

Paragraph	Label content	Inner and outer packaging label	Paragraph	Label content	Inner packaging label IF: 4 Immediate and outer packaging provided together or 5 Small immediate packaging
1(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');	L/S	4(a) 5(a)	name of the main contact;	L/S
1(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;	L			
1(c)	pharmaceutical form, route of administration, quantity of dosage units;	L	4(b) 5(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; 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;	L
1(d)	the batch or code number identifying the contents and packaging operation;	L	4(c) 5(c)	batch and/or code number identifying the contents and packaging operation;	L
1(e)	a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;	L/S	4(d) 5(d)	a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;	L/S
1(f)	the subject identification number and/or the treatment number and, where relevant, the visit number;	L	4(e) 5(e)	the subject identification number and/or the treatment number and, where relevant, the visit number; and	L
1(g)	the name of the investigator (if not included in (a) or (e));	L/S			
1(h)	directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);	L/S			
1(i)	'For clinical trial use only' or similar wording;	L/S			
1(j)	the storage conditions;	L			
1(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	4(f) 5(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.	L
1(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.	L/S			

UNAUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

Paragraph	Label content	Inner and outer packaging label	Paragraph	Label content	Inner packaging label IF: 4 Immediate and outer packaging provided together or 5 Small immediate packaging
1(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');	L/S	4(a) 5(a)	name of the main contact;	L/S
1(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;	L			
1(c)	pharmaceutical form, route of administration, quantity of dosage units;	L	4(b) 5(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; 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;	L
1(d)	the batch or code number identifying the contents and packaging operation;	L	4(c) 5(c)	batch and/or code number identifying the contents and packaging operation;	L
1(e)	a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;	L/S	4(d) 5(d)	a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;	L/S
1(f)	the subject identification number and/or the treatment number and, where relevant, the visit number;	L	4(e) 5(e)	the subject identification number and/or the treatment number and, where relevant, the visit number; and	L
1(g)	the name of the investigator (if not included in (a) or (e));	L/S			
1(h)	directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);	L/S			
1(i)	'For clinical trial use only' or similar wording;	L/S			
1(j)	the storage conditions;	L			
1(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	4(f) 5(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.	L
1(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.	L/S			

UNAUTHORISED AUXILIARY MEDICINAL PRODUCTS AND ADDITIONAL LABELLING FOR AUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

Paragraph	Label content	Inner and outer packaging label IF unauthorised auxiliary medicinal products	Paragraph	Label content	Inner and outer packaging label IF additional labelling for authorised IMP
6(a)	name of the main contact;	L/S	7(a)	name of the main contact;	L
6(b)	name of the medicinal product, followed by its strength and pharmaceutical form;	L			
6(c)	statement of the active substances expressed qualitatively and quantitatively per dosage unit;	L/S			
6(d)	batch or code number identifying the contents and packaging operation;	L			
6(e)	clinical trial reference code allowing identification of the clinical trial site, investigator and subject;	L	7(b)	clinical trial reference code allowing identification of the clinical trial site, investigator, sponsor and subject;	L
6(f)	directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);	L/S			
6(g)	'For clinical trial use only' or similar wording;	L/S	7(c)	'For clinical trial use only' or similar wording.	L
6(h)	the storage conditions; and	L			
6(i)	period of use (expiry date or retest date as applicable).	L			

L: Mandatory Label text

L/S: 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.

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UNAUTHORISED AUXILIARY MEDICINAL PRODUCTS AND ADDITIONAL LABELLING FOR AUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

Paragraph	Label content	Inner and outer packaging label IF unauthorised auxiliary medicinal products	Paragraph	Label content	Inner and outer packaging label IF additional labelling for authorised IMP
6(a)	name of the main contact;	L/S	7(a)	name of the main contact;	L
6(b)	name of the medicinal product, followed by its strength and pharmaceutical form;	L			
6(c)	statement of the active substances expressed qualitatively and quantitatively per dosage unit;	L/S			
6(d)	batch or code number identifying the contents and packaging operation;	L			
6(e)	clinical trial reference code allowing identification of the clinical trial site, investigator and subject;	L	7(b)	clinical trial reference code allowing identification of the clinical trial site, investigator, sponsor and subject;	L
6(f)	directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);	L/S			
6(g)	'For clinical trial use only' or similar wording;	L/S	7(c)	'For clinical trial use only' or similar wording.	L
6(h)	the storage conditions; and	L			
6(i)	period of use (expiry date or retest date as applicable).	L			

L: Mandatory Label text

L/S: 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

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