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.

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Point in time view as at 31/01/2020.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, Article 66.