EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Public Health and Risk Assessment
Pharmaceuticals

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Registration of Manufacturer, Importer or Distributor of Active Substance (used in Medicinal Products for Human Use)

Union Format for Registration of Manufacturer, Importer or Distributor of Active Substance (used in Medicinal Products for Human Use)

Title	**Union Format for Registration of Manufacturer, Importer or Distributor for Active Substance (used in Medicinal Products for Human Use)**
Date of adoption	May 2012
Date of entry into force	By 2 January 2013
Supersedes	New
Reason for revision	
Notes	

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An agency of the European Union

<Letterhead of Validating Authority>

Union Format for Registration[1] of Manufacturer, Importer or Distributor of Active Substances

1. Registration number

2. Name or corporate name of registrant

3. Permanent or Legal address of registrant

4. Address(es) of site(s) where registered activities take place

All relevant sites should be listed if not covered by separate registrations)

5. National legal basis of registration

6. Name of responsible officer of the competent authority of the member state validating the registration[2]

7. Signature[2]

8. Date

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the Union database or with the validating authority.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

[1] Without prejudice to any further national legislative requirements
[2] Optional

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SCOPE OF REGISTRATION

Name and address of the site:

1. MANUFACTURING OPERATIONS Active Substance(s):	
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>*
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>*
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>*
D	**Manufacture of sterile active substance (note Parts A, B & C, to be completed as applicable)**
	1. Aseptically prepared *2. Terminally sterilised*
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** *This section should be completed 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*

2. IMPORTATION AND DISTRIBUTION OPERATIONS			
A	**Importation** *(list all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)*		
	Active substance	*3rd country manufacturer (name & address)*	*Distributor (name & address)*
B	**Distribution**		
	Active substance(s) (list all active substances for which distribution operations apply)		

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

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Name of responsible officer of the competent authority of the member state validating the registration[1]

Signature[3]

[1] Optional