Developing an updated regulatory framework for unregistered pharmacy staff

Purpose
To provide Council with an overview of the historical background, current practice and existing policies in relation to unregistered pharmacy staff.

To seek agreement to change the regulatory framework for staffing in pharmacy.

Recommendations
The Council is asked to discuss the key themes in this paper and to agree the following recommendations:

i. That the regulatory framework for education and training of unregistered pharmacy staff in registered pharmacies should change

ii. That the executive should develop and consult on new guidance for owners of pharmacies on staffing to sit underneath principle 2 of the standards for registered pharmacies (that ‘staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public’)

iii. That the draft guidance should incorporate and include key requirements in relation to minimum training requirements as appropriate

iv. That the GPhC should confirm that any upcoming accreditations for DA or MCA courses should be ‘rolled over’ until new guidance is approved and the new regulatory framework is confirmed

1. Introduction
1.1 We have carried out a range of consultations and evaluation exercises in the last two years which have provided useful background and insight into the role, functions and accountability for unregistered pharmacy staff working in registered pharmacies.
1.2 A key publication was *Tomorrow’s pharmacy team (2015)*. This discussion document highlighted key issues we wished to seek feedback on, including the education and training requirements for the whole pharmacy team. We had excellent responses including feedback that all members of the pharmacy team should cover a common set of skills and abilities including professionalism, good communication skills, and effective working in multi-professional teams.

1.3 However there have been a range of initiatives, in addition to the discussion document, *Tomorrow’s pharmacy team*, led by the GPhC and others which have informed the outline proposals in this paper and will feed into the draft guidance, subject to Councils approval. These include:

i. *Independent investigations by Which?* in 2004, 2008 and 2013 highlighted the variable advice provided to patients from some high street pharmacies.

ii. *Our consultation on the standards for pharmacy professionals (2016)*: A common theme emerged on the need for guidance for organisations and owners in relation to other unregulated groups, such as non-pharmacist managers and pharmacy support staff.

iii. *The evaluation* of the GPhC’s approach to regulating community pharmacies (2015): The evaluation considered the impact of our standards for registered pharmacies and the wider regulatory framework including the engagement of the whole pharmacy team.

iv. *Seminar on professionalism under pressure*: At this event in October 2016, we heard feedback from attendees on staff training and indicated our intention to produce guidance for owners on unregistered pharmacy staff.

v. *Online workshop discussion (January 2017)*: More recently, we have launched an online workshop to seek feedback from pharmacy professionals and pharmacy owners about what quality means in pharmacy practice, with a particular focus on safety, effectiveness, and patient experience.

1.4 Alongside these external exercises we have also reviewed our own policies, specifically our policy on minimum training requirements for dispensing / pharmacy assistants and medicines counter assistants (see Appendix 2) and our current standards for registered pharmacies.

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2. [https://www.pharmacyregulation.org/sites/default/files/evaluating_the_gphcs_approach_to_regulating_community_pharmacies_final_report.pdf](https://www.pharmacyregulation.org/sites/default/files/evaluating_the_gphcs_approach_to_regulating_community_pharmacies_final_report.pdf)
2. **Background**

2.1 Up until 2005, there were no education and training requirements for unregistered pharmacy staff, including staff supporting the dispensing process and supply of medicines.

2.2 From January 2005, the Royal Pharmaceutical Society of Great Britain (RPSGB) policy stated pharmacists had a professional obligation to ensure that dispensing/pharmacy assistants and medicines counter assistants were competent in the areas in which they were working, to a minimum standard equivalent to the relevant units of the Pharmacy Service Skills Scottish/National Vocational Qualification (S/NVQ) level 2 qualification, or were undertaking training towards this (see Appendix 1 for further information).

2.3 The current practice of the GPhC in relation to unregistered pharmacy staff was adopted in 2010 from the RPSGB’s minimum training requirements, which also saw the continuation of accreditation of dispensing assistant (DA) and medicines counter assistant (MCA) courses.

2.4 The GPhC minimum training requirements policy, which was approved by Council in 2011, places a responsibility on individual pharmacists to ensure staff working in a pharmacy are competent for the role they undertake. It’s first paragraph states:

> “It is requirement of the standards of conduct, ethics and performance that pharmacists must delegate effectively. This includes the requirement for them to establish that anyone they delegate a task to has the knowledge and skills to carry out the task safely and effectively:

> 7.4 Take responsibility for all work you do or are responsible for. Make sure that you delegate tasks only to people who are trained to do them, or who are being trained.”

