

Report on the responses to the consultation on the rules under the Pharmacy Order 2010

8 June 2010

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Executive summary

1. In 2010, the General Pharmaceutical Council (GPhC) will replace the Royal Pharmaceutical Society of Great Britain (RPSGB) as the regulator for pharmacists, pharmacy technicians and registered pharmacies. The GPhC will be aligned with key principles in the White Paper *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century*¹ to enhance confidence in the health professions regulators and to make protection of patients and the public the first priority.
2. To enable us to regulate effectively, and provide a clear framework to sustain and enhance the development of high quality pharmacy practice, the GPhC has been given the power in the Pharmacy Order 2010² ('the Order') to make rules in a number of areas including fitness to practise, appeals, statutory committees & their advisers, fees and registration. The rules need to be made within the scope and powers provided by the Order.
3. We do not intend to create unnecessary burdens but to ensure that regulation is proportionate to the risks it addresses and the benefits it brings.
4. The GPhC published draft rules covering the above five areas for consultation on 16 February 2010 and the consultation closed on 4 May 2010. We are very grateful to all who took the time to respond to the consultation, and very pleased with the relatively high level of response for a consultation of this type, particularly in view of that fact that, as a new organisation, we needed to consult on several sets of rules together. The GPhC has given careful consideration to all the views expressed. The wide range of comments and suggestions received is reflected in this report.
5. Overall, most respondents felt that the draft rules contained adequate protection for patients and the public, that they set out the necessary provisions in a clear and comprehensive manner and that they were written within the scope of the Order. Most did not feel qualified to comment on whether there were any further equality considerations that should be taken into account in the drafts.
6. A number of issues were nevertheless raised by respondents. Those that provoked the most debate are summarised in paragraphs 7 to 21 below.

¹ Department of Health, *Trust, Assurance and Safety - the regulation of health professionals in the 21st Century* 2007

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

² The Pharmacy Order 2010

http://www.opsi.gov.uk/si/si2010/uksi_20100231_en_1

General

7. **Rules v. Order.** There were a number of comments on matters relating to the Pharmacy Order rather than the rules. These related, for example, to the introduction of a rolling register, which is considered in paragraph 14 below and Section 4 of this report.
Our response: The Order has already been made and the rules must therefore be consistent with the Order. They must also be made within the rule-making powers given in the Order.
8. **Communication.** Several respondents flagged up the scale of the proposed changes and urged the GPhC to communicate them effectively and in a timely manner to existing RPSGB and prospective registrants.
Our response: We are conscious of the importance of clear communication of changes that will affect registrants, particularly the move to a rolling register, the change from 'retention' of registration to 'renewal', and the timetable for renewals.
9. **Regulatory burden.** Some respondents made the general comment that the rules were too restrictive or onerous, and that they ran the risk of duplication with other authorities.
Our response: In general, the GPhC has aimed to include a degree of flexibility in the rules and to be proportionate. For example, we have adjusted the Registration Rules to avoid the necessity for people who leave the Register and later wish to return to resubmit all the information required for an initial application. We plan to review the rules once we have gained sufficient experience of how they are operating, and will keep in mind the need to be proportionate when carrying out this review.
10. **Environment vs. individual.** Several comments expressed a feeling that the rules were insufficiently reflective of the importance of the practice environment (e.g. health & safety issues) and the responsibility of owners.
Our response: The GPhC has recently consulted on interim standards for owners, superintendent pharmacists and pharmacy professionals in positions of authority. The Council will consider the responses to that consultation and agree the standards. There are no rules in place currently relating to pharmacy owners, superintendent pharmacists and premises but the GPhC plans to consult on such rules in due course .
11. **Timeliness.** Some respondents called for the hearings and appeals process needs to be timely.
Our response: The GPhC will inherit a caseload from the RPSGB and will also be dealing with cases under its own legislation. Our aim is for proceedings to be just, timely and efficient. We shall keep this aim in mind when considering the detailed arrangements, guidance and procedures under the Order and rules.

Fees

12. Comments about the draft fees rules included areas in which people felt that the relative levels of certain fees were inequitable, areas where fees seemed to be missing, and appeals to the GPhC to set fees that reflected

the true cost of the processes involved.

Our response: We have decided not to proceed with the 2010 Fees Rules. Instead we will bring the 2011 Fees Rules, which we have recently published for consultation, into effect from the date when regulation transfers to the GPhC. The 2011 Fees consultation document addresses a number of the points raised in this consultation. Others are covered in this report. We will consider any additional points together with the responses to the consultation on the 2011 Fees Rules

Registration

13. **Service of documents.** Several respondents raised concerns about the possibility of email as a vehicle for the delivery of documents.
Our response: We recognise that, where a registrant provides an email address to the GPhC for general purposes, this may not necessarily mean that they are content to receive documents by email that need to be served under the rules. A registrant's email address will only be used for the service of documents under the rules with their agreement.

14. **Rolling register.** This topic generated a great deal of comment, most, though not all, of it adverse. Employer groups in particular flagged up the ensuing administrative complexity and additional cost they would incur as a result.
Our response: The move to a rolling register stems from the Pharmacy Order rather than the rules and it is not possible to arrange for all renewals to be due at the same time. For registrants who transfer automatically from the RPSGB to the GPhC, the Order states that renewal will be due on 31 December, as now, so they will be unaffected by this change. For people joining the GPhC Register after the transfer, renewal will be due on the anniversary of the date of first registration, so this could be at any time during the year.
We recognise the need to communicate this change clearly to pharmacists, pharmacy technicians and employers.

15. **Renewal timetable.** Many respondents commented on the requirement for renewal notices to be sent out three months before the expiry of registration; and for registrants to return these, with payment, two months before the expiry of registration. The majority felt the timeframe was too long, and many thought there should be provision for a statutory final demand.
Our response: This is linked to the change from retention to renewal of registration. The introduction of the renewal concept is part of the modernisation of pharmacy regulation, in which registration is for a fixed period and has to be renewed. Registration is therefore much more like a licence which has to be renewed before it expires, rather than a membership of an association.
The Order provides that an entry in the Register will cease to be valid after one year unless it is renewed, so the renewal process must be completed before the expiry date (31 December for registrants who transfer automatically to the GPhC). As required by the Order, there will be no 'period of grace'. For the same reason, it would not be possible to send a final demand to anyone who had not renewed their registration by

the expiry date as their registration would already have ceased to be valid. The onus is therefore on us to ensure we send out the renewal notices in good time and on registrants to return them by the deadline with the information and the fee required. The timescales for the return of renewal applications are set out in the Order, so it is not possible for the rules to state a deadline of less than two months before the expiry date. Again, we are aware that this is an important change which must be communicated clearly to pharmacists, pharmacy technicians and employers. We are also looking at ways in which we can ease the transition to the new timetable this year and help ensure that registrants are aware of when they need to apply for renewal. This is likely to include reminding registrants about renewal deadlines.

We will review the renewal process after the 2011 renewals are completed and consider whether we can make improvements in the legislation and in our procedures.

16. **Overseas registration.** Concerns were expressed by various types of respondent that it appeared that those living and working overseas would not be able to register with the GPhC.

Our response: The Order states that, to be entitled to register with the GPhC, a person must intend to practise in Great Britain, the Channel Islands or the Isle of Man. However, pharmacists and pharmacy technicians working overseas will be able to register with the GPhC – and pay the normal fees – provided that they intend to return to practice in Great Britain, the Channel Islands or the Isle of Man in the future. There is no requirement to practise in this country during each year of registration.

All those on the RPSGB's practising registers will transfer automatically to the GPhC's register when regulation transfers from the RPSGB to the GPhC. However, given that the GPhC will be a new regulator, it will not be possible for a former RPSGB registrant to be 'restored' to the GPhC's register once the GPhC is up and running – they would need to apply as a new applicant.

Statutory committees and their advisers

17. **Committee chairs.** Several respondents, both individuals and organisations, felt there should be a requirement, rather than a discretionary provision, for the chair of the Fitness to Practise Committee to be legally qualified.

Our response: Our intention is that the rules should allow for the chair of any of the statutory committees to be legally qualified or lay. The GPhC recognises the importance of access to legal advice and this would be provided in either circumstance. We also recognise the advantages of having a chair with an appropriate legal qualification and relevant experience. However, we do not wish to restrict the eligibility criteria more than is necessary in the rules – such matters can be considered as part of the appointments process, for example, through recruitment criteria.

Fitness to practise & disqualification

18. **Fitness to practise criteria.** These have generated the highest volume of comment of any provisions in these draft rules, both about whether the suggested approach was appropriate (in particular, it was suggested that the criteria were too detailed and should instead be drafted in the form of broad headings), and about individual criteria.

Our response: The Order requires us to include fitness to practise criteria in the rules. We are grateful for the detailed attention that respondents gave to this topic. We have considered the helpful feedback received and, in response to the views expressed, we have reframed these provisions so that they reflect broad principles rather than detailed criteria.
19. **Disclosure provisions.** Respondents expressed a range of views on the proposal to require disclosure as soon as reasonably practicable rather than to specific deadlines and on other aspects of disclosure and listing.

Our response: The changes are intended to allow less complex cases to be dealt with more quickly and can be supplemented with case management directions. We have adjusted the rules to provide that the person concerned should serve their case no later than 28 days before the hearing. We shall review the operation of these provisions and the rules as a whole in the light of experience.
20. **Agreement of undertakings.** Some respondents advised that the Fitness to Practise Committee should be given power to accept undertakings without a hearing.

Our response: The Order does not allow for the Fitness to Practise Committee to accept undertakings without a hearing. To provide more flexibility, we have adjusted the rules to allow the Investigating Committee to agree undertakings where a registrant admits that their fitness to practise is impaired, rather than limiting this to cases of deficient professional performance or adverse health.
21. **Costs and cost orders.** Various objections were raised regarding the making of costs orders for hearings. The GPhC was urged to conduct proceedings in the most cost-effective manner and a number of detailed suggestions were made as to how costs arising from processes and committee activities could be reduced.

Our response: The GPhC will always aim to conduct proceedings in a cost-effective manner. We nevertheless think it appropriate to include provisions for costs orders in the rules. We have adjusted the rules so that the requirement to serve and file a schedule of costs is discretionary rather than mandatory, so that it would not be necessary if neither party was seeking a costs order. Where a person is appointed to assess the costs, that person would also determine how the costs of the assessment are to be apportioned.

1. Introduction

Context

- 1.1 In 2010, the General Pharmaceutical Council (GPhC) will replace the Royal Pharmaceutical Society of Great Britain (RPSGB) as the regulator for pharmacists, pharmacy technicians and registered pharmacies. The legislation to establish the GPhC - the Pharmacy Order 2010³ ('the Order') - was approved by the Privy Council on 10 February 2010. This Order takes forward recommendations in the Government's White Paper *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century*⁴ to establish a new regulator for pharmacy in Great Britain. The GPhC will be aligned with key principles in the White Paper designed to modernise and strengthen the regulation of healthcare professionals to ensure patient, public and professional confidence in the regulatory bodies and to make protection of patients and the public the first priority.
- 1.2 The new arrangements will ensure that the pharmacy profession is regulated according to the same principles as other healthcare professions. These principles have been developed to improve public confidence in regulation in general, and to ensure independent regulation. They are designed so that Councils:
- place a clear focus on public protection and patient safety
 - are generally smaller and more board-like, focussing on strategic issues and oversight of their executives
 - become more accountable to Parliament, submitting annual reports to the UK Parliament and the devolved administrations as appropriate
 - have faster more transparent procedures.
- 1.3 The principal functions of the GPhC include:
- setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD)
 - establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies
 - establishing fitness to practise requirements, monitoring pharmacy professionals' fitness to practise and dealing firmly and fairly with complaints
 - approving qualifications for pharmacists and pharmacy technicians; and
 - maintaining a register of pharmacists, pharmacy technicians and pharmacy premises.

³ The Pharmacy Order 2010

http://www.opsi.gov.uk/si/si2010/uksi_20100231_en_1

⁴ Department of Health, *Trust, Assurance and Safety - the regulation of health professionals in the 21st Century* 2007

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

- 1.4 To enable us to regulate effectively, and provide a clear framework to sustain and enhance the development of high quality pharmacy practice, the GPhC has been given responsibility under the Order to make rules in a number of areas including fitness to practise, appeals, statutory committees & their advisers, fees and registration. We will use these rules as a major tool in the delivery of pharmacy regulation in England, Scotland and Wales.
- 1.5 We do not intend to create unnecessary burdens through regulation but to make rules that are proportionate to the risks they address and the benefits they bring. The aim is that the rules should be flexible to enable us to be forward looking and responsive to change.

