Policy proposals and draft Rules under Section 60 of the Health Act 1999: Responses to the consultation on the core draft rules

Purpose
To note the response to the consultation on new Registration / Fitness to Practise procedures to be implemented under the Pharmacists and Pharmacy Technicians Order (2006).

To consider the need for any policy changes in the light of the consultation responses.

Strategic objective domain
An organisation that consistently performs as a regulator, professional representative, leader and publisher.

Recommendations
Council is asked to consider and agree 14 recommendations as highlighted in Section 2.1-2.12, which are grouped under relevant questions in the consultation document.

1. Background

The Society began its reform programme over three years ago, with the aim of ensuring that its procedures reflect the standards required of a modern, effective regulatory and professional body. The key outcomes of this programme include the new Royal Charter and the draft Pharmacists and Pharmacy Technicians Order (2006).

On 27 March 2006, the Department of Health issued a consultation on the draft Pharmacists and Pharmacy Technicians Order (2006). Throughout the Government's process of drafting its Order, the Society has taken every opportunity to influence Governmental decisions and has also sought to secure other necessary changes to the law, most notably to incorporate pharmacy technicians into its remit. The changes heralded by this Order will enable the Society to strengthen its important role in protecting patients and to continue to promote high standards of pharmacy practice. Under the Order, the Society will be required to make a number of Rules, and these Rules will set out much of the detail about how the requirements of the Order are to be implemented in practice.

Whilst approval of the Privy Council is necessary before the Rules become part of UK law, the Rules themselves are to be made by the Society's Council following the completion of the consultation process. The Consultation was about the new procedures for registration and fitness to practise which are required by the Order. During 2005, the Council spent a considerable amount of time developing policy underpinning the new draft Rules and procedures. In drafting and developing policy, our priority has been to ensure both the protection of the public and the fair treatment of members of the Society. This will be achieved by increased openness and transparency in the decision-making process.

Prior to the external Consultation, the Society's Council were provided with drafts of all consultation documents for consideration, and were invited to send in comments between 2 May and 26 May 2006. The consultation documents were approved by the President before the commencement of the consultation.

In total, the Society received 54 responses to the consultation. 48 responses used the Society's questionnaire. The remaining 6 were in the form of general comments. Not all those responding on the Society's questionnaire, answered all questions. A summary of responses is annexed at Appendix 1.

The consultation ran between 3 July 2006 and 22 September 2006. Prior to the consultation, three articles were published in *The Pharmaceutical Journal*, with the last article being published on the day before the consultation was due to start. The articles invited the Society's members to visit the website on which a detailed overview document, and draft Rules relating to Registration and Fitness to Practise were published. In addition, the members were invited to fill in an on-line questionnaire, which sought their views on the new procedures. Copies of the overview document and the questionnaire were sent to 476 external stakeholders. A copy of the overview document is attached at Appendix 2.

2. Analysis of Consultation responses.

The responses were generally supportive of the Council's proposals and provided useful and constructive comments on aspects of the new procedures. Where there was general agreement, Council may consider that is no need to revisit its existing policy. From the consultation, it appears that there may be some areas for further consideration. However, only three questions on the questionnaire received a majority of responses against the proposed arrangements. These were Q1 (ii); Q2; and Q26. These areas related to the issues of automatic removal from the Register for non-payment of the annual retention fee; requirements for applicants for registration to provide a certificate issued by a medical practitioner to confirm their good health; and whether the costs of a hearing should include the costs of medical examination, performance assessments and associated reports.

Q9 related to the suggested criteria for identifying a complaint as being suitable for "fast-tracking" through the Society's new Fitness to Practise procedures. The majority of responses were in favour of the suggested criteria. However, a significant number of responses suggested some amendments. Similarly, a number of potentially useful comments were also received in response to Q7 and Q8 (criteria for referring cases to a hearing), although the overwhelming majority of responses were in favour of the existing/suggested criteria.

2.1 Registration Processes (Questions 1 to 3)

The responses revealed overwhelming support for the Council's decision to employ the same registration processes for Pharmacists and Pharmacy Technicians.

Concern was raised about automatic removal from the Register for non-payment of the annual retention fee. The nub of the concern was the potential for administrative and postal errors to result in removal. The majority of respondees wanted a further two month period after the due date, in which to pay the retention fee.

The majority of respondees considered that applicants for registration should attest to their good health by means of a self declaration. A frequently expressed concern was the cost of obtaining medical certificates. The view expressed by the Royal College of General Practitioners was that medical certificates should only be issued after a full medical examination. In addition, it was considered that certificates would only be valid on the day of issue. The view was also expressed that it would be desirable to have uniformity with the requirements of other bodies responsible for maintaining registers of healthcare professionals.

The majority of respondees considered that no additions should be made to the pharmacy technician qualifications set out in the Society's draft Registration Criteria.

