TABLE 1: SUMMARY OF LABELLING DETAILS (§26 TO 30)

a) name, address and telephone number of the sponsor, contract research organisation 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.

(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.

GENERAL CASE
For both the primary and secondary packaging (§26)

Particulars a[4] to k

PRIMARY PACKAGE
Where primary and secondary packaging remain together throughout (§29)[5]

a[6] b[7] c d e

PRIMARY PACKAGE
Blisters or small packaging units (§30)[5]

a[6] b[7,8] c d e

[4] The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not appear on the label where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times (§ 27).

[5] When the outer packaging carries the particulars listed in Article 26.

[6] The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not be included.

[7] Route of administration may be excluded for oral solid dose forms.

[8] The pharmaceutical dosage form and quantity of dosage units may be omitted.