Consultation process

- 1.6 The draft rules consultation was published on 16 February and the consultation closed on 4 May 2010.
- 1.7 The consultation covered:
- 2010 Fees
 - Registration
 - Appeals
 - Statutory committees and their advisers
 - Fitness to practise and disqualification
- 1.8 Where appropriate, the draft rules were based, as a starting point, on those of the current pharmacy regulator. However, changes were made where necessary to improve clarity, efficiency and to ensure that the rules would be in line with the new statutory powers in the Order.
- 1.9 The consultation documents were published on our website and hard copies were made available. The consultation was widely publicised in the relevant media and professional journals and presentations were given to stakeholder groups on request.
- 1.10 We received 98 full responses to the consultation. A further five responses were received on the fees rules, two on the statutory committees rules, nine on the registration rules and 16 on the appeals rules (none related solely to the fitness to practise and disqualification rules) . All responses have been reviewed as part of developing this report.
- 1.11 The tables below show the breakdown of the consultation responses:

The countries to which respondents' comments relate

	UK	England	Northern Ireland	Scotland	Wales	Skipped Question	Total
Number of responses*	70	49	1	12	9	31	172

**more than one box could be ticked*

Respondent type

	Member of the public	Health & social care professional	Organisation	Skipped question	Total
Number of responses	6	78	35	11	130

Area of work – Responses received from individuals

NHS	Education	Social care	Union	Private health	Pharmaceutical industry/company
62	12	2	1	5	12

Voluntary	Trade body	Regulatory body	Professional body	Other	Skipped question	Total
2	0	3	3	16	36	154*

**more than one box could be ticked*

Area of work – responses received from organisations

NHS	Education	Social care	Union	Private health	Pharmaceutical industry/company
19	1	0	2	0	2

Voluntary	Trade body	Regulatory body	Professional body	Other	Skipped question	Total
2	3	6	4	10	87	136*

**more than one box could be ticked*

1.12 Annex A lists all those who were content to be identified as respondents to the consultation. The names of those who did not wish their names to be published have been withheld.

1.13 The Council has reviewed the outcome of the consultation and agreed amendments to the rules prior to seeking Privy Council approval and their coming into force.

2 General comments (on rules as a whole)

What we heard

Q.1 Do you think that these draft rules set out the necessary provisions in a clear and comprehensive manner?

	Agree	Disagree	Don't know	Unanswered
Number	34	9	11	44
Percentage	63%	16.7%	20.4%	

- 2.1 Several respondents noted that the rules were couched in 'legal language'. While some acknowledged the necessity for this, and the majority felt that they were as clear as they could be under the circumstances, it was suggested that simple, clear guidance, perhaps in the form of flowcharts, would be needed so that registrants could understand them.

Q.2 Do you think that these draft rules are written within the scope of the powers of the Order?

	Agree	Disagree	Don't know	Unanswered
Number	34	4	16	44
Percentage	63%	7.4%	29.6%	

- 2.2 Hardly any respondents felt qualified to answer this question; the majority simply said they assumed or expected that this should be the case. Others felt this would only be known once appeal case law was established.
- 2.3 Those few who presumably did feel qualified to comment agreed that the rules were written within the scope of the Order.
- 2.4 One respondent felt that the draft rules were broad enough to provide the approach that the GPhC would require in order not to create unnecessary burdens through regulations but should be flexible enough to manage the risks in a proportionate manner.

Q.3 Do you think that there are any equality considerations that should be integrated into these draft rules?

	Agree	Disagree	Don't know	Unanswered
Number	16	11	21	50
Percentage	33.3%	22.9%	43.8%	

- 2.5 Many respondents felt unqualified to comment on this. Others felt there were no such considerations to be taken into account, or that the drafts took appropriate account of equality issues.
- 2.6 Some raised the position of women on maternity leave or who were taking career breaks or working part-time to care for children (with consequent low or zero income) and the lack of provision for them to pay a reduced fee or to

remove themselves temporarily from the practising register. It was pointed out that this issue would become more urgent as the proportion of women coming onto the register was increasing.

- 2.7 One organisation acknowledged that racial equality had been considered in the impact assessment report, but felt that ethnicity had been handled inappropriately as primarily an overseas applicant issue. It urged the GPhC to commission independent research, review its processes, put into place an adequate and public policy of monitoring ethnicity data for all fitness to practise cases, and to compare its record and publish the findings against the record of other regulators where non-white registrants form a substantial minority of registrants.
- 2.8 It was suggested that interim suspension orders would affect different types of registrant unequally, in that e.g. NHS employees might continue to receive pay and benefits while the subject of such an order while other employee groups, and the self-employed, would not. This respondent felt that professional indemnity insurance alone would not protect the latter groups.
- 2.9 The question was raised of whether the rules complied with the relevant human rights legislation.
- 2.10 One respondent was concerned by the discontinuance of a separate health committee and felt it was unclear how the equality issues of, say, someone with temporary mental health problems would be balanced against the need to protect the public and patients by temporarily removing the person from the register.
- 2.11 One respondent felt that the draft rules would unfairly favour the GPhC and place registrants at a disadvantage.
- 2.12 An organisation was concerned that any consideration of individual practice should include registrants with appropriate knowledge of that sector or specialist practice, especially as specialist and clinical advisers will be excluded from the private deliberations of the committee.

Q.4 Do you think that these draft rules contain adequate protection for patients and the public?

	Agree	Disagree	Don't know	Unanswered
Number	33	2	10	53
Percentage	73.3%	4.4%	22.2%	

- 2.13 Several respondents agreed that the draft rules contained adequate protection for patients and the public, while others disagreed.
- 2.14 One organisation believed that there were some profound omissions in respect of protecting patients and the public, which fell into two main categories:
- insufficient focus on pharmacy premises and the link between errors and environmental issues

- lack of regulation of non-pharmacists in positions of authority.
- 2.15 Others who disagreed felt that the rules were too burdensome for registrants, would cause employers significant technical problems in the first year and would therefore risk creating a shortage of registrants, which could result in potential harm to patients.
- 2.16 Another had expected to see rules dealing specifically with education, training, experience and continuing professional development, and believed that, although the Council would set the standards, rules would also need to be in place for these standards in order to further protect patients and the public.
- 2.17 It was suggested that there was an urgent need to look at specialisations from the public/patient perspective. This respondent felt that superintendent pharmacists were an obvious candidate for specialist annotation, as the draft rules indicated that such appointments involved extra responsibilities and the public would therefore need to know appointees were 'suitable'.
- 2.18 It was pointed out that the rules in isolation could not contain all the requirements for protection of patients and the public, but needed to be considered in association with the standards.
- 2.19 Others felt the draft rules contained more than enough protection for patients and the public, and not enough for registrants.
- 2.20 Others felt it was hard to judge at this stage, one on the basis that there was little evidence to suggest that the existing arrangements had failed the public. Still others found the question hard to answer.

Q.5 Do you have any other comments about these rules that you would like us to consider?

	Agree	Disagree	Don't know	Unanswered
Number	36	19	4	39
Percentage	61%	32.2%	6.8%	

Consultation design

- 2.21 Several respondents found the questionnaire unhelpful or difficult to use.
- 2.22 One body felt that the GPhC had already made up its mind on the content of the rules and wished only to take account of comments on implementation.

Regulatory approach

- 2.23 Some respondents made the general comment that the rules were too restrictive or onerous, and that they ran the risk of duplication with other authorities. One body said that the GPhC would have to ensure that it consulted properly with its stakeholders in order to mitigate this.
- 2.24 One respondent felt that the rules on occasion set out too precisely how things were to be done and thus ran the risk of becoming outdated too quickly.

- 2.25 One organisation felt that the draft rules in large part achieved the aspiration that the GPhC should *'become an exemplar of modern professional regulation: effective in protecting patients, agile in identifying and responding to change, and balanced in its approach to risk and regulation'*⁵, and that they set out processes in clear terms in a way which would support innovations in practice and technological development.
- 2.26 An organisation believed that the owners of pharmacy premises should be held ultimately responsible for the provision of safe environments for practice, and welcomed the extension of the regulatory powers relating to premises.

Review

- 2.27 One respondent urged the GPhC to review the rules after a set time to ensure they were working well. Another supported review from time to time but pointed out that the cost and burden of changing the rules must be anticipated and should only happen where the benefits outweighed the risks.

Communication

- 2.28 Several respondents flagged up the scale of the proposed changes, and urged the GPhC to communicate the changes effectively and in a timely manner to existing RPSGB and prospective registrants.

Our response

- 2.29 We received a substantial response to this consultation and a wide range of comments. We are grateful to everyone who took the time to respond.
- 2.30 We have summarised the comments relating to each set of rules, together with our response, in subsequent sections of this report.
- 2.31 The GPhC exists to protect, promote and maintain the health, safety and wellbeing of the public and patients who use or need pharmacy services.
- 2.32 Some of the comments we received related to the Pharmacy Order rather than the rules. We have touched on some of these points in this report. The Order has already been made and the rules must therefore be consistent with the Order. They must also be made within the powers given in the Order.
- 2.33 Government solicitors have a formal role in advising the Privy Council as part of the quality control of rules proposed by statutory regulators. This formal Privy Council advisory role is discharged independently of the policy function of Department of Health officials. Clearance of draft rules by the Privy Council's advisers in this way confirms that the proposed rules are:
- compatible with the relevant legal powers (the Pharmacy Order 2010 and the Medicines Act 1968 in this case);

⁵ CHRE's *Advice to the Department of Health and the Pharmacy Regulation and Leadership Oversight Group on Aspects of the Establishment of the General Pharmaceutical Council* (November 2008)

- consistent with the overall scheme which the Order requires the GPhC to implement; and
- compatible with general public law principles and relevant overriding legal obligations around matters such as data protection, equality and human rights, and European law.

2.34 In general, we have aimed to include a degree of flexibility in the rules. Some of the comments we received relate to details which we think would be better considered as we develop procedures and guidance to support the rules.

2.35 These first sets of rules are those that the GPhC needs to have in place when regulation transfers from the RPSGB to the GPhC. Further rules will follow. We are currently consulting on the 2011 Fees Rules. We also plan to consult in due course on rules relating to continuing professional development and to pharmacy owners, superintendent pharmacists and premises.

2.36 We are conscious of the importance of clear communication of changes that will affect registrants, particularly the move to a rolling register, the change from 'retention' of registration to 'renewal', and the timetable for renewals. These points are covered in this report but we will provide further information on these and other matters in advance of the transfer of regulation to the GPhC.

2.37 We plan to review the rules once the GPhC is established and we have gained sufficient experience of how they are operating.

3 Draft rules – 2010 fees

What we proposed

3.1 This consultation sought to highlight new provisions within the draft 2010 Fees rules, which will allow us to set fees in connection with entry in the GPhC's register⁶ ('the Register'). The focus of this consultation was on the arrangements to enable the GPhC to collect fees during the remainder of 2010. These rules are not concerned with either the 2010 retention fees for existing registrants, which have already been set by the Royal Pharmaceutical Society of Great Britain, or the 2010 retention fees for premises, which have been set by the Department of Health. A separate consultation on the 2011 Fees rules, including renewal fees, is now underway.

What we heard

Consultation Questions

(Please note some respondents did not answer the questions directly, and so are not recorded as doing so in the numbers below, but provided comments, either here or elsewhere in the consultation, which reflected on these questions and which are included below the numbers in each instance).

Q.1 Do you think that these draft rules set out the necessary provisions in a clear and comprehensive manner?

	Agree	Disagree	Don't know	Unanswered
Number	0	0	0	5
Percentage	0%	0%	0%	100%

3.2 One respondent commented that the numbering system should be clearer.

Q.2 Do you think that these draft rules are written within the scope of the powers of the Order?

	Agree	Disagree	Don't know	Unanswered
Number	0	0	0	5
Percentage	0%	0%	0%	100%

Q.3 Do you think that there are any equality considerations that should be integrated into these draft rules?

	Agree	Disagree	Don't know	Unanswered
Number	0	0	0	5
Percentage	0%	0%	0%	100%

3.3 Several people felt that the relative levels of certain fees were inequitable on the grounds that the difference did not reflect the actual cost. For example, several respondents felt that pharmacy technicians should not pay less than pharmacists, on the assumption that they would cost the same to regulate.

⁶ Provisions to accept direct debit arrangements to collect fees are contained within the draft Registration rules

Others felt that fees for individual registrants were being unfairly inflated because the premises fees did not reflect the true cost of premises regulation.

- 3.4 One organisation felt that the fee for applying to rejoin the Register, together with the associated costs involved, would be disproportionately burdensome to most returners (who were assumed to be either women or individuals returning after a break incurred by caring duties, poor health or accidents) as at the time of rejoining they would be on a low or zero income.
- 3.5 Some respondents raised the question of a low income fee. This was not covered in this consultation, as these rules do not include renewal fees, but is covered in the current consultation on the 2011 Fees rules.
- 3.6 The Equality Impact Assessment (EqIA) raised a question about the differing fees applying to overseas applications for registration.
- 3.7 The EqIA also questioned the differing periods of UK work experience required from prospective pharmacy technicians, as a person applying from overseas would need to work a minimum of 28 hours per week over at least two years, while a 'suitably qualified UK person' can gain registration by completing 14 hours per week work experience over a two year period via a 'route b' application.

Q.4 Do you think that these draft rules contain adequate protection for patients and the public?

	Agree	Disagree	Don't know	Unanswered
Number	0	0	0	5
Percentage	0%	0%	0%	100%

- 3.8 One respondent felt that insufficient information was presented at this stage to answer this question, but that sufficient funds would need to be available to the GPhC so that all registered premises could be inspected at least once every 3 years, with those premises which had deficiencies being inspected more often. Sufficient funds should be available to support the defence of the GPhC in the High Court, should that be required.
- 3.9 It was suggested that the fee levels would deter registrants from joining professional organisations, to their and the public's detriment.

Q.5 Do you have any other comments about these rules that you would like us to consider?

