European Medicines Agency
Inspections

London, 3 March 2005
Doc. Ref. EMEA/INS/GMP/82801/2005

COMMUNITY BASIC FORMAT FOR MANUFACTURERS/ IMPORTERS AUTHORISATION

1. Authorisation number

2. Name of authorisation holder

3. Adress(es) of manufacturing/ importing site(s)
(All authorised sites should be listed if not covered by separate licences)

4. Legally registered address of authorisation holder

5. Scope of authorisation and dosage forms

ANNEX I and/ or ANNEX II
(Separate Annexes for different sites should be used if not covered by separate licences)

6. Legal basis of authorisation

7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8. Signature

9. Date

10. Annexes attached

Annex I and/or Annex II

Optional Annexes as required:
Annex 3 (Adresses of Contract Manufacturing Site(s)
Annex 4 (Adresses of Contract Laboratories)
Annex 5 (Name of Qualified Person)
Annex 6 (Name of responsible persons)
Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)
Annex 8 (Manufactured/ imported products authorised)

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ANNEX I

SCOPE OF AUTHORISATION (delete the sections that do not apply or use yes/no)
Name and adress of the site:

Human Medicinal Products
Veterinary Medicinal Products

AUTHORISED OPERATIONS
1.1 Manufacturing Operations (according to part 1)
1.2 Importation of Medicinal Products (according to part 2)

1 MANUFACTURING OPERATIONS	
- authorised manufacturing operations include total and partial manufacturing, batch release and certification, importation, storage and distribution of specified products and dosage forms unless informed to the contrary; - quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items; - if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.	
1.1	Sterile Products 1.1.1 aseptically prepared (list of dosage forms) 1.1.2 terminally sterilised (list of dosage forms) 1.1.3 batch certification only (list of dosage forms)
1.2	Non-sterile products (list of dosage forms) 1.2.1 batch certification only (list of dosage forms)
1.3	Biological medicinal products (product types should be specified under the relevant sections eg. allergens, antibodies, vaccines, viral vaccines, rDNA etc.) 1.3.1 Blood products 1.3.2 Immunological products (e.g. live, inactivated, viral, bacterial or other vaccines) 1.3.3 Cell therapy products (e.g. autologous, allogeneic, xenogeneic, viable, non-viable or others) 1.3.4 Gene therapy products (e.g. viral vectors, plasmids, cells or others) 1.3.5 Biotechnology products (e.g. produced in eukaryotic cells, in microbial cells) 1.3.6 Products of human, animal, plant or microbial extraction 1.3.7 batch certification only (list of product types from 1.3.1 – 1.3.6/dosage forms)
1.4	Other products or manufacturing activity (any other relevant manufacturing activity/ product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials, medicinal gases, herbal or homoeopathic products, bulk or partial manufacturing etc.)
1.5	Packaging only 1.4.1 Primary packing (list of product types/dosage forms) 1.4.2 Secondary packing
1.6	Quality Control testing (optional list of analysis techniques)

2 **IMPORTATION OF MEDICINAL PRODUCTS** - authorised importation activities without manufacturing activity - authorised importation activities include storage and distribution unless informed to the contrary	
2.1	Quality control testing of imported medicinal products (optional list of analysis techniques)
2.2	Batch certification of imported medicinal products 2.3.1 Sterile Products 2.3.1.1 aseptically prepared (list of dosage forms) 2.3.1.2 terminally sterilised (list of dosage forms) 2.3.2 Non-sterile products (list of dosage forms) 2.3.3 Biological products (product types should be specified under the relevant sections eg. allergens, antibodies, vaccines, viral vaccines, rDNA etc.) 2.3.3.1 Blood products 2.3.3.2 Immunological products (e.g. live, inactivated, viral, bacterial or other vaccines) 2.3.3.3 Cell therapy products (e.g. autologous, allogeneic, xenogeneic, viable, non-viable or others) 2.3.3.4 Gene therapy products (e.g. viral vectors, plasmids, cells or others) 2.3.3.5 Biotechnology products (e.g. produced in eukaryotic cells, in microbial cells) 2.3.3.6 Products of human, animal, plant or microbial extraction 2.3.4 Other products (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases; herbal or homoeopathic products etc.)

ANNEX II

SCOPE OF AUTHORISATION (delete the sections that do not apply or use yes/no)
Name and adress of the site:

Human Investigational Medicinal Products	for phase I, II, III clinical trials (optional)

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

1 MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS - authorised manufacturing operations include total and partial manufacturing, batch release and certification, importation, storage and distribution of specified products and dosage forms unless informed to the contrary; - quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items; - if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.	
1.1	Sterile Products 1.1.1 aseptically prepared (list of dosage forms) 1.1.2 terminally sterilised (list of dosage forms) 1.1.3 batch certification only (list of dosage forms)
1.2	Non-sterile products (list of dosage forms) 1.2.1 batch certification only (list of dosage forms)
1.3	Biological medicinal products (product types should be specified under the relevant chapters eg. allergens, antibodies, vaccines, viral vaccines, rDNA etc.) 1.3.1 Blood products 1.3.2 Immunological products (e.g. live, inactivated, viral, bacterial or other vaccines) 1.3.3 Cell therapy products (e.g. autologous, allogeneic, xenogeneic, viable, non-viable or others) 1.3.4 Gene therapy products (e.g. viral vectors, plasmids, cells or others) 1.3.5 Biotechnology products (e.g. produced in eukaryotic cells, in microbial cells) 1.3.6 Products of human, animal, plant or microbial extraction 1.3.7 batch certification only (list of product types/ dosage forms)
1.4	Other products or manufacturing activity (any other relevant manufacturing activity/ product type that is not covered above e.g. sterilisation of active substances, manufacturing of biological active starting materials, medicinal gases, herbal or homoeopathic products, bulk or partial manufacturing etc.)
1.5	Packaging only 1.4.1 Primary packing (list of product types/dosage forms) 1.4.2 Secondary packing
1.6	Quality Control testing (optional list of analysis techniques)

1.7	Blinding

2 IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS - authorised importation activities without manufacturing activity - authorised importation activities include storage and distribution unless indicated to the contrary	
2.1	Quality control testing of imported products (optional list of analysis techniques)
2.2	Batch certification 2.3.1 Sterile Products 2.3.1.1 aseptically prepared (list of dosage forms) 2.3.1.2 terminally sterilised (list of dosage forms) 2.3.2 Non-sterile products (list of dosage forms) 2.3.3 Biological products (authorised product types should be specified under the relevant chapters eg. allergens, antibodies, vaccines, viral vaccines, rDNA etc.) 2.3.3.1 Blood products 2.3.3.2 Immunological products (e.g. live, inactivated, viral, bacterial or other vaccines) 2.3.3.3 Cell therapy products (e.g. autologous, allogeneic, xenogeneic, viable, non-viable or others) 2.3.3.4 Gene therapy products (e.g. viral vectors, plasmids, cells or others) 2.3.3.5 Biotechnology products (e.g. produced in eukaryotic cells, in microbial cells) 2.3.3.6 Products of human, animal, plant or microbial extraction 2.3.4 Other products (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homoeopathic products etc.)