

# Developing and implementing standard operating procedures for dispensing

## 1. Background and Scope

From January 1, 2005, the Royal Pharmaceutical Society is to introduce a requirement for pharmacists to put in place and operate written Standard Operating Procedures (SOPs) within individual pharmacies covering the dispensing process, including the transfer of prescribed items to patients. The requirement will apply to both the hospital and community sectors and will cover all of the activities which occur from the time that prescriptions are received in the pharmacy or by a pharmacist until medicines or other prescribed items have been collected or transferred to the patient.

This document sets out the areas of the dispensing process for which SOPs will be required and provides guidance on how to write them.

### 1.1 Why the requirement is being introduced

To comply with clinical governance requirements, healthcare professions are being required to put in place strategies for risk management and harm minimisation. The Society's requirement is part of a process of assuring clinical governance in the pharmacy setting. Pharmacists will continue to be accountable for the dispensing process, but in developing and working to SOPs will be able to examine/benchmark current practice and ensure that systems of practice operating within pharmacies are safe. SOPs should allow for the continual improvement of standards of service and provide evidence of commitment to protecting patients. In addition, changes in legislation arising from the Health Act 1999 may lead to the establishment of procedures for regulating those working in support of a profession and SOPs will go some way to address this.

For all of the reasons outlined above, it is recommended that pharmacists develop and implement SOPs ahead of the requirement to do so in 2005.

### 1.2 What is a standard operating procedure?

While most hospital and industrial pharmacists, and some community pharmacists, particularly those who work for multiples, will be familiar with SOPs, for many the concept will be new. Quite simply, a standard operating procedure specifies in writing what should be done, when, where and by whom.

### 1.3 The benefits of SOPs

- SOPs help to assure the quality and consistency of the service;
- SOPs help to ensure that good practice is achieved at all times;
- SOPs provide an opportunity to fully utilise the expertise of all members of the pharmacy team;
- SOPs enable pharmacists to delegate and may free up time for other activities;
- SOPs help to avoid confusion over who does what (role clarification);
- SOPs provide advice and guidance to locums and part-time staff;
- SOPs are useful tools for training new members of staff;
- SOPs provide a contribution to the audit process.

#### 1.4 Professional accountability for tasks that are delegated

The Society's Code of Ethics<sup>1</sup> states that pharmacists assuming responsibility for any function whether as an employee, locum, adviser or otherwise are professionally accountable for all decisions to supply a medicine and offer advice. As part of this accountability they must ensure that if any tasks are to be delegated, they are delegated to persons competent to perform them.

In future, pharmacists who delegate parts of the dispensing process to others will be required to document within their SOPs the tasks that can be delegated and to which staff. This process will provide an opportunity to clarify roles within the pharmacy. Staff will be clearer as to when they should refer to the pharmacist, and be more aware of the limits of their own competence.

The extent to which tasks are delegated will depend on sector of practice, the workload, nature of the pharmacy and, most importantly, the qualifications and capabilities of the staff. Those pharmacists who employ competent support staff will be able to use SOPs to safely delegate the technical aspects of the dispensing process, potentially freeing up time for the development of clinical services such as medicines management.

N.B. Additional training for responsibilities which extend beyond core training and competencies must be considered.

#### 1.5 Other related initiatives

It is Council policy that from January 1, 2005 all staff within a pharmacy who are involved in dispensing activities (e.g. in the assembly of a prescription, including the generation of labels) will need to be competent to a minimum standard (or undertaking training in this respect). This is additional to the requirement for SOPs. A new qualification for dispensing assistants in community and hospital pharmacies<sup>2</sup> is being developed. The new qualification is of a different standard from existing higher-level qualifications for pharmacy technicians.

## 2. **Dispensing procedures**

The service specification for the supply of prescribed medicines is set out in part 3 of the Code of Ethics. This includes the statement that every prescription must be professionally assessed by a pharmacist to determine its suitability for the patient.

A pharmaceutical assessment<sup>3</sup> of a prescription (often referred to as the professional check) will not eliminate the risk of a dispensing error occurring and dispensing accuracy checks should always be undertaken. Wherever possible the accuracy check should be carried out by a second person.

This means that under normal circumstances, a pharmacist will undertake a pharmaceutical assessment of every prescription presented for dispensing and,

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<sup>1</sup> Code of Ethics and Standards of Good Professional Practice. Medicines, Ethics and Practice: a guide for pharmacists. Royal Pharmaceutical Society of Great Britain, (25) July, 2001, p83

<sup>2</sup> Assistant Technical Officers (ATOs) in hospital pharmacies.

