



Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

Pharmacy Order 2009 Consultation
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Dear Colleagues

The Pharmacy Order 2009 – proposals for consultation

I am pleased to enclose the RPSGB's response to the consultation on the draft Pharmacy Order. As the current regulator for pharmacy in Great Britain and the organisation that will form the foundation of the future professional leadership body, we have structured our response in two parts, reflecting the regulatory and professional leadership viewpoints.

The regulatory section of the response also includes an annex listing technical questions and comments on the draft Order, which has been informed by input from across the Society's regulatory functions. This is intended both to help ensure that the GPhC's legislation is fit for purpose from the outset and to allow those who are likely to be implementing the Pharmacy Order to have a clear understanding of the legislation and the thinking behind it.

As you know, the Order is an essential step in ensuring that pharmacy regulation will be fit for the future, and supported by strong professional leadership. We look forward to continuing to work with you to achieve the best possible outcome for the public, patients and pharmacy.

Yours sincerely

A handwritten signature in black ink, appearing to read 'J. Holmes'.

Jeremy Holmes
Chief Executive & Registrar

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Consultation on Pharmacy Order 2009

Response from the Royal Pharmaceutical Society of Great Britain

The Royal Pharmaceutical Society of Great Britain (the Society) is very pleased to have the opportunity to respond to the consultation on the Pharmacy Order. We have a keen interest in ensuring that the GPhC's regulatory framework is robust, fair, proportionate, transparent, accountable and efficient. The regulator must inspire the confidence of the public and the professions it regulates.

As the current regulator for pharmacy in GB and the organisation that will form the foundation of the future professional leadership body, we have structured our response in two parts, reflecting the regulatory and professional leadership viewpoints.

Part 1. Focussing on Regulation

The consultation document poses a number of specific questions which we have addressed below, together with some additional points we would like to raise. In particular, we wish to highlight four specific issues:

- We welcome the emphasis on public protection and the promotion of well-being in the main objective proposed for the GPhC and would ask that this also gives due emphasis to the quality of care. This emphasis should help to maintain and reinforce public confidence in pharmacy regulation.
- The Society has long sought updated legislation on the regulation of pharmacy premises. We welcome the provisions proposed to enable the GPhC to regulate registered pharmacies in a way which reflects both changes in pharmacy practice and the range of registered pharmacy premises.
- The Pharmacists and Pharmacy Technicians Order 2007 (PPTO) includes transitional provisions for the grandparenting period which will run for two years after the commencement of statutory regulation of pharmacy technicians. These should be carried over into the Pharmacy Order as the grandparenting period should still be in progress when regulation transfers to the GPhC.
- We welcome the intention to transfer members of the RPSGB's statutory committees to the closest equivalent committees in the GPhC but believe that this should also include members of the RPSGB's Registration Appeals Committee.

We have expanded on these points below. We have also included in our response an annex listing detailed technical questions and comments on the draft Order (Part 1 Annex A) which we hope will be helpful. This builds on the knowledge which the Society's Council and staff have gained during the development of the PPTO and the Health Care and Associated Professions (Miscellaneous Amendments) Order 2009. It is intended both to help ensure that the GPhC's legislation is fit for purpose from the outset and also to allow those who will be implementing the Pharmacy Order at the GPhC to have a clear understanding of the legislation and the thinking behind it.

Q1. Do you support having, as a main objective of the GPhC, a provision giving due emphasis to the importance of public protection and well-being?

We support this provision. The Society currently has a main objective which is focused clearly on protecting, promoting and maintaining the health and safety of the public. The additional emphasis on well-being reflects the contribution of pharmacy to the maintenance and promotion of health and well-being.

The White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* stated, as a key principle, that the overriding interest of health professions regulators should be the safety and quality of care that patients receive from health professionals¹. We therefore believe that the GPhC's main objective, and those of other health regulators, should also give due emphasis to the quality of care.

We note that the draft main objective of the GPhC is worded as follows: 'The main objective of the Council (including its staff and committees) **in exercising such of its functions as affect the health, safety or well-being of members of the public** is to protect, promote and maintain the health, safety and well-being of members of the public'. This reflects the wording of art 4(1) of the PPTO. It does not, however, reflect the wording of other regulators' objectives. For example, the HPC's governing legislation states that the Council's main objective '**in exercising its functions** shall be to safeguard the health and well-being of persons using or needing the services of registrants'. The main objectives of the GMC and NMC similarly refer to the Council 'exercising its functions' and do not restrict this to refer to only some of the regulator's functions. It may therefore be appropriate to adjust the main objective in the draft Order to read 'The main objective of the Council (including its staff and committees) in exercising its functions is to protect, promote and maintain the health, safety and well-being of patients and members of the public'.

Q2. Do you agree that these duties will improve co-operation and co-ordination between professional regulators and key stakeholders?

The duties in the draft Order to consider the interests of registrants and prospective registrants, and to co-operate with other regulators and key stakeholders, are similar to the Society's current duties under art. 4(2) of the PPTO. Hence, while we support these provisions, we regard them as a continuation of developments begun under the PPTO rather than a new departure.

The duties in the draft Order should encourage improved co-operation and co-ordination but will not of themselves achieve this outcome. As an independent regulator, the GPhC will need to consider how and to what extent it can build on current good practice to achieve and demonstrate good co-operation and co-ordination, working with a range of stakeholders for the public benefit.

The GPhC, and other health professions regulators, will need to have mechanisms in place for effective stakeholder engagement and be able to demonstrate how this informs decision making and strategic planning, so as to maintain the confidence of the public and the professions.

Q3. Do you agree with the new, more flexible arrangement for establishing the GPhC constitution?

We agree that having the details of the GPhC's constitution set out in a Privy Council order will make any future changes easier to achieve.

¹ *Trust, assurance and safety: the regulation of health professionals in the 21st century*, para 6, pg 2. Department of Health. London. February 2007

We look forward to having the opportunity to comment on the draft Constitution Order for the GPhC, in the same way that other regulators have had the opportunity to comment on their draft Constitution Orders.

Q4. Do you agree that reducing the number of statutory committees will reduce the bureaucracy associated with regulating pharmacy and will increase flexibility for the Council to discharge its duties?

Discharging statutory functions other than through a statutory committee should provide greater flexibility, helping to create an agile regulator which is responsive to changes in pharmacy practice and public expectations. It may also help the GPhC to be cost-effective. This should nevertheless be balanced against the advantages to both the regulator and those who are regulated of having clear provisions set out in rules, reducing ambiguity and the risks of costly and damaging legal challenge. Fitness to practise cases, registration and registration appeals will be covered by rules under the Order but it appears that education and CPD will be covered by standards and a CPD framework and not by rules. Nevertheless, the GPhC's decisions in these areas will have important consequences, requiring a sound legal basis. Decisions on education matters could mean that a person would be unable to register eg. if they failed the registration examination at their last possible attempt. Refusal to accredit a course could mean the loss of millions of pounds' worth of investment for an education provider. Decisions relating to CPD records could mean that a registrant would no longer be able to practise. We appreciate that the Government's intended policy direction is to avoid rules and SIs where possible but we are conscious that this is an untested approach to what are contentious areas. We would therefore ask whether consideration could be given to whether rules governing these functions could be drafted in flexible terms.

It will be important that the GPhC's powers and duties, and registrants' obligations in relation to education and CPD are clear and well understood by the public, professions and all relevant stakeholders.

The RPSGB trusts that the GPhC will maintain distinct, appropriate and sensitive arrangements for the handling of cases with a health dimension, rather than returning to a position where all fitness to practise cases were dealt with under conduct procedures. The PPTO and its associated rules spelled out requirements in this respect that have proved most beneficial in practice, and the RPSGB understands that the wording of the draft Pharmacy Order will permit, though not prescribe, that similar arrangements be maintained.

Q5. Do you agree that the UK Parliament and the Scottish Parliament should play an enhanced role in relation to monitoring of the GPhC, facilitated by improved arrangements for notification of information relating to its activities?

We welcome the provisions for accountability to Parliaments, together with the recognition that, to ensure public confidence, the professional regulators must be independent and seen to be independent². The arrangements for demonstrating accountability should be proportionate in terms of both regulatory burden and cost.

The consultation document (although not the draft Order) refers to 'Accountability of the GPhC to the UK Parliament, Scottish Parliament and Welsh Ministers'. The regulation of pharmacists across Great Britain is reserved to the Westminster Parliament. The Westminster Parliament also has responsibility for the regulation of pharmacy technicians in England and Wales whereas the regulation of pharmacy

² *Creating a New Professional Regulator for Pharmacy*, para 6.1, pg 15. Department of Health. London. December 2008

technicians in Scotland is devolved to the Scottish Parliament. Health professional regulation is not currently devolved in Wales. Hence, while we have no objection to the GPhC's reports being provided to the Welsh Assembly by the UK Parliament, it should be recognised that this would not reflect statutory accountability. It is also important to note that, as an independent regulator rather than a Non-Departmental Public Body, the GPhC will be accountable to Parliaments but independent of Governments. Hence, if the Welsh Assembly were to be given legislative powers relating to health professional regulation in future, the GPhC would then be accountable to the Welsh Assembly and not to Welsh Ministers.

We note that further discussions are planned with the regulators on the nature and content of the strategic plans referred to in the draft Order and in other regulators' legislation. The RPSGB would wish to contribute to these discussions. Care must be taken to ensure that the implementation of these provisions does not impinge upon the regulators' independence from government. Such provisions should not be brought into effect until agreement has been reached with the regulators on the nature and content of the strategic plans.

Q6. *Do you agree with placing a requirement on the GPhC to publish a description of the arrangements it has in place to ensure it adheres to good practice in relation to equality and diversity? If you agree, what would you want to see included in such a description?*

Openness and transparency in this area will be essential to ensuring public confidence, and we agree that the GPhC should report on its arrangements with regard to equality and diversity, giving evidence to demonstrate how it ensures that its activities meet legal requirements and CHRE standards in this area. We would expect such reports to make reference to the GPhC's equality and diversity scheme, its priorities in this area, the actions taken to implement the scheme since the publication of the previous report and the outcomes and learning points which have resulted. This should form part of the GPhC's strategic planning and be reflected in performance data and in a culture of continuous improvement. We would expect to see a commitment to good practice in equality and diversity from the outset, in the recruitment of the GPhC council, and throughout its work.

Q7. *Do you agree that the GPhC should be given reserve powers to register suitably experienced people, and allow additional pharmacists to act as prescribers, during an emergency?*

The Society, in its response to the consultation on the Health Care and Associated Professions (Miscellaneous Amendments) Order 2009, agreed with the principle that the RPSGB should be given reserve powers in such a case. It is therefore appropriate that these powers should now be given to the GPhC. The Society also asked that it be given powers to temporarily register people as pharmacy technicians in an emergency. These were not included in the Health Care and Associated Professions (Miscellaneous Amendments) Order 2009 and we are pleased to see such provisions in the draft Pharmacy Order.

We have the following comments on the detail:

Art 23(5)(b) would allow the Registrar to revoke an emergency registration for any reason at any time, including where there were grounds for suspecting that the person's fitness to practise might be impaired. Art 23(7) indicates that none of the fitness to practise provisions of the draft Order would apply to 'emergency registrants', other than the article relating to appeals against fitness to practise decisions. This would not be workable as none of the appealable fitness to practise decisions listed in the Order would be relevant to emergency registrants, given that Part 5 of the Order will not apply to them. If the Registrar had grounds for

suspecting that a person's fitness to practise might be impaired, he would simply remove that person from the register under 23(5)(b). It would not be workable to run appeals procedures in these circumstances. Similarly, art 24 should indicate that there would no appeals procedure linked to the removal of annotations to register entries under art 24(3).

It is possible that people might not be willing to accept emergency registration. This raises the question of whether individuals should be able to opt out if an entire group of persons is to be temporarily elevated in status (e.g. those who had recently left the register voluntarily). This should be made clear but, in any case, emergency registrants would be expected to comply with professional standards and act within their competence, as detailed currently in the RPSGB's Code of Ethics³. This suggests that art 37 (standards in respect of conduct, practice and performance) should apply to emergency registrants, as should arts 38-39 (disclosure of information: general, and disclosure of fitness to practise matters in the public interest), particularly as art 38(1) refers specifically to persons registered under art 23(1)(b).

