Annex 13 Labeling Requirements for the EU

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Annex 13 Labeling

§ 26 Listing of 11 labeling particulars that should appear on labels

allows for absence if justified (e.g., IRT)

§ 27 Main contact address/phone can be provided on patient leaflet or card instead of label

§ 28 Label particulars in official language(s) of trial countries

Annex 13 Labeling

§ 29 Reduced list of 5 particulars that should appear on primary packages intended to remain together with secondary packages labeled with all 11 particulars

§ 30 Reduced list of 5 particulars that should appear on small primary packages, such as blisters and ampoules; secondary packages labeled with all 11 particulars should be provided.

Annex 13 Labeling

§ 31 Symbols/pictograms may be used; additional information, warnings, and/or handling instructions may be added

§ 32 Labeling of approved commercial products should not be obscured:

- add name of main contact and trial reference code

§ 33 Over labeling procedure to change the use-by date

Annex 13 Labeling

a) Main contact name, address, phone
b) Dosage form, route, quantity (If OL, name/strength)
c) Batch number
d) Trial reference code
e) Subject ID number
f) Investigator name
g) Directions for use
h) “For clinical trial use only”
i) Storage conditions
j) Period of use
k) ‘Keep out of reach of children’

Annex 13 Labeling

§ 26 Table I summarizes the contents of Articles 26-30 that follow. Labeling should comply with the requirements of Directive 2003/94/EC. The following information should be included on labels, unless its absence can be justified, e.g. use of a centralised randomization system:

a) Name, address and telephone number of the sponsor, contract research organization or investigator (the main contact for information on the product, clinical trial and emergency unblinding);

b) pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the name/identifier and strength/potency;

c) the batch and/or code number to identify the contents and packaging operation;

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

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

f) the name of the investigator (if not included in (a) or (d);

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

h) "For clinical trial use only" or similar wording;

i) the storage conditions;

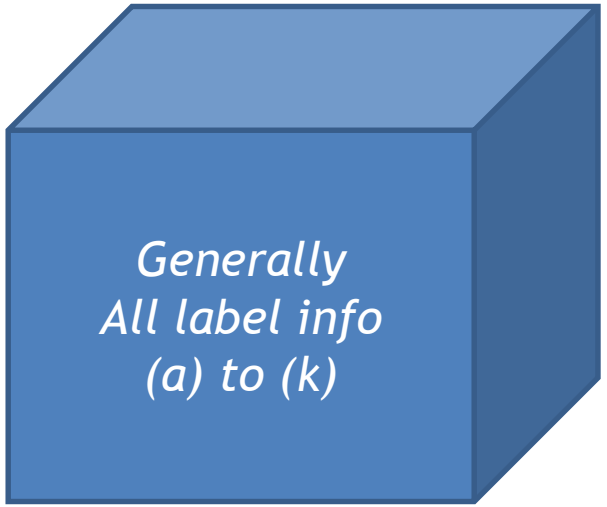
j) period of use (use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity; and

k) "Keep out of reach of children", except when the product is for use in trials where the product is not taken home by subjects

Source: http://ec.europa.eu/health/files/eudralex/vol-4/2009_06_annex13.pdf

§26 General Case

Outer/Secondary Packaging



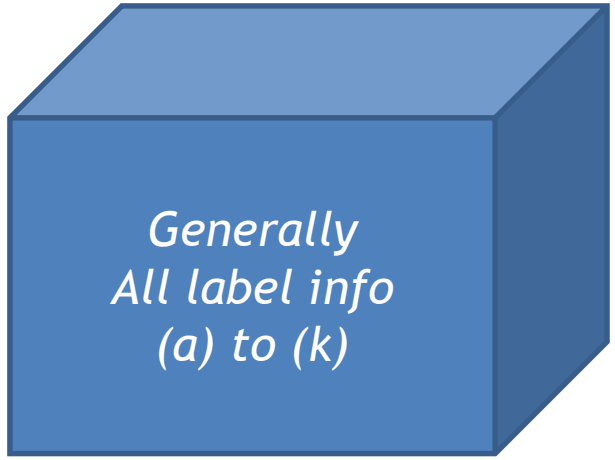
Immediate/Primary Packaging

Generally all label info (a) to (k)

§29 Primary/Secondary Packaging Remain Together

If limited labeling of immediate packaging is desired and both packaging remains together throughout use

Outer/Secondary Packaging



Immediate/Primary Packaging

(a) Contact name

(b) Dosage form; Route; Qty; if OL, name/strength

(c) Batch/code no.

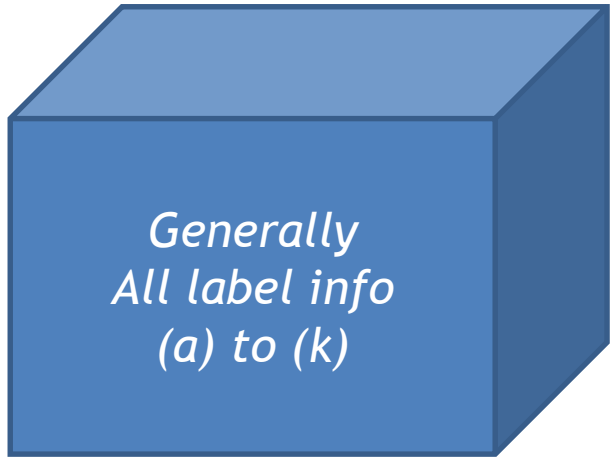
(d) Trial code

(e) Subject ID (visit no.)

§30 Small Primary Packaging provided with Secondary Packaging

If immediate packaging is too small to hold all information
e.g., blisters or ampoules

Outer/Secondary Packaging



Blisters or Ampoules

(a) Contact name

(b) Route
If OL, name/strength

(c) Batch/code no.

(d) Trial code

(e) Subject ID (visit no.)

Example Single Panel Label

d Protocol No.: EXT901-202
EudraCT No.: 2016-123456-78

f Investigator Name: _____ Subject No.: _____ e

b Contents: 20 tablets EXT-901 50 mg

g **Directions: Take medication by mouth as directed by your physician.**

i Store below 30°C. Protect from light.

h **For Clinical Trial Use Only. Keep Out of Reach of Children** k

j Expiry: 01/2017 Lot No.: 987654 c

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