<sup>3</sup> The pharmaceutical assessment has been defined as the point at which pharmacists apply their knowledge to establish the safety, quality, efficacy and perhaps cost-effective use of drug treatments specified by a prescriber.

once the prescription has been assembled, someone other than the person who assembled it will perform an accuracy check. In many pharmacies a pharmacist will choose to undertake the accuracy check. In some pharmacies, dispensing accuracy checks are beginning to be undertaken by qualified pharmacy technicians who have undergone additional training and competence assessment. These technicians, known as “accredited checking technicians”, will be checking the accuracy of dispensed items that have been assembled by another person.

### **3. Content of the SOP**

All pharmacies operate differently, and SOPs will need to reflect this. However, there are some general principles that will apply. SOPs should:

- be pharmacy specific;
- be dependent on the competence of the staff working in that pharmacy;
- under normal circumstances, be applicable at all times, i.e. not dependent on the presence of the pharmacist under whose authority the procedure was prepared.

There is no single template that can be applied to all pharmacies. However, because of a number of requests for further guidance, the Society will work with other pharmacy bodies to produce some examples of SOPs that can be tailored to meet the requirements of different pharmacy settings.

SOPs should cover all aspects of the dispensing process, including the delivery of the medicine or product to the patient, and must comply with professional requirements applying to the dispensing process as set out in the Code of Ethics. The added-value of the pharmaceutical service i.e. the pharmacist’s professional input into the assessment of the safety and appropriateness of a prescription and in the provision of information and counselling when completed prescriptions are transferred to patients, should be explicit. SOPs should define the process and specify which activities must be carried out personally by a pharmacist, including the pharmaceutical assessment<sup>3</sup>, which activities can be delegated to identified competent support staff and how the checks for accuracy are to be carried out. It is good practice for SOPs to incorporate an audit trail so that the pharmacist can determine who is responsible for each aspect of the process.

SOPs should help to ensure that, other than in exceptional circumstances, recommended procedures are followed at all times. Their introduction provides an opportunity for pharmacists to define and assess their own practice, to communicate this to staff and help to improve team-working within the pharmacy.

### **4. Working with SOPs**

#### **4.1 Availability**

It is important that SOPs are readily available to relevant staff at all times. This is particularly important in the case of locums.

#### **4.2 Pharmacies with no dispensary support staff**

The requirement to put in place and implement SOPs covering the dispensing process will apply to all pharmacies, including those where no dispensary support

staff are employed and the pharmacist works single-handedly. In such situations SOPs will provide valuable guidance to locums.

#### 4.3 Guidance to locums and other pharmacists on following SOPs prepared under the authority of another pharmacist

Each SOP should specify an appropriate level of responsibility for each member of staff involved in the dispensing process. This should be based on an assessment of each person's competence and level of qualification. In the absence of the pharmacist under whose authority the SOP has been prepared pharmacists should not increase the responsibility of a member of staff whose qualifications and competence they are unsure of. For example, it would not be appropriate to ask someone to prepare labels if this is not something that they normally do. It would, however, be appropriate to decrease the responsibility of an unfamiliar member of staff if this is considered necessary and appropriate. The professional judgement of the pharmacist in charge of a pharmacy at any given time must remain paramount. It is good practice to report any concerns arising when following a procedure developed by another pharmacist. These concerns should be addressed to the pharmacist under whose authority the SOP has been prepared.

In some cases, locums may wish to develop their own SOPs covering the pharmacies in which they normally work. These should fall within the parameters of the SOP prepared by the pharmacist in charge or superintendent pharmacist and may form part of the locum's agreement to work at a particular pharmacy.

#### 4.4 Non-conformance

There may be exceptional circumstances where it is necessary or appropriate to work outside a SOP, e.g. in the event of computer breakdown. In these situations the professional judgement of the pharmacist in charge must remain paramount. As is currently the case pharmacists should be in a position to intervene at any stage of the dispensing process when this is considered to be appropriate.

It is good practice to record incidences of non-conformance with SOPs. In some cases it may be possible to anticipate situations where changed circumstances will apply. These should be reflected within the SOPs. Some pharmacists might find it helpful to prepare separate SOPs to be followed in the event of predictable circumstances, e.g. procedures to be followed in the event of computer breakdown.