Art 18 (fitness to practise matters before registration) would not seem applicable to emergency registrants as the Registrar would have the option of simply removing the person under 23(5)(b). It would also seem inappropriate for art 21 (indemnity arrangements) to apply to emergency registrants as it would be impractical for them to obtain cover, although it is not clear what would happen in relation to the provision of indemnity during an emergency. It is also unclear whether indemnity arrangements obtained by permanent registrants in normal circumstances, as required by article 21, would cover those registrants for exceptional, higher-risk activities taken in time of emergency. This could result in people being unwilling to come forward to provide pharmacy services in an emergency without assurance that they will be given appropriate indemnity cover, which would reduce the pool of people available to provide patient care at such a time. We therefore anticipate that Crown indemnity would be required for both permanent and emergency registrants in an emergency and would welcome clarification of Governments' thinking on this point.

It is not clear what would happen if an allegation arose relating to someone who was normally registered as a pharmacy technician but had been temporarily registered as a pharmacist under the emergency provisions. Could their 'emergency' registration be removed by the Registrar and fitness to practise proceedings be taken against them in respect of their 'permanent' registration?

Given that it is not proposed that the GPhC will maintain a non-practising register, the GPhC will need to consider how it would retain or obtain contact details and information on former registrants so as to create an emergency list eg. for use in a pandemic where there was a severe shortage of pharmacy professionals. Planning for such emergency situations should involve a range of stakeholders.

Q8. Do you agree that the link between standards set for education and training and safe and effective practice will enhance patient safety and public confidence in the profession?

We understand that one of the GPhC's key functions will be setting and securing standards of education and training. The explicit link in the Order between such standards and safe and effective practice is helpful as part of the broader aim to

³ "2.6 In an emergency take appropriate action to provide care and reduce risks to patients and the public, taking into account your competence and other options for assistance or care available.... 5.3 Recognise the limits of your professional competence; practise only in those areas in which you are competent to do so and refer to others where necessary. " *Code of Ethics for Pharmacists and Pharmacy Technicians* RPSGB. August 2007.

ensure that health professional regulators focus on patient safety and well-being and public protection. It will be essential to make this aim clear to the public and other key stakeholders, so as to secure public confidence. We nevertheless believe that the standards for education and training in pharmacy are already set with the aim of securing safe and effective practice for the future and would wish to see the GPhC's educational standards focus on quality of care, as well as safety.

There is a range of drivers which may influence educational standards. It is important that the GPhC works closely with the professional leadership body and also that it engages with other key stakeholders such as patients and the public, the NHS and other employers, higher education institutions and funders of education providers to inform the ongoing development and upholding of standards.

Standards should be publicised in an open and transparent way so that patients and the public have clear information on what they can expect of the profession.

Q9. *Do you agree that extending the remit of visitors to cover all settings where pharmacy education and training are provided will enhance quality assurance arrangements in an appropriate way?*

It is helpful to have explicit provisions for the appointment of visitors and for those visitors to undertake functions relating to a range of education & training providers.

It would be helpful if the term 'visitor' could be covered in the Explanatory Notes to the Order, as it is not widely understood in this context. We are aware, for instance, that the term is a generic one that covers a number of different roles, and we trust that the GPhC will work with others to reduce the burden on providers by avoiding duplication of visits whenever possible.

Q10. *Do you agree that these provisions will provide the GPhC with more flexibility to review and update its CPD requirements in order to keep pace with developments in science, technology and practice while retaining appropriate safeguards?*

The Society has been seeking statutory CPD provisions for several years and looks forward to this being introduced through the Pharmacy Order.

As we have noted under Q5 above, arrangements such as a CPD framework should provide greater flexibility but we would welcome reassurance that such an arrangement would be as robust and clear as having CPD arrangements set out in rules.

It is essential that the CPD framework can accommodate the range of types of pharmacy practice, so that all registrants can undertake CPD which is relevant to their work. We welcome the recognition in art 32(3)(b) that the CPD undertaken should reflect the registrant's scope of practice and the environment in which they practise.

It will be important to ensure that employers are supportive of the CPD approach adopted by GPhC. Although CPD will be a statutory requirement, it will be more successful and effective if the GPhC, at an early stage of its formation, engages with employers to encourage them to support their registrant employees in meeting the regulator's CPD requirements. It should also be noted that health professionals in conflict zones (eg. registrants serving in the military) could have difficulty completing CPD records, and the CPD framework should take this into account.

In relation to sanctions for failure to comply with CPD requirements, we suggest that consideration be given to allowing the GPhC to remove an annotation from a registrant's entry in the register rather than removing them from the register altogether eg. if they had undertaken CPD relating to their general practice but not relating to their specialist annotation (see our comments on specialist annotations below).

Q11. Do you agree that the proposed fitness to practise arrangements for the pharmacy profession strike the right balance between public confidence/patient safety and fairness to healthcare professionals?

We are content with the proposed fitness to practise arrangements in general. We note the intention to transfer the GPhC's adjudication functions to the Office of the Health Professions Adjudicator (OHPA) at some future date and would emphasise that there should be an independent audit of OHPA's functions to help inform decisions on whether these functions should be transferred to OHPA.

Given the intention that all health professional regulators will transfer adjudication to OHPA in time, it would seem appropriate to involve all the regulators in consultations about OHPA procedures and rules at this stage. This could help to avoid the inclusion of features which might make it more difficult or less attractive for other regulators to participate in future. Involving all the regulators now would also allow OHPA to benefit from a range of experiences so that it can incorporate best practice.

We are conscious of the work undertaken by CHRE on harmonising sanctions across health professions regulators. CHRE indicated that it intended to test the various terms used to describe sanctions by conducting research with patients and the public. It would be helpful to reflect the results of this research in the Pharmacy Order, if they are available in time.

Q12. Do you agree that the powers provided to the GPhC are sufficient to ensure the adequate regulation of registered pharmacies?

We are pleased to see the provisions proposed to enable the GPhC to regulate registered pharmacies in a way which reflects both changes in pharmacy practice and the range of registered pharmacy premises, from 'hub and spoke' assembly factories to more traditional community pharmacies, internet pharmacies, manufacturing pharmacies, pharmacies using robotics and pharmacies where analysis of blood products is taking place. This should enhance protection, safety and quality for all users of services provided from registered pharmacies.

The Society has been seeking up to date provisions for the regulation of registered pharmacies for many years. While the system for service delivery to patients has become more complex, regulation has been static. A submission was made to the Department of Health (DH) in 2003 but it was not possible to make such changes through a section 60 Order at that time. More recently, a submission was made in early 2007 to Lord Carter of Coles' working party on pharmacy regulation. Similarly, the Society has sought over several years to have the provision for the inspectorate incorporated in the statutory framework for pharmacy regulation, with the appropriate powers for the regulation of registered pharmacies and the investigation of fitness to practise issues.

The new provisions should allow the regulator to set appropriate standards for different types of pharmacies. We believe these standards should also be applied to premises such as those hospital and prison pharmacies that are not currently required to be registered. Importantly, the new provisions should allow the regulator to tailor regulation more closely to risk, allowing regulation of pharmacy

premises to be both proportionate and effective. In relation to proportionality, we are pleased to note that the GPhC will work with others to ensure that the burden of inspection is kept to a minimum, thereby avoiding duplication of inspections whenever possible.

Q13. Do you agree with the more flexible approach proposed in relation to fee setting for registered pharmacies?

Again, this is something that the Society has been seeking for many years. We therefore welcome this approach which should help to ensure proportionality.

The DH is also aware that the Society has long had concerns that premises fees have not fully reflected the associated costs, meaning that the financial burden on individual registrants has increased. We therefore welcome the intention that registration fees for both premises and individual registrants will be set by the GPhC. This should enable full cost recovery of the regulator's inspection and enforcement activities while also ensuring that there is an equitable balance between premises and individual fees, reflecting the risks associated with both.

Q14. Do you agree that the additional powers provided to the inspectorate of the GPhC will ensure that adequate investigations into allegations of fitness to practise can be pursued?

Again, the Society has sought updated powers for the inspectorate previously and is pleased to see its proposals reflected in the Pharmacy Order.

Q15. Do you agree that the GPhC Council should be empowered to have a more flexible approach to fee setting?

We are pleased that the draft Order provides for flexibility in fee-setting. As noted above, this is a significant change in relation to premises fees. With regard to individuals' fees, the PPTO already provides flexibility and the Society already levies different fees for practising and non-practising registrants, as well as a low-income fee and a facility for staged payment of fees.

Q16. Do you agree that the transitional provisions set out in Schedule 5 to Part 7 of the draft Pharmacy Order 2009 are fair? and

Q17. Do you agree that the transitional provisions set out in Schedule 5 to Part 7 of the draft Pharmacy Order 2009 are clear?

It is of course appropriate that fitness to practise cases which have begun under the existing legislation should be completed under those provisions, and that students and pre-registration trainees should not be disadvantaged by the transfer of regulation to the GPhC.

We note that the draft Order contains provisions to cover the transfer of relevant staff, property, rights and liabilities to the GPhC. When the GPhC is established, eligible staff will transfer from the Society to the GPhC under the Transfer of Undertakings (Protection of Employment) Regulations. The Society's regulatory responsibilities are being transferred but the Society and its assets will continue to exist and will form the basis of the new professional leadership body. Some items that are essential to the maintenance of the regulatory functions, such as databases and records, will need to be transferred to the GPhC to allow it to take over these functions but it is not anticipated or contemplated that the Society's buildings or other assets will be transferred to the GPhC.

It is important that the arrangements for the transition are fair and clear to both the public and registrants. It is not in the interests of either that there should be undue delays in completing cases. The Society is looking to the DH for financial support to ensure that the RPSGB's caseload can be dealt with as expeditiously as

possible in the period preceding the transfer of regulation to the GPhC. It is not appropriate that the GPhC should be hobbled at the outset by a significant legacy of cases.

Supplementary Comments

There are a number of other points we wish to raise about provisions in the Order. These are set out below.

Protected titles – Sch 4, Pt 1, para 1(12)

We believe that the titles of “pharmacist” and “pharmacy technician” should continue to be restricted to those suitably qualified and registered with the GPhC. We believe that the public are more likely to associate these titles, rather than the titles ‘registered pharmacist’ or ‘registered pharmacy technician’, with the relevant professions. However, the GPhC should allow former registrants who are no longer registered with the GPhC to describe themselves as “former” or “retired” pharmacists/pharmacy technicians. The future introduction of revalidation may provide opportunities for further review of this area.

The PPTO includes a transitional provision relating to protected titles, which we have commented on below (see “***Transitional provisions – Sch 5***”, p. 14).

Non-practising register

The broader definition of “practising” in the draft Pharmacy Order will encompass more members than is currently the case with the PPTO definition. However, not all of these registrants will wish either to remain on a register that is restricted to practising registrants, or to describe themselves as “former” or “retired” pharmacists or pharmacy technicians.

The GPhC should consider maintenance of a non-practising register. This should be beneficial to the public, registrants and the GPhC, in that it could provide access to a suitable pool of expertise in case of emergency (e.g. a flu pandemic) and could facilitate return to practice for those on career breaks.

We note that art 8(2) of the draft Order states ‘A person is not entitled to be entered in the Register as a pharmacist or a pharmacy technician if that person does not intend to practise in Great Britain, the Channel Islands or the Isle of Man’. The nearest equivalent article in the PPTO (art 11(2)) was included to take account of the non-practising register but it is not clear why this article would be needed now. All GPhC registrants will have to meet requirements in relation to maintaining fitness to practise eg. CPD, completing relevant declarations and, in due course, revalidation. So long as they continue to meet these requirements, they would be considered as fit to practise, whether or not they intended to do so.

We recognise that CPD could be problematic if someone was not practising but art 8(2) could cause significant difficulties for persons wishing to remain on the register but not practising within GB for a period eg when travelling, working overseas, looking after children or acting as a carer. It is not clear over what period a registrant could state that they intended to practise in GB/CIs/IoM without actually doing so. For example, some voluntary organisations might require or ask a pharmacist or pharmacy technician who wished to undertake voluntary work overseas to maintain their registration in GB whilst doing so, particularly if they were working in countries where there was no effective local system of regulation. In addition, pharmacists employed in the pharmaceutical industry might work overseas for considerable periods but need to be able to return to work in GB at short notice. Registrants working in the military would also need to maintain their GPhC registration when working overseas.

Functions of the GPhC – art 4(3)(c)

This states that part of the GPhC's functions will be to establish requirements 'by reference to which registrants must demonstrate that their fitness to practise is not impaired'. Such requirements should apply to both registrants and prospective registrants but it may not be reasonable for them to be required to prove a negative in this way. We suggest that this wording be reviewed.

Proficiency in English -- art 9(6)

The opening up of European borders has enabled practitioners to move freely within Europe to practise their skills. Given the number of countries involved, there is a great diversity of language within Europe. From a patient perspective of safety and confidence, communication is key to building trust in the patient-practitioner relationship, insofar as the interpretation and communication of clinical information must enable the patient to clearly understand the information given.

