

DRAFT PHARMACY ORDER 2009 – CORE SCRIPT RPSGB

Slide 1 – Speaker introduction

Slide 2 – Creation of GPhC

1. The establishment of the GPhC is being led by the Chief Pharmaceutical Officer for England, Dr Keith Ridge, and he is being supported by a Transition Team consisting of key staff from the Department of Health and the Royal Pharmaceutical Society of Great Britain (RPSGB). The team is working on key transition issues such as HR, finance, IT, and accommodation.
2. The subject of regulatory support and development for the GPhC is being led by the Professor of Pharmacy Practice at the University of Manchester, Peter Noyce, who is also the professional advisor to PRLOG. This covers the support the regulator will need from other organisations to carry out its role.
3. All regulatory responsibilities will be transferred from the Royal Pharmaceutical Society of Great Britain to the GPhC.
4. When established the GPhC will cover England, Scotland and Wales only.
5. The GPhC is expected to be established in shadow form in the autumn of 2009, and to become operational in 2010. It is anticipated that it will have a physical presence in England, Scotland and Wales, but there have been no decisions on what types of regulatory activities will take place in each of these countries.
6. Policies and standards for the GPhC will be developed and consulted on during the organisation's shadow phase from autumn 2009.

Slide 3 – Why?

7. Following two reviews of professional regulation in 2006 (Donaldson and Foster), the Government published the White Paper *Trust, Assurance and Safety: the regulation of health professionals in the 21st century* in February 2007.
8. It stated the intention to set up a General Pharmaceutical Council (GPhC) for pharmacists, pharmacy technicians and premises, to which the RPSGB's existing responsibilities for regulation would transfer. The White Paper also set out a number of other changes to professional regulation.
 - Assuring independence: governance and accountability
 - Revalidation
 - Tackling concerns: the local role
 - Tackling concerns: the national role
 - Education: the role of the regulatory bodies
 - Information about healthcare professionals
 - New roles and emerging professions

9. The Lord Carter of Coles working party reported in May 2007 and recommended the establishment of the Pharmacy Regulation and Leadership Oversight Group (PRLOG) to oversee the establishment of the GPhC.
10. The reports of the *Trust, Assurance and Safety* White Paper working groups, e.g. non-medical revalidation, will be influential in determining aspects of regulatory development for the GPhC.

Slide 4 – Why?

11. *Trust, Assurance & Safety* set out the key principles for the regulation of health professionals in the UK:
 - The overriding interest should be the safety and quality of care that patients receive from health professionals
 - Regulation needs to sustain the confidence of the public and professionals through demonstrable impartiality. Regulators need to be independent of Government, professionals and all other interest groups.
 - Regulation is as much about sustaining, assuring and improving professional standards, as it is about identifying and addressing poor practice or bad behaviour
 - Regulation should not create unnecessary burdens, but be proportionate to the risk it addresses and the benefit it brings.
12. Significant progress has been made in pharmacy in the last 10 years, but there is much still to be achieved.
13. The NHS faces pressing health challenges and increasing demands, and pharmacy has a major role to play in delivering high quality healthcare closer to people's homes.
14. The primary focus will be expanding pharmacy's role in promoting health and preventing illness.
15. Pharmacists will also be encouraged to use their clinical skills to start to treat minor illnesses and prescribe medicines.
16. To achieve this vision, pharmacists and pharmacy technicians will need to keep step with the latest developments in medicines, technology and science.
17. As the pharmacy profession develops, so does the need for effective professional regulation.
18. Modern regulation is far more than just a means of discipline – it is about the development of high quality pharmacy practice in the new environment, in order to maintain public confidence in the pharmacy profession.
19. The vision for pharmacy regulation is to ensure patient safety through providing a framework for:

- Improving the quality of care for the public
- Enabling the pharmacy profession to develop its practice.

