

More guidance on minimum competence requirement

The Royal Pharmaceutical Society is to introduce minimum competence requirements next year for dispensing and pharmacy assistants involved in providing pharmacy services. Last week's *Pharmaceutical Journal* included a centre pull-out giving guidance on how pharmacists can use a transitional provision — a “grandparent clause” — to ensure that existing assistants can continue working without needing a new qualification. On this and the following two pages we publish further guidance in the form of answers to frequently asked questions, interspersed with a series of worked examples.

The information does not apply to staff who work solely as medicines counter assistants or those with pharmacy technician qualifications who are intending to register with the Society.

1. Why has the Society decided to regulate pharmacy support staff?

A combination of different drivers and enablers has led to the Society's decision to move towards the regulation of pharmacy support staff.

The Government has set out new minimum requirements for bodies regulating health professions in response to a number of high profile incidents, including the Shipman case and the Kennedy report into children's heart surgery at Bristol Royal Infirmary.

The Government has also indicated that, as part of NHS modernisation, professional regulation should be extended to cover all those who have a direct impact on patient care because of the potential to cause harm to patients through poor practice. In theory this would apply to all pharmacy support staff, since most staff are in direct day-to-day contact with

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patients or members of the general public who seek pharmacy-related advice and services.

2. Who does the policy apply to?

From 1 January 2005, the policy on minimum competence requirement will apply to any new member of staff or to staff new to a role that falls within those pharmacy services agreed by the Council in October 2003. The policy covers dispensing/pharmacy assistants working under the supervision of a pharmacist in the community, hospital or other pharmacy sector. However, some staff may be exempt from further training (see Question 3).

The policy mainly covers employees undertaking dispensary-related duties but does also encompass staff in a hospital pharmacy setting who may not necessarily be based in the dispensary, eg, assistant technical officers working in a manufacturing unit or staff who put stock away, etc.

In certain scenarios, some staff may undertake dispensing-related tasks that either fall outside, or are only partly covered by, the scope of the policy. The Society's Council has agreed that from 1 January 2005, there will also be a requirement for pharmacists to have in place written standard operating procedures (SOPs) covering dispensing activities. Thus, for staff undertaking dispensing-related tasks not covered by the scope of minimum competence requirements, these tasks can be

incorporated into a SOP. The onus will be on the supervising pharmacist to decide how the policy is interpreted at a local level.

3. Some of my staff have many years of experience. Will they now have to undertake further training?

Existing staff will not have to undertake further training provided they meet the requirements of a “grandparent clause” that will operate until the end of December 2004. A supervising pharmacist will have to complete a declaration of competence for each member of staff falling into this category, a copy of which must be sent to the Society and will be kept on record for future reference.

Staff will be exempt from further training under the grandparent clause if they:

- Have previously completed an approved course for dispensing/pharmacy assistants and been declared competent by a supervising pharmacist, or
- Have relevant work experience and have been assessed and declared competent by a supervising pharmacist.

Please note that any employee in current employment who has not been declared exempt from further training under the grandparent clause arrangements will, from 1 January 2005, be required to undertake an accredited course.

4. Under the grandparent clause arrangements, what is meant by “relevant work experience”?

“Relevant work experience” is a term that applies to staff who are deemed to be competent (by the supervising pharmacist)

Example 1: Experienced assistant with no formal training

Background: Ann has worked as a full-time dispensing assistant in a community pharmacy for over 20 years. She is very experienced but has never undertaken any sort of formal certificated dispensers' training course. Her job description covers: “assist in the supply of prescribed items”, “assist in the assembly of prescribed items”, “order, receive and store pharmaceutical stock” and “assist with the supply of pharmaceutical stock”.

Assessment: As Ann has not undertaken a prior dispensers' training course, the supervising pharmacist should use the support guide to help assess Ann's competence in her assigned duties. The pharmacist will need to read through the support guide and systematically check that Ann has satisfactorily met and understands all the different criteria for the units that apply to her work.

Possible problem: Reading through the support guide, under “Assist in the assembly of prescribed

items”, you see a section relating to pharmacy law. You are unclear about Ann's level of understanding of pharmacy law and are uncertain whether she should be declared competent for this unit.

Action: The guide only requests a basic understanding of pharmacy law. You could ask Ann some simple questions to assess her knowledge, eg, what is the difference between GSL products, pharmacy medicines and POMs in terms of supply? Is Ann aware that Controlled Drugs may have certain restrictions on storage and supply? Can Ann recognise a label on a poison?

Declaration: Once you are satisfied that the criteria for each work activity has been satisfactorily met then fill out the “declaration of competence” form and tick only those boxes that relate to Ann's work. Send the signed and completed declaration form back to the Society. Remember to take copies of the form for the employer and Ann.

Example 2: Assistant who works in a specialist area

Background: Nigel works part-time (Mondays and Wednesdays) in a hospital pharmacy at assistant technical officer level. He is based in the centralised intravenous additive services unit, not the dispensary, and has not undertaken a formal certificated training course for dispensing/pharmacy assistants. His job description covers: “assist with the preparation of aseptic products”.

