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 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.

Status:
Point in time view as at 31/12/2020.

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, Article 61.