issue written confirmations, then under normal circumstances it would be expected that a written confirmation would be the basis for importation of active substances from that country. |
| 1. details of gmp certification   Any differences between the name and address supplied above and those details supplied on the GMP certificate must be justified in order to ensure efficient processing of the application.  Name of authority which issued the GMP certificate:  Inspection date referenced on GMP certificate:  Period of validity of GMP certificate\* (if stated):  (\*this is 3 years from the date of inspection unless otherwise stated)  *Please attach a copy of the GMP certificate to this application form.* |

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| 1. details of waiver applicant   The waiver application may be submitted by either a site which has been registered with the HPRA for importation activities in Ireland relating to active substances, or by an authorised manufacturer/importer of human medicines in Ireland which is using the imported active substance for manufacture of medicines for human use (excludes investigational medicinal products) at its manufacturing address. If the importation activities (purchase of the active substance from a third country site or acting as the direct site of physical importation of the active substance) are being carried out directly by an authorised manufacturer of human medicines then both sections 4A and 4B below should be completed. |
| **4A. ACTIVE SUBSTANCE IMPORTER**  Active substance importer’s registration no.:  Importation activity carried out for this active substance *(tick all that apply)*  Procurement (purchasing)  Site of physical importation  Registered name of importer:  Registered address of importer:  Eircode: |
| **4B. AUTHORISED MANUFACTURER OF HUMAN MEDICINES USING IMPORTED ACTIVE SUBSTANCE**  Manufacturer’s/importer’s authorisation no. :  Name of authorised manufacturer:  Manufacturing site address:  Eircode:  Country: Ireland |
| 1. Applicant details:   Applicant name:  Applicant postal address:  Eircode:  Applicant contact number:  E-mail address: |
| 1. signature of waiver applicant   Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:  Name (print):       Position: |

Send to:

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