Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance)

CHAPTER 4

SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

Article 10

Summary of product characteristics

By way of derogation from Article 11 of Directive 2001/83/EC, the summary of the product characteristics for advanced therapy medicinal products shall contain the information listed in Annex II to this Regulation, in the order indicated therein.

Article 11

Labelling of outer/immediate packaging

By way of derogation from Articles 54 and 55(1) of Directive 2001/83/EC, the particulars listed in Annex III to this Regulation shall appear on the outer packaging of advanced therapy medicinal products or, where there is no outer packaging, on the immediate packaging.

Article 12

Special immediate packaging

In addition to the particulars mentioned in Article 55(2) and (3) of Directive 2001/83/EC, the following particulars shall appear on the immediate packaging of advanced therapy medicinal products:

(a) the unique donation and product codes, as referred to in Article 8(2) of Directive 2004/23/EC;

(b) in the case of advanced therapy medicinal products for autologous use, the unique patient identifier and the statement ‘For autologous use only’.

Article 13

Package leaflet

1 By way of derogation from Article 59(1) of Directive 2001/83/EC, the package leaflet for an advanced therapy medicinal product shall be drawn up in accordance with the summary of product characteristics and shall include the information listed in Annex IV to this Regulation, in the order indicated therein.

2 The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.

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Point in time view as at 31/01/2020.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1394/2007 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.