	Yes	No	Don't know	Unanswered
Number	5	0	0	0
Percentage	100%	0%	0%	0%

Cost and transparency

- 3.10 Many respondents urged the GPhC to set fees that reflected the true cost of the processes involved. In particular, premises fees were felt by several respondents to be too low (although one respondent asked why the restoration of a pharmacy premises should be subject to the full fee irrespective of the part of the year when the premises is restored). One respondent suggested that premises should be charged per inspection, so that those which required more frequent inspection would pay more. Other fees were felt by some to be too high (e.g. fee for providing certificates of good standing, or for scrutinising applications from EU applicants) or too low (e.g. the fee for overseas applications) in relation to the true cost.
- 3.11 A couple of respondents thought that either specific (such as the application fee together with an initial entry fee for new registrants) or general fee levels were too high, or unjustified (e.g. the fee to provide a certificate) and others simply asked the GPhC to 'keep fees reasonable'.
- 3.12 Some respondents either did not understand, or asked for reassurance, that the initial entry fee would only be applicable to those joining the Register after the transfer of regulation, and that those RPSGB registrants who had already paid for 2010, and whose registration would transfer to the GPhC automatically on the transfer date, would not have to pay it.

Perceived inconsistencies and omissions

- 3.13 Several respondents noted inconsistencies across the fee structures for the various types of registrant, or fees that seemed to be missing. Comments included:
- a) there did not seem to be a fee set for restoration to the register following non-payment of fees
 - b) fees for restoration should comprise an application fee (payable whether or not the application was successful) and a restoration fee
 - c) new premises should be subject to an application fee as well as an initial entry fee, as are individuals
 - d) there should be a fee for application and a restoration fee for annotation of a premises entry to denote a specialisation
 - e) there was no mention of fees for the minor relocation of premises – this should be treated as continuation of an existing business rather than a new business for fees purposes
 - f) there should be a fee for restoring premises to the register following disqualification
 - g) fees for restoration following voluntary removal or removal by the Fitness to Practise Committee should be equivalent to the renewal fee, but fees for restoration for other reasons (e.g. non-payment of fees, failure to provide information, fraudulent or incorrect entries) should be higher.

Mitigations and methods of payment

- 3.14 There was support for the proposals for the Registrar to have the power to waive fees wholly or in part, and in specified circumstances to allow fee payments by instalments. One respondent asked that provision be made in the rules to allow fees to be paid by various methods e.g. annual direct debit or direct debit instalments.
- 3.15 A couple of respondents felt that newly qualified registrants should be helped in some way, e.g. by being permitted to pay by instalments. One organisation pointed out that the rolling register could create significant financial difficulty for pre-registration pharmacist trainees, as they would be required to pay their pre-registration exam fee, their initial entry onto the register fee and also their annual renewal fee all within the space of a few months, and would be on a pre-registration trainee salary when paying the exam and initial entry fees.

Miscellaneous

- 3.16 A respondent suggested that the GPhC should set timescales for completion of key tasks and remedies for failure to comply with these. It was also suggested that where the GPhC makes an error there must be no additional charges for correcting that error.
- 3.17 It was suggested that the GPhC might wish to consider registering undergraduate students and pre-registration trainees for a nominal fee.
- 3.18 A number of detailed drafting points were also made and have been taken into account in the final versions of the rules.

Our response

- 3.19 We have recently published our draft 2011 Fees Rules for consultation. The consultation on the 2011 Fees Rules closes in August and these rules will need to be in place for the 2011 renewal process in autumn 2010.
- 3.20 In the light of the anticipated transfer of regulation to the GPhC, we have decided not to proceed with the 2010 Fees Rules. Instead we will bring the 2011 Fees Rules into effect from the date when regulation transfers to the GPhC.
- 3.21 The 2011 Fees consultation document addresses a number of the points raised in this consultation. Others are covered below. We will consider any additional points together with the responses to the consultation on the 2011 Fees Rules.

Equality issues

- 3.22 We consider that differing fees applying to overseas applications for registration are justified in relation to the work required in assessing these applications to ensure that all registrants meet the regulator's requirements.

Requirements for registration as a pharmacy technician

- 3.23 We consider that the difference in acceptable work experience required of overseas applicants and 'route (b)' UK applications is justifiable. This point is specific to overseas qualified applicants who apply under the transitional arrangements prior to 30 June 2011. After that time, all applicants for registration as a pharmacy technician, with the exception of those with rights under EU legislation, must have a UK qualification in order to register. Those with overseas qualifications can 'fast track'. This is a simpler alternative than the OSPAP/pre-registration model for overseas pharmacists and likely to be more cost-effective for prospective registrants.
- 3.24 The transitional arrangement of 28 hours per week work experience for two years for those with non-UK qualifications was introduced because we are aware that there are many overseas-qualified pharmacists working in GB in pharmacy technician roles, many of whom have years of relevant experience working in senior roles. This provision is not a requirement for registrants to work a minimum number of hours in order to maintain their registration – it relates solely to the requirements for registration as a pharmacy technician.
- 3.25 Requirements for 'route (b)' were written to accommodate the small number of potential registrants with UK pharmacy technician qualifications but little or no work experience in a pharmacy. The absolute minimum of 14 hours over two years in a pharmacy was introduced as a result, for applications during the transitional period ending on 30 June 2011.
- 3.26 In general, we cannot assume that work experience outside the UK is equivalent to work experience in the UK as a registrant would need to be familiar with the context of practice in this country.

Costs and transparency

- 3.27 Our intention is to align the structure and levels of fees more closely with the relevant costs. As yet, we don't have all the information we need to fulfil this intention but we are moving in this direction. The Council will monitor the costs of regulation and keep these factors in mind when setting future fees for each category of registrant and will seek to ensure a consistent approach.
- 3.28 There has been some confusion about the 'certificate of good standing' and the 'notice of registration' mentioned in the rules. The GPhC will not issue registration certificates but will provide a notice of registration when an application for registration or renewal is granted. There will be no charge for a notice of registration unless a replacement is required. A certificate of good standing is issued to provide evidence of a registrant's standing on our register; for example, if they wish to apply for registration with an overseas regulator. A charge is proposed for such certificates.
- 3.29 The initial entry fee will only be applicable to those joining the Register after the transfer of regulation. RPSGB registrants who transfer automatically to the GPhC on the transfer date will not have to pay this fee.

Miscellaneous

3.30 There are no provisions for registration of students or pre-registration trainees in the Order so this is not an option at this time.

4 Draft rules – registration

What we proposed

4.1 This consultation sought to highlight new provisions within the draft registration rules, which set out various matters relating to the GPhC's Register including the detailed provisions relating to entry for pharmacists, pharmacy technicians and premises, and the renewal of entries. Provisions relating to appeals against appealable decisions were set out within a separate set of rules⁷.

What we heard

Consultation Questions

(Please note some respondents did not answer the questions directly, and so are not recorded as doing so in the numbers below, but provided comments, either here or elsewhere in the consultation, which reflected on these questions and which are included below the numbers in each instance).

Q.1 Do you think that these draft rules set out the necessary provisions in a clear and comprehensive manner?

	Agree	Disagree	Don't know	Unanswered
Number	3	0	0	6
Percentage	100%	0%	0%	

4.2 One respondent was unclear as to the meaning of Rules 16(2) and 17(2) (restoration of register entries and annotations).

Q.2 Do you think that these draft rules are written within the scope of the powers of the Order?

	Agree	Disagree	Don't know	Unanswered
Number	2	0	1	6
Percentage	66.7%	0%	33.3%	

Q.3 Do you think that there are any equality considerations that should be integrated into these draft rules?

	Agree	Disagree	Don't know	Unanswered
Number	1	0	1	7
Percentage	50%	0%	50%	

4.3 The Equality Impact Assessment made the general comment that the GPhC should collect equality data from relevant groups covered by the rules e.g. applicants for registration, fitness to practise panellists, registrants who are the subject of allegations etc.

⁷ See draft Appeals Committee rules consultation for further information.

Q.4 Do you think that these draft rules contain adequate protection for patients and the public?

	Yes	No	Don't know	Unanswered
Number	2	0	1	6
Percentage	66.7%	0%	33.3%	

- 4.4 One respondent felt that the rules appeared to be framed for the GPhC's convenience and found it difficult to see how they would protect patients and the public.
- 4.5 It was suggested that patients and the public would need to understand clearly how to search the register and look at information in each category, but that they should not have access to the home addresses of registrants.

Q.5 Do you have any other comments about these rules that you would like us to consider?

	Yes	No	Don't know	Unanswered
Number	4	2	0	3
Percentage	66.7%	33.3%	0%	

Equality and diversity data

- 4.6 A regulatory organisation commented that, in the registration rules and elsewhere, it would be better not to specify the kinds of data to be collected for equality & diversity monitoring, as good practice and legislative requirements about such data will change with time.

Service of documents

- 4.7 Several respondents raised concerns about the possibility of email as a vehicle for the delivery of documents, noting for example the limited storage capability of many email accounts, the difficulty in keeping email addresses up to date, and the need for the Registrar to ensure receipt. It was suggested that many law firms would not accept documents by email. One felt that, while email was acceptable in some cases, any final demand or notice should be by way of a recorded or signed-for service.

Fees

- 4.8 One respondent felt that allowing the Registrar to waive fees for low income earners was unfair to the majority and was inappropriate for a regulator. Another welcomed the general flexibility for the Registrar to waive fees in whole or part, but questioned why the Registrar would waive fees in respect of premises, stating that they were by definition commercial entities.
- 4.9 One respondent questioned the provision for an annual renewal fee for an annotation to a registrant's entry in the Register.

Keeping of the Register

- 4.10 One respondent felt that registrants should be required to notify changes to their name or address within one month.

- 4.11 The draft Rules permit the provision of unpublished information from the Register to persons other than the registrant's employer if the Registrar considers it in the public interest to do so. It was suggested that regular reports regarding any such provision should be made by the Registrar to the Council and an anonymised summary made public.
- 4.12 It was suggested that registrants should be able to send alterations to their Register entries via electronic means.

Content of the Register

- 4.13 Two respondents believed that the physical address of a premises, as well as the address of the owner or head office of the body corporate if this was different, needed to be on the Register.
- 4.14 Some respondents objected to the superintendent pharmacist's home address being on the Register, even if it were not published, given the vulnerability of databases.
- 4.15 It was suggested that the rules should cover the need to retain information on former registrants for a period and to record any names formerly used by registrants.
- 4.16 One organisation regretted in the interests of transparency that the Order prohibited the listing of suspended registrants. However, it noted that the draft rules provided an opportunity for GPhC to provide details about suspended registrants to enquirers, alongside information about registrants who had been struck off, and strongly advocated that the GPhC take advantage of this opportunity.
- 4.17 The fact that the rules did not permit the publication of home addresses of registrants was welcomed. One respondent approved the restriction but felt some facility for passing on letters or emails say from pharmacy bodies to their members, or facilitating the sending of invitations to student reunions, would be beneficial.
- 4.18 Objections were raised to the requirement that the Register contain the date of the last review of the registrant's continuing professional development (CPD) record, on the grounds that this had nothing to do with the registrant's registration status and could conceivably disadvantage them in certain situations.
- 4.19 It was suggested that it would be appropriate for a pharmacist's Independent Safeguarding Authority (ISA) number to appear on the Register.

Countersignature

- 4.20 A couple of respondents objected to the need to have documents verified by notaries or solicitors as onerous and costly.

- 4.21 Another welcomed the proposal to harmonise the arrangements for certification of copies of marriage certificates and render them more flexible.
- 4.22 Some respondents welcomed the proposal that pharmacy technicians as well as pharmacists should be able to countersign an application form. Another objected to it on the grounds that a pharmacist's expertise and professional training provided useful quality control.
- 4.23 One respondent sought clarification on whether a pharmacy technician could sign off a pre-registration trainee pharmacist and also what experience a pharmacist or pharmacy technician would require in order to be a counter signatory.

Consistency

- 4.24 One respondent thought in the interests of consistency and transparency, that applicants for restoration and renewal, as well as for initial registration, should be required to declare those matters listed at art 51(1)(e)-(n) in the Order, including convictions, cautions, regulatory body determinations and barring decisions.
- 4.25 Some respondents felt that the provision for entry of premises onto the Register for up to three years at a time in certain circumstances was inconsistent with the requirement for individual registrants to renew annually. One respondent supported the proposals for premises, and did not understand why such an approach was not being taken for registrants, concurrent with the CPD cycle, or ultimately, the revalidation cycle, with appropriate safeguards.
- 4.26 Some respondents noted that the rules contained detail on penalties for fraudulent registration or error, but were silent on the possibility of GPhC error.

Renewal of annotations

- 4.27 An objection was raised to the proposal that an annotation would need to be renewed annually, on the grounds that there was no public or other benefit to be derived from registrants being required to send in the same documentation as they did the previous year.

Voluntary removal

- 4.28 One respondent noted the provision for the Registrar to accept an application for voluntary removal from the Register when fitness to practise investigations or proceedings are underway in exceptional cases, and wondered what would constitute an exceptional case for this purpose.
- 4.29 An organisation argued that the policy of not allowing those facing potential fitness to practise proceedings to voluntarily remove themselves from the Register served no public interest purpose, and could be counter to the public interest. It suggested instead that such registrants should be allowed to remove themselves but that the relevant information be left on file in the event that such a registrant tried to subsequently re-register with the GPhC or any other regulator.

- 4.30 Another appreciated the principle but felt there had to be room for discretion in the interests both of compassion, and of public safety in the event of delays to the hearing of cases. It pointed out that there might be occasions when a conscientious registrant might like to suspend their registration while issues were investigated, and it wished to see guidance on circumstances where the Registrar might allow an application for voluntary removal/ suspension.
- 4.31 It was pointed out that superintendent pharmacists of corporate bodies with a large number of pharmacies could be likely to be involved in an investigation at one of the body's branches most of the time, and that this should not preclude the honourable withdrawal of a superintendent from the Register.

