**Annex 13 labelling requirements for CTIMPs**

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| 1 | Name, address and telephone number of Sponsor or investigator (the main contact for information on the product, clinical trial and emergency unblinding) |
| 2 | Pharmaceutical dosage form, route of administration, quantity of dosage units (and name / identifier and strength / potency in case of open trial) |
| 3 | The batch and/or code number to identify the contents and packaging operation |
| 4 | Trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere |
| 5 | Trial subject identification number/treatment number and where relevant the visit number |
| 6 | Name of investigator (if not included in 1 or 4) |
| 7 | Directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject of person administering the product) |
| 8 | “For clinical trial use only” or similar wording |
| 9 | The storage conditions |
| 10 | The 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 |
| 11 | “Keep out of reach of children” except when the product is for use in trials where the product is not taken home by subjects |