



*Skipton House
80 London Road
London
SE1 6LH*

*Tel: 020 7972 2000
Direct Line: 020 7972 2833
Fax No: 020 7972 1186*

18th March 2008

Dear Colleague

Please find attached a second update from the Pharmacy Regulation and Leadership Oversight Group (PRLOG) on the work to set up the General Pharmaceutical Council (GPhC).

The PRLOG held its third meeting on 4 March and its agenda covered:

- Implementation of the current Section 60 Order
- Establishment of the GPhC
- Regulatory development
- Professional body update
- Devolved issues
- Transition arrangements: ongoing regulation; human resources; communications; finance.

A wide range of areas are covered in the update, and, in particular, we'd like to draw your attention to the statutory, three-month consultation with the professions on the draft Section 60 Order legislation in the summer (subject to Parliamentary approval of the current Health and Social Care Bill).

In advance of the consultation, the Department of Health, with the support of the devolved administrations in Scotland and Wales, is seeking views on key questions which could be highlighted in the formal consultation. Please see the briefing for further details about the scope of the consultation. **We would be grateful if you would feedback your views to anne.spence@dh.gsi.gov.uk by Monday 31st March.**

We hope you will find this update useful and we would be grateful if you would cascade it to your colleagues and members as you feel appropriate.

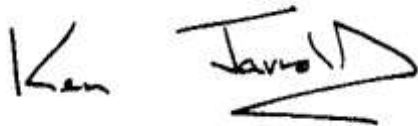
Finally, here is the link to the PRLOG web pages where you will find this update and the latest documents:

- The worked example for pharmacy professional regulation – from the Government’s Delegated Powers Memorandum which sets out how every delegated power in the Health and Social Care Bill is intended to be used
- A pharmacy regulation timeline.

http://www.dh.gov.uk/en/Managingyourorganisation/Humanresourcesandtraining/Modernisingprofessionalregulation/Pharmacyprofessionalregulation/DH_081562

Please do continue to send us your feedback and suggestions.

Yours faithfully

Handwritten signature of Ken Jarrold, consisting of the name 'Ken' followed by a stylized 'Jarrold'.

Ken Jarrold CBE
PRLOG Chair

Handwritten signature of Dr Keith Ridge, appearing as 'K.W. Ridge' with a long horizontal stroke.

Dr Keith Ridge
Chief Pharmaceutical Officer
Department of Health
England

Handwritten signature of Professor Bill Scott, written in a cursive style.

Professor Bill Scott
Chief Pharmaceutical Officer
Scottish Government

Handwritten signature of Carwen Wynne-Howells, written in a cursive style.

Carwen Wynne-Howells
Chief Pharmaceutical Adviser
Welsh Assembly Government

PHARMACY REGULATION AND LEADERSHIP OVERSIGHT GROUP

BRIEFING – MARCH 2008

1. The third meeting of the Pharmacy Regulation and Leadership Oversight Group (PRLOG) was held on 4 March 2008. This brief highlights the main updates the group received, and the advice it gave to the Department of Health.
2. The key developments are:
 - The Department is deferring the introduction of new arrangements for education and continuing professional development (CPD) until the establishment of the General Pharmaceutical Council (GPhC) in January 2010. This will allow the GPhC legislation to be developed alongside the arrangements for education and CPD to ensure the powers reflect the proposed operational procedures and the best models for future practice.
 - There will be a statutory, three-month consultation with the professions on the draft Section 60 Order legislation in the summer (subject to Parliamentary approval of the current Health and Social Care Bill). In advance of the consultation, the Department is seeking views on key questions which could be highlighted in the formal consultation.
 - PRLOG members advised that the GPhC will need to have a physical presence in each of the countries involved in the GPhC – currently England, Scotland and Wales. Northern Ireland Ministers have yet to decide their final position on whether the regulatory functions of the Pharmaceutical Society of Northern Ireland (PSNI) will be transferred to the GPhC.