2.5 The minimum training requirements policy provides further details on the “professional obligation” that pharmacists have for ensuring staff are enrolled on certain courses within three months of commencing specific roles.

2.6 It is important to recognise that pharmacy services, and associated roles, are developing to reflect what is needed across different employers in various settings. The terms MCA and DA do not represent precise roles and DA in particular is an umbrella term for a variety of roles supplying medicines to the public.

2.7 This policy is in need of review.

i. It references standards (conduct, ethics and performance) which are soon to be replaced
ii. It refers to previous versions of national occupational standards which were reviewed and updated in 2016

iii. The regulatory approach is significantly out of step with the outcomes-focussed approach to pharmacy regulation supported by Council

iv. It places accountability for training and delegation on pharmacists including references to fitness to practise sanctions, rather than owners

v. The policy does not reflect the role of pharmacy technicians which, since the policy was developed, are now a regulated profession bound by the standards of conduct, ethics and performance

vi. It does not reflect the diversity of roles within pharmacy and is based on outdated definitions of ‘support staff’

vii. There are a range of historic exemptions to the policy which – as time passes – do not provide the right level of assurance

3. Developing an updated approach

3.1 The current policy framework was developed before the GPhC was established and needs to reflect the new statutory framework and regulatory approach.

3.2 It is critical that we consider not just the legal framework but also the impact any changes may have on staff training so that we can achieve our objectives for this work.

3.3 We see the objectives of this work as follows:

i. To strengthen and assure the framework around staffing within pharmacy

ii. To consider whether we can use our tools more effectively to assure the public that the pharmacy team has the appropriate skills, qualifications and competencies to provide safe and effective care

iii. To ensure accountability for the competence of the unregistered pharmacy staff moves away from pharmacy professionals, to employers

iv. To look beyond narrow and outdated definitions of ‘support staff’ and update our approach to cover all unregistered staff which would include other groups who are involved in pharmacy services from registered pharmacies.

3.4 It is important to note that the responsibility for pharmacy professionals to ensure they only delegate to people who have the knowledge and skills to carry out the task safely and effectively will continue – a requirement in standards of conduct, ethics and performance. This requirement is reflected
in the new standards for pharmacy professionals which were agreed in October 2016 and will come into force later this year. Under Standard 9: *Pharmacy professionals must demonstrate leadership*, we say people receive safe and effective care when pharmacy professionals ‘delegate tasks only to people who are competent and appropriately trained or are in training; and exercise proper oversight.’

4. **Using our statutory powers**

4.1 The GPhC has a number of statutory functions in relation to registered professionals (pharmacists and pharmacy technicians) as well as registered pharmacies.

4.2 While we do not regulate unregistered pharmacy staff, we know they are often the first point of contact with patients and the public, and have an important contribution to make within the pharmacy team.

4.3 Part 2 of the Pharmacy Order 2010 sets out Council’s functions and in particular requirements to set standards for pharmacy professionals and to set and promote standards for the safe and effective practice of pharmacy at registered pharmacies.

4.4 The powers to set education standards and accredit courses which lead to registration (for pharmacists and pharmacy technicians) are set out in detail in Part 5. There are no equivalent powers to accredit courses for unregistered pharmacy staff.

4.5 The Pharmacy Order does, however, provide powers in relation to publication of guidance. This is set out in Schedule 1, Article 6 (2):

**The Council’s duties in respect of publications**

6.—(1) The Council must from time to time publish or provide in such manner as it sees fit information about the regulation of pharmacists, pharmacy technicians and registered pharmacies.

(2) The Council may from time to time publish or provide in such manner as it sees fit guidance to registrants, employers and such other persons as it considers appropriate in respect of the standards for the education, training, supervision and performance of persons who are not registrants but who provide services in connection with those provided by registrants.

5. **Key considerations**

5.1 In considering how best to address our role and the review of education and training of unregistered pharmacy staff, a number of challenges have emerged which we need to consider:
• The importance of registration and the need to distinguish between the expectations of registrants and non-registrants
• The need to be clear about the function of our standards for registered pharmacies, any supporting guidance as well as the role of inspection
• The need to look purposefully at our wider statutory functions (including recognising that inspection is only in relation to registered pharmacies and not hospital or other settings)
• The need for us to avoid attempting to define job roles, but consider wider areas of scope of practice and the skills mix through outcomes
• The need to be clear about the responsibilities of owners, superintendent pharmacists and responsible pharmacists

6. **The difference between registered and unregistered pharmacy staff**

6.1 We hold a register of pharmacists, pharmacy technicians and pharmacy premises. Unregistered pharmacy staff are other staff within the pharmacy team who are not registered with us but are involved in pharmacy services at or from a registered pharmacy.