20. The changes to pharmacy professional regulation are part of an integrated set of developments to UK pharmacy services to meet future health needs. These include:

- The expanded role for pharmacists and pharmacy technicians:
 - Pharmacists as independent prescribers.
 - Pharmacists with special interests – in areas such as dermatology, diabetes and drug misuse (England only).
 - Consultant pharmacists in hospital specialties such as cancer.
 - Pharmacists registered as specialists on the UK Public Health Register.
 - Community pharmacists developing local clinical services.
 - Pharmacy technicians delivering more services directly to people.
 - Provision of public health services such as sexual health and smoking cessation services.
- The community pharmacy contracts provide the infrastructure to allow new ways of working.
- The White Paper *Pharmacy in England: building on strengths – delivering the future*, was published in April 2008. It outlined the increasingly clinical focus for the profession, and the development of pharmacies as ‘healthy living’ centres. The consultation on the proposals for legislative change, which flow from the White Paper was published in August 2008.
- *One Wales*, published in 2007, which set the direction of travel for development of services in Wales and builds on earlier ‘Remedies for Success’ – a pharmacy strategy for Wales (2002).
- A further look at pharmacy’s role in the wider healthcare system has been led by Lord Darzi, whose report, *High Quality Care for All*, on the NHS Next Stage Review was published in June 2008.
- The *Responsible Pharmacist Regulations* which are the first step in freeing up pharmacists from their traditional dispensing role to use their clinical skills to better effect and to improve the range of health services available in the pharmacy.

Slide 5 - Benefits

21. The Government is aiming to achieve the following benefits from the change:

- Sending a clear message to the public that patient safety is paramount in the provision of medicines and other pharmacy services
- Ensuring registered professionals are fit to safely deliver a wide range of services to the public

- Regulation is as much about sustaining, assuring and improving professional standards, as it is about identifying poor performance or bad behaviour
 - Regulation should not create unnecessary burdens, but be proportionate to the risk it addresses and the benefit it brings
 - Ensuring the regulator has the agility to respond to public expectations and advances in practice
 - Providing a framework for continuing professional development and revalidation
 - Providing a framework for setting standards for advanced levels of practice
 - Ensuring greater openness about pharmacy through the involvement of more lay people on the Council
22. The vision for pharmacy is that regulation will be designed to support and enable the working lives of pharmacists and pharmacy technicians, and open up pathways to a satisfying career, rather than purely as a means of discipline.
23. The Government is harmonising the regulation of health professionals according to a set of key principles. These include independence from the Government and profession.

Slide 6 – How?

24. The Department of Health (DH), which is setting up the GPhC, and the Pharmacy Regulation and Leadership Oversight Group, which is advising on the process, will be consulting and involving professionals to ensure we have the best possible regulatory body and that views are taken into account.
25. They will also be working closely with other stakeholders involved in advising on the professional leadership body to try to ensure that the demerger is as seamless as possible.
26. The PRLOG has been set up to work with stakeholders to make sure the establishment of the GPhC happens efficiently, safely and effectively.
27. Its aim is to ensure the best regulatory system for the public, patients, carers, the profession and the Government.
28. It is an oversight, not an executive, group and it also has a role to monitor the continuity of professional regulation in pharmacy during the period of separation from the professional body, and to advise Ministers regularly of progress. The Group is as much concerned about ongoing regulation as the transition of the regulatory functions to the GPhC.
29. A key element of the PRLOG's work is to engage with stakeholders to ensure their views are heard and fed into the process.
30. The PRLOG held its first meeting in August 2007, and has met quarterly since.