#### 4.5 Monitoring incidents

Monitoring incidents occurring during the dispensing process, i.e. all errors identified, not just those that reach the patient, is a useful means of reviewing procedures and identifying any that may need modifying. It is also a useful way of monitoring individual capabilities and identifying training requirements.

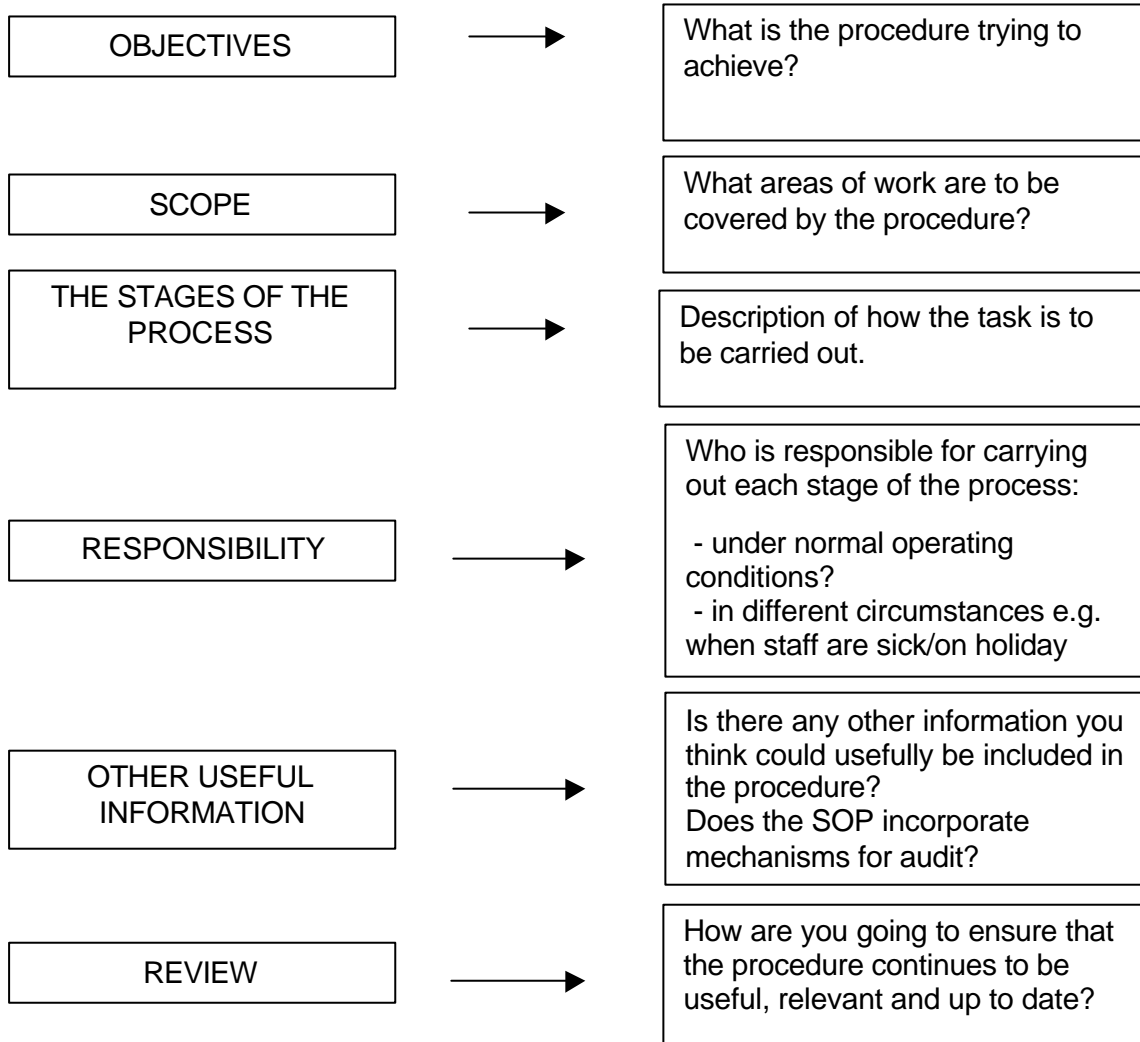
Pharmacists should consider implementing a separate procedure for incident monitoring. Audit packs on monitoring and evaluating dispensing errors are available from the Society's Audit Development Fellow or from the Audit web site [www.rpsqb.org.uk/audhome.htm](http://www.rpsqb.org.uk/audhome.htm).

