



Royal Pharmaceutical Society Of Great Britain

Legal and Ethical Advisory Service Fact Sheet: Six

Monitored dosage systems and Compliance aids

Introduction

This is an information sheet designed to be of assistance to pharmacists. The contents have not been issued as Council policy, but it is intended as a resource which pharmacists may use to review their practices and policies. It is not intended to interpret the law, the Code of Ethics or Council policies, but offers common sense guidance on issues of topical interest.

If any queries should arise, please do not hesitate to contact the Legal and Ethical Advisory Service on 020 7572 2308. Emails may be sent to leadvice@rpsgb.org

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In addition, it should be remembered that the issues addressed in this fact sheet will be within the enforcement jurisdiction of the Medicines and Healthcare products Regulatory Agency. Contact details can be found in the Appendix at the end of this fact sheet.

1. General guidance

Where the term 'compliance aid' is referred to in this fact sheet, please note that this includes monitored dosage systems (MDS).

The compliance aid should be filled directly from stock containers in accordance with a valid prescription. It is possible to place controlled drugs into compliance aids, so long as appropriate enquiries have been made as to the stability of the product in such a container. Where a controlled drug (CD) requires safe custody, the compliance aid must be stored in the CD cabinet prior to collection. Where an entry in the CD register is required, this should be made at the time of supply.

Compliance aids are subject to the labelling and leaflet requirements of "dispensed medicinal products" and therefore are required to be labelled in accordance with the legislation pertaining to the type of product. For dispensed relevant medicinal products the legislation is the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, as amended and for dispensed non-relevant medicinal products the legislation is the Labelling Regulations 1976, as amended. It may be difficult to comply with the legislation when using some systems where there may be inadequate space for the labels to be affixed. However, not labelling a dispensed medicine, in accordance with the relevant legislation, may constitute an offence.

The patient should be advised that if the contents of the compliance aid are spilt, the patient should not try to put the medication back into the compliance aid, but should return to the pharmacy with the original containers. The patient should be advised that no other person must re-pack or tamper with the supply after dispensing from the pharmacy.

The Society would not recommend that a pharmacist re-dispenses medicines originally dispensed elsewhere, into compliance aids. The pharmacist who fills and checks a compliance aid containing medicines which had originally been dispensed elsewhere, would become liable for re-dispensing them. If a pharmacist was to use medicines dispensed by another pharmacy to fill a compliance aid, it would be difficult for them to be certain of the quality and safety of those products and the pharmacist would be unaware of the storage conditions the medicines would have been kept in by the patient before bringing them in for re-dispensing. There would therefore be a risk of errors arising by following this procedure. Should there be a defect in the products, the pharmacist who had re-packaged these medicines would have a degree of responsibility for the supply and would have to justify the reasons for carrying out this activity.

Additionally the pharmacist re-dispensing would not have sight of the doctor's original prescription and would therefore be dispensing against the labels produced by the original supplying pharmacy. Once again the re-dispensing pharmacist would be reliant on the accuracy of the original pharmacy's dispensing, and labelling. If the original pharmacy had made an error, the re-dispensing pharmacist would have no way of knowing this without the authorising prescription to check against and would be perpetuating the error.

2. Labelling

The guidance for the labelling of compliance aids is divided into two sections. The first section concerns the labelling of compliance aids where there is adequate space for dispensing labels to be affixed. The second section deals with compliance aids where there is insufficient space for dispensing labels.

a). Labelling of compliance aids where there is space for a dispensing label to be affixed

A dispensing label must be generated for each item dispensed into the compliance aid and this label attached directly to the container. The requirements for labelling a dispensed medicinal product require the date of dispensing to be on the label and therefore any old labels must be removed from the container. On each occasion that a medication is dispensed into the container, a new label must be affixed.

It is recommended that a card or similar, providing details of physical appearance of the contents of the compliance aid is kept with it, to facilitate identification.

b). Labelling of compliance aids where there is insufficient space for a label to be affixed

It is only where patient care would otherwise be undermined, that a pharmacist should contemplate filling compliance aids where there is inadequate room for a suitable label.

Where there is no space on the compliance aid to affix the dispensing labels to allow them to be read clearly, the following procedure should be followed:

(i) Dispense the medication in accordance with the prescription into normal dispensing containers and label fully, as a dispensed medicinal product.

(ii) At the patient's request, decant the dispensed medicine into the compliance aid, in accordance with the dosage instructions on the prescription. Label the compliance aid with "see original dispensing containers, dispensed on (the date of dispensing) from (Pharmacy name)" for dosage instructions.

(iii) The pharmacy must keep records to ensure that an audit trail exists to identify details of the medicines decanted and dispensed into the compliance aid.

3. Patient Information Leaflets

It is a requirement of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, as amended (in accordance with the related European Directive) that a patient information leaflet (PIL) is provided on each occasion a relevant medicinal product is supplied. Pharmacists must therefore ensure that a PIL is supplied with every dispensed medicinal product included in a compliance aid.

Where a prescription is to be dispensed into compliance aids which will be supplied to a patient in instalments, e.g. on a weekly basis, a PIL must be supplied for each product dispensed at every instalment. This is because there may have been changes made to the PIL accompanying the medicine since the previous instalment was supplied.

As the most important reason for supplying a leaflet is patient information and patient safety, every effort should be made to supply a leaflet. In the first instance, pharmacists should

contact manufacturers directly to try and obtain additional copies of leaflets. Pharmacists should also be aware of web based versions of leaflets. Leaflets are available through the Electronic Medicines Compendium. (www.emc.medicines.org.uk). These could be printed out and supplied by pharmacists with dispensed medicinal products to ensure compliance with the Regulations. As a last resort, pharmacists may have to consider photocopying manufacturers' leaflets if practicable. This could breach copyright, but pharmacists may be left with no alternative. Pharmacists may therefore wish to seek independent legal advice before undertaking any photocopying. In any event, copies must only be supplied with that manufacturer's product and care must be taken to ensure that only the latest version of a leaflet is copied.

4. Filling of compliance aids

Practice guidance regarding the filling of MDS and compliance aids is currently being revised and will be integrated into new guidance relating to care homes.

5. Further information

For further information regarding the requirements of the pharmacy contract, in England and Wales, and the Disability Discrimination Act 1995 (DDA), please contact the Pharmaceutical Services Negotiating Committee (see Appendix).

In Scotland, there is no specific linked provision to the DDA. There is, however, the Medicines Compliance Support Initiative under which an assessment should be carried out before a compliance aid is provided. This is provided for all eligible patients not purely those coming forward because of DDA issues. For further information, please contact Community Pharmacy Scotland (see Appendix).

In addition, an article was published in the Pharmaceutical Journal on 21st January 2006 (Vol. 276, pp 75-81) regarding the stability of medicines in compliance aids. This article can be viewed using the link below:

http://www.pjonline.com/pdf/articles/pj_20060121_stable.pdf

Further information on the stability of medicines in compliance aids can also be obtained directly from manufacturers and a variety of other reference sources.

APPENDIX

The Medicines and Healthcare products Regulatory Agency

Tel: 020 7084 2000

Website: www.mhra.gov.uk

Email: info@mhra.gsi.gov.uk

The Pharmaceutical Service Negotiating Committee

Tel: 01296 432 823

Website: www.psn.org.uk

Email: psnc@psnc.org.uk

Community Pharmacy Scotland

Tel: 0131 467 7766

Website: <http://www.communitypharmacyscotland.org.uk/>