Premises applications and owners

- 4.32 An organisation objected that, while the Registrar would have to refuse restoration applications where there were concerns about the impact of health, safety and well-being on members of the public, there were no equivalent requirements where there were such concerns about the impact on those employed at the premises. It felt that the GPhC should take an active interest in environmental issues created by employers at the application stage, given their potential impact on public safety.
- 4.33 One respondent noted that the application form for premises where the business was to be carried on by a representative had to include the name of the responsible pharmacist. The respondent felt that this was probably meant to read 'superintendent pharmacist' as the responsible pharmacist was not constant for all the pharmacy's opening hours and might be a locum.
- 4.34 An organisation noted the requirement for a premises application to contain the names of all of the directors of a body corporate and the registered or principal address of the body corporate, but felt that as the superintendent pharmacist represents the company on behalf of its directors the only name that should appear was the superintendent's. It was pointed out that the NHS already required fitness to practise declarations to be made about all directors.
- 4.35 It was mentioned that there appeared to be no way of identifying if any owners or partners had been disqualified from being a company director.
- 4.36 It was noted by two respondents that the draft rules were unclear on whether a minor relocation of a premises would be classed as a new entry to the register or a variation of the original registration.
- 4.37 One respondent pointed out that when the ownership of a premises changed the new owner would be required to provide a plan showing the internal layout of the premises, and felt this was unnecessary and would duplicate the information already held by the GPhC.

Requirements for entry to the Register

- 4.38 Two respondents questioned why the GPhC required so many documents (for example, the requirement for a signed photograph if the applicant has also provided a passport containing a certified likeness of the applicant). Another

objected to the need to provide evidence of an applicant's nationality at the point of registration. An organisation felt that the requirements to provide certain documentation in support of an application involved unnecessary duplication in some cases and assumed that all applicants possessed a passport, which is not held by all citizens.

- 4.39 It was pointed out that reference is made to additional documents which the Registrar may request but no explanation given of when these documents would be requested. This respondent felt potential registrants would need to know under what circumstances additional information would be requested.
- 4.40 The draft rules stated that the registrant must sign and date a renewal application. One respondent asked whether this meant that registrants would no longer be able to make their submissions electronically.
- 4.41 It was suggested that a Criminal Records Bureau (CRB) check should be an employers' requirement, if appropriate, and not mandatory for registration, as there might be legitimate reasons why one was not required, and the backlog in CRB applications could unfairly delay an application to the GPhC Register.
- 4.42 A respondent felt the requirement for applicants to provide a declaration of good physical and mental health might cause concerns, in that ill-health of itself did not necessarily call into question an applicant's fitness to practise.
- 4.43 One organisation felt that the language around good physical and mental health at registration should be replaced with a single assessment of whether someone is fit to practise, in line with CHRE's work on health conditions.

Restoration to the Register

- 4.44 It was noted that the draft rules provided for restoration only within 12 months of removal, while the GPhC intended to implement a return to practice policy, with a two year period. In order to allow for consistency between the rules and the policy that is ultimately adopted, it was suggested that the GPhC might consider a more flexible provision at this point.
- 4.45 One respondent felt that while the restoration requirements included reference to fitness to practise, this was not necessarily related to confidence or competence.
- 4.46 In relation to applications for restoration from individuals after longer than twelve months' absence, a respondent argued that the rules should provide for the Registrar to determine, in individual cases:
- whether additional education, training or experience is required before restoration; and
 - whether specific CPD is required after restoration.
- and should enable the Registrar to determine that restoration is to be granted subject to the applicant agreeing to comply with appropriate undertakings with regard to CPD.

Registration for those based overseas

- 4.47 An organisation that employed several pharmacists and pharmacy technicians supporting Armed forces personnel and families overseas in a British health care setting, and that required all its professional employees to be registered with their respective UK regulator was concerned that these pharmacy registrants might be precluded from registration because they were not practising in Great Britain.
- 4.48 Some respondents thought that registrants overseas could only be registered with the GPhC if they signed a declaration that they would work in Great Britain during the year of registration. They acknowledged that the GPhC as a regulator will be focussed on the protection of the GB population but pointed out that some less affluent countries use UK regulators to assure standards of practice, and felt that some registrants might no longer be able to practise in such jurisdictions.
- 4.49 The position of those currently on the RPSGB's overseas (non-practising) register who were practising overseas was raised by one respondent. A respondent who did not want to transfer to the RPSGB's practising register immediately in order to ensure automatic transfer to the GPhC questioned the need for former RPSGB registrants to go through the same process of entry as a newly qualified registrant once the GPhC opened its doors.

Rolling register

- 4.50 This topic generated a great deal of comment, most, though not all, of it adverse. A few respondents supported, or appreciated the rationale behind, the concept but more did not. Employer groups in particular flagged up the ensuing administrative complexity and additional cost they would incur as a result. Additionally, in 2010, those employers who paid their employees' registration fees (i.e. the majority of multiples) , and who had paid the 2010 fees to the RPSGB in early 2010, would have to pay twice in one year, with no allocated budget to do so. The move away from a set renewal date for all registrants would increase administrative complexity when, for example, reimbursing fees and checking locum status.
- 4.51 It was also noted by several respondents that the change would appear to add complexity and unnecessary cost to the GPhC's processes as it would need to keep track of each registrant's renewal date rather than use a standard date, and that this cost would be passed on to registrants. One respondent asked for assurance that the GPhC's systems would be able to manage this additional complexity from day one, given that employers (and the public) would need confidence that the Register was accurate on a daily basis.
- 4.52 An employer group, amongst others, pointed out that it would be essential for the registrant's renewal date to appear on the register.
- 4.53 Many respondents emphasised the importance of early and effective communication of this change, and the new deadlines for renewal fees, to registrants, and some flagged up that certain groups (e.g. locums and pharmacy technicians) would present particular communications challenges

which would need to be resolved if people were not to accidentally lose their registration and incur the inconvenience and cost that this would entail.

- 4.54 One organisation said it would rather see persons entering the register charged a proportion of a full year fee with all registrants paying an annual renewal fee on a fixed date away from any bank holiday.
- 4.55 One respondent asked whether it was possible to change the date for renewal of fees so as to be in line with the tax year.

Renewal timetable

- 4.56 Many respondents commented on the requirement for renewal notices to be sent out three months before the expiry of registration; and for registrants to return these, with payment, two months before the expiry of registration. The majority felt the timeframe was too long. Some urged the GPhC to consider a reduction of the deadlines to two months and one month respectively. Another respondent suggested that the 'three month' requirement could be phased in to help registrants adjust to the change.
- 4.57 Several respondents felt the draft provisions placed the burden of administration (i.e. ensuring that renewal notices have been received) on the registrant, which they felt to be inappropriate, and they felt that there should be a statutory provision for the sending of a final demand by the GPhC.
- 4.58 One group suggested that the change would result in a Christmas hiatus where, for several days, employers might be utilising pharmacists and technicians who were no longer on the register (on the assumption that there would be no staff in the GPhC's office until Tuesday 4th January to carry out the removal of registrants who had not paid by 31st December 2010 or respond to enquiries about the status of a registrant).
- 4.59 As with the rolling register, many respondents emphasised the importance of early and effective communication of this change.

Miscellaneous

- 4.60 It was suggested that the demise of the non-practising register was detrimental to the public.
- 4.61 Concern was expressed that no mention had been made in the draft rules of how registrations would be transferred from the RPSGB to the GPhC.
- 4.62 It was pointed out that if current RPSGB registrants were to be awarded new numbers on transferring to the GPhC, this would impact on some organisations which use pharmacists' and pharmacy technicians' registration numbers as IDs in their internal processes.
- 4.63 A number of detailed drafting points were also made and have been taken into account in the final versions of the rules.

Our response

Equality and diversity data

4.64 Given that the provision of equality monitoring information by registrants is voluntary and is not part of the registration process, the Council's view is that the rules should not mandate us to ask particular questions. There is no intention to discontinue monitoring but dealing with this outside the rules will provide flexibility and enable us to keep up to date with changing requirements.

Service of documents

4.65 We recognise that, where a registrant provides an email address to the GPhC for general purposes, this may not necessarily mean that they are content to receive documents by email that need to be served under the rules. A registrant's email address will only be used for the service of documents under the rules with their agreement.

4.66 The fact that the rules make no provision for a statutory final demand is linked to the change from *retention* in the Register to *renewal* of registration. This is an important change which stems from article 25 of the Order. Currently, a registrant's entry is retained in the RPSGB's register until it is removed (for example, as a result of voluntary removal or removal for non-payment of fees). Under the Pharmacy Order, a registrant's entry in the Register is valid for one year from the date it was made. If it is not renewed before that time, it ceases to be valid. This means that it would not be feasible for us to send a final demand to any registrant who had not renewed their registration before its expiry date as their entry would have already ceased to be valid. In this situation, the entry could not be renewed and the person concerned would need to apply to be restored to the Register. This change from retention to renewal means that the onus is on us to ensure that we send out renewal forms on time but also on registrants to ensure that they complete their renewal applications in time for us to process them before their registration expires.

Fees

4.67 The issue of renewal fees is covered in the draft 2011 Fees Rules which have been issued for consultation. In relation to waiver of premises fees: while most registered premises are commercial entities, they are not so by definition. We think it is helpful to retain this flexibility in relation to both premises and registrants.

4.68 The registration rules provide for the possibility of a renewal fee for annotations to registrants' entries. However, the draft 2011 Fees Rules, which have now been published for consultation, do not propose a renewal fee for annotations. We nevertheless think that the Council should have the flexibility to set such a fee if, for example, it became apparent that the costs of regulation of registrants with annotations were higher because of the risks associated with specialist types of practice. This would be in keeping with our intent to align the structure and levels of fees more closely with the relevant costs.

Keeping of the Register

- 4.69 We agree that changes to a registrant's name or address should be notified to the Registrar within one month. We also agree that we should enable registrants to supply registration details online or electronically as far as possible.
- 4.70 The Council will be considering a framework to provide assurances and monitor risks relating to the exercise of its functions. This will be considered outside the rules.

Content of the Register

- 4.71 It is important to distinguish here between the Register itself – the GPhC's database containing current and historical data relating to the registration of each registrant and registered pharmacy - and the searchable 'register' which will appear on the GPhC's website, which is a list derived from the Register database. The rules relating to the content of the Register apply to the Register database but a number of the comments received seem to relate to the published list.
- 4.72 We agree that the Register should include any former names under which a registrant has practised, and that it should include the physical address of a registered premises as well as the owner's address.
- 4.73 We are conscious of the need to protect sensitive information but consider it essential that the Register database includes the home addresses of registrants, including superintendent pharmacists, even though we would not publish those addresses. A regulator needs to be able to contact those who are on its register. This is in keeping with a registrant's duty to notify the Registrar of changes to their home address.
- 4.74 We would retain information relating to register entries as appropriate but do not intend to use this information for purposes which are not linked to regulation.
- 4.75 In relation to concerns about recording the date of the last review of a registrant's CPD record in the Register; it is important that the database includes details of when a registrant's CPD record was last reviewed. Art 19(6) of the Order specifies the information which must appear in the published list, which does not include the dates of CPD reviews. This would not prevent the GPhC from including additional material in the published list but it we would consider the interests of both the public and registrants in making such decisions.
- 4.76 We will consider adjusting the rules to take further account of the Independent Safeguarding Authority and the equivalent Scottish arrangements at a later date.

Countersignature

- 4.77 We think it is appropriate to provide greater consistency and flexibility by requiring that, where relevant, copies of documents should be certified by a notary or a solicitor.

4.78 We consider that pharmacy technicians, as registered professionals themselves, are capable of taking on the role of countersigning applications for registration and remain of the view that it is appropriate to harmonise the provisions relating to pharmacists and pharmacy technicians in this way. It should be noted that countersigning an application is a separate process from signing off a pre-registration trainee pharmacist, which could not be done by a pharmacy technician.

Consistency

4.79 In relation to whether it should be possible for registrants' entries in the Register to be renewed for up to three years: art 25(1) of the Order provides that any renewal of a registrant's entry in the Register is valid for one year so it would not be possible to extend this period for registrants.

4.80 We would not expect to levy additional charges to correct an error made by the GPhC.

4.81 We agree that the rules should require an applicant for renewal or restoration of registration to declare any matter covered by art 51(1)(e)-(n) of the Order.

Renewal of annotations

4.82 The annual renewal of annotations is linked to the change from retention to renewal of registration. An annotation can only be valid while the register entry to which it relates is valid. The Order provides that a registrant's entry in the Register cannot be valid for longer than a year without renewal, so it will also be necessary for annotations to be renewed annually. However, the process need not be over-burdensome: the rules allow for the requirements for renewal of an annotation to differ from those for application for an annotation.

Voluntary removal

4.83 At first glance, it might seem sensible to allow someone who is the subject of a fitness to practise allegation to leave the Register voluntarily. However, this would mean that the facts about the allegation would not be determined. The person concerned could then apply to rejoin the Register or to register with another regulator even though an investigation of the allegation might have led to a determination that their fitness to practise was impaired. While the GPhC could be aware of any outstanding allegation, another regulator would not be aware, as the person could present a clean fitness to practise record. This would not be in the public interest and would not uphold public confidence in the profession. It would be open to the Fitness to Practise Committee to make an interim suspension order under art 56 of the Order to prevent such a registrant from practising while they remained on the Register, where this was thought appropriate. In other cases, a registrant might decide that they would not practise whilst an investigation was ongoing even though they remained on the Register.

4.84 There could nevertheless be cases where it would be appropriate to accept an application for voluntary removal in these circumstances; for example, where a

registrant was terminally ill and the public interest would not be served by instituting fitness to practise proceedings.