#### 4.6 Audit trails

Where SOPs incorporate a requirement for audit trails, these should be based on specific, accountable activities. Audit trails will need to give details of the name(s) of the individual(s) concerned and will need to identify the accountable pharmacist.

## 5. Outline for Preparing Standard Operating Procedures

For each procedure think about the following:



## 6. Guidance on writing SOPs

For convenience, the guidance is set out under six headings:

- Prescription handling
- Assessment of the prescription for validity, safety and clinical appropriateness
- Making interventions and problem solving
- Assembly and labelling of required medicine or product
- Accuracy checking procedure
- Transfer of the medicine or product to the patient

It is suggested that, as a minimum, SOPs are drafted covering all of these areas. Where appropriate, the six areas can be broken down further. All SOPs should

specify the order of events applicable to the pharmacy under normal operating conditions (recognising that, within the province of the pharmacist, these may change). Processes may be grouped under different headings if it is felt that this will better reflect the circumstances operating within a particular pharmacy. Account should be taken of variables, such as sickness, holidays, locums and other temporary staff, volume of work and resources available.

It is recommended that an overarching document is prepared stating how the SOPs are to be used and how they will be monitored. The document should also set out the updating process and what to do in the event of any deviation from the recommended procedures.

#### 6.1 Who should write them

In normal circumstances, the development of SOPs should be overseen by the pharmacist who is in day to day charge of the pharmacy. That pharmacist will be accountable for the SOP. There will, however, be situations in which this is not practical, for example where there is no pharmacist manager and the pharmacy is being supervised by locums. In this situation the superintendent pharmacist will be accountable for ensuring that SOPs are developed and implemented. In the case of multiples, templates or guidance on preparing SOPs may be prepared centrally. It is important that any templates are prepared in such a way that they can be tailored to meet the specific circumstances applicable within different pharmacies.

The name of the pharmacist under whose authority the SOP was prepared should be clearly specified.

It is good practice to involve all staff involved in the dispensing process in the preparation of SOPs or tailoring of SOP templates. This will help to engage staff and ensure that the procedures specified are followed.

#### 6.2 Layout

SOPs can be drafted in many different formats e.g. algorithm-based, bulleted points or as detailed information. It may be useful to incorporate references to other material such as “in-house” documents, manuals, reference books or computer based information, within the SOP. A reference numbering system may be used.

#### 6.3 Keeping SOPs up to date

SOPs should be clearly marked with the date of preparation and/or date of review/amendment. They should be kept up to date and relevant at all times and should be regularly reviewed to allow for changes in practice or circumstances, for example, legislative changes or changes of staff. In the absence of any obvious changes, reviews should be undertaken at least once every two years.

When SOPs are first drafted, or when new members of staff are appointed, it is good practice to ask staff to sign to say they have read and understood them. As well as clarifying staff roles, this can also offer an opportunity for staff training and development. Pharmacists should ensure that any changes to SOPs are brought to the attention of relevant staff.

## 7. Areas of the dispensing process to be covered by Standard Operating Procedures

This part of the document is set out in a conventional order. The order of events within a SOP should reflect the operating practices within the pharmacy.

The following principles apply to all stages of the dispensing process and should be taken into consideration when drafting SOPs:

- Patient confidentiality must be maintained at all times;
- Appropriate information must be provided to the patient or the patient's representative and, where possible, understanding of this information should be checked;
- When necessary applicable reference sources should be used, e.g. Drug Tariff on contractual issues, Medicines, Ethics and Practice for legal/ethical queries, BNF for clinical queries, etc.

### 7.1 Prescription handling

The SOP should ensure that for all prescriptions handled by the pharmacy:

- Patient details are checked and confirmed;
- The patient or representative has signed the reverse of the form (NHS prescriptions only);
- Prescription charges are collected promptly and correctly or patient exemptions are checked, as applicable;
- The prescription is passed on for pharmaceutical assessment and assembly;
- Patients/representatives are advised of waiting times and procedures for collection or delivery, including opening hours where appropriate;
- Necessary documentation is completed;
- Legal and professional requirements for record keeping, records management, endorsement and, where appropriate, submission for pricing are upheld.

#### Notes:

1) Under normal circumstances prescriptions are brought to the pharmacy by a patient or representative, but this will not always apply. The pharmacy may offer a prescription collection service. Occasionally, prescriptions are telephoned through by a GP, although under normal circumstances, the pharmacy should be in possession of the original hard copy prescription before the supply is made. Any member of the multi-disciplinary team might be involved, particularly in the hospital sector where prescriptions may be forwarded to the pharmacy electronically or by fax. Electronic transfer of prescriptions within the community sector is likely to occur in the future.