Recommendation 1: The systems for the collection of the annual retention fee for pharmacists and pharmacy technicians should be made the same.

Recommendation 2: The Council should consider whether or not to retain the current system for pharmacists in which a reminder is sent and a further two months are allowed for payment of the retention fee, and to extend the same process to pharmacy technicians.

Recommendation 3: The Council should consider whether or not a recent medical certificate should be required as part of the process of applying for registration.

2.2 Good Character (Questions 4 to 7(i))

There was broad support for the definition of "Good Character" proposed by the Society's Council, and for the draft assessment framework set out in the Consultation Document. The majority of respondees also agreed that the assessment framework should be used in determining whether or not applicants for registration were of "Good Character" for the purposes of registration with the Society. A number of useful suggestions for inclusion in the assessment framework were received. These are set out at pages 8 and 9 of Appendix 1. In summary, the suggested additions are:

a) evidence of CPD;
b) findings of dishonesty or lack of personal integrity made by a civil court;
c) evidence of plagiarism or cheating;
d) evidence from current and previous employers; and
e) declarations from the applicant.

With the exception of CPD, these items are already implicit in the requirement on the Registrar, as part of the assessment framework, to take into account "information about the applicant which has been brought to the attention of the Registrar".

The potential difficulty with inclusion of CPD is that applicants may not be able to undertake CPD without first being admitted to the Register.

In relation to the table of "aggravating features", a number of useful suggestions were made. These included conduct or behaviour involving:

a) trafficking in any medicines liable to misuse;
b) discrimination on the grounds of sexual orientation, gender and age;
c) threats to the safety of patients and professional colleagues;
d) terrorism;
e) bringing the profession into disrepute.

In respect of breaches of the law, a suggestion was also made that acting in accordance with conscience of professional judgement should viewed as a potential mitigating factor.

Recommendation 4: The Council should consider whether or not to include any of the factors listed above in the Good Character Assessment Framework.

2.3 Referral Criteria (Questions 7(ii) to 9)

There was broad support for the criteria currently used by the Infringements Committee in deciding whether or not to refer a case for a hearing. In relation to proposals implementing

the Society's new powers to deal with performance and health issues, and criteria for "fast tracking" a case through the Society's new fitness to practise procedures, a number of useful suggestions were made. These are set out at pages 10 to 13 of Appendix 1.

Recommendation 5: The Council should require the Infringements Committee and the Chair of the Law and Ethics Committee to consider the suggestions received from the Consultation Response, and bring proposals to Council for decision in December 2006.

2.4 Deficient Professional Performance (Questions 10 to 12)

There was majority support for the definition of "Deficient Professional Performance" proposed by the Society's Council, and for the draft performance assessment framework set out in the Consultation Response. The majority of respondees also agreed with the draft proposals for the composition of performance assessment teams. A number of useful comments were received in respect of these matters and are set out at pages 13 and 15 of Appendix 1.

Further work needs to be undertaken on the development of procedures for assessing professional performance.

Recommendation 6: The issues raised should be considered by the Law and Ethics Committee as part of a future workstream on detailed proposals for the assessment of professional performance.

2.5 Role of Specialist Adviser (Questions 13 to 14)

There were a number of useful comments received about the role of the Specialist Advisers under the new procedures. These comments are set out at pages 15 -16 in Appendix 1. There was general consensus that such advisers should be objective and independent, and should advise on matters within their sphere of competence.

Recommendation 7: The Council should incorporate the requirement for objectivity and independence into the rules and appointments process.

2.6 Interim Orders (Questions 15 to 16)

A number of useful suggestions were received, in respect of the circumstances in which an interim order should be made. These suggestions are set out at pages 16 and 17 of Appendix 1.

Recommendation 8: Draft Guidance on when to apply for an interim order should be prepared for the Registrar. The draft Guidance will be brought to the Law and Ethics Committee for consideration in due course.

2.7 Undertakings/Conditions (Questions 17 to 21)

A number of useful suggestions were received, in respect of the potential undertakings and conditions that could be accepted or imposed by the new Fitness to Practise Committees. These are set out at pages 19 to 23 of Appendix 1. As the Council is aware, decisions on individual cases are a matter for the new Committees.

The majority of respondees considered that employers should have a role in monitoring and enforcing undertakings and conditions in place. However, it was acknowledged that there were practical difficulties in respect of locums and self employed registrants, and those who wished to change employment. It was also recognised that, where no disciplinary proceedings had been brought against the employer, the Society might not

actually have the power to require the employer to monitor conditions imposed on a registrant.

Recommendation 9: The comments and suggestions should be passed to the new Committees for consideration.

2.8 Suspension and removal from the Register (Questions 22 and 23)

A number of useful comments and suggestions were received in respect of circumstances in which it might be appropriate to suspend a registrant, or remove his name from the Register.
These comments and suggestions are set out at pages 23 and 24 of Appendix 1. Again, the decision to suspend or remove a person's name from the Register will be a matter for the new Committees.

