Notification of Marketing Status of Human Medicines

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

For details of the requirements, please see the ‘Guide to Notifications of Marketing Status of Human Medicines’.

**Note: For temporary cessations to marketing (i.e. medicine shortages), please complete a ‘Notification of Medicinal Product Shortage from the Marketing Authorisation Holder’ form.**

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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:      Telephone number:      Fax number:      Email:       |
| 2 marketing Notification[ ]  The product has been/will be marketed from *(insert date)*:       |
| 3 Non-marketing Notification [ ]  Marketing of the product will cease from *(insert date)*:      [ ]  Product has never been marketed since authorisation granted. [ ]  This notification is not being made at least two months before cessation of marketing for the following reason:       |
| 4 request for an exemption[ ]  The product has not been marketed for a consecutive period of three years and an exemption from the application of the sunset clause is claimed for the following reason(s):       |

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| 5 reasons for non-marketing*Please tick the relevant box and provide 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: Date of notification:  |
| 6 products for which marketing is to cease permanentlyCurrent 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:     [ ]  Where the product ceases to be marketed permanently and there is no therapeutic alternative please confirm that the HSE has been notified of the intended withdrawal. |
| 7 signature of applicantSignature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Print/type name:      Status (job title):      Date:       |

Please return the completed form by email to: medstatus@hpra.ie.