Notification of Withdrawal of Authorisations or Certificates for Human Medicines

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

For details of the requirements, please see the ‘Guide to Withdrawal of Authorisations or Certificates for Human Medicines’.

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| 1. PRODUCT DETAILS |  |
| (Invented) Name:  Active substance(s):  Pharmaceutical form(s) and strength(s):  Authorisation or certificate number(s):  Name and address of authorisation or certificate holder:    Contact name (and address):  Telephone number:  Fax number:  Email: | |
| 1. WITHDRAWAL Notification   Date for proposed withdrawal of the authorisation or certificate:  Reasons for withdrawal (*please tick the relevant box and give brief details)*  Commercial:  Quality, including GMP issues:  Safety issues:  Efficacy issues:  Where the marketing of a product ceases for reasons of quality, safety or efficacy, please give details of the main contact name and department in the HPRA which has been notified of the issue.  Contact HPRA name: Contact HPRA department:  Current usage data for the medicinal product:  Market share percentage (compared to generic equivalent if applicable): **%**  Number of units supplied per month:  Volume of prescriptions:  Are there therapeutically-equivalent products on the Irish market? *(Please give details.)* | |
| **3** I confirm that the HSE has been notified of the intended withdrawal.  Yes  Not applicable as the product is not marketed. | |
| 1. signature of applicant   Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print/type name:  Status (job title):  Date: | |

Please return the completed form by email to: [submissions@hpra.ie](mailto:submissions@hpra.ie)