Variation or Immediate Notification of Change to Registration of Manufacturer, Importer or Distributor of Active Substances

Applicant Details

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| Name or corporate name of registrant:  Organisation Management Service ID (ORG ID):  Registration number:  Company registration office number:  Permanent or legal address of registrant:  Eircode:  Organisation Management Service Location ID (LOC ID):  Address of site where registered activities take place in Ireland:  Eircode:  Organisation Management Service Location ID (LOC ID):  Registration number:  If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):  Name and address of applicant to whom correspondence should be addressed:  Eircode:  Contact telephone number:  Email address of applicant: |
| Type of Registration currently held  Active substance registration for human use  Active substance registration for veterinary use  Manufacturer active substance registration  Importer active substance registration  Distributor active substance registration  **Note: separate applications are required for each type of registration identified above.** |
| QUALITY IMPACT ASSESSMENT  (Please include details of the potential quality impact of the changes included in this variation/notification): |

Proposed variation to the registration

1. MANUFACTURING OPERATIONS

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| 1a. Do you propose to vary manufacturing operations on site?  Yes  No  If yes, please outline these changes in the present and proposed wording section provided below.  If additional APIs have been manufactured on site, please use the ‘new active substance’ section to provide detail on that manufacturing activity for that API.  1b. Have there been any changes that may impact your API-GMP certificate?  Yes  No  If yes, please specify: | |
| **1c. Proposed wording**  Please specify the precise present and proposed wording underlining or highlighting the changed words. | |
| **Present Wording** | **Proposed Wording** |
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**1d. New active substance:**

Active substance(s):

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| **A** | **Manufacture of active substance by chemical synthesis** |
|  | 1. Manufacture of active substance intermediates  2. Manufacture of crude active substance  3. Salt formation/purification steps: <free text> (e.g. crystallisation)  4. Other <free text> |

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| **B** | **Extraction of active substance from natural sources** |
|  | 1. Extraction of substance from plant source  2. Extraction of substance from animal source  3. Extraction of substance from human source  4. Extraction of substance from mineral source  5. Modification of extracted substance <specify source 1,2,3,4>  6. Purification of extracted substance <specify source 1,2,3,4>  7. Other <free text> |

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| **C** | **Manufacture of active substance using biological processes** |
|  | 1. Fermentation  2. Cell culture <specify cell type> (e.g. mammalian/bacterial)  3. Isolation/purification  4. Modification  5. Other <free text> |

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| **D** | **Manufacture of sterile active substance** (*note Parts A, B and C, to be completed as applicable*) |
|  | 1. Aseptically prepared  2. Terminally sterilised |

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| **E** | **General finishing steps** |
|  | 1. Physical processing steps <specify> (e.g. drying, milling/micronisation, sieving)  2. Primary packaging (enclosing/sealing the active substance within a packaging material which is in direct contact with the substance)  3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.)  4. Other <free text> (for operations not described above) |

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| **F** | **Quality control testing**  *Complete this section only if any parts of sections A, B, C, D, E are completed.* |
|  | 1. Physical/chemical testing  2. Microbiological testing (excluding sterility testing)  3. Microbiological testing (including sterility testing)  4. Biological testing |

1. IMPORTATION OPERATIONS

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| **2a. Do you propose to vary importation operations on site?**  Yes  No  If yes, please outline these changes in the present and proposed wording section provided below. |

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| **2b. Proposed wording**  Please specify the precise present and proposed wording underlining or highlighting the changed words. | |
| **Present Wording** | **Proposed Wording** |
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1. DISTRIBUTION OPERATIONS

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| **3a. Do you propose to vary distribution activities on site?**  Yes  No  If yes, please outline these changes in the present and proposed wording section provided below. |

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| **3b. Proposed wording**  Please specify the precise present and proposed wording underlining or highlighting the changed words. | |
| **Present Wording** | **Proposed Wording** |
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DECLARATION

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| I declare that the above particulars are, to the best of my knowledge and belief, correct.  Signature:  Date:  Print name:  Title/position: |

Checklist of Documents

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| The following information must be submitted with the application (except where not applicable).  *Please tick the checkboxes below to confirm the documents have been included with the application*.  Letter of application  Completed application form  Site master file if available (active substance manufacturers only)  Signed declaration  Relevant fee |
|  |

**Send to**:

Licensing Section,

Compliance Department,

Health Products Regulatory Authority

Earlsfort Centre,

Earlsfort Terrace,

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

Email: [compliance@hpra.ie](mailto:compliance@hpra.ie)