The Society is concerned that Article 9(6) may serve to compromise patient safety as it would prevent the GPhC from testing exempt persons to ensure that they are proficient in the knowledge and use of English. We believe this restriction should be removed. It is difficult to see how any applicant (exempt or not) could meet the standard of proficiency which the Council considers necessary for the safe and effective practice of pharmacy without being competent in the English language. Lack of such competence could put patients at obvious risk.

We have considered the position with regard to language testing in Europe. Article 53 of Directive 2005/36/EC states that "Persons benefiting from the recognition of professional qualifications shall have a knowledge of languages necessary for practising the profession in the host Member state".

The EU Commission is not against language testing per se but refers to this needing to be proportionate and not part of the recognition of qualification process. The Commission's view is set out in their guide to Language Knowledge dated 9 November 2006 (MARKT D/15748/2006-EN) and in the Transposition Guide on Directive 2005/36/EC dated 2 August 2007 (MARKT D/3412/2/2006/EN).

It would be in keeping with the spirit of the Directive to regard 'recognition' and 'registration' as two distinct stages of a process. In Stage 1, the GPhC would 'recognise' the pharmacy qualification as one which entitles the holder to mutual automatic recognition as it complies with the minimum training requirements and is listed in the Directive. Stage 2 would be the application for registration - these persons have then benefited from the recognition of professional qualifications and should have a knowledge of languages necessary for practising the profession in the host Member state. This should mean that, following recognition but prior to registration, the GPhC should be able to ascertain the language competency of an EEA pharmacist in a 'proportionate' manner ie. based on a minimum standard of language proficiency which the Council considers necessary for the safe and effective practice of pharmacy in Great Britain.

We therefore believe that article 9(6) should be amended to remove the restriction on language testing in the interests of patient safety and confidence. Any language testing should be proportionate, in line with Directive 2005/36/EC.

CPD requirements after restoration to the register – art 26(3)(c)(ii) – and Specific obligations and powers of the Council in respect of education and training – art 33(a)(iii)-(iv)

Article 26(3)(c)(ii) provides for the Council to determine that an application for restoration to the register should be granted subject to the applicant agreeing to comply with undertakings concerning CPD. Although the Council would be accountable for the delivery

of all the GPhC's functions, this arrangement does not seem consistent with the separation of functions between those who make policy (ie. the Council) and those who apply it in individual cases. In the absence of a statutory CPD committee, we suggest that such decisions be taken by the Registrar, who would be able to seek expert advice as required. Such advice could potentially be provided by a non-statutory Education Committee. It would not seem necessary to refer every decision for expert advice as some cases, such as a refusal to supply a CPD record, might be clear-cut. Criteria could also be agreed to assist the Registrar.

It is also unclear how the Council would fulfil the obligations imposed on it by art 33(a)(iii)-(iv) (to determine education & training to address fitness to practise matters, in respect of restoration to the register and in respect of registration in another part of the register) without becoming involved in the application of Council policy in individual cases.

Specialist annotations - CPD Art 32(2) and FtP sanctions Art 43(2)

Article 32 refers to the possibility of removing someone from the register for failing to meet CPD requirements. It would be helpful for the GPhC to have the option of removing an annotation from someone's entry in the register rather than removing them from the register altogether eg. if they had undertaken CPD relating to their general practice but not relating to their specialist annotation. This would be a proportionate response. This is also relevant to the situation where a registrant acquires a specialist annotation but does not make use of it (eg. attains prescriber status but does not prescribe): if they were to retain the annotation, it would be important that they keep their knowledge up to date.

Similarly, under article 43(2), there might be performance, or even conduct, issues, which could be addressed by removing a specialist annotation from a person's entry in the register. It would be helpful to clarify whether this should be included as a potential sanction in the Order or whether it would be covered by a conditional registration order.

Appealable decisions - art 28(1)(b)-(e) & (j)

Art 28(1)(b)-(e) & (j) provide for registration decisions to be appealable to the Appeals Committee. The equivalent provisions in the PPTO (42(1)) stated that such decisions were appealable only if the person's application, in its form & manner and as regards the information provided with it, complied with the requirements in rules. Equivalent wording should be included in the Pharmacy Order, to avoid a situation where an applicant would be able to appeal against a decision not to register them even when they had failed to provide the relevant information, leading to unnecessary hearings and costs.

Education and training – art 31

It would seem appropriate for this article to refer in addition to the acquisition of experience (as does the PPTO), as this would also be relevant to achieving the standards of proficiency required in order to be registered.

We note that the Order does not contain provisions equivalent to art 64 of the PPTO (education and training outside the United Kingdom), nor does it oblige the GPhC to accredit pharmacy degrees in Northern Ireland (art 14(c), PPTO). We would welcome reassurance that art 31(6) of the draft Order would allow the GPhC to approve pre-registration training in the Channel Islands and Isle of Man, or training of up to 13 weeks' duration in the EEA, as the RPSGB may currently. We would also welcome confirmation as to whether this provision would allow the GPhC to accredit MPharm courses in Northern Ireland if it chose to do so.

We would also welcome confirmation that the Order would allow the GPhC to require prospective registrants to meet the requirements for education, training and experience prior to registration within a set period (as an alternative to the current limit of four attempts

at the registration examination), so as to ensure that knowledge is current at the point of registration, and to make exceptional arrangements in individual cases where appropriate.

Completing the registration process

We are aware that a number of people have begun the process towards registration as a pharmacist but not completed it at graduation, and have then lost touch with the RPSGB. For example, someone might begin the pre-registration programme but not complete it, or fail the registration examination but not come back for a retake, or gain their MPharm degree then commence pre-registration training ten or more years later. Under current byelaws people can leave the pre-registration programme and return at any point, perhaps having no contact with pharmacy practice, other than as a patient, in the intervening period.

This presents risks to the health and safety of the public as, by the time someone completes the registration process, the knowledge base underpinning their practice may no longer be current. Similarly they may re-join the pre-registration programme with out-of-date knowledge and no relevant timely experience. We had hoped to address this anomaly through education rules under the PPTO but these were overtaken by the transition to the GPhC. We understand it is not intended that the GPhC should have education rules, and that relevant issues will need to be addressed through non-statutory rules and processes. It would therefore be much appreciated if the Pharmacy Order could address this difficulty explicitly in the body of the Order and in the transitional arrangements. This might be achieved through a transitional arrangement giving anyone who has obtained a pharmacy degree but not registered, a period within which they would need to complete the registration process. This should be coupled with a power to set a maximum period within which new prospective registrants would be required to complete the process from commencing their MPharm to registration as a pharmacist. Given that this would generally take five years, a suitable maximum period might be ten years. This could be considered in the non-statutory rules going forward once the current situation, which affects around 100 individuals, is rectified.

Similar provisions would be required for pharmacy technicians. Prospective pharmacy technicians with non-standard qualifications would need to register during the two-year grandparenting period following the commencement of statutory registration but there may be others who have obtained, or will obtain, the required S/NVQ3 qualification some time before seeking registration. We are aware that other healthcare professionals, and indeed other professions, have similar time limitation requirements for completing qualifications for registration.

Information on prospective registrants – art 38

We welcome the inclusion of both registrants and prospective registrants in art 38 (Disclosure of information: general). The Society's experience suggests that this will be a significant improvement. The equivalent article in the PPTO (art 46) does not cover prospective registrants and this creates considerable difficulty for the Society in discharging its statutory functions relating to the fitness to practise of prospective registrants. This change should mean that the GPhC will not encounter similar difficulties.

It would be helpful if separate consideration could be given to the availability of information on prospective registrants across the GB countries to inform workforce planning and the planning of education & training eg. for NHS workforce development groups. Procedures or Memoranda of Understanding might usefully be drawn up with relevant stakeholders to facilitate appropriate sharing of information and to promote understanding of, and confidence in, the process.

Consultation on rules – art 55(3)

Art 55(3) would appear to oblige the GPhC to consult primary care organisations and all the other groups listed every time a rule change is proposed. This would be a significant extension to the requirement under the PPTO (art 66(3)), where primary care organisations must be consulted only on rules relating to proceedings. Wording similar to art 4(5) of the draft Pharmacy Order would allow consultation to be tailored as appropriate to the rules in question.

Definition of 'lay' – Sch 1, Pt 1, para 1(1)(b)

The draft Order defines lay Council members as those who are not and have never been registered, and do not hold qualifications which would entitle them to apply for registration with the GPhC. The concept of a registrable qualification in pharmacy is complex and can be time-consuming to assess. It seems unlikely that the Appointments Commission would be able to assess whether an applicant for lay membership who held a pharmacy qualification actually held a registrable qualification. The applicant might also be unsure. For example, any EEA national with an EEA qualification might claim to have a registrable qualification. However, they might not have rights to automatic registration under the Directives but would be required to complete a period of adaptation before registering. The qualification plus the period of adaptation would then give them the registrable qualification.

The current registrable qualification for those applying for registration as a pharmacist in Great Britain for the first time is:

- A pharmacy degree (MPharm) accredited by the Society for the purposes of registration, plus satisfactory completion of the preregistration scheme (competence in all Performance Standards) and a pass in the registration examination; or
- OSPAP postgraduate diploma, plus satisfactory completion of the preregistration scheme (competence in all Performance Standards) and a pass in the registration examination.

The registrable qualification has changed over time eg. MPharm introduced 1997 (first graduates in 2001); registration examination introduced 1993; performance standards training programme introduced 2000/01.

Persons holding a registrable qualification would therefore include:

- A person holding a degree accredited by the Society for the purposes of registration, who had also satisfactorily completed the pre-registration scheme and the registration examination but had then opted not to register. Only a handful of people would be likely to be in this position. The main reason for people doing this is because they are about to go to another country where the training they have already completed will be acceptable for the purposes of registration without the need for having been registered in GB. This is estimated to be less than 20 people per year and is decreasing as regulators in other countries tighten up their requirements;
- A person who had registered before the current pre-registration scheme and registration examination were introduced but had then resigned from the register. Such a person would be excluded from lay membership as a former registrant in any case. Another person who held the same academic qualification (eg a BPharm gained in the 1970s) but had not completed the pre-registration scheme at that time would be deemed not to have a registrable qualification. A person who held the same academic qualification and had successfully completed the pre-registration scheme at that time but not registered would also be deemed not to have a registrable qualification, as his qualification would not meet the current requirements for registration.

- Pharmacists registered by a Competent Authority in an EEA Member State might be deemed to have a registrable qualification, under the EU Directives applying to free movement of professionals. EEA pharmacists do not need to register with a professional body in their home State to be eligible to apply to register in GB. It is the possession of a Directive-compliant qualification which leads to the automatic recognition of that qualification. All Directive-compliant qualifications which comply with the minimum training requirements set out in the Directive are potentially registrable qualifications. The complicating factor here is that a Directive non-compliant qualification can, in defined circumstances, lead to automatic recognition if the holder has worked for 3 consecutive years in the last 5 years in a Member State - the registrable qualification is then the Directive non-compliant qualification plus the 3 consecutive years of practice.

It would be preferable, and simpler, to define a lay person as someone who is not and has never been registered as a pharmacist or a pharmacy technician, either in Great Britain or elsewhere. We nevertheless recognise that, for example, someone who had failed the Society's registration examination three times and therefore been unable to register might not seem appropriate as a lay member. In addition, a non-registrant Head of a School of Pharmacy could be considered to represent a conflict of interest as a lay member. Individual applicants for appointment to the GPhC should therefore be assessed carefully by the Appointments Commission.

Council members' remuneration – Sch 1, Pt 1, para 3

Art 34(13)(a) provides for the payment of fees and allowances in respect of visitors 'including the payment of allowances to employers of visitors for the purposes of enabling visitors' to perform functions under the Order. It would be much appreciated if similar wording could be included in Sch 1, Pt 1, para 3, to allow payments to be made to Council members' employers. This could be very helpful in enabling NHS-employed registrants to serve as Council members without any adverse impact on their pension rights.

More broadly, we believe that the GPhC, in determining Council members' remuneration, should take account of the report on *Enhancing Confidence in Healthcare Professional Regulators*⁴, which is aimed at promoting consistent good practice in regulators' governance arrangements.

Transitional provisions – Sch 5

The PPTO includes transitional provisions for the grandparenting period which will run for two years after the commencement of statutory regulation of pharmacy technicians (PPTO Sch 5, para 6). In addition, Art 29(3) of the PPTO (Offences relating to the Register of Pharmacy Technicians) provides that a person may use the title 'pharmacy technician' without committing an offence until the end of the two-year grand-parenting period which follows the coming into force of art 29 or, if that person has applied to be registered as a pharmacy technician during that period, until their application has been disposed of. These provisions need to be carried over into Sch 5 of the Pharmacy Order as the grandparenting period should still be in progress when regulation transfers to the GPhC.

