**SCOPE OF AUTHORISATION** (delete the sections that do not apply or use yes/no)

**ANNEX 2**

Name and address of the site:

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| --- |
| Human Investigational Medicinal Products (optional) |

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| AUTHORISED OPERATIONS  Manufacturing Operations of Investigational Medicinal Products (according to part 1)  Importation of Investigational Medicinal Products (according to part 2) |

|  |  |
| --- | --- |
| **Part 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS** | |
| **1.1** | **Sterile investigational medicinal products** |
|  | *1.1.1 Aseptically prepared (processing operations for the following dosage forms)*  1.1.1.1 Large volume liquids  1.1.1.2 Lyophilisates  1.1.1.3 Semi-solids  1.1.1.4 Small volume liquids  1.1.1.5 Solids and implants  1.1.1.6 Other aseptically prepared products <free text> |
|  | *1.1.2 Terminally sterilised (processing operations for the following dosage forms)*  1.1.2.1 Large volume liquids 1.1.2.2 Semi-solids  1.1.2.3 Small volume liquids  1.1.2.4 Solids and implants  1.1.2.5 Other terminally sterilised prepared products <free text> |
|  | *1.1.3 Batch certification* |

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| **1.2** | **Non-sterile investigational medicinal products** | | | | |
|  | *1.2.1 Non-sterile products (processing operations for the following dosage forms)*  1.2.1.1 Capsules, hard shell  1.2.1.2 Capsules, soft shell  1.2.1.3 Chewing gums  1.2.1.4 Impregnated matrices  1.2.1.5 Liquids for external use  1.2.1.6 Liquids for internal use  1.2.1.7 Medicinal gases  1.2.1.8 Other solid dosage forms  1.2.1.9 Pressurised preparations  1.2.1.10 Radionuclide generators  1.2.1.11 Semi-solids  1.2.1.12 Suppositories  1.2.1.13 Tablets  1.2.1.14 Transdermal patches  1.2.1.15 Other non-sterile medicinal product <free text > | | | | |
|  | *1.2.2 Batch certification* | | | | |
| **1.3** | **Biological investigational medicinal products** | | | | |
|  | *1.3.1 Biological medicinal products (list of product types)*  1.3.1.1 Blood products  1.3.1.2 Immunological products  1.3.1.3 Cell therapy products  1.3.1.4 Gene therapy products  1.3.1.5 Biotechnology products  1.3.1.6 Human or animal extracted products  1.3.1.7 Tissue engineered products | | | | |
| 1.3.1.8 Other biological medicinal products < | | | free text | > |
|  | *1.3.2 Batch certification (list of product types)*  1.3.2.1 Blood products  1.3.2.2 Immunological products  1.3.2.3 Cell therapy products  1.3.2.4 Gene therapy products  1.3.2.5 Biotechnology products  1.3.2.6 Human or animal extracted products  1.3.2.7 Tissue engineered products | | | | |
| 1.3.2.8 Other biological medicinal products < | | | free text | > |
| **1.4** | **Other investigational medicinal products or manufacturing activity** | | | | |
|  | *1.4.1 Manufacture of:*  1.4.1.1 Herbal products  1.4.1.2 Homoeopathic products | | | | |
| 1.4.1.3 Other < | free text | > | | |
|  | *1.4.2 Sterilisation of active substances/excipients/finished product:*  1.4.2.1 Filtration  1.4.2.2 Dry heat  1.4.2.3 Moist heat  1.4.2.4 Chemical  1.4.2.5 Gamma irradiation  1.4.2.6 Electron beam | | | | |
|  | *1.4.3 Other <free text>* | | | | |

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| **1.5** | **Packaging** | | |
|  | *1.5.1 Primary packing*  1.5.1.1 Capsules, hard shell  1.5.1.2 Capsules, soft shell  1.5.1.3 Chewing gums  1.5.1.4 Impregnated matrices  1.5.1.5 Liquids for external use  1.5.1.6 Liquids for internal use  1.5.1.7 Medicinal gases  1.5.1.8 Other solid dosage forms  1.5.1.9 Pressurised preparations  1.5.1.10 Radionuclide generators  1.5.1.11 Semi-solids  1.5.1.12 Suppositories  1.5.1.13 Tablets  1.5.1.14 Transdermal patches | | |
| 1.5.1.15 Other non-sterile medicinal products < | free text | > |
|  | *1.5.2 Secondary packing* | | |
| **1.6** | **Quality control testing** | | |
|  | *1.6.1 Microbiological: sterility* | | |
|  | *1.6.2 Microbiological: non-sterility* | | |
|  | *1.6.3 Chemical/Physical* | | |
|  | *1.6.4 Biological* | | |

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

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| **Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS** | | | |
| **2.1** | **Quality control testing of imported investigational medicinal products** | | |
|  | *2.1.1 Microbiological: sterility* | | |
|  | *2.1.2 Microbiological: non-sterility* | | |
|  | *2.1.3 Chemical/Physical* | | |
|  | *2.1.4 Biological* | | |
| **2.2** | **Batch certification of imported investigational medicinal products** | | |
|  | *2.2.1 Sterile Products*  2.2.1.1 Aseptically prepared  2.2.1.2 Terminally sterilised | | |
|  | *2.2.2 Non-sterile products* | | |
|  | *2.2.3 Biological products*  2.2.3.1 Blood products  2.2.3.2 Immunological products  2.2.3.3 Cell therapy products  2.2.3.4 Gene therapy products  2.2.3.5 Biotechnology products  2.2.3.6 Human or animal extracted products  2.2.3.7 Tissue engineered products | | |
| 2.2.3.8 Other biological medicinal products < | free text | > |
|  |  | | |
| **2.3** | **Other importation activities** | | |
|  | *2.3.1 Site of physical importation* | | |
| *2.3.2 Importation of intermediate which undergoes further processing* | | |
| *2.3.3 Biological active substance* | | |
| *2.3.4 Other <free text>* | | |

Any restrictions or clarifying remarks related to the scope of these Importing operations

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