Recommendation 10: The comments and suggestions should be passed to the new Committees for consideration.

2.9 Costs (Questions 24 to 27)

The majority of respondees considered that, where an application for costs is made to a Fitness to Practise Committee by the Society, those costs should not include the costs of the initial medical examination or performance assessment of the registrant, and the resulting first report, incurred by the Society as a necessary part of bringing the case. This endorses the decision already taken by the Council in October last year, that such costs should be borne by the Society, and not by the registrant.

A number of useful suggestions were made by respondents about the circumstances in which the new Committees should exercise their power to award costs, and what those costs should cover. These comments are set out at pages 24 and 25 of Appendix 1.

Recommendation 11: A draft policy on circumstances in which the Society should seek to recover costs incurred, and the contents of those costs, should be prepared for the Law & Ethics Committee to consider in due course.

2.10 Restoration (Questions 28 to 32)

There was very broad support for the matters that the Society's Council suggested should be taken into account by the new Disciplinary Committee when deciding whether or not to restore a person's name to the Register.

It was suggested that account should be taken of the views of patients and the original complainant. victims.

There were, in addition, a number of useful suggestions about the sorts of evidence that the Disciplinary Committee should take into account when deciding whether or not to restore a person's name to the Register. These suggestions are set out at pages 25 - 29 of Appendix 1.

Similarly, a number of useful suggestions were also received about the sorts of evidence that the Registrar should take into account when deciding whether or not to restore a person to the Register following voluntary removal from the Register for a period exceeding 12 months. These suggestions are set out at pages 27 and 28 of Appendix 1. One respondent suggested that such evidence should only be required after a person has been off the Register for a period of 18 months.

A number of useful suggestions were received about the content and format of refresher training which could provide evidence of suitability for restoration to the Register. These suggestions are set out at pages 28 to 29 of Appendix 1.

Recommendation 12: Suggestions on matters and evidence to be taken into account by the new Disciplinary Committee should be passed to that Committee for consideration. Proposals on the content and format of refresher training should be presented to Education Committee for consideration in due course.

2.11 General Comments (Question 33)

A number of additional comments received from the respondees are set out at page 29 of Appendix 1.

2.12 Additional issues identified

1. It has been identified that, if a pharmacist with a Bachelors level pharmacy qualification voluntarily removed his name from the Register, or was removed for non-payment, they would be unable to return to the Register. This is because the current draft of the Registration Criteria only refers to the Masters level qualification, and applications for registration require the Registrar to have regard to the qualifications set out in the Registration Criteria when considering the application for restoration. A similar issue arises in relation to pharmacy technician qualifications.

Recommendation 13: The draft Registration Criteria should be amended to ensure that a former registrant's existing qualifications, taken together with previous inclusion on the Register, should automatically count as evidence of appropriate qualification for restoration to the Register.

2. The draft Order requires the Council to decide what the function of the Investigating Committee should be.

   The Order also empowers the Investigating Committee to decide, in individual cases, whether or not an allegation should be referred to the Disciplinary or Health Committees.

   The Order further requires the Registrar, save in such cases as the **Council may prescribe**, to refer all allegations of impairment of fitness to practise, to the Investigating Committee.

   The Council has already decided that (save in exceptional circumstances) cases which are more than 5 years old should not be referred to the Investigating Committee. In October last year, the Council further agreed that convictions resulting in sentences of imprisonment not be referred to the Investigating Committee but should be automatically referred to the Disciplinary Committee.

   Rule 7(1) of the draft Fitness to Practise (Procedure) Rules, approved for consultation by the Council, state that:
   "The function of the Investigating Committee shall be to —

   (a) consider any allegation referred to it by the Registrar……;

   (b) with regard to relevant case law, any guidance issued by the Chair of the Disciplinary Committee and to its own decisions, issue guidance to the Registrar on allegations that should not be referred to it."

Recommendation 14:
That subject to agreement of Department of Health Lawyers:

(a) The wording of draft Rule 7(1) (b) be amended to read:

"(b) W*ith regard to relevant case law, any guidance issued by the Chair of the Disciplinary Committee and to its own decisions, makes recommendations to the Council on allegations that should not be referred to it."*

The Council would then have the option of amending the Rules to prescribe additional categories of case that should not be referred to the Investigating Committee.

(b) The existing guidance approved by Council in respect of certain road traffic offences (attached at Appendix 3) should be incorporated into the draft Rules.

3. Risk implications

Failure to make decisions about the Rules would leave the Society at continuing risk of challenge due to the inadequacies of the powers and procedures stemming from our current legislative framework.