Members of Committees – Sch 5, para 2(1)

We welcome the intention to transfer members of the RPSGB's statutory committees to the closest equivalent committees in the GPhC. It makes sense to build on the experience and training of existing panellists. However, the provisions do not cover members of the RPSGB's Registration Appeals Committee (art 7(1)(f) of the PPTO). There is a good deal

⁴ Niall Dickson, King's Fund and DH – regulation, workforce (2008). *Implementing the White Paper 'Trust, Assurance and Safety': Enhancing confidence in healthcare professional regulators – final report and DH response to recommendations*, London: Department of Health

of commonality between the matters covered by this committee and the remit of the proposed Appeals Committee so we would be grateful if art 7(1)(f) of the PPTO could be added to para 2(1).

Financial and audit matters – Sch 5, Pt 1, para 16(1)(c)

This paragraph provides for the GPhC carry out functions ‘expedient consequent on the dissolution’ of the Society. It is not intended that the Society be dissolved and this provision should therefore refer to functions consequent on the transfer of the Society’s regulatory functions to the GPhC.

Cancellation of Council elections in 2010 – Sch 5, Pt 1, para 17

We welcome the inclusion of these provisions to avoid the Society being obliged to hold a Council election within a short period before the transition to the GPhC and the professional leadership body. This should allow resources which would otherwise have been expended on the election process to be used to support the transition, and allow continuity of membership, experience and knowledge on the Council during the latter part of the transition period.

Name of the organisation and distinction between the Council and the organisation

The term ‘pharmaceutical’ is often thought to refer to the pharmaceutical industry rather than the pharmacy profession. It might therefore be preferable to use a more easily understood name for the new regulator. One option would be ‘General Pharmacy Council’. The survey results highlighted in the White Paper *Pharmacy in England: building on strengths – delivering the future* stated that ‘The term ‘pharmacy’ is well understood’⁵, so it would seem logical to use this term in the name of the new regulator.

Alternatively, the opportunity might be taken to give the new regulator a name that would be more meaningful to the public and patients, such as ‘General Pharmacy Regulator’. This would also enable a distinction to be made between the regulator as an organisation and a legal entity, and the Council, as the governing body of the organisation. With the terminology proposed for the GPhC, the organisation and its governing body would both be termed ‘the Council’. This is also the case with other health professions regulators and can lead to confusion about whether a reference to, for example, ‘the GMC’ or ‘the Council’ is intended to refer to the organisation as a whole or its governing body.

It would seem helpful for the GPhC’s terminology to enable a distinction to be made between the organisation and its governing body. This would also help to emphasise the strategic role of the governing body as envisaged in the White Paper *Trust, Assurance and Safety*.

Insufficient evidence

Under the PPTO and current rules, it is not clear what options are open to the Society as to whether the Investigating Committee should refer an allegation in circumstances where it appears to the Society (and its external legal advisers) that there is insufficient evidence to provide any realistic prospect of a finding of impairment. It is not clear whether the Society has to proceed to have that allegation heard by the Disciplinary/ Health Committee, with all the consequences in terms of stress to the registrant, loss of resource to pursue other cases, and costs to both parties (and potential costs liability for the Society following the eventual hearing), or whether the Society could simply offer no evidence. Even if the Society could offer no evidence in these circumstances, it seems that the allegation would still have to proceed as far as a hearing/case management meeting, with attendant costs consequences.

⁵ *Pharmacy in England: building on strengths – delivering the future* pg 14. Department of Health. London. April 2008

The Society is managing this issue currently by including, within its threshold criteria for non-referral of cases, those cases where there is no prospect of obtaining sufficient evidence to prove impairment of fitness to practise. It would nevertheless be helpful if the Pharmacy Order could include a specific provision to permit the GPhC to cease to pursue an allegation in circumstances where the Registrar considers that the facts, if established, would not be capable of amounting to impairment of fitness to practise or that there is no reasonable prospect of obtaining sufficient evidence to prove impairment of fitness to practise.

Part 1 Annex A

Additional questions and comments on consultation draft of Pharmacy Order

Art 1(3)

Our understanding is that this means that, once the GPhC council is in place and the Order is made, the council can make rules and set standards for the GPhC. It would be possible for consultations on draft standards or rules to take place before the full GPhC council was in place and before the Order was made but the GPhC council would still need to undertake some consultation itself to satisfy the requirements of arts 4(5) and 55(3). Is that correct?

Art 3 – definition of ‘registrant’

This does not encompass registered pharmacy premises. How does this fit with the definition of ‘the Register’ and the reference to ‘as respects any registrant’ above this?

Art 4(10)

What happens if the information requested is not provided? Is there a need to state that this may be treated as misconduct?

Art 4(10)(e)

How does this provision fit with the requirements in art 21 for individual registrants to have adequate professional indemnity arrangements?

Art 4(11)(b)-(c)

Should b(i) & (ii) and (c)(i) & (ii) all refer to ‘in the UK or elsewhere’?

4(11)(c) refers to a body corporate; how would a partnership be covered?

4(11)(c)(i)-(ii) refer to offences with which a corporate body has been charged or investigations into that body’s conduct; should they also refer to offences with which its directors have been charged or investigations into directors’ conduct?

Art 4(13)

Would it be helpful to add ‘or any other enactment’ to the end of this paragraph, in case there is a wish to confer further enforcement functions on the GPhC through other legislation in the future? Sch 1, Pt 2, para 1(e) has a provision along these lines but this relates only to the Inspectorate.

Art 4(15)

What does ‘officers’ mean here? This could cause confusion as this term is used by the RPSGB to refer to the President, Vice-President, Treasurer & Immediate Past President. It may be helpful to use another term or to define ‘officers’ in the Interpretation article.

Art 6(6)

For the avoidance of doubt, should words be added to this article along the lines of ‘and where the Registrar does so, a reference in this Order, in rules under this Order or in any other enactment to the Registrar, if it relates to that matter, shall include reference to the person so authorised’?

Art 7(3)

We presume that ‘protected’ in this article means restricted by law but are not sure what ‘designated’ means here. Presumably the GPhC would not want to record titles which a registrant was entitled to use as a result of their qualifications, education and training but which did not relate to their registration by the GPhC or to an annotation in the register.

Would it be clearer to say 'protected or prescribed', so as to refer to titles that were restricted by virtue of legislation, including by rules under this Order?

Art 7(4)(c)

Would it be helpful to include something about recording the name of a registrant? (It may be necessary to record someone's legal name and the name under which they practise). If so, art 11(1)(b)(i) re. information to be provided by applicants should mirror this – currently, this refers only to the name under which an applicant practises or intends to practise, which may not be the registrant's legal name in some cases.

Art 7(5)

Is there a need to mention premises registered under s74C of the Meds Act here too?

Art 7(7)

Is it appropriate to say 'the Register' here or would it be better to refer to any lists published under 7(6) above? Presumably the GPhC would not give the public access to the Register database (which would contain sensitive data, including registrants' home addresses) but this paragraph could suggest that it should do so.

Art 7(8)(k)

The pharmacies as such will not order drugs etc. Would it be preferable to say something like 'pharmacies designated as pharmacies from which drugs, medicines and appliances may be ordered in a specified capacity', to match the wording in s74D(1)(a) of the Medicines Act 1968?

Art 9(6)

Should the reference to art 8(1)(c)(iii) be a reference to 8(1)(a)(iii)?

Art 10(1)

We think the words at the end of this paragraph ie. 'having successfully ... Regulations' should be deleted. We had previously queried the equivalent words in art 23(1) of the Pharmacists and Pharmacy Technicians Order 2007 (PPTO) as we did not think they were relevant to 23(1)(c)(ii) – this refers to requirements which could be imposed under the Second General Systems Directive and we did not think that the persons in (aa) & (bb) could benefit from these. At the time, we were advised that the words were permissive and could be left in place for the time being. However, these words have since been deleted from the PPTO by art 83(b)(ii) of the European Qualifications (Health & Social Care Professions) Regulations SI 2007/3101.

Art 11(1)(b)

Should a provision similar to this article be added to the new s74A of the Medicines Act 1968? It may also be helpful to include the equivalents of arts 11(2)-(5) in the new s74A.

Art 11(8)

We think this should say 'evidence of E's health', not 'fitness to practise'.

Art 11(9)

We would be grateful if the reference to 'a certificate' could be changed to 'certificates', so as to allow the GPhC to obtain a certificate from the competent authority and an extract of the judicial record, rather than simply 'a certificate' Annex VII of Directive 2005/36/EC permits the RPSGB to require 'documents issued by Competent Authorities' showing that the applicant is of good character or repute and not prohibited or suspended from pursuing their profession because of serious professional misconduct or a criminal offence.

Art 11(11)(a)

We would be grateful if the 'or' at the end of this provision could be changed to 'and', as persons who may have fitness to practise matters pending may be more likely to use free movement to avoid conduct proceedings in the Member State of qualification

Art 12(2)

We suggest that this should read:

'Where the Registrar refuses to enter, renew or restore an annotation or removes an annotation in respect of a specialisation in the Register, the Registrar must send to the last known home address of the person making the application for entry, renewal or restoration of the annotation, or in respect of whom an annotation was removed, a statement in writing giving that person notice of the reasons for the decision and of any right of appeal to the Appeals Committee under article 29.'

We believe this should state 'any right of appeal', as there would be no right of appeal if an entry or renewal was refused because the correct fee was not paid nor, presumably, if the applicant failed to provide the required information.

Art 13(6)(b)

Could the reference to 'any document required' include additional information to determine an applicant's fitness to practise?

Art 17(2)

The draft Health Care and Associated Professions (Miscellaneous Amendments) Order 2009 (HCAP Order 2009) proposed changing 'pharmacist or pharmacy technician' to 'person whom the Registrar General believes to be a registrant'. It would seem helpful to include this change in this Order.

Art 17(5)

Should 'from the Register' be changed, in both places, to 'from the Register or a part of the Register'?

Art 18(1)(a)

The reference to 'prescribed circumstances' here would seem to mean that these would have to be specified in rules. This could potentially lead to inflexibility &/or to people whose fitness to practise was impaired slipping through the net because their circumstances did not fit within the provisions in the rules. The PPTO wording refers to 'involvement in a serious matter'. We understand that a "serious matter" would be regarded as a matter that would be likely to affect the pursuit of practising as a pharmacist or pharmacy technician, as applicable. Is there a specific reason for the change of wording?

Art 18(3)

Would it be helpful to say 'If a person fails to comply, or if in respect of that person there is a failure to comply, with rules...'?

Art 18(4)

Should 'from the Register' be changed to 'from the Register or a part of the Register'?

Art 19(2)

We think this should state 'any right of appeal' eg. there would be no right of appeal if the fee had not been paid.

Arts 20(2) and 21(9)(b)

Should 'from the Register' be changed to 'from the Register or a part of the Register'?

Art 23(2)

Should this state 'in the Register or in part of the Register', to allow for the possibility of pharmacy technicians being temporarily registered as pharmacists under the emergency provisions? If so, this would also apply to the remaining provisions in this article.

Art 24(1)(b)

Should this say 'who are of a type', not 'the type'?

Art 24(3)(b)

There is a need to make clear here that there would be no right of appeal.

Art 25(3)

Should this say 'in respect of an entry or renewal of an entry'?

Art 25(5)

This refers to the 'Register of registered pharmacies' but there is only one Register, with different parts, so would it be helpful to say something like 'in relation to entries of registered pharmacies in the Register'?

Art 26(1)(f)

Should art 21(7) be mentioned here too?

Art 26(3)(e)

Should the reference to art 25(1)(a) be to 25(1)(b)?

Art 26(5)

We think this should be 'any right of appeal' eg. there would be no right of appeal if the fee had not been paid or the relevant information not provided.

Art 27

Should there be an offence relating to misrepresentation as to whether a registrant is entitled to practise only in compliance with specific conditions/undertakings, or as to a registrant's previous fitness to practise history?

Art 28(1)(d)

Is there a need to say 'from the Register or from part of the Register' here eg. if someone was registered as a pharmacist and as a pharmacy technician but only applied to renew one of these registrations? There may also be a need to say 'or part of the Register' in 28(1)(e), (f), (g), (h), (i) & (k).

Art 28(1)(e)

Should this say 'to enter, renew or restore'?

Art 28(1)(f)

This refers to rules under 12(1)(a) or (b). Should this be simply 'rules under 12(1)', as all of 12(1) is relevant to the rules, especially 12(1)(e)?