IMPLEMENTATION OF THE PHARMACISTS AND PHARMACY TECHNICIANS ORDER (PPTO) 2007

3. Good progress has been made in implementing the PPTO 2007. The new, modernised fitness to practise machinery has been in place since the end of March 2007. Statutory registration of pharmacy technicians will be implemented as soon as the necessary changes to the PPTO, to extend the relevant provisions to Scotland, have been approved by the UK and Scottish Parliaments. However, in some respects, the world has moved on.
4. The PPTO 2007 was designed:
 - Before publication of *Trust, Assurance and Safety* which radically altered the policy framework, introducing a new context for healthcare regulation, pharmacy included. The various workstreams established by the White Paper continue to evolve.

- Ahead of other developments including: the Health and Social Care Bill and the provisions it makes for modernising pharmacy regulation; the forthcoming pharmacy White Paper in England; the modernising agenda of the Council for Healthcare Regulatory Excellence (CHRE); and wider developments in professional leadership.
5. Following debate on the phased implementation of the PPTO at the November 2007 meeting of PRLOG, the Chair wrote to stakeholders informing them that the Department of Health would be undertaking a critique of the PPTO from both a policy and legal perspective. He signalled that it was likely there would be a delay in implementing some of the remaining provisions – particularly those relating to education and CPD.
 6. Departmental solicitors and policy officials have now completed the critique which has been shared and discussed with Royal Pharmaceutical Society of Great Britain (RPSGB).
 7. Now the exercise is completed, it is important to emphasise that there is no intention to discard the majority of the PPTO provisions. For example, the critique identified the fitness to practise systems that the RPSGB operates now as state of the art. Unless advised otherwise, or circumstances change, these are likely to be operated by the new regulator in a very similar manner. The Department also recognises that the RPSGB has met its commitments in working towards the previously agreed implementation plan for the remaining PPTO provisions.
 8. However, the Department has taken the decision to defer implementation of the remaining education and CPD provisions of the PPTO until the GPhC is established in January 2010. This will:
 - Allow all parties to focus on development of a modernised legislative framework for the GPhC that reflects the changes that have taken place since the PPTO was laid in December 2006.
 - Enable the new regulator to discharge all its responsibilities, including those for education and CPD, in a way that supports best models for future practice.
 - Make clear the link between the regulator's primary functions, setting standards of competence, education and training, and safe and effective practice.
 - Ensure the profession is not faced with two sets of changes in a relatively short period of time (15 months) and that the costs of setting up one system, only to replace it with another, are avoided.
 9. The Department and RPSGB remain absolutely committed to the development of a robust CPD framework and a quality assurance framework for professional education that supports pharmacy professionals as they move to

take on the increasingly higher levels of clinical responsibility envisaged for the future.

10. While compulsory CPD does not in itself guarantee safe and effective levels of clinical practice, it should help to ensure that practitioners are kept aware of advances in practice, and have the opportunity to learn new skills, acquire new knowledge and develop approaches to learning which promote safe practice and identify any developmental or remedial needs.
11. The need to record CPD is already a professional requirement in the RPSGB's Code of Ethics. 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. The four Chief Pharmaceutical Officers (CPhOs) continue to actively promote this as a matter of best practice. It will be important that over the next two years all pharmacists and pharmacy technicians develop their CPD portfolios so that they are prepared for the introduction of statutory CPD when the GPhC opens.
12. The Department and RPSGB are working together to develop transitional arrangements that will allow CPD records created in the lead up to the introduction of a statutory requirement to form part of the assessment process from 2010, as appropriate.

ESTABLISHMENT OF THE GPhC

Update on legislation

13. PRLOG members were informed that the Department is currently working on the draft Section 60 Order – the more detailed (or 'secondary') legislation needed to establish the GPhC. There will be a statutory, three-month consultation on the proposed Order in the summer (subject to Parliamentary approval of the current Health and Social Care Bill).
14. In advance of the formal consultation, the PRLOG advised that the Department seeks views on key areas which could be highlighted in the consultation. This would need to be carried out with the awareness that statutory consultations are focused, rather than broad, exercises and that there is a limit to their scope.
15. The PRLOG also heard that the Health and Social Care Bill, which is the primary legislation for the creation of the GPhC, is likely to receive Royal Assent in July, following which the draft Section 60 Order can be published for consultation.
16. The Health and Social Care Bill will also establish the Care Quality Commission (CQC). The CQC is the new regulator for health and adult social care across England, which will replace the Healthcare Commission, Mental Health Act Commission and Commission for Social Care Inspection.