31. The group has 21 members from all four countries in the UK. Ken Jarrold CBE, previously a Strategic Health Authority Chief Executive and Director of Workforce at the Department of Health, is the chair. The Society's President is also a member of the PRLOG.
32. The PRLOG's remit includes Scotland and Wales. The Health and Social Care Act 2008 gives Northern Ireland Ministers the powers, should they wish to use them, to separate regulation and leadership in NI, and to form a UK regulator for pharmacy. NI Ministers have deferred their final decision on this issue until the GPhC is up and running.
33. The Health and Social Care Act 2008, which received Royal Assent on 21st July 2008, includes enabling legislation to create the GPhC.
34. A section 60 Order is an Order made under s60 of the Health Act 1999. The Health and Social Care Act 2008 Schedule 8 extends the remit of a section 60 Order. This extension of power allows the creation of the GPhC and the transfer of all regulatory functions from the RPSGB to the GPhC. The extension also allows provisions to be made in relation to the registration of retail pharmacies and the regulation of use of premises for the purposes of a retail pharmacy. This is new as the previous Pharmacists and Pharmacy Technicians Order 2007 (PPTO) did not refer to pharmacy premises.
35. The Order will need to be laid in both the Scottish and Westminster Parliaments and is subject to affirmative resolution. This means that the Order cannot be amended by the Parliaments, but must stand or fall as it is.
36. The recruitment advertisement for the chair of the council of the GPhC can be placed once the Order is laid, and it is anticipated that the Chair is due to be appointed by summer 2009. Once the Chair is appointed, the recruitment of other Council members can commence. It is likely that in the first instance appointments will be made by the Appointments Commission.

Slide 7/8/9 – Draft Pharmacy Order 2009 – What's new?

37. For the first time the draft Order makes the link between standards setting and safe and effective practice explicit. This should help the regulator to focus on outcomes and become truly patient focussed.
38. The draft Pharmacy Order 2009 allows the GPhC to set standards in Rules for premises, education, entry to the register, retention on the register, continuing professional development, amongst others. Before the GPhC sets Rules, it is under a duty to consult with different groups of people including service users, ensuring that the patients and public are involved from the start in defining how the new regulator carries out its functions

Slide 10 – Draft Pharmacy Order 2009- What's new?

39. The GPhC will be independent of the Government and professionals.

40. No major changes have been planned to the operation of the fitness to practise machinery. In line with Government policy, there has, however, been a move to reduce the number of statutory committees and the draft Pharmacy Order 2009 proposes 3 statutory committees as opposed to the 6 that are currently provided for in the PPTO.
41. There will no longer be a separate Health and Disciplinary Committee, but one Committee vested with all relevant powers. Often issues of health and misconduct are inextricably interwoven and there is a perceived benefit in allowing one statutory committee deal with both the issues together. The details of how the Fitness to Practise Committee will work will be contained within Rules that are made under the Order. These Rules will be drafted as part of the further work to set up the GPhC and will be subject to formal consultation.
42. To enable the regulator to operate in a flexible manner, the draft Order provides for legally-qualified or lay chairs for the committees, leaving it to the GPhC to decide what is best for regulation.
43. The Health and Social Care Act 2008 makes changes to s60 of the Health Act 1999 so that regulators' adjudication functions can be transferred to the Office of Health Professions Adjudicator (OPHA) in the future. The intention is that the GPhC should transfer its adjudicating functions to OPHA sometime after establishment.

Slide 11/12 – Draft Pharmacy Order – What's new?

No further notes.

Slide 13 –Draft Pharmacy Order – What's new?

44. It is proposed that there will no longer be a non practising register for either pharmacists or pharmacy technicians. It is the view that the GPhC should maintain registers of those healthcare professionals who are fit to practise and have maintained their CPD. Those individuals who do not wish to join the practising register of the GPhC may be eligible to join the new professional leadership body (subject to decisions being made about the membership).
45. The GPhC will maintain only one register of pharmacists, pharmacy technicians and premises. This register will be split into parts as determined by the GPhC.
46. The GPhC will have power to set all fees (including for premises) and operate flexible fee structures, if required. This allows the GPhC to respond to future changes in the pharmacy profession. For example, the GPhC could choose to operate a differential fee structure for premises depending on turnover etc or to set fees for low income registrants.