Art 28(1)(n)

Would the appeals provisions cover:

- Approval of underpinning knowledge/qualifications for pharmacy technicians?
- Approval of preregistration tutors (including completion of training programmes by tutors)?
- Approval of training sites and training programmes (may be separate in future)?
- Approval of delivery of training programmes for preregistration tutors?
- Approval of entry to preregistration year?

- Signing off of training (staged/final reports) and adjustments to preregistration training for individuals?
- Decisions in relation to overseas applicants to complete an MPharm as opposed to an OSPAP?

Art 28(1)(q)

Should this also cover refusal to renew an entry?

Art 28(2)(b)

Should the reference to art 9(1)(c)(i) be to 9(1)(d)(i)?

Art 29(1)

The 28 days runs from the date on which the GPhC sends the person a statement of the reasons for its decision. Does this mean that, in order to qualify, the notice of appeal would have to be received by the Registrar within 28 days of the date shown on the statement of reasons for decision?

Art 29(4)(d)

What are the limits of matters which could be covered in the Appeals Committee's directions? Is this any broader than in (4)(c) above?

Art 30(3)(d)

This should refer to the relevant court's directions, not the Appeals Committee's directions.

Art 31(1)(a)

Should this also refer to the standards to be achieved in order to have an annotation in the Register?

Art 31(1)(b)(ii)

Would this allow the GPhC to carry out fitness to practise checks relating to health on applicants applying for eligibility to enter an OSPAP? Also, should the Order include a provision relating to requirements for admission to, and continued participation in, education & training relating to specialisations? (not covered by 33(a))

Art 31(2)

We are not clear what 'such matters' means here. Does this need to refer to establishing, publishing & promoting standards and then go on to relate this to the specification of outcomes of education & training?

Art 31(5)(a)

Is there a need for a reference to arts 9(1)(a) & 10(1)(a) here? The article could possibly also refer to 9(1)(c)(iii) or 9(1)(d)(ii)(bb) and the equivalents for pharmacy technicians. Again, the provisions should allow for preregistration training to be either integrated with the MPharm or separate from it.

Art 32(1)(a)

At the end of 32(1)(a), is there a need to state 'as a pharmacist or a pharmacy technician' or 'or in part of the Register'? It would be helpful to specify that both sets of standards (ie for pharmacists & for pharmacy technicians) should be established, published & promoted, as they are very different.

Art 32(1)(c) & (d)

It is not clear how the 'requirements and conditions' in (d) would differ from the 'criteria' in (c)? Would the criteria set out what must be achieved or demonstrated and the requirements state how or how often or how well eg. 80% every 5 yrs? Alternatively, if

only one term is needed, would it be better to use 'requirements and conditions' to link with 2(e)(i) below?

Art 32(1)(e)(i)

Would the 'rules' referred to here be rules as covered by art 55 or something else? If it is something else, would it be helpful to use a different term eg. 'requirements or conditions' as in (e)(i) below? There will be a need for clarity on this and also on whether the GPhC can require a prospective or retrospective declaration or both.

Art 32(1)(e)(ii)

Is it necessary to say that the review will take place against the framework?

Art 32(2)(c)

Would the words in brackets fit better in 32(2)(b) above? It may also be helpful to insert similar words into 32(1)(b) – this would clarify that Council sets CPD standards for both general and specialised practice.

Art 32(2)(e) & (f)

Would be helpful to be explicit about the powers to remove or suspend eg. 'by the Registrar'?

Art 32(4)

We think this should refer to 'any right of appeal' as, in accordance with (5) below and with 28(1)(m), this would be an appealable decision only where the person had provided a CPD return that, in its form & manner and as regards the information provided, complied with the requirements of the framework. We would not anticipate that there would be a right of appeal where someone had simply refused to cooperate.

Art 33

The heading of the article says 'obligations and powers' but these are all 'musts'. Would it be helpful to split these into obligations and powers? Also, the article states 'the Council must'. There may be a need for an equivalent to art 16(3)(a) in the PPTO, allowing the Council to authorise the Registrar to perform functions.

Will these provisions allow the GPhC to determine requirements relating to preregistration tutors, to determine the functions of tutors and to remove tutors who no longer satisfy the requirements?

Will the GPhC have the power to make adjustments to standard arrangements in exceptional cases for the completion of approved qualifications or additional education, training or experience by candidates or prospective candidates, and also to deal with appeals in relation to results &/or conditions of assessments?

Art 33(c)

Because everything in art 33 is a 'must', this would seem to oblige the GPhC to have examiners and to pay them (but also see comment below). Would this be better as a power? We understand that the intention is to provide flexibility eg. the GPhC could have examiners and run assessments itself or it might decide to outsource this.

We are not sure of the distinction here relating to assessments 'which involve examiners'. Should this be 'which do not involve examiners' and, if so, will this provide flexibility given that everything in art 33 is a 'must'? The GPhC should be able to run a national examination or other assessment using GPhC examiners but also to be able to run other assessments which may or may not involve the examiners.

Art 34(6)

This refers to 'at least one of the visitors'. Does this mean there must always be more than one visitor?

Art 34(7)(a)(i)

Should visitors' reports be linked more explicitly with the standards & requirements set by the Council under 31(1)(b)? It may be more appropriate for visitors to check standards and look at the nature & quality of the education provision in relation to support of the standards.

Art 34(11)

It is not clear what 'take any steps' means here. Would this prevent the GPhC, for example, requesting some more information during this period, or does it mean action under art 36?

Art 34(3)

This refers to information and assistance required by the Council. Should it also refer to information and assistance required by a visitor or visitors?

Art 35(5)

Should 'qualification' be mentioned here too (it appears in 31(5)? (This also applies to 36(3))

Art 36(2)(a)

Does this mean that the Council can make rules setting out other measures which may be imposed on providers but would not mean that the conditions applied in a particular case would have to be set out in rules?

Art 36(7)

Should 'and notify them of any right of appeal to the Appeals Committee' be added here?

Art 38(5)

Should both 38(5)(a) & (b) refer to 'the person against whom the information or document is sought'?

Art 39(1)

Should this also cover disclosure of information relating to owners of pharmacy premises, including partners in a partnership and directors of a body corporate?

Art 40(1)(l)

Could a sanction issued by another regulator prior to any determination be regarded as impairment under this subparagraph eg. a warning issued at a preliminary stage without a determination as such?

Art 40(1)(m)

Should 'or the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007' be added here? Presumably this would be considered as a fitness to practise issue?

Art 41(1)

Arts 40 & 43 refer to a 'person' who is the subject of an allegation but 41(1) refers only to registrants. This could present difficulties eg. if someone had resigned voluntarily from the register under art 20 then applied for restoration under art 26 but declared a conviction that they had acquired while off the register. The Registrar would presumably refer the case to the Fitness to Practise Committee for it to decide whether or not that person should be restored to the register (if they refused restoration, this would then be appealable to the

courts under art 47(1)(a)) but it is not clear that the Committee can consider an allegation relating to a non-registrant because of the wording of 41(1).

Art 41(3)

Should the reference to paragraph 2(a) be to 2(b)?

Art 41(4)(a)

Would the registrant have any ongoing duty to update the Registrar with any changes to the information provided during the course of an investigation/proceedings eg. if s/he changes employer?

Art 41(4)(c)

Should there also be an obligation to inform the people mentioned here of the outcome of the investigation?

Art 41(6)(b)

We think 'if the person making the appeal is not domiciled' should be replaced by 'if the registrant is not domiciled'.

Art 42(2)

It may be preferable to say something like 'decides' rather than 'determines' here, to avoid potential confusion as 'determines' is usually used to refer to determinations about fitness to practise after a hearing. It is not anticipated that the Investigating Committee will hold hearings and make determinations about fitness to practise – it may close a case with a warning or advice, with the consent of the person concerned, or may refer the case to the Fitness to Practise Committee.

Art 43(1)

We think that 'an individual assessor under article 43(2)(c)' should be replaced by 'an individual assessor or an assessment team under article 44(2)(c)'.

It would also be helpful to replace 'must determine' with, say, 'must determine, except in such circumstances as may be prescribed, whether...' as it may not always be in the public interest for a case to proceed eg. if the person concerned is terminally ill.

Art 43(2)(a)(i)

This appears to make it optional for the fitness to practise committee to direct that a warning be recorded against a registrant's entry in the register but we understand it is CHRE's intention that all fitness to practise outcomes should be recorded against registrants' entries in the register

Art 43(2)(d)

This does not include the third head under which interim orders may currently be made ie that it is otherwise in the public interest. Is this a deliberate omission? (See also subpara 3(b)(v))

Art 43(3)

It would seem clearer if 'following a review' was moved eg. to after 'it may', as this could be read as if the first direction referred to in this paragraph was made after a review. In addition, the wording implies that the only sanction that cannot be reviewed is removal from the register but this also applies to a warning or advice.

Art 43(3)(a)(i)

Should this say 'impaired solely by reason of...'? Otherwise, if there are a number of allegations that have resulted in a suspension, one of which relates to health, this would

seem to prevent the committee changing the direction to removal from the register at a review hearing.

Art 43(3)(b)(iv)

This paragraph refers to a register entry being suspended but 43(3)(b)(iv) relates to the imposition of conditions, not to suspension. Also, is it appropriate to exclude the committee from directing, on review, that a person be removed from the register for non-compliance with conditions relating to health, given that the reasons for removal would be non-compliance, rather than ill-health directly?

Art 44(6)

Would it be more appropriate to provide for the Investigating Committee or Fitness to Practise Committee to direct the Registrar to seek a court order?

Art 45

Should this article include a provision explaining what will happen if the determination was based solely on a criminal conviction and that conviction is subsequently appealed successfully and overturned?

Art 43(3)(c)

This does not refer to the third head on which an interim order may be imposed currently ie in the interests of the person concerned. Is this a deliberate omission?

Art 46(10)

Should this refer to paragraphs (6) and (9), or to 'paragraph (6) or (9)'?

Art 47(1)(a)

This refers to arts 46 & 26. Art 26 does not seem to provide for referrals to the fitness to practise committee other than where someone has breached an undertaking to comply with conditions. Also, art 46 does not refer to art 26. Should it be the Registrar's decision to refuse an application for restoration under art 26 for a fitness to practise reason (albeit that rules under 26(3)(d) might provide for the Registrar to seek the advice of the fitness to practise committee)? If 47(1)(a) is to refer to the Registrar's decision, then 47(4)(c) will need to refer to 'the Registrar or the fitness to practise committee, as in 47(4)(d).

Would a decision to refuse an application for registration (as opposed to restoration) for a fitness to practise reason be appealable to the Appeals Committee or to the courts?

Art 50(2)(a)

Is this intended to apply to any party to the case or to cover wider groups eg. complainants, witnesses etc?

Art 50(2)(b)

This refers to disqualification of an individual or a body corporate. Should it refer to a partnership or would the partners all be disqualified as individuals?

Art 50(2)(b)(ii) and (c)

This refers to '...fitness to practise proceedings on any other occasion when the Committee is considering making an interim suspension order...'. Should this be '...fitness to practise proceedings **or** on any other occasion when the Committee is considering...'?

Art 50(2)(c)

Presumably this means simply that the rules should contain provisions allowing the person concerned to be represented and could not be interpreted as meaning that the GPhC would have to provide funds to enable a person to be represented?

Art 50(3)(c)(ii)

Could the rules referred to here provide for the breach to be treated as misconduct by a committee other than the committee to which the undertakings were given?

Art 50(3)(d)(i) and (j)

Is there provision for disqualification cases to be considered by the Investigating Committee?

Art 50(3)(d)(i) and (j)(i)

Should these provisions also refer to a partnership?

Art 50(3)(h)(ii)

Should this cover failure to co-operate with the investigation as well as with the committee?

Art 51(1)(a)

The RPSGB has never held hearings of the Investigating Committee but art 59 of the PPTO allows for rules to cover such hearings, as does art 50 of this Order. Should 51(1)(a) & (b) and 51(4) therefore also cover the Investigating Committee?

Art 51(1)(b)

The current wording we have in art 60(1)(b) of the PPTO states 'may issue' rather than 'may apply for the issue'. What difference would this change make?

Art 51(5)(a)

Is this also relevant to the Appeals Committee? Also, should 51(5) cover the Investigating Committee, to prevent any difficulties where a case was considered at two meetings of the Investigating Committee?

Arts 52 & 53

Please could arts 52 & 53 be permissive ie. 'may appoint'? The GPhC could then provide in rules that, for example, a legal adviser must be appointed if the chair is not legally-qualified or that a clinical adviser must be appointed where the GPhC has a medical expert attending to give evidence, but the registrant does not. If circumstances or views changed, the GPhC could then alter the rules more easily than would be the case with the Order.