Regardless of the way in which a prescription it is presented, the principles for processing remain the same. The SOP should specify how each method of receipt should be dealt with.

2) Pharmacists may consider developing a separate SOP to cover telephoned prescriptions so that they can be assured that legal requirements will be complied with. The procedure should define who may deal with the telephone call and how the call can be authenticated.

## 7.2 Assessment of the prescription for validity, safety and clinical appropriateness

The SOP should ensure that when prescriptions are assessed for safety and clinical appropriateness the following areas are covered, if known:

- Assessment of whether the prescription is legally valid;
- Where appropriate, whether the items on the prescription are prescribable under the NHS;
- Assessment of whether the prescription includes an appropriate dosage form and appropriate route of administration;
- Appropriateness according to patient's condition;
- Dosage within therapeutic range;
- Duration of treatment;
- Appropriateness according to patient's parameters (age, weight, etc.) and previous medication. This is particularly important for treatments with a narrow therapeutic index, oncology preparations, or for babies and young children;
- Compatibility with other medication;
- Consistency with formularies, clinical guidelines and protocols (including shared care protocols, patient group directions);
- Possible side effects;
- Risk of adverse drug reactions;
- Potential for non-concordance, inappropriate use and misuse by patient;
- Contra-indications.

The SOP should ensure that, when parts of the assessment process are delegated to competent dispensary staff, relevant information is brought to the attention of the pharmacist who will make a judgement as to its significance and what action needs to be taken.

### Notes:

- 1) It is recognised that, in different environments, different levels of information are available.
- 2) In a hospital setting, the pharmaceutical assessment of the prescription may occur on wards or at the point of receipt by the pharmacist in the dispensary before the prescription is assembled by dispensing staff. In the community, dispensing staff or counter assistants may receive the prescription and undertake an initial assessment before the prescription is passed on for assembly with the remaining assessment undertaken by the pharmacist.
- 3) Information from various sources may enable the pharmacist to assess the prescription, for example, information obtained from ward rounds, the patient, the patient medication record (PMR).
- 4) Assessing the prescription for legal validity does not mean that the pharmacist has to recognise the signature of the prescriber.

## 7.3 Interventions and problem solving

A procedure for dealing with interventions should be specified, as should circumstances in which other members of staff may perform certain tasks, for example, to clarify details with a prescriber, and at what stage this should occur, i.e. before or after discussion with the pharmacist. SOPs should also include procedures for liaison with other health professionals and/or patients as appropriate.

Notes:

1) Recording details of interventions on pharmacy patient medication record systems is recommended wherever possible and practical. It is recognised that not all current dispensary computer systems have this facility.

#### 7.4 Assembly and labelling of required medicine or product

The SOP should ensure that when prescriptions are assembled:

- The medicine or product matches the prescription and is in date;
- It is assembled using correct equipment and processes;
- It is packed and labelled appropriately;
- Appropriate records are made;
- Health, hygiene and safety procedures are followed at all times.

Notes:

1) Re-labelling or additional labelling of existing supplies, e.g. at ward level in hospital requires specific training and a separate SOP.

2) The SOP should enable pharmacists to review the actual processing of prescriptions, to ensure that there is a logical workflow appropriate to the staff and premises. By tackling each element in isolation, pharmacists can ensure safe systems of working. Consideration should be given within the SOP to error minimisation, for example, not dispensing from labels, and to the level of competence of those staff permitted to produce labels.

3) The SOP should specify usual quantities dispensed in relation to calendar packs. e.g. where the quantity specified on the prescription does not equate to an exact number of calendar pack strips.

#### 7.5 Accuracy checking procedure

- There should be an accuracy check within the procedure.
- Additional competence assessment and/or training is required to assure appropriate checking.
- The SOP should be clear about which persons are competent and authorised to check.
- Wherever possible the check should be undertaken by a second person.
- Self-checking is not recommended other than in exceptional circumstances in which procedures are in place to assure patient safety and where it is in the patient's best interest to do so.

Note:

1) Accuracy checking is covered within the preregistration competencies and performance standards, but the current BTEC and S/NVQ Level 3 qualifications for pharmacy technicians do not cover this task.

2) Within community pharmacy it is good practice to incorporate boxes on the pharmacy label to accommodate the initials of the person who has dispensed the prescription and the person who has performed the professional check. An additional box may be required for the accuracy check. In hospitals, a pharmacist will normally sign the prescription to indicate that a professional check has been

undertaken. The dispensing label will normally incorporate space to accommodate the initials of the assembler and the checker.