6.2 Responsibilities can range from, but are not limited to, provision of information to customers on symptoms and products, sale and supply of medicines, prescription receipt and collection including assembly and dispensing of prescribed items, delivery of medicines, as well as ordering, receiving and storing pharmaceutical stock.

6.3 Unregistered pharmacy staff also include managers who have responsibility for leading and managing teams and co-ordinating many aspects of the day-to-day operations.

6.4 There is an important distinction between registered pharmacy staff and unregistered pharmacy staff.

6.5 Registered pharmacy professionals – pharmacists and pharmacy technicians – have wider obligations and responsibilities as regulated professionals and are bound by the requirements of professional regulation. This involves meeting all of the standards we set for education and training, continuing professional development, and professional conduct.

6.6 This is not the case for unregistered pharmacy staff who are primarily accountable to their employer. It is the employer who has responsibility for the impact their work has on patients and the public.

7. **Proposed approach**

7.1 As set out above we have given consideration to a wide range of factors in reviewing the regulatory framework for staff, that are both complex and
interdependent, which have given us reason to review our approach to ensuring a competent and empowered pharmacy team.

7.2 There are a number of key strands we wish to take forward:
   i. Develop guidance for owners on management of the pharmacy team
   ii. Provide within that an updated regulatory framework
   iii. Incorporate key elements of the minimum training requirements policy into the draft guidance document
   iv. Review and update our inspection decision framework⁴ and inspectors evidence bank to ensure our enforcement work is consistent with our updated policy
   v. Set out and communicate interim arrangements – particularly to owners and to education and training providers and qualifications bodies, as we consult on guidance.

8. Guidance for owners on managing the pharmacy team

8.1 For the past two years we have been promoting the concept of person-centred professionalism as well as looking at how the education and training of the pharmacy team should evolve to respond to the new challenges and opportunities they face.

8.2 We intend to produce guidance to sit under the standards for registered pharmacies to set out the key areas that are needed to support a competent and empowered pharmacy team and to ensure the safe and effective practice of unregistered pharmacy staff.

8.3 The current outline for the guidance is to include:
   i. Clinical and corporate governance (including workforce management)
   ii. Education and training requirements
   iii. Knowledge, skills and development
   iv. Creating a person-centred environment
   v. Roles in management

8.4 Guidance would specify that unregistered pharmacy staff must be competent to a given level⁵ which would be agreed in consultation with the sector.

8.5 While guidance would focus on the role of the pharmacies we regulate, we are aware that unregistered pharmacy staff work across a range of other settings, including hospitals andGP surgeries. We believe we will

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⁴https://www.pharmacyregulation.org/sites/default/files/Inspection%20Decision%20Making%20Frame work%20Nov%202013.pdf
⁵Words to the effect of 'equivalent to the relevant knowledge and skills of a nationally recognised Level 2 qualification and delivered by a reputable training provider'
increasingly see services and roles expanding to meet the changing needs across all sectors.

8.6 This relates to how team management and systems within the pharmacy contribute to safe and effective care, and refers to wider issues of clinical governance with links to corporate governance (sometimes referred to within the NHS as Integrated Governance)^6^.

9. **Standards for registered pharmacies and our inspection decision-making framework**

9.1 Principle 2 of the standards for registered pharmacies states: *Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.*

9.2 The decision-making framework requires that staff are trained in accordance with published GPhC policy. Its sets out a number of indicators describing a more holistic approach to training which focusses on the pharmacy taking a broader interest in:

i. The skills mix for the roles and services provided

ii. Staff being actively encouraged to reflect on their performance and identify learning needs

iii. Development plans being in place

iv. Protected time for training being available

9.3 We will review these requirements to consider how they can be strengthened to reflect and refer to new guidance.

9.4 Following consultation on guidance, we will consider the necessary updates to the inspection decision-making framework and evidence bank, and reflect the feedback received.

10. **Transition arrangements**

10.1 We currently accredit MCA/DA courses on a three yearly cycle. Whilst we undertake consultation with the sector to inform our future approach, we propose that we will not accredit any new courses or any courses which are due for reaccreditation.

10.2 However we will undertake a thorough review of the current provision and extensions may be offered, subject to recommendations of the accreditation team, until a revised regulatory model is agreed by Council.

10.3 We will signal to stakeholders our intention to review the minimum training requirements policy, including the requirement for GPhC accreditation. We will continue to monitor the existence and quality of appropriate training.