47. There is no explicit intention for the GPhC to provide for the registration of any students (undergraduates, pre-registration pharmacists, or pre-registration pharmacy technicians) at this stage.
48. The Department's view is that the safety of the public can be assured by
 - a. Carrying out pre-education checks to discover any factors which might indicate prospective students' unsuitability for training as a pharmacist or a pharmacy technician, or which might indicate areas where they might need extra support;
 - b. Monitoring and supporting students in training, including if necessary ending the training of individuals who might be unsuited to these professions or may no longer be eligible to register even if they qualified;
 - c. Providing education on the responsibilities of a registered professional including maintaining fitness to practise and adherence to a code of conduct.

Slide 14 – Draft Pharmacy Order 2009 – What's new?

49. The Department of Health deferred implementation of the remaining education and CPD provisions of the PPTO. This was to allow a clear focus on the development of the legislative framework for the GPhC which takes into account the legislative changes that have taken place since the PPTO was laid in December 2006.
50. While a delay is disappointing, it will ensure the profession is not faced with two sets of changes in a relatively short period of time and that the costs of setting up one system, only to replace it with another, are avoided.
51. It is important that pharmacists and pharmacy technicians begin to develop their CPD portfolios so they are prepared for statutory CPD when the GPhC starts in 2010. Transitional arrangements are being formulated that will allow CPD records created in the period before the statutory requirement, to form part of the assessment process.
52. The need to record CPD is already a professional requirement in the RPSGB's Code of Ethics and all pharmacists and pharmacy technicians are required to sign a declaration relating to their CPD when they apply to be retained on the registers every year.
53. A growing number of pharmacists and pharmacy technicians are already recording their CPD using the RPSGB's web-based recording system.
54. The draft Pharmacy Order 2009 sets out the framework for CPD, linking standards setting with safe and effective practice. The framework is underpinned by criteria for CPD. This flexible approach to standards setting and CPD allows the regulator to be more able to respond to changes within the professions and regulation. Prior to setting criteria, the GPhC will be required to consult on its proposals.

55. Whilst the draft Pharmacy Order 2009 does not specifically mention revalidation, the report of the Government White Paper Working Group on non medical revalidation was published in November 2008. The RPSGB has begun work on producing a standards framework for revalidation (subject to consultation with the profession and relevant stakeholders – see article 4(5) of the draft Pharmacy Order 2009). Once the standards framework has been produced, against which assessments can be made, the RPSGB will begin to pilot efficient, workable and affordable methods of revalidation. Non- medical revalidation will be set against the backdrop of the high level revalidation principles published by the working group. It is not anticipated that revalidation will become mandatory prior to 2012.

Slide 15 – Draft Pharmacy Order 2009 – What’s new

56. The draft Order contains provisions within it for the GPhC to make Rules and/or standards (subject to appropriate consultation) in relation to the areas shown on the slide. Of particular interest are the powers to make Rules relating to standards in relation to pharmacy premises, superintendent pharmacists and owners of pharmacies as these are new and are not contained within the PPTO.

There is now an explicit link between standards and safe and effective practice.

Slide 16 - Next steps

57. The advertisements for the chair and council will be placed in 2009 and these positions will be appointed to in summer/autumn 2009. All will be independently appointed through the Appointments Commission.

58. The Appointments Commission aims to ensure that as many people as possible know about the opportunities to be considered for public appointments. In most instances, this is done through advertising, although other means are used e.g. mailing list, local and national networks. All applications are considered by an expert panel, which includes an independent assessor, whose job is to ensure all decisions are made fairly. The panel decide who are the best candidates and make recommendations to the appointing authority. CHRE has recommended that the GPhC’s council should have a sufficiently broad range of interests in view of the wide range of stakeholders in pharmacy regulation. However, CHRE also recommends that there should be no representative members on the new council and no reserved places for interest groups. All members, whether registrant or public should be appointed against defined competencies.

Slide 17 – Any questions?