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 X

LABELLING

Article 66

Unauthorised investigational and unauthorised auxiliary medicinal products

1 The following information shall appear on the outer packaging and on the immediate packaging of unauthorised investigational medicinal products and unauthorised auxiliary medicinal products:

a information to identify contact persons or persons involved in the clinical trial;

b information to identify the clinical trial;

c information to identify the medicinal product;

d information related to the use of the medicinal product.

2 The information which is to appear on the outer packaging and immediate packaging shall ensure subject safety and reliability and robustness of the data generated in the clinical trial, while taking account of the design of the clinical trial, whether the products are investigational or auxiliary medicinal product, and whether they are products with particular characteristics.

The information which is to appear on the outer packaging and immediate packaging shall be clearly legible.

A list of information which is to appear on the outer packaging and immediate packaging is set out in Annex VI.

Article 67

Authorised investigational and authorised auxiliary medicinal products

1 Authorised investigational medicinal products and authorised auxiliary medicinal products shall be labelled:

a in accordance with Article 66(1); or

b in accordance with Title V of Directive 2001/83/EC.

2 Notwithstanding point (b) of paragraph 1, where the specific circumstances, provided for in the protocol, of a clinical trial so require in order to ensure the safety of the subject or the reliability and robustness of data generated in a clinical trial, additional particulars relating to the identification of the clinical trial and of the contact person shall appear on the outer packaging and the immediate packaging of authorised investigational medicinal products. A list of these additional particulars appearing on the outer packaging and immediate packaging is set out in section C of Annex VI.

Article 68

Radiopharmaceuticals used as investigational medicinal products or as auxiliary medicinal products for a medical diagnosis

Articles 66 and 67 shall not apply to radiopharmaceuticals used as diagnostic investigational medicinal products or as diagnostic auxiliary medicinal products.

The products referred to in the first paragraph shall be labelled appropriately in order to ensure the safety of the subject and the reliability and robustness of data generated in the clinical trial.

Article 69

Language

The language of the information on the label shall be determined by the Member State concerned. The medicinal product may be labelled in several languages.

Article 70

Delegated act

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in respect of amending Annex VI in order to ensure subject safety and the reliability and robustness of data generated in a clinical trial or to take account of technical progress.

Status:
Point in time view as at 31/01/2020.

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, CHAPTER X.