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^6^https://www.pharmacyregulation.org/sites/default/files/Council%20September%202012%20understanding%20issues%20within%20pharmacy%20team.pdf
through our regulation of registered pharmacies and through our ongoing relationships with awarding bodies and training providers.

11. **Risk implications**

11.1 Our intention is to encourage and enable improvements in training and a more effective regulatory framework.

11.2 There are risks that will need to be carefully managed for any move away from our current approach. A significant change such as this, not properly managed, monitored and reviewed, could see reductions in the quality of training. We will need to monitor the impact closely through a variety of research and evaluation tools.

11.3 We recognise that a move away from accreditation of certain courses could lead to changes to the market in course provision, and uncertainty if we do not communicate effectively.

11.4 However, if we do not change our approach, we risk constraining courses to narrow roles and restricting flexibility in the way pharmacies operate.

11.5 This is an opportunity to ensure pharmacy services, and associated roles, are developing to reflect what is needed across different employers in various settings.

11.6 In order to address the regulatory impact and risk, we will conduct a formal evaluation of the impact of any move to a new regulatory model within 12 months of implementation.

11.7 In the interim, we will continue to reflect on feedback from inspectors’ visits including how owners are demonstrating they are supporting a competent and empowered pharmacy team, as well as how pharmacies are performing against standard 2.1⁷ and 2.2⁸ specifically. We will monitor complaints made to GPhC about knowledge, skills and competence of staff that are not registered with us, and we will seek feedback from training providers about student numbers and demand for courses.

12. **Communications**

12.1 It is important that we provide clarity to key interest groups about our immediate intentions in relation to accreditation of unregistered pharmacy staff courses and our direction of travel. This includes being clear on changes to the regulatory framework, as well as development of updated or new policies, guidance or inspection tools.

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⁷ There are enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided

⁸ Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training
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12.2 We will engage with the sector before agreeing any recommendation on a revised regulatory model to ensure the safe and effective practice of unregistered pharmacy staff.

13. Next steps

13.1 If Council agrees to the recommendations in this paper, we will come back to a future Council meeting for approval of guidance for owners to support principle 2 of the standards for registered pharmacies, following consultation with stakeholders.

13.2 We will set out consequential changes we are proposing to inspection as well as our communications and engagement plan.

Recommendations

The Council is asked to discuss the key themes in this paper and to agree the following recommendations:

i. That the regulatory framework for education and training of unregistered pharmacy staff in registered pharmacies should change

ii. That the executive should develop and consult on new guidance for owners of pharmacies on staffing to sit underneath principle 2 of the standards for registered pharmacies (that ‘staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public’)

iii. That the draft guidance should incorporate and include key requirements in relation to minimum training requirements as appropriate

iv. That the GPhC should confirm that any upcoming accreditations for DA or MCA courses should be ‘rolled over’ until new guidance is approved and the new regulatory framework is confirmed

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01 March 2017
Glossary

NVQ  National Vocational Qualifications
A work based qualification which is centred on competency. The learner produces evidence of what they do in their work situation which becomes the basis of a portfolio that is assessed against the relevant national occupational standard.

SVQ  Scottish Vocational Qualifications
Operate in the same way as NVQs, but are used exclusively in Scotland.

NOS  National occupation standards
Describe the skills, knowledge and understanding needed to undertake a particular task or job to a nationally recognised level of competence. They focus on what the person needs to be able to do, as well as what they must know and understand to work effectively.

MCA  Medicines Counter Assistant
Involved in the sale of over-the-counter medicine and works under the supervision of a pharmacist. A medicines counter assistant is trained to offer advice on common ailments and must know when to refer a customer to a pharmacist.

DA   Dispensing Assistant
Responsibilities can range from, but are not limited to, provision of information to customers on symptoms and products, sale and supply of medicines, prescription receipt and collection including assembly and dispensing of prescribed items, delivery of medicines, as well as ordering, receiving and storing pharmaceutical stock.
Policy on minimum training requirements for dispensing / pharmacy assistants and medicines counter assistants

1.0 Introduction

1.1 It is requirement of the standards of conduct, ethics and performance that pharmacists must delegate effectively. This includes the requirement for them to establish that anyone they delegate a task to has the knowledge and skills to carry out the task safely and effectively.

7.4 Take responsibility for all work you do or are responsible for. Make sure that you delegate tasks only to people who are trained to do them, or who are being trained.

