Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)

CHAPTER IX

MANUFACTURING AND IMPORT OF INVESTIGATIONAL MEDICINAL PRODUCTS AND AUXILIARY MEDICINAL PRODUCTS

Article 60

Scope of this Chapter

This Chapter shall apply to the manufacture and import of investigational medicinal products and auxiliary medicinal products.

Article 61

Authorisation of manufacturing and import

1 The manufacturing and import of investigational medicinal products in the Union shall be subject to the holding of an authorisation.

2 In order to obtain the authorisation referred to in paragraph 1, the applicant shall meet the following requirements:

a it shall have at its disposal, for manufacture or import, suitable and sufficient premises, technical equipment and control facilities complying with the requirements set out in this Regulation;

b it shall have permanently and continuously at its disposal the services of at least one qualified person who fulfils the conditions of qualification set out in Article 49(2) and (3) of Directive 2001/83/EC ('qualified person').

3 The applicant shall specify, in the application for authorisation, the types and pharmaceutical forms of the investigational medicinal product manufactured or imported, the manufacturing or import operations, the manufacturing process where relevant, the site where the investigational medicinal products are to be manufactured or the site in the Union to which they are to be imported, and detailed information concerning the qualified person.

4 Articles 42 to 45, and point (e) of Article 46 of Directive 2001/83/EC shall apply *mutatis mutandis* to the authorisation referred to in paragraph 1.

5 Paragraph 1 shall not apply to any of the following processes:

a re-labelling or re-packaging, where those processes are carried out in hospitals, health centres or clinics, by pharmacists or other persons legally authorised in the Member State concerned to carry out such processes, and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres or clinics taking part in the same clinical trial in the same Member State;

b preparation of radiopharmaceuticals used as diagnostic investigational medicinal products where this process is carried out in hospitals, health centres or clinics, by pharmacists or other persons legally authorised in the Member State concerned to carry

out such process, and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres or clinics taking part in the same clinical trial in the same Member State;

c the preparation of medicinal products referred to in points (1) and (2) of Article 3 of Directive 2001/83/EC for use as investigational medicinal products, where this process is carried out in hospitals, health centres or clinics legally authorised in the Member State concerned to carry out such process and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres or clinics taking part in the same clinical trial in the same Member State.

6 Member States shall make the processes set out in paragraph 5 subject to appropriate and proportionate requirements to ensure subject safety and reliability and robustness of the data generated in the clinical trial. They shall subject the processes to regular inspections.

Article 62

Responsibilities of the qualified person

1 The qualified person shall ensure that each batch of investigational medicinal products manufactured in or imported into the Union complies with the requirements set out in Article 63 and shall certify that those requirements are fulfilled.

2 The certification referred to in paragraph 1 shall be made available by the sponsor at the request of the Member State concerned.

Article 63

Manufacturing and import

1 Investigational medicinal products shall be manufactured by applying manufacturing practice which ensures the quality of such medicinal products in order to safeguard the safety of the subject and the reliability and robustness of clinical data generated in the clinical trial (‘good manufacturing practice’). The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to specify the principles and guidelines of good manufacturing practice and the detailed arrangements for inspection for ensuring the quality of investigational medicinal products, taking account of subject safety or data reliability and robustness, technical progress and global regulatory developments in which the Union or the Member States are involved.

In addition, the Commission shall also adopt and publish detailed guidelines in line with those principles of good manufacturing practice and revise them when necessary in order to take account of technical and scientific progress.

2 Paragraph 1 shall not apply to the processes referred to in Article 61(5).

3 Investigational medicinal products imported into the Union shall be manufactured by applying quality standards at least equivalent to those laid down pursuant to paragraph 1.

4 The Member States shall ensure compliance with the requirements of this Article by means of inspections.

Article 64

Modification of authorised investigational medicinal products

Articles 61, 62 and 63 shall apply to authorised investigational medicinal products only as regards any modification of such products not covered by a marketing authorisation.

Article 65

Manufacturing of auxiliary medicinal products

Where the auxiliary medicinal product is not authorised, or where an authorised auxiliary medicinal product is modified while such modification is not covered by a marketing authorisation, it shall be manufactured according to the good manufacturing practice referred to in Article 63(1) orto at least an equivalent standard, in order to ensure appropriate quality.

Status:
Point in time view as at 16/04/2014.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, CHAPTER IX.