EUROPEAN
COMMISSION

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ANNEX

ANNEX

to the

COMMISSION DELEGATED REGULATION (EU) .../...

amending Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products for human use

ANNEX

Annex VI to Regulation (EU) No 536/2014 is amended as follows:

(1) Section A is amended as follows:

(a) in Section A.2.1.4, points (e) and (f) are replaced by the following:

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

(b) in Section A.2.2.5, points (e) and (f) are replaced by the following:

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

(2) Section B is amended as follows:

(a) the number of point "6." is replaced by "6.1.";

(b) the following paragraphs B.6.2 and B.6.3 are added:

"6.2. In the case where the immediate and outer packaging are intended to remain together, the outer package shall carry the particulars listed in section B.6.1. The immediate packaging shall carry the particulars listed in section B.6.1 with the exception of the period of use (expiry date or re-test date as applicable) that can be omitted."

"6.3. If the immediate packaging takes the form of blister packs or small units such as ampoules, on which the particulars listed in section B.6.1 cannot be displayed, an outer packaging shall be provided bearing a label with those particulars. The immediate packaging shall contain the particulars listed in section B.6.1 with the exception of the period of use (expiry date or re-test date as applicable) that can be omitted.";

(3) Section D is amended as follows:

(a) in section D.9 points (b), (c) and (d) are replaced by the following:

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

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

(d) paragraph 6.1, points (b), (d), (e) and (h);"

(b) in section D.9 the following point (e) is added:

"(e) paragraph 6.1, point (i), with the exception of cases in which the period of use (expiry date or re-test date as applicable) can be omitted from the inner packaging in accordance with sections B.6.2 and B.6.3."