17. The Department will consult shortly on which health and social care services – including, for the first time, NHS providers – will be required to register with the new CQC in order to provide services. As pharmacies are registered with the RPSGB (and, in the future, the GPhC), it is not anticipated that they will also be required to routinely register with the CQC. However, in time, pharmacies may expand their activities into new fields that might require them to register with the CQC.
18. The Government has published a Delegated Powers Memorandum which sets out how every delegated power in the Health and Social Care Bill is intended to be used. The worked example for pharmacy professional regulation, covering key functions including setting of standards, fitness to practise, education and training, registration of practitioners and premises, and inspection, is now published on the PRLOG website.
19. The timescales for the legislation, which are subject to Parliamentary approval, are also published on the PRLOG website.

Operational model of the GPhC

20. PRLOG members were invited to comment on the first draft of a proposed high-level organisational structure for the GPhC and the next steps in developing the model. Benchmarking with other regulators, together with an independent review of the financial model, will also take place as the transition proceeds. They were reminded that the structure is a first draft and that this, in fact, will be a decision for the GPhC in 2009.
21. The draft structure is being developed to provide a model for costing purposes to inform the Regulatory Impact Assessment which must accompany the consultation on the draft Section 60 Order. They were also informed that legal advice is that the Transfer of Undertakings (Protection of Employment) Regulations (TUPE) are likely to apply to RPSGB staff who transfer to the GPhC, and this will involve a formal consultation with staff in due course.
22. Among a range of comments, members advised that the GPhC will need to have a physical presence in each of the countries involved in the GPhC and that these 'offices' needed to be fully integrated into the structure of the organisation. The countries involved are currently England, Scotland and Wales. Northern Ireland Ministers have yet to decide their position on whether pharmacy regulation in Northern Ireland will be part of the GPhC.

REGULATORY DEVELOPMENT WORK

23. The PRLOG members were informed that several of the White Paper working groups, e.g. non-medical revalidation, have still to report. This will be influential in determining aspects of regulatory development for the GPhC.
24. As a consequence, action to consider and assemble the expert resources agreed at the last PRLOG meeting has been delayed until there is a clearer picture of the emerging regulatory landscape. The outputs from these parallel

workstreams will be vital in scoping and prioritising the aspects of regulatory development required for pharmacy.

25. The Department and the CHRE have agreed the terms of a future-proofing exercise which is planned for completion by June 2008. This will be based on the CHRE framework *Standards for Good Regulation* and will incorporate best practice from the regulators of other healthcare professions.
26. Particular emphasis will be placed on the growing clinical responsibilities of the pharmacy workforce and the developing quality management approach, within the NHS, to securing safer systems and operations.

DEVOLVED ADMINISTRATIONS UPDATE

27. The Health and Social Care Bill gives Northern Ireland Ministers the powers, should they wish to use them, to transfer the regulatory functions of the PSNI to the GPhC. Northern Ireland Ministers have yet to decide their final position on this.

TRANSITION ARRANGEMENTS

28. The Department informed the PRLOG that it has secured extra resources of £2.9 million for the development for the GPhC, including projects on IT and the separation of records. This is in addition to the £3 million (£1.5 million in each of the financial years 2008-09 and 2009-10) that Health Minister Ben Bradshaw announced at the British Pharmaceutical Conference in September 2007.
29. In addition, a formal Transition Team, involving key staff at the Department and RPSGB, will be set up to report on progress to the PRLOG, and a formal project plan will be developed. Pensions will be an early priority for the team.
30. The PRLOG members acknowledged these positive developments and highlighted that there are still some very important issues around pensions and business continuity to be addressed.

FURTHER INFORMATION

31. For documents and further information about the PRLOG please see the website at:

www.dh.gov.uk/en/Managingyourorganisation/Humanresourcesandtraining/Modernisingprofessionalregulation/Pharmacyprofessionalregulation/DH_081562

32. The next meeting of the PRLOG is on 12 June 2008.