

# Maintaining running balances of stock in Controlled Drug registers

In the light of the Shipman Inquiry, it is to become mandatory for health care professionals to maintain running balances of stock in Controlled Drug registers.

The following guidance has been prepared by the Royal Pharmaceutical Society's **Practice and Quality Improvement Directorate**

Following the Government's response to the fourth report of the Shipman Inquiry, pharmacists and other health care professionals who supply Controlled Drugs are being encouraged to maintain a running balance of stock in their Controlled Drug registers as a matter of good practice.

It is intended that running balances will eventually become a mandatory requirement for all Controlled Drug registers in about 2007. In advance of this, pharmacists are advised to begin to review their current procedures and develop standard operating procedures to maintain running balances.

Running balances of Controlled Drug stock have been common practice in hospitals for a number of years and recently running balances have also been maintained by some community pharmacies. To clarify the legal situation on the maintenance of running balances, the Home Office has stated that it is content for persons to include a running balance in a Controlled Drug register provided that the specific requirements of the Misuse of Drugs Regulations are adhered to.

## Controlled Drug registers

The Misuse of Drugs Regulations 2001, as amended, state the fields of information that must be recorded for all Schedule 1 and 2 Controlled Drugs supplied or received. Full details of these requirements can be found in Section 1.2.11 of 'Medicines, ethics and practice: a guide for pharmacists'. Pharmacists are now advised that in addition to recording the information required by legislation, it is good practice to maintain a running balance of such Controlled Drug stock.

Some community pharmacies already record running balances. The National Pharmaceutical Association is in the process of revising the format of the Controlled Drug register it produces to allow running balances to be maintained. The new format is also likely to include space to record other details that are expected to become mandatory in the future.

Pharmacists who wish to revise their current register layout to incorporate running balances must ensure that they continue to comply with the following legislative requirements for registers, namely

- The minimum record requirements, as defined in the Misuse of Drugs Regulations 2001, must be recorded
- Entries must be in chronological sequence
- A separate part of the register must be used for each class of drug

- The class of drug must be specified at the head of each page
- The register must not be used for other purposes
- The register must be kept at the premises to which it relates
- Entries must be made on the day of transaction or on the next day following.

If desired, separate parts of the register can be used for different drugs or strengths of drug comprised within a class of drug (note: this is recommended to help ensure running balances are effectively maintained and monitored)

## Maintaining running balances

It is the pharmacist's responsibility to ensure that records are made in the Controlled Drug register and running balances are maintained in line with the pharmacy's standard operating procedures.

The record of drugs obtained or supplied must be made on the day of the transaction or the next day following. The running balance of drug remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals. Although there is no mandatory requirement for how often stock should be reconciled with theoretical balances, the aim of running balances is to ensure irregularities are identified as quickly as possible.

When developing standard operating procedures for the reconciliation process, consideration should be given to a number of factors, including the volume and frequency of CD dispensing, dispensary workflow and staffing arrangements. More frequent reconciliation may be required in pharmacies that dispense a high volume of CDs, or in pharmacies where there is not a regular pharmacist in charge.

Regular reconciliation — eg, at the time of dispensing or at the end of each day — will allow any errors or discrepancies to be more easily identified. The Society advises that the running balance should normally be checked with the physical amount of drug each week. If discrepancies arise, more frequent reconciliation should be undertaken until the problem is resolved.

The task of reconciling stock could be delegated to an appropriately trained member of staff, but pharmacists will retain responsibility for overseeing this process and ensuring that appropriate action is taken if discrepancies arise. To help provide a verifiable audit trail it is advisable to initial and date the register each time stock is reconciled. Where one person is

routinely responsible for reconciling stock it is advised that another appropriately trained person periodically review their work.

## Dealing with discrepancies

Standard operating procedures should clearly define the action that should be taken if a discrepancy between the theoretical and actual balance of stock arises, stating, for example, what action the pharmacist should take, when and how the pharmacy owner or superintendent pharmacist should be notified and what records should be made. Pharmacists who become aware of discrepancies should ensure that steps are taken to try to establish a reason for the discrepancy. Checks should be made against prescription details, patient medication records, wholesaler invoices and any other appropriate records. Once resolved, a note should be made in the register correcting the discrepancy in the balance. Such amendments should be by a dated marginal note or footnote.

It is advisable to keep appropriate records of the action taken when discrepancies arise. Pharmacy owners and superintendent pharmacists are also advised to ensure that systems are in place to allow effective monitoring of records so that patterns or recurring reasons for discrepancies can be identified.

If, after investigation, the discrepancy cannot be resolved or the discrepancy is such that there is immediate cause for concern, the police and/or a Society inspector or appropriate investigating authority should be notified.

## Liquid preparations

It is recognised that discrepancies are most likely to arise with liquid preparations. Most original packs of liquid preparations have some degree of overage. This can vary from manufacturer to manufacturer and between different batches from the same manufacturer. The Home Office has confirmed that manufacturers' overage can become part of pharmacy stock, provided appropriate records are made to account for this, ie, the overage should be entered in the obtained section of the register.

Discrepancies may also arise as a result of the measurement process or spillage. Where a pharmacist can be satisfied that any overage or loss of liquid preparations are a result of manufacturer's overage, measurement (manual or electronic) or spillage, a record should be made of this and the running balance corrected to take account of the overage or loss. Whenever possible, spillages should be witnessed and the record initialled by a second person.