Assessment: As Nigel has not undertaken a prior training course for dispensing/pharmacy assistants, the supervising pharmacist should use the support guide to help assess Nigel's competence in the work assigned to him. The pharmacist will need to read through the support guide and systematically check that Nigel has satisfactorily met and understands all the different criteria for the unit that applies to his work.

Declaration: As for Example 1.

through work experience in those activities that fall within the scope of the policy (see Question 7). The support guide in last week's eight-page *PJ* pull-out aims to help the supervising pharmacist make a decision as to whether or not a member of staff working as a dispensing/pharmacy assistant can satisfactorily be declared competent in the duties they undertake against the unit(s) specified under the grandparent clause.

5. Do the grandparent clause arrangements cater for employees who are on career breaks, etc?

For staff not in current employment — such as those on career breaks or maternity leave — who intend to return to work after 31 December 2004 the exemption under the grandparent clause has been extended by a year until a cut-off point of 31 December 2005. After this date staff who have not been declared competent will have to complete an accredited course.

6. Is the regulatory framework for dispensing/pharmacy assistants a legal requirement?

No. The minimum training standard for dispensing/pharmacy assistants is a professional requirement rather than a statutory requirement.

7. What is the scope of the Society's policy?

From 1 January 2005, pharmacists will have a professional obligation to ensure that all staff involved in those pharmacy services agreed by the Council in October 2003 are competent to a minimum standard equivalent to the new Scottish/National Vocational Qualification (S/NVQ) level 2 qualification in pharmacy services or are undertaking training towards this qualification.

The requirement will apply to staff involved in any of the following activities:

- Sale of over-the-counter medicines and the provision of information to customers on symptoms and products*
- Prescription receipt and collection*
- The assembly of prescribed items (including the generation of labels)
- Ordering, receiving and storing pharmaceutical stock
- The supply of pharmaceutical stock
- Preparation for the manufacture of pharmaceutical products (including aseptic products)
- Manufacture and assembly of medicinal products (including aseptic products)

(*Note: See Question 13 for information concerning accredited medicines counter assistants' courses)

8. From 1 January 2005, how will the new policy be implemented?

The Council has taken a pragmatic approach to implementing the minimum standard and has accepted advice from employers and training providers that, so long as staff are



competent to perform those tasks that fall within their roles and responsibilities, it is not necessary for all of them to undertake the full S/NVQ qualification. A flexible, modular approach to training has been adopted, allowing staff to complete only those training units relevant to assigned tasks. What this means in practice is that there will be several ways of complying with the new standard.

Staff will be able to comply with the minimum standard of competence, relevant to the job role, in one of four ways:

- Successful achievement of the pharmacy services S/NVQ level 2
- Successful achievement of the units of the S/NVQ level 2 that are relevant to the roles and responsibilities undertaken by the assistant.
- Successful achievement of a training programme accredited to be of an equivalent level to S/NVQ level 2
- Successful achievement of the units of an accredited training programme of an equivalent level to S/NVQ level 2 that are relevant to the roles and responsibilities undertaken by the dispensary assistant.

The Society is in the final stages of closing negotiations leading to the appointment of an agent to accredit the non-S/NVQ courses. Course providers will be invited to submit courses for accreditation in the near future.

9. Are any time limits specified for either the commencement of training or the completion of a course?

Yes. Dispensing/pharmacy assistants should be enrolled on a training programme within three months of staff starting their role (or as soon as is practical with local training arrangements). Training should be completed within three years.

10. I may in the future decide to move from the community setting to hospital pharmacy. Will my exemptions under the

Example 3: Assistant who completed a course 10 years ago

Background: Janet, a part-time dispensing assistant in a community pharmacy, completed a certificated dispensers' training course 10 years ago. Her job description covers: "assist in the supply of prescribed items", "assist in the assembly of prescribed items" and "assist with the supply of pharmaceutical stock".

Assessment: Janet's course may be among those approved for dispensing/pharmacy assistants mapped for course content equivalence under the grandparent clause. The pharmacist should check the list in the *PJ* pull-out to identify the scope of work the mapped course covered as this would help when completing the declaration of competence form.

Possible problem: Janet's course did not cover "assist in the supply of pharmaceutical stock"

but Janet wants to be judged competent in this unit.

Action: Members of staff who wish to be judged competent in a unit that is not covered by their recognised prior course will undergo a competency assessment (using the support guide) by a supervising pharmacist against the standards in the unit. Janet's competence can be assessed using both the criteria of the prior course and the support guide.

If an employee fails to demonstrate competence in a particular unit relating to an assigned task, the supervising pharmacist may consider top-up training and submitting the declaration form to the Society at a later date.

Declaration: As for Example 1.

Example 4: Assistant who completed a non-approved course

Background: Val works as a full-time pharmacy assistant working in a hospital pharmacy. She completed the department's in-house training course for pharmacy assistants two years ago and gained top marks. Her job description covers: "assist in the supply of prescribed items", "assist in the assembly of prescribed items" and "prepare to make pharmaceutical products".

Assessment: Val's course may have been included in the list of approved courses for dispensing/pharmacy assistants mapped for course content equivalence under the grandparent clause. The supervising pharmacist should check the list in the PJ pull-out.