Would the references in arts 52 & 53 to a 'person or body to appoint' cover a group similar to the RPSGB's Appointments Group ie. a group established by the Council to undertake this function? Sch 1, Pt 1, para 4(d) refers to 'person, body or committee'. Would it be helpful to add 'or committee' in arts 52 & 53?

Art 56(1)

Could 'and pharmacy technician' be added at the end of this paragraph please? Directive 2005/36/EC relates to both pharmacists and pharmacy technicians and describes both the mutual automatic recognition route and the General System route to the register cf. European Communities (Recognition of Professional Qualifications) Regs 2007 SI 2007/2781 and amendment of this by the draft HCAP Order 2009 Article 33

Art 56(3)

It would be helpful to clarify what the evidence of 'formal qualification' awarded by the Council is for the purpose of the Directive.

Art 56(4)

This states '...the Secretary of State may give directions to the Council to comply with its functions specified in Schedule...'. The current wording, in art 64A(4) of the PPTO, refers

to directions 'in connection with its functions specified in Schedule...'. What is the thinking behind the change and what is its effect?

Art 59(2)

Is there a need to state that this would also cover rules made under any of the articles mentioned with art 55(1)? Also, would this article apply even if the rules related solely to reserved matters?

Schedule 1

Para 1

It is not clear what 'fully registered' would mean, here and in (b)(i) below, as there is no provision for provisional or partial registration. Could the Order perhaps say something like 'who are entered in the Register as a pharmacist or a pharmacy technician'?

1(1)(b)(i),

This may need to say 'are not and have never been registered as a pharmacist or a PT', so that this would not be read as referring only to registration with the GPhC.

1(4)

Presumably this does not prevent the PC directing the Appointments Commission to appoint the first GPhC members? Is a qualifier needed?

2(1)(a)

This states that the Constitution Order must include provision with regard to the number of registrant and lay members of Council. Would this allow the PC to give the Appointments Commission some flexibility eg. to say that there should be at least X lay members, rather than specifying an exact number? PRLOG has recommended a Council of 14 members, at least half of whom should be lay

2(1)(h)

Does this need to say anything about which the circumstances in which the chair may be removed from office or is this covered sufficiently by reference to 'members'?

9(1)(e)(ii)

This seems to suggest that any other enforcement functions conferred on the Council would necessarily have to be discharged via the inspectorate. It may be better to make this more permissive. (also see art 4(13))

10(1)

What would 'duly authenticated document showing authority' mean in this context?

10(3)

This refers to 'entry to a registered pharmacy'. Should it also cover other premises?

11(1)

Should there be a power for an inspector to seize evidence eg. medicines, computers?

11(3)

Should this say anything about records being in a legible form? Is there a need to provide for the possibility that the records will contain personal information, or is that covered sufficiently under art 38?

16(6)

Does this need to cover the possibility of an appeal failing by virtue of its non-prosecution?

Schedule 2

2(4)

It would be helpful to separate references to 7(5)(a) & (b) in subsections 2(3) & (4). If entitlement ceases due to 7(5)(b) ie. a disqualifying decision, the Registrar must remove that person from the Register. If entitlement under Sch 2 ceases due to 7(5)(a) ie. becoming established, 'may remove' is more appropriate as the Registrar would remove any reference to that person being registered by virtue of Sch 2 but they could still be registered by virtue of having become established.

2(5)

Does this mean that visiting practitioners will be subject to the GPhC's CPD requirements and administrative provisions relating to the Register? This also applies to 10(9) with regard to pharmacy technicians.

4(2)(e)(ii)

Should such certificates confirm any conditions applying to the practitioner's practice?

5(2)

Should this refer to '3(9)(a) and (e)' or to '3(9)(a) or (e)'?

7(2)

Should paragraph 6(4) be mentioned here as well as 6(2)?

7(7) and 10(5)

Should these say 'from the Register or part of the Register', to allow for the possibility of a visiting practitioner who was entitled to practise both as a pharmacist and as a pharmacy technician?

9(2)(b)

Should the equivalents of Pt 1, sub-paras 1(2)(c)-(d) be added here?

10(3)

Should this refer to sub-paragraph (1) or subparagraph (2)?

Schedule 3

There is a need to add to this to take account of statutory regulation of pharmacy technicians. SI2007/ 2781 defines Competent Authority in Article 4 and its functions in Article 5 but if the functions are listed in the Order against Articles in Directive 2005/36/EC, should it relate these functions to both pharmacists and pharmacy technicians or at least refer to SI2007/2781 here?

In addition, references to 'pharmacy qualifications' may need to be clarified to indicate whether they relate to pharmacist or pharmacy technician qualifications or to both.

Schedule 4, Part 1

Is there a need to amend the Safeguarding Vulnerable Groups Act 2006 in respect of Sch 3, Pt 3, para 16(4)(c) – this designates RPSGB as a body making findings of fact – and to amend the references in the table in subsection 7 to the registers maintained under the PPTO and the registrar appointed under the PPTO? (cf draft HCAP Order 2009 Sch 5, Pt 1, subpara 9(2)(b)).

Also, is there a need to amend s17(5)(c) of the Protection of Vulnerable Groups (Scotland) Act 2007, plus subsection (5) (list of relevant health regulatory bodies) in the new section 30A of this Act which will be inserted by the draft HCAP Order 2009 Sch 5, Pt 2, para 12?

1(2)(b)(iv)

Should this refer to 4(13) rather than 4(12)?

1(3)(c) and 1(4)(b)

Is there a need to add 'other than the UK' after 'relevant European State'?

New s74A of the Medicines Act 1968

Should this section include provisions about rules relating to applications for registration of premises, along the lines of 74B (2)-(3) below but including annual renewal applications & accompanying declarations?

Should subparagraph (10) refer to notifying the applicant of any right of appeal to the Appeals Committee?

New s74C of the Medicines Act 1968

Is there a need to define 'emergency' in relation to ss74C & 74D, along the lines of that included in art 3(3) of this Order?

Is the list in subparagraph (6) intended to be exhaustive? If not, would it be helpful to say something like 'may include but are not limited to'?

New s74D of the Medicines Act 1968

Would it be helpful to add to subparagraph (4) 'without the registrar removing the equivalent annotations of the other members of the group or by virtue of a decision to remove the annotations made by virtue of subsection (1)(b) of all the members of the group', so as to match art 24(4)?

New s74E of the Medicines Act 1968

Should subparagraph (3) refer to notifying the person concerned of the reasons for the decision and of any right of appeal to the Appeals Committee?

Is there a requirement for owners of registered pharmacies to notify the GPhC of changes to ownership or of changes to partners or directors?

Could subparagraph (6) please provide that an application for restoration would need to be made in the manner determined by the Council?

Subparagraph (6) includes both 'may restore' and 'must restore'. It is not clear whether or not this is permissive.

1(12)

We think the words to be inserted in s78 should begin 'not a pharmacist registered...'. A comma should also be inserted between 'pharmacist' and 'member of the Pharmaceutical Society of Northern Ireland'.

1(14)(a) and (15)(a)(i)

What does the term 'officer' mean in these provisions?

1(16)

How does this change fit with the definition of 'Pharmaceutical Society' in (18)(b) below, to cover both the GPhC and PSNI?

1(17)

Is anything further required in relation to the amendments to ss108-110 of the Medicines Act 1968 under s31 of the Health Act 2006 (not yet in force)? In addition, do we need to

amend ss128(4)-(5) of the Medicines Act 1968, and Sch 3, para 16, to substitute GPhC for RPSGB?

2(3)

The proposed definition refers to Sch 1 of the Order but we think this should refer to Sch 2.

Should the entry in Sch 1 to the Poisons Act 1972 (Constitution of Poisons Board), referring to the RPSGB Council, be amended?

3(a)

Should this state 'after "The General Osteopathic Council", insert...'?

Schedule 4, Part 2

There is a need to ensure that all roles restricted to pharmacists registered in Part 1 of the register of pharmacists under PPTO once Part 3 was introduced by SI2007/3101 remain restricted to those persons registered as pharmacists in the register maintained under Article 7(1) of the Pharmacy Order 2009 with the exception of those who are registered by virtue of Schedule 2 of the Order. This applies to independent and supplementary prescribers, superintendents and owners of retail pharmacies. See also paragraphs 22, 37, 38, 41, 42 43 and 44.

Is there a need to amend the Family Health Services Appeal Authority (Procedure) Rules 2001 (SI 2001/3750), to substitute GPhC for RPSGB in the definition of 'appropriate professional registration body' in reg 2?

Is there a need to amend para 2(3)(e) in Sch 2 to the Medicines (Bal Jivan Chamcho Prohibition) (No. 2) Order 1977 (SI 1977/670), so as to refer to the Pharmacy Order?

Is there a need to amend the Local Health Boards (Constitution, Membership and Procedures) (Wales) Regulations 2003 (SI 2003/149) re criteria for Pharmacy member in Sch 2, Pt 2, para 14?

Is there a need to amend the Approved European Pharmacy Qualifications Order of Council 2007 (SI 2007/564) and/or the European Communities (Recognition of Professional Qualifications) Regulations 2007 (SI 2007/2781), to change the Competent Authority entry from RPSGB to GPhC? (cf draft HCAP Order 2009 Sch 4, Pt 3, para 33)?

Is there a need to amend the National Health Service (Tribunal) (Scotland) Regulations 2004 (SSI 2004/38) re. definition of 'relevant professional body' in reg 2(1)?

Is there a need to amend the National Health Service (Discipline Committees) (Scotland) Regulations 2006 (SSI 2006/330) re. definition of 'pharmacist' in Pt 1, reg 2(1) and definition of 'relevant professional body' in Pt 2, reg 4(6)(a)(iv)?

Is there a need to amend the Regulation of Care (Social Service Workers) (Scotland) Order 2005 (SSI 2005/318) re. reference to RPSGB in s3(1)(l) (Excluded persons)?

Is there a need to amend the Misuse of Drugs Regs (2001/3998) to substitute GPhC for RPSGB in regs 8(2)(j) and 9(2)(h)?

Is there a need to amend the National Health Service (Local Pharmaceutical Services etc.) Regulations (2006/552), Part 4, s16 (sharing of information received), to change references to the RPSGB to the GPhC?

There may be a need to amend the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789). Regulation 4

relates to requirements as to 'qualified persons' (QPs) concerning the manufacture, assembly or importation of medicinal products. The list of people considered to be eligible to be named on a manufacturer's licence as a QP is currently held jointly by the RPSGB, Royal Society of Chemistry (RSC) and Institute of Biology (IoB). It is anticipated that the professional leadership body (PLB) based upon the RPSGB will continue this function when regulation transfers to the GPhC. This does not preclude the possibility that the legislation should be changed to refer to those registered as pharmacists by the GPhC - the PLB could still have the role of assessing those pharmacists for suitability to be named as a QP and could still hold the joint list with the RSC and IoB. However, it does not appear to be an automatic conclusion that the legislation will need to be changed in this way because the RPSGB, RSC and IoB will all be professional bodies in the future, with similar status. It would not seem appropriate for the GPhC to undertake assessments for suitability to be named as a QP and to keep the joint list with the RSC and IoB. The GPhC could decide to annotate the register to indicate pharmacists who had passed such an assessment. The PLB could then potentially have a role in carrying out the assessments. However, the annotation would be solely a GPhC function and not a joint exercise with the IoB and RSC. If the legislation is changed to refer to pharmacists registered by the GPhC but the PLB carries out the assessments, it might be necessary for the legislation to refer to both bodies ie. to refer to pharmacists who are regarded by the RPSGB as fulfilling the provisions of the Directive. One option could be to maintain the reference to members of the RPSGB but to amend the SI to refer to the members referred to in article 5(1)(a) of the RPSGB Charter (once the proposed amendments come into effect). This would restrict it to pharmacists who are members of the RPSGB - as now.

Is there a need to amend the Misuse of Drugs Regulations 2001 (SI 2001/3998), regulations 8 and 9, to amend the references to persons authorised by the RPSGB in relations to ss108-109 of the Medicines Act 1968?

Is there a need to amend the Regulation of Care (Social Service Workers) (Scotland) Order 2005 (SSI 2005/318)? Sch 3 provides that persons registered by the RPSGB are excluded from the description of social service workers in art 2.

The Building Society (Business Names) Regulations 1998 (SI 1998/3186 – see Schedule to regs) seem to provide that a building society cannot use the term 'apothecary' in its business name without the approval of the RPSGB (or the Worshipful Society of Apothecaries of London). The use of other terms in the Schedule is subject to the approval of the GOC, GDC & NMC so we need to consider whether the GPhC should be the approving authority here.