2.0 Purpose of policy

2.1 Under Schedule 1 Article 6(2) of the Pharmacy Order 2010, the Council may make from time to time or publish in such manner as it sees fit guidance to registrants, employers and such other persons as it considers appropriate in respect to standards for the education, training, supervision and performance of persons who are not registrants but who provide services in connection with those provided by registrants.

2.2 The purpose of this policy is to set out minimum training requirements for dispensing / pharmacy assistants and medicines counter assistants so that pharmacists delegate the tasks set out in this policy to pharmacy assistants and medicines counter assistants with the appropriate knowledge and skills.

3.0 Policy statement

3.1 Medicines counter assistants

Pharmacists have a professional obligation to ensure that any assistant who is given delegated authority to sell medicines under a protocol should have undertaken, or be undertaking an accredited course relevant to their duties.

The requirement is that courses should cover the knowledge and understanding associated with units Pharm 05 (unit 4) Pharm 07 (unit 5) and Pharm 32 (Unit 15) of the Pharmacy services skills NVQ level 2 (QCF), entitled:

- Assist in the sale of medicines and products (unit 4)
- Receive prescriptions from individuals (unit 5)
- Assist in the issuing of prescribed items (unit 15)

Assistant must be enrolled on a training programme within three months of commencing their role (or as soon as practical within local training arrangements) and the programme must be completed within a three-year time period.

3.2 Dispensing / pharmacy assistants

Pharmacists have a professional obligation to ensure that dispensing / pharmacy assistants are competent in the areas in which they are working to a minimum standard equivalent to the
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Pharmacy Service Skills NVQ level 2 (QCF) qualification or undertaking training towards this. This applies to staff working in the following areas:

- 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)

The requirement can be met by completing a training programme relevant to the job role and there are four acceptable ways of doing this:

- Successful achievement of Pharmacy Service Skills NVQ level 2 (QCF)
- Successful achievement of relevant units of the Pharmacy Service Skills NVQ level 2 (QCF)
- Successful achievement of a training programme accredited by the GPhC to be of an equivalent level to Pharmacy Service Skills NVQ level 2 (QCF)
- Successful achievement of relevant units of a GPhC accredited training programme of an equivalent level to Pharmacy Service Skills NVQ level 2 (QCF)

Assistants must be enrolled on a training programme within three months of commencing their role (or as soon as practical within local training arrangements) and the programme must be completed within a three-year time period.

3.3 Exemptions to minimum training requirements

The following staff are exempt from the need to undertake the training detailed above:

- Pre-registration trainee pharmacists.
- Students currently studying on an MPharm degree.
- Students currently studying on an Overseas Pharmacists’ Assessment Programme (OSPAP).
- Assistants who qualified prior to January 2005 and who were declared competent under the grandfathering clause to meet the knowledge and understanding associated with one or more units of the S/NVQ level 2 Pharmacy Services. Exemption applies only to those of areas of work in which the supervising pharmacist declared the Assistant competent. NB should the Assistant’s role or place of work have changed, additional training may be required.
- Assistants who hold one of the qualifications listed in Appendix 1. These qualifications are those recognised until 30 June 2011 for registration as a pharmacy technician, under transitional arrangements. From 1 July 2011 the title pharmacy technician will be protected by law, and may only be used by those registered with the General Pharmaceutical Council. NB Assistants will need to undertake the relevant content of an approved training course if the qualification they hold did not cover all areas of their current role. This will be particularly relevant where staff have only completed specific units or changed their place of work.

Policy on minimum training requirements for dispensing pharmacy assistants and medicines counter assistants.
September 2011
It is a pharmacist’s responsibility to ensure that staff are appropriately trained for the role they undertake.

It is the pharmacist's responsibility to delegate tasks to appropriately trained staff. To ensure an Assistant’s knowledge and understanding remain up to date, it may be necessary that an Assistant who either holds a qualification completed a significant time ago, or has taken a prolonged break from the role, undertakes relevant units of an approved training course.

4.0 Application of policy
4.1 We will recognise and approve qualifications and training programmes to meet the minimum training requirements and make a list of these publicly available.

4.2 We will inform pharmacists of their obligations under this policy.

4.3 We will enforce this policy through our fitness to practise process and take appropriate action against registrants who fail to comply with this policy.

5.0 Measurement and evaluation
5.1 We will gather information on this policy through:
   - Complaints made against registrants related to this policy,
   - The results of fitness to practise cases related to this policy,
   - Enquiries made by registrants and others about this policy,
   - Feedback from pharmacy training providers, and
   - Feedback from Inspectors' visits.

5.2 This information will be reviewed on an ongoing basis and evaluated when the policy is reviewed.