Possible problem: The course was not submitted to the Society for mapping and it does not appear on the list of approved prior courses acceptable under the grandparent clause arrangements.

Action: As Val's course is not on the approved list, the supervising pharmacist should use the support guide to help assess Val's competence in her assigned work duties. The pharmacist will need to read through the support guide and systematically check that Val has satisfactorily met and understands all the different criteria for the units that apply to her work.

Declaration: As for Example 1.

grandparent clause arrangements still be valid? Will the new employer update the "declaration of competence" form?

If, from January 2005, you move jobs, you will still be exempt from having to undertake further training in those units where you have previously been declared as being competent. If, however, you undertake any new role(s) that falls within the scope of the Society's requirements but for which you are not covered, then you will be required to undertake some accredited top-up training relating to your new role(s).

A copy of the signed "declaration of competence" form should be retained by the dispensing/pharmacy assistant to show to any future potential employers.

The "declaration of competence" form is a one-off record showing an employee's competence at a particular period in time and will not need to be updated by the new employer.

11. If a dispensing/pharmacy assistant moves jobs and makes an error in their new job through lack of competence, does responsibility lie with the pharmacist who declared them competent under the grandparent clause arrangements or with the new pharmacist employer?

It is the responsibility of the supervising pharmacist making the signed declaration that the named member of staff is competent in the duties indicated. It would, however, be the responsibility of any new employer to ensure that the requisite level of competence has been maintained. If the new employer believed that the dispensing/pharmacy assistant was not fully competent in an area where the assistant had previously been declared as being competent, then the onus would still be on the new employer to use his or her professional judgement and take suitable steps in consultation with the employee in terms of deciding whatever further training might be required. Thus, in terms of any possible errors in the new job through lack of competence, responsibility lies with the new employer.

12. Why is the Society keeping a copy of the declaration? Is this the first step

towards the registration of pharmacy assistants?

The Society is keeping a copy of the form for possible future reference. Potential new pharmacist employers might, for example, wish to check a dispensing/pharmacy assistant's credentials.

The Society has taken the view that, while it should have a role in the regulation of all pharmacy support staff groups, registration is only planned at this time for pharmacy technicians. This is because dispensing/pharmacy assistants and medicines counter assistants work either under the direct supervision of a pharmacist or, in the future, under a registered pharmacy technician. The Society's view is that dispensing/pharmacy assistants and medicines counter assistants can be regulated adequately by minimum training standards allied to written standard operating procedures.

13. What is the position of assistants selling medicines over the counter?

Since 1996 it has been a professional requirement of the Society that any assistant who is given delegated authority to sell medicines under a protocol should have undertaken, or be undertaking an accredited medicines

counter assistant (MCA) course relevant to their duties. The current requirement is that courses should cover the following areas:

- Sale of over-the-counter medicines and the provision of information to customers on symptoms and products
- Prescription receipt and collection

Assistants will be exempt from the requirement for a declaration of competence by a pharmacist or further training in the above two units, provided they have successfully completed an accredited MCA course or have previously been considered to have met the Society's requirements for MCAs.

Assistants should be enrolled on a training programme within three months of staff starting their role (or as soon as is practical with local training arrangements) and training should be completed within three years.

14. Will training courses accepted under the grandparent clause for pharmacy technicians (ie, those equivalent to the S/NVQ level 3 qualification in pharmacy services) automatically be accepted under the grandparent clause arrangements for dispensing/pharmacy assistants?

Yes. Pharmacy services S/NVQ level 3 is higher than level 2 and therefore anyone who has a qualification that meets the requirements of the grandparent clause for pharmacy technicians exceeds the requirements at level 2. Therefore training courses accepted under the grandparent clause for pharmacy technicians will automatically meet the requirements of the grandparent clause for dispensing/pharmacy assistants and a declaration form will not need to be completed for this level of staff.

A list of courses meeting the requirements of the grandparent clause for pharmacy technicians is available on the Society's website (www.rpsgb.org) under "Regulation of pharmacy technicians: summary of Council decisions".

Example 5: Assistant who transfers to a new employer

Background: Gavin works as a dispenser in a busy community pharmacy. The supervising pharmacist sends the Society a signed and completed "declaration of competence" form indicating the areas in which Gavin is deemed to be competent. In spring 2005, Gavin applies for a new job in another community pharmacy and starts work after the new pharmacist employer has double-checked his exemptions under the grandparent clause with the Society. The new employer is aware that from January 2005, dispensing/pharmacy assistants who move jobs are exempt from having to undertake further training in those units where they have previously been declared as being competent.

Possible problem: The new employer is concerned that Gavin may not be fully competent in an area

where he had previously been declared as being competent.

Action: The onus is on the new employer to use his or her professional judgement and take suitable steps in consultation with Gavin in terms of deciding whatever further training might be required. If a dispensing/pharmacy assistant makes an error in a new job through lack of competence, responsibility lies with the new employer. Hence the pharmacist should manage this scenario in the same way as for any other performance issue.

Declaration: The "declaration of competence" form is a one-off record showing an employee's competence at a particular period in time and will not need to be updated by the new employer.