- 4.85 We recognise that, in a company with many community pharmacies, there may be ongoing investigations relating to a branch but they will not necessarily relate to the fitness to practise of the superintendent pharmacist. If the superintendent applied for voluntary removal, the Registrar would have to determine whether any outstanding investigations or proceedings related to the superintendent's fitness to practise and, if so, whether there were exceptional circumstances to allow the resignation from the Register.

Premises applications and owners

- 4.86 The rules provide that the Registrar must refuse an application for restoration of premises if the Registrar considers that restoring the premises to the Register would prejudice the health, safety or well-being of members of the public. Concern was expressed that this did not cover the health, safety or well-being of employees but employees and registrants could be considered as within the scope of 'the public' for this purpose.

- 4.87 We recognise that the references to 'responsible pharmacist' in the rules have caused some confusion. These provisions relate solely to instances when a pharmacy business is being run by a representative because of the death or disability of the owner. In these circumstances, there is no superintendent pharmacist or pharmacist owner in place so we need to ask for the name of the responsible pharmacist to verify that the pharmacy business is operating lawfully at the relevant time.

- 4.88 We think it is appropriate that an application for premises registration on behalf of a body corporate should list the names of the directors. We have not included provisions to identify if individual owners are disqualified from being a company director as this would not, of itself, prevent someone operating as a sole trader.

- 4.89 Although directors may make fitness to practise declarations for NHS purposes, not all registered pharmacies hold NHS contracts and these requirements relate solely to England, so they would not fulfil the GPhC's GB-wide regulatory remit.

- 4.90 The Medicines Act 1968 makes no reference to 'minor relocations' - this is an NHS contractual term. Our interpretation of the Act is that the registration of premises not already on the Register is a fresh application.

- 4.91 We would not require new plans to be submitted for a straightforward change of ownership but would do so in some circumstances, for example where the premises had been off the Register for a refit.

Requirements for entry to the Register

- 4.92 The rules do not require all applicants to possess a passport but allow for any other evidence of nationality that is acceptable to the Registrar. Evidence of nationality is required as it can have an impact on an individual's rights under

relevant legislation. A signed photograph is also important, particularly with the growth of identity fraud.

- 4.93 The rules have been adjusted to allow the Registrar to dispense with requirements to provide documents, information or evidence as appropriate when a former registrant applies to return to the Register or an application is made to re-register premises.
- 4.94 The Registrar may, where reasonable, require additional information or evidence to determine someone's application. This provides flexibility; for example, in a case where someone cannot provide the standard documentation.
- 4.95 The evidence we require in relation to health is for the purposes of art 23(5) in the Order i.e. to determine whether an applicant's fitness to practise is impaired. We have retained the current wording relating to physical and mental health as it relates to the relevant provisions in the Order.
- 4.96 We agree that renewal applications should be able to be made online.
- 4.97 The requirement for a Criminal Records Bureau/Disclosure Scotland check is not new and, in our view, is reasonable. It would not be a standard requirement for registration applications but only when further information is required.

Restoration to the Register

- 4.98 The rules provide for restoration within a set period after an entry was removed from the Register. After that period, an applicant would need to apply for re-entry to the Register in a similar way to someone applying to join the Register for the first time. However, the rules have been adjusted to avoid the necessity for people who leave the Register and later wish to return to resubmit all the information required for an initial application.
- 4.99 We agree that, where an individual applies to return to the Register, the Registrar should be able to determine, in individual cases, whether any additional education, training or experience should be required before restoration.

Registration for those based overseas

- 4.100 The Order states that, to be entitled to register with the GPhC, a person must intend to practise in Great Britain, the Channel Islands or the Isle of Man. However, pharmacists and pharmacy technicians working overseas will be able to register with the GPhC – and pay the normal fees – provided that they intend to return to practice in Great Britain, the Channel Islands or the Isle of Man in the future. There is no requirement to practise in this country during each year of registration.
- 4.101 All those on the RPSGB's practising registers will transfer automatically to the GPhC's register when regulation transfers from the RPSGB to the GPhC. However, given that the GPhC will be a new regulator, it will not be possible

for a former RPSGB registrant to be 'restored' to the GPhC's register once the GPhC is up and running – they would need to apply as a new applicant.

Rolling register

- 4.102 The move to a rolling register stems from the Pharmacy Order rather than the rules: art 25 of the Order states that a person's entry in the Register will be valid for one year from the date of registration or of renewal. It is not possible to arrange for all renewals to be due in, say April.
- 4.103 For registrants who will transfer automatically from the RPSGB to the GPhC, the Order states that renewal will be due on 31 December, as now. For people joining the GPhC Register after the transfer, renewal will be due on the anniversary of the date of first registration, so this could be at any time during the year.
- 4.104 We recognise the need to communicate this change clearly to pharmacists, pharmacy technicians and employers.

Renewal timetable

- 4.105 This is linked to the change from retention to renewal of registration. The introduction of the renewal concept is part of the modernisation of pharmacy regulation, in which registration is for a fixed period and has to be renewed. Registration is therefore much more like a licence which has to be renewed before it expires, rather than a membership of an association.
- 4.106 The Order (art 25) provides that an entry in the Register will cease to be valid after one year unless it is renewed. This means that the renewal process must be completed before the expiry date, which will be 31 December for registrants who transfer automatically to the GPhC. It will not be possible to complete the renewal process after the expiry date, as the entry will have ceased to be valid, so there will be no 'period of grace'. For the same reason, it would not be possible to send a final demand to anyone who had not renewed their registration by the expiry date as their registration would already have ceased to be valid. The onus is therefore on us to ensure we send out the renewal notices in good time and on registrants to return them by the deadline with the information and the fee required.
- 4.107 The timetable for the return of renewal applications is determined by art 24 of the Order. It provides that the Registrar must, within one month of receiving an application, acknowledge receipt and inform the applicant of any missing documentation that is needed. The Registrar is then given a month to decide the matter starting with when he or she has all the documents and the fee. These timescales are set out in the Order, so it is not possible to state a deadline of less than two months before the expiry date in the rules.
- 4.108 Again, we are aware that this is an important change which must be communicated clearly to pharmacists, pharmacy technicians and employers. We are also looking at ways in which we can ease the transition to the new timetable this year and help ensure that registrants are aware of when they

need to apply for renewal. This is likely to include reminding registrants about renewal deadlines.

- 4.109 We will review the renewal process after the 2011 renewals are completed and consider whether we can make improvements.

Miscellaneous

- 4.110 The transfer of registrations from the RPSGB to the GPhC is covered by the Order rather than the rules, as is the fact that the GPhC will not have a non-practising register.

- 4.111 RPSGB registrants who transfer to the GPhC will acquire new registration numbers. We will provide further information in advance of the transfer date.

5 Draft rules – appeals

What we proposed

- 5.1 This consultation sought to highlight new provisions within the draft Appeals rules, which set out the functions of the Appeals Committee and the procedures to be followed in proceedings before that committee. All decisions that are appealable under the provisions of the Order, apart from decisions where the appeal lies to the courts, will be covered by these rules. This means that these rules cover appeals in relation to registered pharmacy premises and educational institutions or providers (where approvals have been withdrawn, or refused) as well as appeals by registrants.

What we heard

Consultation Questions

(Please note some respondents did not answer the questions directly, and so are not recorded as doing so in the numbers below, but provided comments, either here or elsewhere in the consultation, which reflected on these questions and which are included below the numbers in each instance).

Q.1 Do you think that these draft rules set out the necessary provisions in a clear and comprehensive manner?

	Agree	Disagree	Don't know	Unanswered
Number	6	4	0	6
Percentage	60%	40%	0%	

Q.2 Do you think that these draft rules are written within the scope of the powers of the Order?

	Agree	Disagree	Don't know	Unanswered
Number	5	0	5	6
Percentage	50%	0%	50%	

Q.3 Do you think that there are any equality considerations that should be integrated into these draft rules?

	Agree	Disagree	Don't know	Unanswered
Number	4	3	4	5
Percentage	36.4%	27.3%	36.4%	

- 5.2 The Equality Impact Assessment (EqIA) suggested that the Appeals Committee procedures should explicitly state a list of 'reasonable adjustments' the GPhC would make to accommodate a person's disability in communications and during hearings, and the adjustments they would consider when determining whether a registrant's fitness to practise was impaired.

Q.4 Do you think that these draft rules contain adequate protection for patients and the public?

	Agree	Disagree	Don't know	Unanswered
Number	4	1	4	7
Percentage	44.4%	11.1%	44.4%	

Q.5 Do you have any other comments about these rules that you would like us to consider?

	Yes	No	Don't know	Unanswered
Number	2	6	1	7
Percentage	22.2%	66.7%	11.1%	

Advice and evidence

- 5.3 Some respondents felt that, in the interests of natural justice, private deliberations of the committee should be minuted and any legal advice from the legal adviser be made available to the appellant.
- 5.4 One respondent felt that the committee must not unreasonably withhold the admission of late submissions of written evidence if this would further the aims of fairness and justice.

Service of documents

- 5.5 One organisation commented that appeals required a higher level of care in communication and that any document served by post should be either registered or signed for on receipt. Further, it should be incumbent on the Registrar to take all reasonable steps to re-serve the documents should there be a failure in the first attempt.

Case management meetings

- 5.6 A regulatory organisation noted that a case management meeting might be conducted by the chair or, if the chair is not legally qualified, by a legal adviser who would be empowered to issue case management directions and give opinions on questions of law and admissibility of evidence, in the absence of the committee that they were appointed to advise. Whilst acknowledging that the adviser's opinions were not binding on the committee, the respondent felt it inappropriate that the legal adviser should make decisions that would influence the principal hearing, when a lay chair had been appointed to deal with the case. It noted that there was also no guarantee that the legal adviser at a case management meeting would also be the adviser at the principal hearing. It would prefer that the chair, even if not legally qualified, should conduct case management meetings, with a legal adviser present.
- 5.7 One organisation felt that the draft rules would ensure that a suitably qualified individual would chair the case management meeting and thus would improve the cost efficiency of the process.
- 5.8 A regulatory organisation noted that there seemed to be no penalty for ignoring case management directions except the displeasure of an appeals committee, which could impact when a postponement or adjournment is sought. It asked

whether there were other mechanisms for ensuring that case management directions have effect.

Efficiency

- 5.9 One regulatory organisation noted that the draft rules provided for the Appeals Committee to seek the advice of the Investigating Committee or the Fitness to Practise Committee. It felt the power for the Investigating Committee to advise the Appeals Committee was unnecessary and could create delays, and suggested that it be removed.
- 5.10 The requirement to serve and file a schedule of costs would be mandatory under these and the draft fitness to practise rules, even when a party is not seeking costs. One regulator thought this was unnecessary, time consuming and costly, and proposed that it should be discretionary rather than obligatory.
- 5.11 Some respondents urged that proceedings should be timely in order not to compound the associated stress, and be undertaken in the most cost effective manner with the minimum of adjourned hearings.
- 5.12 It was suggested that the level of competency of committee members must be assured through standardised training and independent appraisal.

Our response

Adjustments to accommodate disability

- 5.13 We think these matters should be covered outside the rules, to provide flexibility. For example, the range of appropriate adjustments could depend upon the registrant's scope of practice.

Advice and evidence

- 5.14 We do not consider that the private deliberations of the Committee should be recorded but the Committee must state its decision and the reasons for its decision in the presence of the parties. In addition, the Statutory Committees & their Advisers Rules, which apply to the Appeals Committee, provide that, where a legal adviser tenders advice in the absence of the parties or their representatives, the legal adviser must repeat the advice tendered to the Committee before the parties or their representatives in attendance at the hearing, and the parties or their representatives must have a reasonable opportunity to comment on the advice before the Committee makes its decision.
- 5.15 The rules would allow a party to adduce written evidence at a hearing which had not been submitted in accordance with the rules in exceptional circumstances. The Committee would consider the interests of fairness and justice when deciding whether it was appropriate to allow such evidence.
- 5.16 For witnesses whose first language is not English, we have ensured that the Committee may direct that their evidence be given through an interpreter.

Service of documents

- 5.17 In general, we consider the provisions relating to service of documents to be appropriate. However, in relation to service by email, we recognise that, where a registrant provides an email address to the GPhC for general purposes, this may not necessarily mean that they are content to receive documents by email that need to be served under the rules. A registrant's email address would only be used for the service of documents under the rules with their agreement. If service failed, there would have been no service. The rules provide that, where an appellant is not present or represented at a hearing, the secretary must adduce evidence that all reasonable efforts have been made to serve the Notice of Hearing on the appellant.
- 5.18 Where a document is sent by post, the rules provide that it must, unless sent by a service which records the date of delivery, be sent by first class post and will be treated as having been served on the day after it was posted.

Case management meetings

- 5.19 We agree that case management meetings should be chaired by a legally-qualified chair or by a lay chair with a legal adviser but not by a legal adviser alone. This also applies to the Fitness to Practise & Disqualification Rules and the Statutory Committees & their Advisers Rules.

Efficiency

- 5.20 We agree that the power for the Investigating Committee to advise the Appeals Committee is unnecessary; it has therefore been removed.
- 5.21 Non-compliance with case management directions could be taken into account when a costs order was being considered.
- 5.22 We agree that the requirement to serve & file a schedule of costs should not be mandatory but should apply only when a party is seeking or intends to seek an order for payment of its costs.
- 5.23 Our aim is for proceedings to be just, timely and efficient. We shall keep this aim in mind when considering the detailed arrangements and procedures under the Order and rules.