Similarly, the Company and Business Names Regulations 1981 (SI 1981/1685) seem to provide that, where the term 'apothecary' is used in a business name, approval must be sought from the RPSGB. The use of other terms in the Schedule to these regs is subject to approval by the GOC, GDC & NMC.

We think changes will also be needed to the:

Representation of the People (England and Wales) Regulations 2001;

Representation of the People (Scotland) Regulations 2001;

National Assembly for Wales (Representation of the People) Order 2007;

Representation of the People (Absent Voting at Local Government Elections) (Scotland) Regulations 2007; and

Scottish Parliament (Elections etc. Order) 2007.

These would all be to amend references to registration under the PPTO - cf draft HCAP Order 2009 Sch 4, Pt 6, paras 39, 40 and 42-44

17(2) and further paragraphs

We think the provision mentioned in 17(2) was amended by the PPTO (Sch 1, Pt 2, para 13) to read "Part 1 of the register maintained under article 10(1) of the Pharmacists and

Pharmacy Technicians Order 2007”? In addition, we think the legislation mentioned in paras 18, 19, 21, 22, 24, 26, 30, 32, 35, 36, 37, 38, 41, 42, 43, 44, 45 & 46 below was amended by the PPTO.

17(3)

We think this refers to paragraph 3 of regulation 2 (enforcement). Should the words ‘The General Pharmaceutical Council has power’ be followed by ‘and is under a duty...’?

20

Should this refer to 37(4)(d) rather than 37(4)(a)?

22

Are any changes needed to Sch 4, paras 3(b)(i), 9 & 10 of these regulations?

23

Think these regs were revoked by the PPTO (Sch 1, Pt 2, para 19).

27

Was this provision revoked by SI 2007/121?

28

Were these revoked by SSI 2008/50?

29

Were these revoked by SSI 2007/139?

33

We think these were revoked by SI 2007/2781 European Communities (Recognition of Professional Qualifications) Regulations 2007.

34(a)

We think this change was made in the PPTO

34(b)

There will also be a need to amend the definition of ‘registered pharmacy technician’ which will be inserted by the HCAP Order 2009 – see Sch 4, Pt 3, para 28 of that Order

40

Were these revoked by SI 2008/1284?

43

We think there will also be a need to substitute GPhC for RPSGB in 28(2)(f) in these regulations, and in Sch 4, Pt 1, para 2.

46

We think the reference to the 1954 Act has already been amended to refer to art 10(1) of the PPTO. Should this provision refer to be ‘a pharmacist or a pharmacy technician’? (cf. Sch 4, Pt 3, para 29 of draft HCAP Order 2009)

47(1)

Is there a need to amend the definition of ‘registered pharmacist’ in reg 2?

47(3)

Is there also a need to amend reg 21(b)?

50

Were these revoked by SI 2008/2297? If not, there would also be a need to amend Sch 2, para 10(1)(a).

Schedule 5

The intention is to have all the GPhC's rules & standards in place when regulation transfers to the GPhC but should there be a transitional provision to allow the GPhC to operate using the RPSGB's rules as nearly as possible (not just for old cases), to allow for the possibility that some of the rules/standards are not in place?

On the other hand, if the rules under the PPTO are all to be replaced by GPhC rules/standards by the time that regulation transfers to the GPhC, should the RPSGB's rules be included in the SIs to be revoked via Sch 4 Pt 2?

Similarly, the PPTO's transitional provisions (Sch 2, Pt 1, para 4) provide for the continuance and amendment of the Society's byelaws under the Pharmacy Act 1954. Some of these are still in use for statutory functions. We would not want them to be carried over to the GPhC but this means that the GPhC's rules & standards must be ready before regulation transfers from the RPSGB. If this is achieved, the relevant byelaws under the Pharmacy Act 1954 should be revoked via Sch 4, Pt 2 ie.

Section I (preliminary), byelaw I(2): entries relating to "Accredited course", "Independent Prescriber", "Preregistration trainee", "Register", "Registered", "Registrar", "Registration Examination", "Retention fee", "Supplementary Prescriber".

Section II (fees payable to the Society): whole section

Section XIX (registration of overseas pharmacists): whole section

Section XX (Registrar and registrations): whole section

Section XXI (the register of pharmaceutical chemists): whole section

Section XXII (certificates of registration): whole section

Section XXVII (regulations): whole section

Third Schedule (the annual register of pharmaceutical chemists): whole schedule

Fourth Schedule (fees payable to the Society): whole schedule

1(a)

What about pharmacists or PTs who may be in Part 3 of the register under the PPTO as a 'visiting EEA practitioner' at the time of the transition?

1(b)

We think this should also say 'Part 1 of the register' as we have some non-practising pharmacy technicians on the voluntary register.

3(1)

Does this need to include applications for voluntary removal?

3(2)(a)

Should this refer to the 2007 Order and rules thereunder? Also applies to 3(2)(b) (regulations under 1968 Act?) and to 5(3) and 8(1).

3(3)

It is not clear why this sub-para says 'by the PC by order' and 2(2) above does not (also applies to 6(3)(a) & 7(2) below).

4

Should 'in the Register' be removed from the last line here, as the Register itself would not be published – only lists derived from it cf. art 7(8)(c)?

5(2)

Is it conceivable that the GPhC might want articles within Pt 4 to come into force on different days? If so, it might be appropriate to name a specific article here rather than the whole Part.

7(1)

Should this be 'shall be payable' rather than 'remain payable', as the fees would previously have been payable to the Society, not to the Council?

8(1)

There will be a need to check whether there will still be any proceedings in progress under the old RPSGB Statutory Committee rules, relating to persons or to businesses/premises.

Is there provision for:

Cases in which a registrant has been suspended or had conditions imposed by the RPSGB's DC or HC, which are due for review after the GPhC's Fitness to Practise Committee becomes operational?

Applications for restoration which are made prior to the appointed day but which have yet to be heard on that day?

Cases where an applicant has already made one application for restoration to the RPSGB then makes a second application on or after the appointed day?

12

What is the scheme referred to here?

16(1)(a)

Is this a statement of accounts relating to the old employer (which has a Jan-Dec financial year?)

16(1)(c)

It is not intended that the Society be dissolved, so this wording should be amended.

17(1)

Article (not para) 8 of the Charter refers to members being 'elected in accordance with regulations made by the Council'. The election scheme is contained in regulations made under the Charter.

17(2)(a)

The RPSGB Council needs to remain in its current form until regulation transfers to the GPhC. Might art 4(2) be brought into force so as to create the GPhC council before the transfer of regulation takes place?

17(2)(b)

Is there a need to add 'whichever is sooner' or similar?

Part 2. Focussing on Professional Leadership

Introduction

This section of the response was produced through the RPSGB's National Pharmacy Boards (NPBs) for England, Scotland and Wales, and it focuses on professional leadership. The NPBs in each country are made up of representatives from all sectors of pharmacy practice, and this response reflects that broad voice.

The RPSGB in its professional-body role leads and supports the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

During the transition to de-merger, RPSGB will establish itself as the new professional leadership body (PLB) for pharmacy. This response discusses the new PLB as the RPSGB without its regulatory function and being the body which acts and speaks for the whole profession of pharmacy. Its functions and services will include:

Leadership, representation and advocacy: promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.

Professional development, education and support: helping pharmacists to advance their careers through accredited training courses, career advice and guidance on good practice.

Professional networking and publications: creating a series of communication channels to enable pharmacists to discuss areas of common interest.⁶

We have set out below the key issues in the Pharmacy Order 2009 from the professional leadership perspective, followed by our responses to the consultation questions.

The key issues are:

1. The interface between GPhC and the new PLB and their respective responsibilities on issues of common interest
2. Protection of title and post-nominals
3. The non-practising register
4. GPhC fees
5. GB devolution and country-specific issues

1. The interface between GPhC and PLB and their respective responsibilities on issues of common interest

Modern professional regulation is based on an expectation that the majority of registrants act ethically and aspire to continuously improve their practice and achieve the best outcomes for patients. This model lends itself well to co-operation between regulatory bodies and professional bodies on a wide range of issues. Ideally the regulatory body and professional body will complement each other's activities: the regulatory body will rely on the professional body to lead the profession by driving

⁶ Transitional Committee (2008). The New Professional Body for Pharmacy: the Prospectus. [Prospectus for the new professional body for pharmacy](#)

innovation and setting new aspirations (such as therapy management and prescribing); conversely the professional body needs the regulator to enforce standards and maintain the gateway to the profession. This relationship could be formalised through an agreed statement setting out the two bodies' respective roles and responsibilities, mutual expectations and terms of engagement.

In the context of the relationship with GPhC, the new PLB for pharmacy intends to provide:

- Professional support, which will help its members to meet GPhC's requirements for initial and continuing registration (e.g. through information and advice services, practice guidance and publications)
- Professional development and education, which will help its members to meet GPhC's standards for education, training and CPD (e.g. through careers advice; help to successfully complete the pre-registration year; support for CPD and, in time, revalidation; accreditation and direct provision of training courses and events; and a range of services for those developing advanced or specialist practice)
- Professional networking, which will help its members to maintain and develop their competence by enabling them to contact professionals with similar interests.

We would like to see GPhC and new PLB develop an effective working relationship based on complementarity, founded on a clear mutual understanding of their respective roles and responsibilities and close collaboration on areas of common interest. Beyond the GPhC's remit of ensuring patient safety through ensuring safe and effective practice, the new PLB will also benefit patients by fostering innovation.

In relation to education, it is the opinion of the National Pharmacy Boards that in being proportional and risk based, the regulator should only be concerned with advanced and specialist practice if there is evidence that it poses an increased risk to public or patients. It follows that the GPhC will only need to be involved in standards for post registration education and training in exceptional cases of specialism that require annotation of registrants with the GPhC, the quality assurance of such education and training falls fully within the remit of the PLB.

2. Protection of title and post-nominals

We would like the current protection of the title 'pharmacist' to continue, rather than making the title 'registered pharmacist' the protected title. If the title 'pharmacist' were no longer protected, anyone could call themselves a pharmacist. The profession has worked long and hard to educate the public and other health professions about what it means to be a pharmacist: the lengthy and demanding training that must be undertaken; the unique knowledge of medicines and expertise in their use that pharmacists possess; the nature of their roles, particularly in community pharmacy, hospitals, primary care, community services and in the development of new medicines by the pharmaceutical industry. All of that awareness-raising would be lost if anyone could use the title 'pharmacist'. We are unaware of any evidence that the title 'registered pharmacist' would offer additional benefits in terms of public protection.

At the same time, we urge the government to allow the use of conditional titles such as 'retired pharmacist' or 'former pharmacist' which would allow those who qualified as a pharmacist, but are no longer practising as one, to retain their professional identity, so long as they do not practise as a pharmacist or mislead anyone about their current registration status.

It is the expectation of the NPBs that, in line with other regulators, the GPhC will not be awarding post-nominals.

3. Removal of the non-practising register

We acknowledge and agree with the broader definition of the term "practising" used in the Order, which will encompass more areas of work within pharmacy than is currently the case for the practising register

However, we are concerned that the lack of a non-practising register could make it more difficult for pharmacists taking a career break to return to the register. GPhC should ensure that there is a clear route for return to practice after such a break and it should work with other stakeholders (e.g. the professional bodies, education providers, governments and employers) to ensure that the necessary supports are in place (e.g. return-to-practice courses, supervised work placements etc.) for this to happen.

4. GPhC fees

Pharmacists need both regulation and the support of a professional body, and it is both essential and in the public benefit that the cost of one does not prohibit the other. RPSGB has conducted market research with its members which showed that the majority of pharmacists would join RPSGB when it becomes a voluntary professional leadership body provided that the combined fees paid to GPhC and new PLB do not exceed the current integrated fee levied by RPSGB. Pharmacists will need the leadership and support that the new PLB can provide. That support will have benefits for the safety and quality of care provided by pharmacists, and it will enhance public confidence in the pharmacy profession. It is therefore essential that GPhC's fees do not rise to a level where pharmacists cannot afford PLB subscriptions as well.

5. GB devolution and country-specific issues

We welcome the consultation document's recognition of the importance of devolution in the regulation of healthcare professionals, and in particular that there needs to be a way of ensuring that regulatory body Councils are aware of, and responsive to, the increasingly different provision of healthcare in the UK countries. We strongly recommend that the GPhC Council includes both lay and professional membership from each country to ensure the Council is kept informed on the context for and actual pharmacy practice in each country. There are also some country-specific concerns that Board members have highlighted which are included in the appropriate section below, for example concerns in England around duplication of roles in relation to standards for pharmacy premises.

Q1. Do you support having, as a main objective of the GPhC, a provision giving due emphasis to the importance of public protection and well-being?

