

Records of Supplies of Unlicensed medicinal products

This guidance has been produced by the RPSGB to help support clinical governance in pharmacy. It does NOT apply to licensed products used outside the clinical indications of their licence i.e. “off-label”.

Unlicensed medicinal products should only be used when a licensed alternative is not available.

The MHRA requires you to keep records of supplies of unlicensed medicinal products and preparations (those which do not have a product licence or marketing authorisation in the UK) including “specials”, extemporaneously prepared medicines purchased from an appropriately licensed supplier or preparations imported via an appropriately licensed company.

Any person selling or supplying such a product from a licensed "specials" manufacturer or licensed importing company must keep the following record for 5 years:

- The source of the product;
- The person to whom the product was sold or supplied;
- The date the product was supplied;
- The quantity of each sale or supply;
- The batch number of the product;
- Details of any adverse reactions to the product, which becomes known.

These records must be made available for inspection by the licensing authority.

Any adverse reactions must be reported to the MHRA.

If the product is in response to a prescription, the records must also include the patient's details, prescription details and the date of dispensing.

The specification of the product should be agreed with the supplier and should include strength, formulation and excipients. A copy of this specification should be kept and documentation should also be requested to enable verification of this specification when received.

Also refer to Records of supplies of Extemporaneous Preparations

Top tips for supply of unlicensed medicinal products:

- Most specials manufacturers now supply a certificate of analysis, a certificate of conformity or a similar information sheet with the product. A dispensing label and patient address label can be attached to this sheet along with a reference number. This can be filed as an adequate audit trail. This certificate must include the batch number and expiry details of the product.
- Ensure any calculations are double checked for accuracy.
- Ensure the right strength has been supplied as there may be differences between suppliers.
- Ensure the excipients in the preparation are appropriate e.g. avoid presence of alcohol for young children.
- For imported preparations product licensing information should be supplied in English.
- The onus is on the purchaser to have, or to agree, a specification for the unlicensed product. The specification should be appropriate to the clinical needs of the patient and agreed with the prescriber if necessary. It should form part of the order for the medicine. A copy of the specification should be kept in the pharmacy.