6 Draft rules – statutory committees and their advisers

What we proposed

- 6.1 This consultation sought to highlight new provisions within the draft Statutory Committee and their Advisers rules, which set out various matters relating to the constitution and composition of the three statutory committees of the Council (the Investigating Committee, the Fitness to Practise Committee and the Appeals Committee) and to the functions of the advisers to the statutory committees and other committees of the Council i.e. legal, clinical and specialist advisers.

What we heard

Consultation Questions

(Please note some respondents did not answer the questions directly, and so are not recorded as doing so in the numbers below, but provided comments, either here or elsewhere in the consultation, which reflected on these questions and which are included below the numbers in each instance).

Q.1 Do you think that these draft rules set out the necessary provisions in a clear and comprehensive manner?

	Agree	Disagree	Don't know	Unanswered
Number	0	0	0	2
Percentage	0%	0%	0%	

Q.2 Do you think that these draft rules are written within the scope of the powers of the Order?

	Agree	Disagree	Don't know	Unanswered
Number	0	0	0	2
Percentage	0%	0%	0%	

Q.3 Do you think that there are any equality considerations that should be integrated into these draft rules?

	Agree	Disagree	Don't know	Unanswered
Number	0	0	0	2
Percentage	0%	0%	0%	

Q.4 Do you think that these draft rules contain adequate protection for patients and the public?

	Agree	Disagree	Don't know	Unanswered
Number	0	0	0	2
Percentage	0%	0%	%	

Q.5 Do you have any other comments about these rules that you would like us to consider?

	Yes	No	Don't know	Unanswered
Number	2	0	0	0
Percentage	100%	0%	0%	

Eligibility

- 6.2 One regulator suggested that members of the Appointments Committee should be barred from membership of the statutory committees. Another regretted that the draft rules made no mention of eligibility criteria for members of the Appointments Committee.
- 6.3 One respondent felt that health and social care professionals should not be excluded as lay members of committees. Three respondents felt it should be made clear that members could be from other professions 'as a positive statement' rather than just indicating they must not be from another health or social care profession. Another sought clarification as to whether the prohibition on lay members being 'entered in the register of any regulatory body' applied to all professions, to health professions only, or to pharmacists.
- 6.4 An organisation suggested that 'a high proportion' of pharmacist members of the committees should have to provide evidence at annual review that they had spent at least 40% of their time in pharmacy work engaged in patient facing roles.
- 6.5 It was suggested that cohabiters of GPhC employees, Council or statutory committee members be added to the list of persons who may not be co-opted as a member of a statutory committee.
- 6.6 An organisation warned against discrimination against 'elected union members' of registrant unions as statutory committee members (although in some places the comment seemed to refer simply to union members, rather than members of the union's board).
- 6.7 One respondent agreed that there should be a break between terms of service for committee members but did not agree that members may not sit for more than eight years in 20 years, on the grounds that this would risk losing valuable experience for no clear benefit.

Committee member training, competencies and dealing with concerns

- 6.8 Some respondents, including two regulators, felt the rules should ensure that the level and frequency of training for reserve committee members is to the same standard as that provided to formal committee members.
- 6.9 Competencies for members of statutory committees were welcomed and it was suggested that these should be published.
- 6.10 One organisation felt that a formal complaint procedure involving adjudication by the Appointments Committee should be put in place so that registrants could

object to the Chairman's behaviour if they felt they had been disadvantaged by it.

Committee chairs

- 6.11 Several respondents, both individuals and organisations, felt there should be a requirement, rather than a discretionary provision, for the chair of the Fitness to Practise Committee to be legally qualified (one respondent felt this should also be the case for the deputies), generally on the grounds that to do otherwise would be cumbersome and incur extra costs through adjournments and greater need for legal advisers. One organisation felt strongly that chair should at the least have QC experience and preferably experience as a criminal circuit or High Court judge. Others had no objection, but asked for an explanation of the proposal that the existing requirement for legally qualified chairs should be made discretionary, while still others supported the move.
- 6.12 The proposal that two lay members should be appointed as chair and deputy chair of each of the three statutory committees was welcomed by one respondent on the grounds of flexibility.

Composition of committees

- 6.13 Some respondents felt there were too many lay members on the committees, and felt that these would not be able to make informed decisions.
- 6.14 Others noted the requirement that the number of registrant members at any hearing or associated meeting should not exceed the number of lay members by more than one, and thought that this should be mirrored so that the number of lay members should not exceed registrant members by more than one.
- 6.15 It was also suggested that there would be advantages to having more than one pharmacist sitting at each hearing.
- 6.16 One organisation felt that registrants should have the right to challenge the composition of the committee with the exception of the chair.

Size of committees

- 6.17 One respondent welcomed the proposed increase in the number of members for the Fitness to Practise Committee on the basis that this should alleviate listing problems relating to the availability of members.
- 6.18 It was suggested that the number of Appeals Committee members should be increased to twelve, so that two Appeals hearings could be run at one time if required.

Our response

Eligibility

- 6.19 We consider it self-evident that members of the Appointments Committee should not also be members of the statutory committees. We further believe that it would be inappropriate for a member of the Appointments Committee to

be appointed to a statutory committee until some time after they had left the Appointments Committee. However, our view is that these points, together with other details relating to the Appointments Committee are best covered in policy rather than rules, to ensure flexibility and to reflect the fact that the Appointments Committee is not a statutory committee.

- 6.20 The definition of a 'lay member' of a statutory committee follows the definition of a lay member of the Council in the GPhC's Constitution Order. The definition of a 'regulatory body' for these purposes is in the Order and covers regulators of health and social care professions. Members of other professions would therefore be welcome to apply. Further details relating to appointment or co-option of statutory committee members would be dealt with outside the rules.
- 6.21 An organisation warned against discrimination against elected (presumably board) members of registrant unions as statutory committee members. We feel that for a board member of a registrant union or defence organisation to sit on a panel that was adjudicating on a registrant's fitness to practise would be a clear conflict of interest and should not be permitted. However, the organisation's comment seemed in places to refer to union members (as opposed to persons holding office within the union) and there would be no general prohibition in that instance. The Appointments Committee would consider any potential conflicts of interest when appointing members of the statutory committees.
- 6.22 The bar on serving more than 8 years in a 20-year period follows the provisions relating to the Council. We think this achieves an appropriate balance between retaining experience and bringing in new blood.

Committee member training, competencies and dealing with concerns

- 6.23 We feel it is preferable to cover further detail on training and competencies outside the rules.
- 6.24 It would not be appropriate for the Appointments Committee to have an adjudication role in relation to complaints about statutory committee proceedings. The Order provides that appeals against decisions of the Appeals Committee may be made to the courts. We nevertheless intend to put in place performance management arrangements for all statutory committee members. In the interests of good governance, we have provided that the Appointments Committee must submit a procedure in respect of the removal or suspension of a statutory committee member, or the removal of a person from the reserve list, to the Council, for the Council's approval.
- 6.25 For clarity, we have specified that a person could only be appointed from a reserve list to a position for which he had been placed on the reserve list i.e. persons could only be appointed to a particular committee if they were on the reserve list for that committee and could only be appointed as chair or deputy chair if they were on the reserve list for such a position.
- 6.26 Again for clarity, the rules now provide explicitly that, when the Fitness to Practise Committee is considering whether a person's fitness to practise is

impaired, a tied vote would be treated as a decision that the person's fitness to practise is not impaired.

- 6.27 In relation to the Investigating Committee's functions of considering whether the GPhC should bring criminal proceedings, the rules provide that the Investigating Committee may not determine that criminal proceedings should be brought unless it is satisfied that there is a real prospect of securing a conviction and it is in the public interest to bring the proceedings.

Committee chairs

- 6.28 Our intention is that the rules should allow for the chair of any of the statutory committees to be legally qualified or lay. We recognise the potential advantages of having a chair with an appropriate legal qualification and relevant experience. However, we do not wish to restrict the eligibility criteria more than is necessary in the rules – such matters can be considered as part of the appointments process.

Composition of committees

- 6.29 The requirement that the number of registrant committee members must not exceed the number of lay members by more than one stems from the Order (Sch 1, para 5). The intention is to preclude a substantial registrant majority on a statutory committee. It would not, in any case, be practical to also have a requirement that the lay members must not exceed the registrant members by more than one – this would mean that a hearing could only be held with equal numbers of lay and registrant members and would be likely to lead to unnecessary cancellations and postponements, which would not be in the interests of the public or registrants. Other more specific requirements relating to the make-up of a committee could have a similar impact.

Size of committees

- 6.30 We have increased the number of Appeals Committee members to 12. This should ensure that sufficient members are available to run two Appeals Committee hearings at one time if required. We have also increased the size of the Fitness to Practise Committee to 40 to help ensure that there are sufficient panellists available for hearings.

7 Draft rules – fitness to practise & disqualification

What we proposed

- 7.1 This consultation sought to highlight new provisions within the draft Fitness to Practise & Disqualification Rules, which prescribe the procedures to be followed by the GPhC and its statutory committees when considering three types of allegations: allegations that the fitness to practise of registrants is impaired; allegations that a body corporate should be disqualified and allegations of criminal conduct which the GPhC is under a duty to investigate.
- 7.2 These draft rules reflect the fact that there will no longer be separate statutory health and disciplinary committees. Instead there will be one Fitness to Practise Committee that will deal with all types of fitness to practise cases.

What we heard

Consultation Questions

(Please note that no respondents answered the individual fitness to practise (FtP) consultation, only the full one, and so we do not have numbers for their views on the individual questions, but we do have comments from the full consultation that relate to the specific FtP questions and these are shown below).

Q.1 Do you think that these draft rules set out the necessary provisions in a clear and comprehensive manner?

- 7.3 It was suggested that pharmacists do not understand the terminology used in the rules, and that the interpretation section in particular could give rise to misunderstandings and concerns.
- 7.4 Another respondent felt the draft rules lacked consistency in connection with whether decisions were to be made by the whole Committee or just the chair.
- 7.5 One found the draft rules unclear as to what provision was being made for practitioners with significant health issues.

Q.2 Do you think that these draft rules are written within the scope of the powers of the Order?

[no comments received]

Q.3 Do you think that there are any equality considerations that should be integrated into these draft rules?

- 7.6 The Equality Impact Assessment (EqIA) noted that the fitness to practise criteria included consideration of a registrant's age when the relevant conduct took place. It saw this as potentially discriminatory and suggested it should be removed.

- 7.7 The EqIA also suggested that the rules should explicitly state a list of 'reasonable adjustments' the GPhC would make to accommodate a person's disability in communications and during hearings, and the adjustments they would consider when determining whether a registrant's fitness to practise was impaired.

Q.4 Do you think that these draft rules contain adequate protection for patients and the public?

[no comments received]

Q.5 Do you have any other comments about these rules that you would like us to consider?

General

- 7.8 Some respondents called for the hearings and appeals process needs to be timely. One noted that the stress associated with such events was severe and could be compounded if they were unnecessarily drawn out. Another was concerned that the new rules did not seem to aim to reduce the length of time that hearings were currently taking. One respondent suggested that the rules should include a general provision to the effect that the parties have a duty to co-operate in the just and timely disposal of cases.
- 7.9 One respondent wanted much clearer guidance (including a flowchart) for respondents on the referral and appeals process.
- 7.10 The fact that there would be one Fitness to Practise committee to replace the two RPSGB committees designated to discipline and health was welcomed by one organisation, which sought clarification as to how the divergence of health and misconduct cases would happen practically and called upon the GPhC to make these decisions clear at an early case management meeting.
- 7.11 Some respondents believed that when investigating and applying sanctions, the Committee would need to apply the same criteria to corporate bodies and their superintendent pharmacists, on the grounds that organisations that breach health & safety and working time regulations were not only breaking the law but could give rise to cultures and working practices that were a threat to patient safety.

Interpretation

- 7.12 One respondent noted that there was no clear definition of 'registrant', and felt that the proposed categories of 'applicant concerned', 'person concerned', 'registrant concerned' and 'section 80 party' were unhelpful.
- 7.13 Members of the security staff who are normally present at hearings and act as ushers are not included in the list of those who can be present at a meeting 'in private'. A respondent asked whether it was the intention that for any hearing that is to be held in private, the chair will need to make a ruling that their presence is deemed necessary.

Service of documents

7.14 It was suggested that treating first class post as served the day after it is posted seemed unrealistic.

Duty to provide information to the Registrar

7.15 A respondent pointed out that there was no duty for a registrant to inform the Registrar if she or he had been charged (as opposed to convicted) with a serious offence, saying that, whilst registrants were innocent until proven guilty, the public might prefer them to be actively regulated in this circumstance.

7.16 It was noted that there was no 'catch all' requirement to inform the Registrar of any circumstance that might put in doubt a registrant's fitness to practise.

7.17 It was suggested that it might be appropriate to exclude convictions and cautions for driving offences, which could not result in a prison sentence and did not result in disqualification from driving, from this duty.

7.18 It was pointed out that the duty to inform arose both on investigation and on a determination by a health or social care regulator but only on investigation by a non-health and social care regulator. The respondent suggested that the need for this information would be equal in both cases.

7.19 It was suggested that the draft rules would not ensure notification of the Registrar where the registrant concerned was on the barred list by the Independent Safeguarding Authority (and the Scottish equivalent).

7.20 One registrant wanted more clarity as to what would need to be reported in the case of criminal activity.

Initial action in respect of allegations

7.21 The draft rules indicated that the Registrar should only refer allegations where the registrant is identifiable. Clarification was sought as to whether a referral would take place if it could be ascertained that a misdemeanour had obviously been committed by one person, where more than one registrant could be implicated but no single person could be identified as the perpetrator.