3) In exceptional circumstances only, self-checking may be carried out under the following conditions:

- Where there the pharmacist is the sole person working in the dispensary;
- Where well defined protocols, which the pharmacist is accountable for, have been put in place enabling the self-checking of specific items by those who are trained and competent to do so (currently there are no training programmes that will enable non-pharmacists to develop and demonstrate competence in self-checking for accuracy);
- In hospitals and residential/nursing homes, where a change to a dose of a particular medicine has been made by a prescriber and previously dispensed items are required to be re-labelled; or, where dose labelling is added to routinely available ward/home stock medicines.

## 7.6 Transfer of the medicine or product to the patient

The SOP should ensure that when completed prescriptions are transferred to the patient:

- Completed prescriptions are received by the correct person;
- Appropriate information is provided to the patient or the patient's representative and, where possible, understanding of this information is checked;
- Measuring spoons and oral syringes are provided where appropriate;
- RPSGB standards for delivery of medicines are maintained;
- Provision is made for transfer of dispensed items to patients' representatives.

### Notes:

1) The SOP may stipulate which members of staff are able to give dispensed products and medicines to patients, in circumstances where this is deemed to be appropriate. The SOP should specify circumstances, including particular groups of medicines, in which the pharmacist's personal involvement is considered to be necessary.

2) Pharmacists may wish to consider outlining within the SOP, circumstances under which it is not always necessary to discuss the medication or product with the person to whom it is transferred, e.g. where the person collecting the prescription is not the patient.

3) If a patient has been taking the medication/using the product for a number of years provision of information may not be necessary but the patient should always be given the opportunity to ask questions. The use of open questions e.g. "Is there anything you would like to know about your medicines?" should be advocated.

4) Information to be provided to the patient or patient's representatives may include advice over how to obtain future supplies, e.g. hospital only and how to return/dispose of unused/unwanted medicines.

## 7.7 Other issues

Other issues which pharmacists may wish to address within the SOP include:

- Label generation.
- The use of child resistant containers (CRCs);
- Appropriate packaging, for example, re-packaging of parallel import packs;
- Inclusion of the appropriate patient information leaflet;
- Recording interventions;
- Queries from other healthcare professionals;
- Expiry dates;
- Pre-packing in anticipation of dispensing;
- Dispensing into monitored dosage systems;
- Supply of specials;
- Dealing with “owings”, including procedures to be followed at the time of second dispensing.

### 7.8 Extemporaneous dispensing

The service specification for extemporaneous preparation/compounding is set out in part 3 of the Code of Ethics. A separate SOP should be prepared to cover this area as relevant to the particular pharmacy.

## 8. **Conclusion**

The introduction of SOPs for dispensing will bring many benefits. The preparation of SOPs will require pharmacists to document what they already do. This will make it easier to analyse current ways of working and decide whether better use can be made of dispensary support staff. SOPs will also provide an opportunity to demonstrate professionalism, professional accountability and responsibility to Government, and go some way to tackling the issue of clinical governance within the pharmacy setting.

## 9. **Further sources of information on writing SOPs**

The following is not an exhaustive list and will be added to as further sources of information become available.

- Continuing education packages such as the WCPPE SWEEP<sup>4</sup> package, offer guidance on writing and implementing SOPs.
- International quality management standards e.g. BS EN ISO 9000: 2000

### Specific References:

Writing a Protocol. Phillips S, and Temple, DJ. Pharmaceutical Journal 1994 (253): 570

Quality Assurance and Professional Audit in Community Pharmacy. Phillips S, and Temple, DJ. Pharmaceutical Journal 1992 (251): 208

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<sup>4</sup> The SWEEP programme was commissioned and funded by the Welsh Office (as it was then, now National Assembly for Wales) and prepared by Sheila Phillips, Senior Research Associate, Welsh Centre for Post Graduate Pharmaceutical Education.

## 10. Acknowledgements

The guidance on how to write and implement Standard Operating Procedures was overseen by the Pharmacy Sector Committee of the Science, Technology and Mathematics National Training Organisation on which the major employers of pharmacists and support staff throughout Great Britain are represented. It incorporates intellectual material from the WCPPE SWEEP package developed by Sheila Phillips and funded by the Welsh Office (as it was then, now National Assembly for Wales - see section 9 above). The following individuals were also involved in the development of the guidance.

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