We support this provision. The GPhC will be far more effective in achieving this objective with the pharmacy profession on its side. This can be assisted through close working with the new PLB and the wider profession, as well as the manifestation of its desire to be a proportionate and flexible regulator. For the sake of its reputation within the pharmacy profession the new regulator should make every effort to establish trust at the earliest opportunity. One of the ways in which it can seek to gain this trust is in being transparent in the checks and balances it uses to assess its own performance.

Q2. Do you agree that the duty [to consider the interests of stakeholders] will improve co-operation and co-ordination between professional regulators and key stakeholders?

We agree that GPhC should have a duty to co-operate with its key stakeholders in all of the home countries, but the duty will not in itself improve cooperation and coordination between professional regulators and key stakeholders. RPSGB's experience of implementing a patient and public involvement strategy has shown that achieving real

stakeholder involvement is a long-term enterprise requiring sustained activity on a number of fronts.

We seek further clarification of the objectives of the duty: is it intended to deliver:

- Better information for stakeholders about GPhC's priorities and activities?
- Better coordination of activities between GPhC and its stakeholders (to avoid duplication, conflict etc – this relates to our point above about the complementary roles of the regulatory and the professional body)?
- Meaningful involvement and influence by stakeholders in GPhC's work?

We think all three objectives are necessary for GPhC to be an effective regulator. A key challenge for GPhC will be to gain the trust of the pharmacy profession. Measures for achieving this should include establishing clear processes for cooperation and coordination with the new PLB and communicating clearly with individual pharmacists about how their interests will be taken into account (Article 5(2)(b)).

Q3. Do you agree with the new, more flexible arrangement for establishing the GPhC constitution?

We support the proposal for the details of the GPhC's constitution to be set out in an order of the Privy Council under article 4(2) which should allow for greater flexibility if changes to the constitution are required in future.

We look forward to seeing the specific proposals for GPhC's constitution and being able to comment on them.

Q4. Do you agree that reducing the number of statutory committees will reduce the bureaucracy associated with regulating pharmacy and will increase flexibility for the Council to discharge its duties?

*Trust, assurance and safety*⁷ recommended that "professional regulation should not create unnecessary burdens, but be proportionate to the risk it addresses and the benefit it brings." We support that principle.

Reducing the number of statutory committees will not by itself reduce the bureaucracy associated with regulating pharmacy. GPhC should maximise opportunities for improving the cost-efficiency of all its processes, not just those associated with its statutory committees.

Since many fitness-to-practise cases have health and non-health aspects, it seems likely that the handling of health and other fitness-to-practise cases by a single committee should result in a streamlining of procedures, greater cost-efficiency and faster decision-making, which are to be welcomed. However, the NPBs would like to emphasise that the separation of health issues by the RPSGB was considered as a step forward, as it has allowed compassionate management of cases in this area. We expect that the ability to show such compassion will be manifested in the GPhCs' committee structure.

Q5. Do you agree that the UK Parliament and the Scottish Parliament should play an enhanced role in relation to monitoring of the GPhC, facilitated by improved arrangements for notification of information relating to its activities?

Country-specific issues arise in relation to this question.

Wales

GPhC should submit its annual report, statistical report on fitness-to-practise and strategic plan to the Welsh Assembly Government, not solely Welsh ministers, to ensure an equal opportunity for public debate in Wales to that which will be facilitated in England and Scotland by GPhC's statutory accountability to the UK and Scottish Parliaments. We

⁷The White Paper Trust, assurance and safety: The regulation of health professionals, DH Feb 2007

recognise that because professional regulation is not currently devolved in Wales, GPhC does not have statutory accountability to the assembly.

Scotland

As a GB-wide regulator the GPhC must demonstrate its commitment to working on behalf of the people of each country as health care systems and practices are developed to meet their particular needs. The Scottish Parliament represents the Scottish population and has responsibility for a wide range of policy areas including health, justice, and education. It also has devolved powers for regulation of new professions, including Pharmacy Technicians. The GPhC must, therefore, understand the requirements of the Scottish Parliament and be accountable to it for the full range of its activities.

Q6. Do you agree with placing a requirement on the GPhC to publish a description of the arrangements it has put in place to ensure it adheres to good practice in relation to equality and diversity? If you agree, what would you want to see included in such a description?

We welcome this requirement. The description should include evidence to demonstrate how GPhC ensures that its activities meet legal requirements and CHRE standards in this area. It would also be of benefit to the GPhC in exercising its FTP procedures that the description of arrangements should allow for the use of practitioners with experience in the particular area of practice in question.

Q7. Do you agree that the GPhC should be given reserve powers to register suitably experienced people as pharmacists, and allow additional pharmacists to act as prescribers, during an emergency?

In principle we support this provision, however the NPBs feel that competency is more relevant here than experience in considering how to extend the register in an emergency. Emergency planning should include consultation with all relevant stakeholders, and management of the complex balance of risks to patients that might arise. We understand that this may mean that provision of pharmacy services by the most competent persons available may be preferable for patients than no service at all.

Q8. Do you agree that the link between standards set for education and training and the safe and effective practice of pharmacy will enhance patient safety and public confidence in the profession?

We support the explicit linkage between standards for education and training and the safe and effective practice of pharmacy because this places appropriate emphasis on the outcomes of education and training rather than on educational inputs or processes. Consultation with our own Public Liaison Group has identified that patients and the public want to be assured that pharmacists are competent to perform their roles and have had the appropriate training for them. This provides support for the idea that public confidence in the profession should be enhanced by making the links between educational standards and pharmacy practice more explicit. But GPhC will also need to communicate effectively with the public about the education standards it sets and the standards for pharmacy practice that the public is entitled to expect.

How standards are set and monitored is important:

- Close working between the GPhC and the new PLB will be of paramount importance to both gain the perspective of current practice and to show registrants that such a relationship is in place.
- Other key stakeholders should also be consulted. For example education providers and organisations concerned with the quality and safety of healthcare will be crucial in ensuring that GPhC's consultation processes are meaningful and that the standards set by GPhC are relevant to evolving pharmacy practice.

- GPhC should set standards for safe and effective practice, whereas RPSGB will support role and practice development.
- GPhC must also take into account the devolved nature of healthcare in each of the three GB countries.
- Openness and transparency will be essential to ensuring public confidence.

Q9. Do you agree that extending the remit of visitors to cover all settings where pharmacy education and training is provided will enhance quality assurance arrangements in an appropriate way?

Insufficient information has been provided in the consultation document to answer this question. What is the problem that extending the remit of visitors is intended to solve? And how would extending the remit of visitors enhance quality assurance?

As a general principle the NPBs feel that the remit of visitors should not extend beyond settings providing pharmacy education and training related to recordable qualifications.

Q10. Do you agree that these provisions will provide the GPhC with more flexibility to review and update its CPD requirements in order to keep pace with developments in science, technology and practice while retaining appropriate safeguards?

We agree with these provisions.

Future-proofing is particularly important for the regulation of the pharmacy profession because rapid developments in science and technology are producing new types of medicines and drug devices, pharmacogenetic tests, electronic prescribing, automated dispensing etc, which are reshaping the roles of pharmacists. We therefore welcome the broad provisions for CPD in the Order which will allow for periodic updating of CPD criteria by GPhC in consultation with professional bodies and other stakeholders.

Changes to CPD criteria should be made in close consultation with the profession and professional bodies, including input from specialist areas of pharmacy practice. The requirements for pharmacy professionals should be consistent with those for other health professionals.

Q11. Do you agree that the proposed fitness to practise arrangements for the pharmacy profession strike the right balance between ensuring public confidence/patient safety and fairness to healthcare professionals?

The NPBs are unsure on this question. The powers of the GPhC will not be able to be tested for this balance until they are expressed in rules. We believe the draft legislation provides a framework that could result in the right balance, however a consultation process in respect of the rules will allow a clearer answer.

Q12. Do you agree that the powers provided to the GPhC are sufficient to ensure the adequate regulation of registered pharmacy premises?

We believe that the powers provided in the Order are adequate. It is essential that the regulator discharges its duties in proportion to necessity and in consultation with appropriate stakeholders.

Account must be taken of the divergence of health and social care systems and community pharmacy contracts in each country perhaps resulting in different national requirements. Where public and patient safety is at risk it is to be welcomed that the regulator will have more enforcement powers than previously. In order to avoid duplication and regulatory burden, a principle should be adopted of recognising the other statutory roles of other organisations. This should lead to the formalisation of collaborative working. Further to this point, we believe that in England greater clarity is required on the differing roles of the GPhC, Care Quality Commission (CQC) and local PCTs respectively in relation to pharmacy premises standards. Proposals are outlined in the *Pharmacy in*

England White Paper consultation to extend to PCTs the power to issue remedial action notices to pharmacy contractors. In its response the English Pharmacy Board noted that any work on the extension of PCT powers to regulate pharmacists and pharmacy premises must be undertaken in consultation with the national regulator. Their view is that 'core' premises standards relating to registration should be a GPhC matter, with other bodies drawing on these as required. Premises standards specifically relating to the delivery of advanced practice pharmacy services may be defined by local PCTs, but we are aware of recent moves by some PCTs to specify core standards as well. The government will need to ensure that pharmacy contractors are not subjected to duplicate or inconsistent regulatory requirements, and that the Care Quality Commission also operates in a complimentary manner in this respect.

Similarly in Scotland there will need to be a clear understanding of the respective roles of the GPhC, Scottish Commission for the Regulation of Care, NHS Quality Improvement Scotland and the NHS Boards, and effective systems for collaborative working.

In Wales the respective roles and powers of the Local Health Boards, Community Health Councils and Healthcare Inspectorate Wales need to be considered in relation to the issues of collaboration identified above.

In relation to the drafting of the premises powers within the Order, premises are the responsibility of a pharmacy owner and there needs to be a clear distinction between the responsibilities of the owner and those of individual registered professionals working in the pharmacy. Regulation of premises must also take into account any contractual differences between the GB countries.

The order is focussed very much around implementation within community pharmacy. Where hospital pharmacies are registered with the GPhC, as a principle they should be treated in a uniform manner in relation to premises standards.

Q13. Do you agree with the more flexible approach proposed in relation to fee-setting for registered pharmacies?

We agree with the more flexible approach to fee setting for registered pharmacies. Fairness and transparency will be important in fee setting. It would be equitable and appropriate for those premises which require additional intervention, and so generate additional cost for the regulator, to pay higher fees.

As fees will be set for both registrants and premises the NPBs feel strongly that such fees should relate, as far as possible, to the specific cost of the regulation that would follow. There should be no cross-subsidy in these main areas of fee setting, where the cost of regulation in one is paid for through the fees of another.

Q14. Do you agree that the additional powers provided to the inspectorate of the GPhC will ensure that adequate investigations into allegations of impairment of fitness to practise can be pursued?

The NPBs are pleased to see the RPSGB proposals reflected in the Order, and also wish to see such investigations conducted in a co-ordinated fashion where they involve other regulators. Such co-ordination will need to reflect the varying regulatory processes in each country.

Q15. Do you agree that the GPhC should be empowered to have a more flexible approach to fee-setting?

RPSGB already sets a range of fees and we welcome the ability for GPhC to have a more flexible approach to fee-setting. GPhC's fee levels will need to balance the demands of affordability for pharmacists, cost-efficiency, and equity between different groups of registrants.

Whilst recognising that public protection is paramount it is important to enable innovation in the interest of patient benefit. Registrants who are taking the profession forward with, for example enhanced clinical roles, should not be penalised financially. Annotations to the register, an area the GPhC may look to charge additional fees, should only be introduced when there is demonstrated risk to patient safety. The new PLB should be responsible for quality assuring developing areas of practice. We are keen therefore that this is considered, and while this view may appear to conflict with our response to Q13, it is important that a balance is struck here for the overall benefit of patients and public. The NPBs believe that this will be an important area of consultation between the GPhC and the new PLB.

Q16. Do you agree that the transitional provisions set out in Schedule 5 to Part 7 of the draft Pharmacy Order 2009 are fair?

and

Q17. Do you agree that the transitional provisions set out in Schedule 5 to Part 7 of the draft Pharmacy Order 2009 are clear?

The NPBs feel that the provisions are not clear. The RPSGB will continue to exist after GPhC is established, and RPSGB's physical and intangible assets (buildings, financial reserves, intellectual property etc.) will be retained by the RPSGB for deployment in its redefined role as the professional leadership body.

Eligible staff will transfer from RPSGB to GPhC under the Transfer of Undertakings (Protection of Employment) Regulations.

We do agree with the proposals in the Order relating to FTP cases begun under the existing legislation, students and pre-registration trainees.