7.22 One respondent recommended that the GPhC adopt the equivalent wording in respect of time elapsed since the incident that is used in General Medical Council proceedings, as there is case law on what this provision involves, and to publish guidance as to the criteria to be applied by the Registrar when considering a case more than five years old.

7.23 An organisation strongly supported the provision that anonymous complaints and those where the complainant was not prepared to engage and the allegation was not otherwise verifiable should not be referred. It felt it important, however, that such allegations should not result in the inspectorate conducting 'fishing expeditions' for evidence, whether connected with the complaint or not.

- 7.24 Another respondent felt that ‘whistleblowers’ who risked losing their jobs should be allowed anonymity.
- 7.25 As currently drafted the rules would require the Registrar to refer an allegation directly to the Fitness to Practise Committee instead of the Investigating Committee if he considers that there is a ‘likelihood’ that the Fitness to Practise Committee will direct that the registrant’s name be removed from the Register. One respondent believed that a referral on this basis was potentially prejudicial to a registrant and that the relevant rule should therefore be omitted. If necessary, such cases could be dealt with under the provision allowing direct referral to the Fitness to Practise Committee where the public interest is best served by urgent consideration.

Investigation prior to referral

- 7.26 An organisation drew attention to the requirement in the Pharmacists and Pharmacy Technicians Order 2007 that the regulator should notify any employer of a registrant that they have been referred to the Investigating Committee. The respondent felt this was unfair and urged the GPhC to only send out such a notification to employers in the event that a referral to the Fitness to Practise Committee had been made.
- 7.27 An organisation was unhappy that decisions not to refer a registrant to the Investigating Committee (when they had admitted the error, accepted advice and acknowledged that the decision would be recorded) would be kept on the registrant’s file and could be cited as an aggravating factor in any future cases. Its concerns related particularly to dispensing errors, which it felt should be considered in association with environmental factors. The organisation believed that inspectors should follow quasi-legal processes to protect registrants when investigating and dealing with complaints which do not exceed the threshold for referral and that these processes should be written into the rules.

Investigating Committee

- 7.28 It was proposed that the Investigating Committee should be able to require a registrant to be medically examined so as to enable them to ascertain, for example in a case involving drug or alcohol misuse, whether an incident is a one-off or indicative of a longer-term problem.
- 7.29 Some respondents felt that the committee outcome option of ‘no further action at this time’ seemed prejudicial and that an additional option of ‘no case to answer’ should be available to both the Investigating Committee and the Fitness to Practise Committee.
- 7.30 A respondent noted that the RPSGB rules provided that the Investigating Committee ‘shall’ not hear oral evidence whereas the draft GPhC rules provided that it ‘may’ not hear oral evidence, which suggested to them that it could do so. The respondent wondered whether this was intentional and if so in what circumstances.

- 7.31 An organisation was pleased to see that the Investigating Committee '*may send any written representations received from the person concerned to the informant, if any, for comment*' and thought this should be standard practice.
- 7.32 An organisation noted the removal from the draft rules of the Investigating Committee's power to give a registrant a warning, although that power along with the ability to give advice to a registrant appeared (the respondent felt unhelpfully) elsewhere in article 53 of the Order.
- 7.33 A regulatory organisation agreed that the Investigating Committee may close a case with a warning only when the person concerned admits the allegation but felt it should not be necessary for the person concerned to also agree that it was appropriate to dispose of the case with a warning.
- 7.34 A respondent welcomed the clarification of when an allegation should not be referred to the Fitness to Practise Committee, but felt these exclusions should also apply to referrals to the Investigating Committee.
- 7.35 Two respondents felt that for the Investigating Committee to only reconsider an allegation as a result of the GPhC erring in its administrative duties was too restrictive.
- 7.36 When the Investigating Committee has decided to reconsider an allegation there is no explicit duty to inform the person concerned or the informant of the reason for the reconsideration. Those persons are given an opportunity to make representations about the decision to reconsider and one respondent felt it would be more difficult for them to do this if they did not know on which of the grounds within the rules the decision had been taken.

Fitness to Practise Criteria

- 7.37 The fitness to practise criteria generated the highest volume of comment on these draft rules. Two respondents welcomed the criteria; many more (including three health care regulators) had adverse views:
- i) both about whether the suggested approach was appropriate; for example:
 - a) comments that the criteria had been drafted negatively rather than defining the threshold and scope of acceptable behaviour and were in places unclear;
 - b) concerns that it would be for the Fitness to Practise Committee to determine whether or not conduct or behaviour has been serious, and the criteria could give rise to a perception that the Committee's discretion is being tied,
 - c) some rules talked about 'requirements as to fitness to practise' while others reflected the Order by referring to the Committee considering 'whether the fitness to practise of the registrant is impaired'.
 - ii) the suggestion that they could instead be drafted in the form of broad headings:

- a) one respondent suggested these could complement the conduct, ethics and performance standards. Two others cited as an example those criteria set out in the case of *Zygmunt v General Medical Council* [2008] EWHC 2643 (Admin.)
 - b) It was felt that an over-prescriptive approach would restrict the GPhC from adapting its policies and guidance in response to developments and make loopholes, and extended litigation, more likely.
- iii) and about individual criteria, for example:
- a) the draft criteria were felt to include factors that seemed more appropriate to consider at the sanction stage, and to confuse mitigation with other matters.
 - b) the use of the term 'failure' to enter into undertakings in the absence of any duty to do so.
 - c) One respondent felt that 'recency' should be a key consideration when applying fitness to practise criteria. Another questioned the relevance of the length of time since an incident without some reference to remediation.
 - d) It was felt that true 'insight' was hard to judge.
 - e) An organisation had grave concerns about the potential application of the co-operation criterion, and felt that the exercise of a registrant's legal rights could be taken as non-co-operation.
 - f) One respondent felt that one draft criterion seemed to imply that any given conduct was somehow less serious if it did not relate to the practice of pharmacy. They felt this conflicted with the definition of impairment in the Order.
 - g) It was suggested that the criteria were silent on performance issues.

7.38 One respondent commented that the draft criteria would seem to conflict with and supersede the powers of the Investigating Committee to prepare and publish its referral criteria and for the Fitness to Practise Committee to provide advice to the Investigating Committee on cases that should not be referred to it.

Disclosure provisions

7.39 Some respondents welcomed what they saw as a simpler, pragmatic, less stressful and more flexible approach taken in the draft rules, which avoided specific time limits in favour of a requirement to serve 'as soon as reasonably practicable'.

7.40 Others felt the removal of a specific time limit was unsatisfactory and open to abuse. Some felt the existing time limits worked well. One organisation thought there was no reason why exceptions from time limits could not be made in rules for dealing with cases that should be fast-tracked, but another welcomed the abolition of fast tracking because in its experience the system had not worked.

- 7.41 An organisation that otherwise objected to the removal of specific time limits in the draft rules supported the proposed flexibility in agreeing listings.
- 7.42 One respondent suggested that no useful purpose would be served by having a time estimate from the GPhC for the duration of its case when first serving material on the registrant, because the GPhC would not be in a position to take into account at that point evidence yet to be served by the registrant. Similarly, it was suggested that the agreed time estimate, listing questionnaire and case management directions should be dealt with only after the registrant's statements of evidence had been served.
- 7.43 One organisation felt that full disclosure of a registrant's case should be required no less than 28 days before a hearing. Mutual disclosure of the case could be provided for by way of a practice direction that could be supported by robust case management directions.

Notices of hearing

- 7.44 Two respondents felt that the requirement to give 28 days' notice of hearing could cause considerable difficulties with respect both to the preparation of cases and taking legal advice. There may be occasions when a solicitor or barrister familiar with the case is unavailable. Difficulties and the risk of adjournments could be reduced if listing questionnaires were to allow the parties to indicate dates to avoid and if the rules were to stipulate that before fixing the date of a hearing, the Secretary would have regard to the listing questionnaires.

Interim Orders

- 7.45 The GPhC was asked how it would define the 'date which, in the opinion of the secretary, provides the registrant with reasonable notice of the hearing in the particular circumstances of the case', citing perceived problems with the way this had been interpreted in the past.

Hearing bundles

- 7.46 An organisation felt the proposed continuance of the existing provision for serving hearing bundles was unsatisfactory and had given rise to conflicting decisions of differently constituted disciplinary committees. It felt the same rules for service should apply both to the GPhC and the registrant and further evidence should only be permitted at the discretion of the chair. The respondent also felt that allowing further evidence as late as 14 days before a hearing would cause unfairness and difficulties.

Case management meetings

- 7.47 An organisation noted that the legal adviser could conduct case management meetings where the chair was not legally qualified, and was concerned that this would change the relationship between the legal adviser and the committee, which might not be beneficial.
- 7.48 It was suggested that the case management directions were inconsistent in that whilst the chair might request a case management meeting they could not conduct it if they were not legally qualified.

Evidence

- 7.49 Two respondents felt this draft rule presented problems arising from the chair not needing to be legally qualified. Currently if the chair sees legally inadmissible material the case can continue without the other committee members having seen potentially prejudicial information, but if the full committee were to see prejudicial material that is ruled inadmissible then it might no longer be possible to have a fair hearing and a differently constituted committee would have to be formed before the hearing can take place, causing unnecessary delay and expense.
- 7.50 It was commented that the draft rules covered evidence of determinations by statutory regulators of health and social care professions but not statutory regulators of other professions (of which a registrant might also be a member).
- 7.51 The GPhC was urged to include a provision for fitness to plead in relation to the registrant's ability to understand the issues in the case and the advice received from their representatives.

Agreement of undertakings

- 7.52 Three respondents advised that the Fitness to Practise Committee should be given power to accept undertakings without a hearing.

Consideration of additional allegations

- 7.53 The draft rules provided that where new allegations are received about a case already under consideration, they can be heard at the same hearing where they are of a 'similar kind' or 'founded on the same facts'. One organisation advised consideration of more flexible wording to allow for the appropriate consideration of new material at the same hearing, in the interests of efficiency and the timely disposal of cases, where this could be achieved without compromising the thoroughness with which the new allegations are investigated.

Additional evidence for review hearings

- 7.54 It was suggested that time limits should be set so that a registrant is not presented with new evidence at the last minute.

Procedure at hearings

- 7.55 One organisation felt the draft rules on procedures at different types of hearings were unnecessarily repetitive and that a single procedure with variations only where necessary would be preferable.
- 7.56 A respondent felt there should be some flexibility in the operation of the three-stage process of decision-making, namely findings of fact, whether fitness to practise is impaired, and sanction. In cases where misconduct is alleged and not admitted, the draft rules made no provision for the stage at which misconduct is to be decided by the committee. This would be particularly important in cases concerning negligence. For example, a dispensing error may be admitted and included in the findings of fact but there should be a stage at which the registrant can submit that the negligence is not so serious as to amount to misconduct. It is inappropriate to do this at the 'impairment' stage

because the registrant or registrant's representative will need to know whether misconduct has been found before making submissions on whether such misconduct impairs the registrant's fitness to practise.

Postponements and adjournments

7.57 Two respondents felt there could be times when an adjournment was necessary in the interests of fairness, even though some injustice might be caused to one of the parties, and therefore felt the words 'no injustice' in the proposed rule 40(2)(a) were unduly restrictive and would fetter the committee's discretion.

Disposal of allegations without hearings

7.58 A respondent felt that the draft rules were one-sided in that the GPhC's representative, 'the presenter', would be able to apply to the Investigating Committee for a direction rescinding a referral by the Investigating Committee to the Fitness to Practise Committee, but the registrant or his or her representatives would not be permitted to do the same.

Witness evidence

7.59 It was suggested that the provision that would allow witness statements to be served seven days before the hearing appeared to contradict the draft rules relating to disclosure provisions. The respondent felt witness statements should have been served at an early stage and it would be a recipe for chaos to allow parties to serve further witness statements only 7 days before the hearing.

7.60 A respondent felt the provision to prohibit the committee from asking questions except through the chair was impractical and that the rules would be better phrased as 'may then be questioned, with the leave of the chair, by the Committee or by a clinical or specialist adviser'.

7.61 The GPhC was urged to provide for the use of interpreters for witnesses who did not speak English as a first language.

Costs of the hearing

7.62 An organisation raised many objections to the making of costs orders for hearings including:

- The regulator is the prosecuting authority and should bear the burden of the costs (another organisation felt that a cost order should only be made in exceptional circumstances)
- Registrants should not be deterred from putting forward a defence by the threat of a cost order unless there is a deliberate or wilful denial of the facts merely to obstruct the investigation and the subsequent proceedings.
- If the central argument used in a registrant's defence is to explain the significance of why he or she had pleaded guilty, been given a criminal conviction or accepted a police caution; the fact that the chair does not rule in the registrant's favour should not alone constitute a reason for awarding costs.
- One organisation commented that the costs of hearings could be dramatically reduced if some of what it felt were currently wasteful and

inefficient processes and committee activities could be stopped, and made several detailed suggestions on this head.

7.63 The draft rules give the chair discretion as to whether or not he or she wishes to assess costs summarily or to require the parties to reach an agreement and revert to an assessment by a person appointed for that purpose if they cannot. Apart from its concerns above about the principle of awarding costs, one organisation had concerns about the mechanism, for example:

- The chair's objectivity in assessing costs may be influenced by the fact that he or she was unhappy with some aspect of the defence.
- In this situation, the registrant may not have the wherewithal to challenge either the quantum or the proportion of the costs awarded against him or her, save other than through a High Court Appeal.
- In the event that a chair summarily sets costs, registrants should have the automatic right to have these costs assessed independently if they suspect that they may have been set too high. In the event that an independent assessment finds that these costs are indeed too high, the costs of the assessment should be borne by the regulator, otherwise the costs of such assessment should be borne by the registrant.

