ANNEX VI

LABELLING OF INVESTIGATIONAL MEDICINAL PRODUCTS AND AUXILIARY MEDICINAL PRODUCTS

A.UNAUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

A.1. **General rules**

1. The following particulars shall appear on the immediate and the outer packaging:

(a) name, address and telephone number of the main contact for information on the product, clinical trial and emergency unblinding; this may be the sponsor, contract research organisation or investigator (for the purpose of this Annex this is referred to as the ’main contact’);

(b) the name of the substance and its strength or potency, and in the case of blind clinical trials the name of the substance is to appear with the name of the comparator or placebo on the packaging of both the unauthorised investigational medicinal product and the comparator or placebo;

(c) pharmaceutical form, route of administration, quantity of dosage units;

(d) the batch or code number identifying the contents and packaging operation;

(e) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;

(f) the subject identification number and/or the treatment number and, where relevant, the visit number;

(g) the name of the investigator (if not included in (a) or (e));

(h) directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);

(i) ’For clinical trial use only’ or similar wording;

(j) the storage conditions;

(k) period of use (expiry date or re-test date as applicable), in month and year format and in a manner that avoids any ambiguity; and

(l) ’Keep out of reach of children’, except when the product is for use in trials where the product is not taken home by subjects.

2. Symbols or pictograms may be included to clarify certain information mentioned above. Additional information, warnings or handling instructions may be displayed.

3. The address and telephone number of the main contact shall not be required to appear on the label if subjects have been given a leaflet or card which provides these details and have been instructed to keep this in their possession at all times.

A.2. **Limited labelling of immediate packaging**

A.2.1. *Immediate and outer packaging provided together*

4. When the product is provided to the subject or the person administering the medicinal product in an immediate packaging and outer packaging intended to remain together, and the outer packaging carries the particulars listed in section A.1., the following

particulars shall appear on the immediate packaging (or any sealed dosing device that contains the immediate package):

(a) name of the main contact;

(b) pharmaceutical form, route of administration (may be excluded for oral solid dose forms), quantity of dosage units and, in the case of clinical trials which do not involve the blinding of the label, the name/identifier and strength/potency;

(c) batch and/or code number identifying the contents and packaging operation;

(d) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;

(e) the subject identification number and/or the treatment number and, where relevant, the visit number; and

(f) period of use (expiry date or re-test date as applicable), in month and year format and in a manner that avoids any ambiguity.

A.2.2. *Small immediate packaging*

5. If the immediate packaging takes the form of blister packs or small units such as ampoules on which the particulars required in section A.1. cannot be displayed, the outer packaging provided shall bear a label with those particulars. The immediate packaging shall contain the following:

(a) name of the main contact;

(b) route of administration (may be excluded for oral solid dose forms) and, in the case of clinical trials which do not involve the blinding of the label, the name/identifier and strength/potency;

(c) batch or code number identifying the contents and packaging operation;

(d) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;

(e) the subject identification number/treatment number and, where relevant, the visit number; and

(f) period of use (expiry date or re-test date as applicable), in month and year format and in a manner that avoids any ambiguity.

B. UNAUTHORISED AUXILIARY MEDICINAL PRODUCTS

6. The following particulars shall appear on the immediate and the outer packaging:

(a) name of the main contact;

(b) name of the medicinal product, followed by its strength and pharmaceutical form;

(c) statement of the active substances expressed qualitatively and quantitatively per dosage unit;

(d) batch or code number identifying the contents and packaging operation;

(e) clinical trial reference code allowing identification of the clinical trial site, investigator and subject;

(f) directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);

(g) ’For clinical trial use only’ or similar wording;

(h) the storage conditions; and

(i) period of use (expiry date or retest date as applicable).

C. ADDITIONAL LABELLING FOR AUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

7. In accordance with Article 67(2), the following particulars shall appear on the immediate and the outer packaging:

(a) name of the main contact;

(b) clinical trial reference code allowing identification of the clinical trial site, investigator, sponsor and subject;

(c) ’For clinical trial use only’ or similar wording.

D. REPLACING OF INFORMATION

8. The particulars listed in sections A, B and C, other than those particulars listed in paragraph 9, may be omitted from the label of a product and made available by other means, for example by use of a centralised electronic randomisation system, use of a centralised information system, provided that the safety of the subject and the reliability and robustness of data are not compromised. This shall be justified in the protocol.

9. The particulars referred to in the following points shall not be omitted from the label of a product:

(a) paragraph 1, points (b), (c), (d), (f), (j) and (k);

(b) paragraph 4, points (b), (c), (e), and (f);

(c) paragraph 5, points (b), (c), (e), and (f);

(d) paragraph 6, points (b), (d), (e), (h), and (i).

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, ANNEX VI.