7.64 An organisation was concerned that a number of changes to the procedures, for example the fact that the chairs and deputy chairs do not need to be legally qualified and the consequent increased role of the legal adviser and the ability of the Registrar to refer cases straight to the Fitness to Practise Committee without preliminary assessment by the Investigating Committee, were likely to lead to increased costs.

7.65 The GPhC was urged to conduct proceedings in the most cost effective manner with the minimum of adjourned hearings. It was felt that the level of competency of committee members must be assured through standardised competency-based training and independent appraisal.

7.66 A number of detailed drafting points were also made and have been taken into account in the final versions of the rules.

Our response

Equality

7.67 We consider that adjustments to accommodate disability should be covered outside the rules, to provide flexibility. For example, the range of appropriate adjustments could depend upon a registrant's scope of practice.

7.68 We have removed reference to a registrant's age when the relevant conduct took place from the fitness to practise criteria.

General

7.69 The general comments we received related largely to procedures and guidance. Our aim is for proceedings to be just, timely and efficient. We shall keep this

aim in mind when considering the detailed arrangements, guidance and procedures under the Order and rules.

7.70 The sanctions that may be applied to registrants or to those operating registered pharmacies are set out in the Order and the Medicines Act 1968.

Interpretation

7.71 We have reviewed the rules to ensure that the appropriate term is used when a provision relate to a registrant, an applicant or to someone operating a registered pharmacy. The term 'registrant' is defined in the Order and covers pharmacists and pharmacy technicians. Further information can be provided in guidance.

7.72 If there are people whose presence is generally required at private deliberations of the Committee, the chair could make a general direction that they should be present; it would not be necessary to do this each time.

Service of documents

7.73 In general, we consider the provisions relating to service of documents to be appropriate. However, in relation to service by email, we recognise that, where a registrant provides an email address to the GPhC for general purposes, this may not necessarily mean that they are content to receive documents by email that need to be served under the rules. A registrant's email address would only be used for the service of documents under the rules with their agreement.

7.74 Where a document is sent by post, the rules provide that it must, unless sent by a service which records the date of delivery, be sent by first class post and will be treated as having been served on the day after it was posted.

Duty to provide information to the Registrar

7.75 Requirements to provide information to the Registrar on matters that might impair a registrant's fitness to practise are covered in the registration rules. Applicants for renewal or restoration of registration are required to declare any matter covered by art 51(1)(e)-(n) of the Order. Further information on what should be covered in such declarations would be provided with the relevant forms. The rules (rule 5) also require registrants to notify the Registrar within 7 days of specified occurrences relating to their fitness to practise but these do not include being charged with an offence.

7.76 The references in the rules to investigations or determinations by a regulatory body cover bodies regulating health or social care professions as this is how 'regulatory body' is defined in the Order.

7.77 We will consider adjusting the rules to take further account of the Independent Safeguarding Authority and the equivalent Scottish arrangements at a later date.

Initial action in respect of allegations

7.78 The rules provide that the Registrar may only refer an allegation where the person concerned is identifiable i.e. the person to whom the allegation relates.

An allegation may be a complaint received by the GPhC or information the GPhC has which calls into question a registrant's fitness to practise, whether or not a complaint has been received, so it is possible that an allegation might arise out of an investigation.

7.79 We agree it is sufficient that the Registrar must refer an allegation directly to the Fitness to Practise Committee if: there may be a need for an interim order; the public interest is best served by urgent consideration, the allegation relates to a criminal conviction with a custodial or suspended custodial sentence, or the allegation relates to a finding by another UK health or social care regulator that the registrant's fitness to practise is impaired. We have therefore removed the requirement for the Registrar to make such a referral if he considers there is a likelihood of the Fitness to Practise Committee removing the registrant from the Register.

Investigation prior to referral

7.80 The requirement to notify a registrant's employer of an investigation stems from the Order. The Order states (art 52) that, once a decision has been taken to refer an allegation to the Investigating Committee or the Fitness to Practise Committee, the Registrar must, notify any person by whom the registrant is employed to provide services relating to pharmacy, or with whom the registrant has arrangements to provide such services, of the investigation.

7.81 It is important for public protection that a record is kept of instances where a registrant has admitted an error and accepted advice. The circumstances of each case would be considered in any action taken.

Investigating Committee

7.82 We agree that it may be appropriate for the Investigating Committee to require a person who is the subject of a health allegation to be medically examined. The rules have been adjusted accordingly.

7.83 It is not intended that the Investigating Committee shall hear oral evidence.

7.84 In relation to the suggestion that a new outcome of 'no case to answer' be introduced, the Order details the options open to the Investigating Committee (art 53) and the Fitness to Practise Committee (art 54). The Investigating Committee must determine whether an allegation should be considered by the Fitness to Practise Committee, which must consider the allegations referred to it and determine whether or not the fitness to practise of the person concerned is impaired. It is not open to the committee to say simply that there is no case to answer. However, rule 7 states that the Investigating Committee may dismiss a case and R9(7) states that the Investigating Committee must not refer an allegation unless it is satisfied that there is a real prospect that the Fitness to Practise Committee will make a finding that the registrant's fitness to practise is impaired.

7.85 The Investigating Committee's powers to give advice or a warning appear in rule 7. The person concerned may instead request that the matter be referred to the Fitness to Practise Committee.

- 7.86 The Council will publish threshold criteria separately from the rules, relating to matters that should not be referred to the Investigating Committee.
- 7.87 The Investigating Committee is not confined to reconsidering an allegation only when the GPhC has erred in its administrative handling of the case. Rule 12 covers the circumstances in which reconsideration may occur. We have adjusted the rules to give the Investigating Committee discretion as to the action it should take when it has disposed of a case by agreeing undertakings and subsequently receives information that those undertakings have not been complied with, rather than stating the action to be taken in the rules.
- 7.88 We shall consider other detailed comments as we develop our procedures under the rules.

Fitness to Practise Criteria

- 7.89 The Order requires us to include fitness to practise criteria in the rules. We have considered the helpful feedback received on the draft criteria and, in response to the views expressed, we have reframed these so that they reflect broad principles rather than detailed criteria.

Disclosure provisions

- 7.90 Respondents expressed a range of views on the proposal to require disclosure as soon as reasonably practicable rather than to specific deadlines and on other aspects of disclosure and listing. The changes are intended to allow less complex cases to be dealt with more quickly and can be supplemented with case management directions.
- 7.91 We have adjusted the rules to provide that the person concerned should serve their case no later than 28 days before the hearing.
- 7.92 We shall review the operation of these provisions and the rules as a whole in the light of experience.

Notices of hearing

- 7.93 We have retained the requirement in the rules to give at least 28 days' notice of a hearing, other than an interim order hearing. Rule 21 provides for case management directions requiring each party to provide dates on which they or any witnesses would be unable to attend a hearing. More detailed aspects of procedures will be considered separately.

Interim Orders

- 7.94 Interim Orders are considered where there is an urgent need to suspend a registrant's registration or to make it subject to conditions for reasons of public protection, in the public interest or in the registrant's interest. Because of the urgent nature of such orders, we consider it appropriate to give reasonable notice of the hearing in the particular circumstances of the case.

Hearing bundles

- 7.95 The provisions relating to hearing bundles apply to both GPhC and the person concerned (or their representatives). We think it appropriate to retain a provision for additional evidence to be admitted in exceptional circumstances.
- 7.96 We have adjusted the rules to clarify that a skeleton argument is required only where the case necessitates consideration of a point of law.
- 7.97 We have adjusted the deadlines for hearing bundles and related documents so that the last day before the deadline would normally be a working day, rather than a Sunday. The rules provide that, no later than 16 days before the Monday of the week in which a hearing is to take place, the parties must serve on each other copies of the bundles on which they intend to rely. No later than 9 days before the Monday of the week in which a hearing is to take place, the parties must serve documents on the secretary.

Case management meetings

- 7.98 We agree that case management meetings should be chaired by a legally-qualified chair or by a lay chair with a legal adviser but not by a legal adviser alone. This also applies to the Appeals Committee Rules and the Statutory Committees and their Advisers Rules.

Evidence

- 7.99 There is no intention to exclude legally-qualified persons from appointment as chair or deputy chair of any of the statutory committees. The rules governing such appointments have been worded more flexibly to allow the appointment of a legally-qualified or lay chair, depending on who is the best candidate. In addition, we have sought to provide greater consistency in the rules on matters to be decided by the Committee or by the chair.
- 7.100 The provisions on evidence refer specifically to determinations by health and social care regulators but this would not prevent a determination by another type of regulator forming the basis of an allegation where appropriate.
- 7.101 We think there is sufficient provision for a situation where a registrant was not fit to plead, as the GPhC could consider could consider making an interim order in such a case where appropriate.

Agreement of undertakings

- 7.102 The Order does not allow for the Fitness to Practise Committee to accept undertakings without a hearing.
- 7.103 To provide more flexibility, we have adjusted the rules to allow the Investigating Committee to agree undertakings where a registrant admits that their fitness to practise is impaired, rather than limiting this to cases of deficient professional performance or adverse health.

Consideration of additional allegations

7.104 We agree that the rules should be sufficiently flexible to allow the consideration of additional allegations at a hearing, where it is just to do so. The rules have been adjusted accordingly.

Additional evidence for review hearings

7.105 We consider that the existing provisions are appropriate for review hearings.

Procedure at hearings

7.106 We think it helpful to include separate provisions for different types of hearings, notwithstanding that this entails a degree of repetition.

7.107 In cases where, for example, an error is admitted, the Committee would go on to consider evidence as to whether, on the basis of the facts, the registrant's fitness to practise is impaired. We feel the procedure provides sufficient flexibility to allow proper consideration of a case.

Postponements and adjournments

7.108 Our aim is for proceedings to be just, timely and efficient. We therefore think it appropriate to retain the requirement that an adjournment should cause no injustice to the parties.

Disposal of allegations without hearings

7.109 Given that the GPhC will have statutory responsibility for bringing proceedings under these rules, we think it appropriate that the GPhC's representative should be able to propose that a referral to the fitness to practise Committee be rescinded.

Witness evidence

7.110 We think it appropriate to allow witness statements to be provided at least 7 days before a hearing, unless the chair determines otherwise.

7.111 In relation to committee members asking questions through the chair, the intention is not that committee members would need to pass their questions to the chair but simply that committee members could ask questions with the leave of the chair, as is normal in a formal meeting.

7.112 The rules now provide that, where a witness's first language is not English, the Committee may direct that their evidence be given through an interpreter.

Costs of the hearing

7.113 We will aim to conduct proceedings in a cost-effective manner. We nevertheless consider it appropriate to include provisions for costs orders in the rules.

7.114 We have adjusted the rules so that the requirement to serve & file a schedule of costs is discretionary rather than mandatory, so that it would not be necessary if neither party was seeking a costs order.

7.115 Where a person is appointed to assess the costs, that person would also determine how the costs of the assessment are to be apportioned.

Annex A: Respondents to the consultation

i) Completed response forms from organisations

Association of Pharmacy Technicians (UK)

Association of Women Pharmacists

Association of Teaching Hospital Pharmacists

British Pharmacological Society

Community Pharmacy Scotland

Community Pharmacy Wales

Company Chemists' Association Ltd/Association of Independent Multiple Pharmacies
(joint response)

Council for Healthcare Regulatory Excellence

Daniels Pharmacy Ltd

General Medical Council

Harrogate and District NHS Foundation Trust

Health Professions Council

Institute of Pharmacy Management International

Lothian Area Pharmaceutical Committee

National Pharmacy Association

NHS Central Lancashire

NHS Milton Keynes

NHS Tayside

Nuffield Health

Nursing & Midwifery Council

NW Workforce Development Team

Guild of Healthcare Pharmacists

Royal Pharmaceutical Society of Great Britain (Council and Boards)

Rowlands Pharmacy

Soldiers, Sailors, Airmen and Families Association (SSAFA)

The Pharmacists' Defence Association

ii) Completed response forms from individuals

Alan Hall	Mr A Lipshaw
Barbara Wensworth	Mr P R Karia
Catherine Morlet	Maxine Nichol
Chris Grahame	Michael Dale
Chris Howland-Harris	Mrs Janet Mary Barnes
Colin Lowe	Mrs S Howshall
Conall Watson	Paresh <i>[only name given]</i>
Dr C Heading	Patricia De La Mare
David Gay	Paul Summerfield
David Reissner	Rajeev Vasisht
Dr Neil Doggett	Robert Thomson
Dr Peter Jackson	Ronald Jackson
Dufat <i>[only name given]</i>	Sally Campbell
Elaine Weston	Scott Hillery
Emmanuel Bevillon	Shih Yin Chan
Gary Warner	Shirley Chimaldy
Gill Robson	Sonya Hawkins
Harman Sanghera	Stephen <i>[only name given]</i>
Heather Leake	Stephen Thomas
Ian Grace	Steve Mayers
Jane Dawson	Susan Howshall
Janet Hasell	Thomas Cox
Jean Banks	Valerie Madden
John Paul Smith	William Howells
Jonathan Martin	
Joy Wingfield	
Juan <i>[only name given]</i>	
Kate Douglas	
Kemi Banjo	
Lionel Kramer	
Lucy Barlow	
Md. Quamruzzaman	