The Society has no powers to suspend registration on an interim basis or otherwise and no powers to place conditions on registration. The Statutory Committee only has powers to reprimand or remove an individual from the Register. We have no provision for dealing with health cases, yet have about 120 health cases awaiting referral. We have a growing backlog of disciplinary cases due to the limitations of our Statutory Committee with its one chairman, lack of provision of a deputy and only five committee members.

These inadequacies amount to a serious and on-going risk to the public.

4. Resource implications

The resource implications of implementing the new fitness to practice procedures has been addressed when drafting the Society's budget for 2007 and the proposed provision covers implementation of the Rules. Many of the recommendations in this paper will have no further resource implications to that already identified in the budget process or, if agreed, will not come on-stream immediately.

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Director of Practice and Quality Improvement
Chairman of the Rules Group

Appendix 1

FTP / REGISTRATION RULES – Consultation Results
(48 responses to the questionnaire)

	Question	Yes	No	Don't know	No response	Comments
Q1(i)	The Society has different systems for collection of fees. The retention fee for pharmacists & pharmacy technicians is due 1st January each year. Currently pharmacists who have not paid by 1st January are sent a reminder and allowed a further 2 months to pay their fee. Pharmacy technicians on the voluntary register must pay by 1st January and non-payers are automatically removed from the register Should the systems for pharmacists and pharmacy technicians be the same?	**45**	**1**	**1**	**1**	
Q1(ii)	Should non-payers of the retention fee be automatically removed from the register?	**20**	**24**	**2**	**2**	• Concern about the potential for administration errors. • Reminders should remain.
Q1(iii)	Should people who have not paid their retention fee be allowed a further 2 months to pay before being removed from the register?	**40**	**5**	**0**	**3**	
Q2	Should all applicants for registration provide a recent certificate of good health or should there be a self-declaration with the option to require a medical certificate in some circumstances?	**3**	**38**	**3**	**4**	• 38 want self declaration • 3 want GP certificate **MISCELLANEOUS** • General view was that GP certificate too costly and only reliable for the day it was issued. • There should be a consistent level of requirement for all healthcare

						regulatory bodies. • RCGP is concerned about the criteria necessary to issue a medical certificate and the question of funding.
Q3	Are there any other UK qualifications for pharmacy technicians that you feel ought to be included in the Society's Registration Criteria?	**6**	**20**	**5**	**17**	
Q4	Do you agree with the proposed definition of 'good character'?	**33**	**9**	**2**	**4**	**MISCELLANEOUS** • Age of individual in Assessment Framework not relevant. • Testimonials & character references unlikely to reflect accurately person's character as a pharmacist. • Define '*recency, insight* and *characteristic behaviour'*. Better set of criteria in 2005 Infringement Committee (Procedure Rules). • Concern that published standards of conduct could become out of date. • Concern that cautions unrelated to pharmacy should not automatically result in a finding of bad character.
Q5	Do you agree with the proposal to use Good Character Assessment Framework in determining whether or not a person is of 'good character'?	**35**	**5**	**4**	**4**	**MISCELLANEOUS** • Care to be taken on how allegations/complaints are used. Need for robust mechanism to appeal allegations. Unfounded allegations to be permanently removed from record. • Should also include evidence from previous employer if possible. • A personal declaration from the pharmacist to be required. • Impossible to draw up set of criteria which does not need a measure of judgement if application is to be proportionate to alleged misdemeanour.
Q6	Are there any other matters which you would like see added to the Good Character Assessment Framework?	**8**	**19**	**0**	**21**	• ADD: evidence of CPD.[This is not possible for new applicants] • ADD: civil court findings of dishonesty or lack of personal integrity. • ADD: evidence of plagiarism, cheating; production of falsified documents. • ADD: evidence provided by current and previous employers. • Any good character assessment should be based on the Nolan

						principles.
Q7 (i)	Do you agree that when considering the seriousness of conduct or behaviour in question the list of aggravating factors should automatically qualify the conduct of behaviour as serious?	**33**	**5**	**5**	**5**	**SUBSTANCE MISUSE** • Trafficking in any medicines liable to misuse. **DISCRIMINATIONS** • ADD: discrimination on grounds of sexual orientation, gender and age. **MISCELLANEOUS ADDITIONS** • Threats to individual patient or other professional colleagues' safety. • Conduct involving terrorism • Bringing the profession into disrepute. **BLATANT DISREGARD** • *Blatant disregard for the law'* difficult to define and only matters relevant to fitness to practise should be included in the definition. • Commercial gain above the interests of the public should be included. **MISCELLANEOUS** • Should be mitigating factors including allowance for pharmacists acting in accordance with their conscience or professional judgement.
Q7(ii)	Do you agree with the referral criteria used by the Infringement Committee?	**33**	**6**	**3**	**6**	**AMENDMENTS / ADDITIONS** • Add terms of service breaches. • Do not include '*lack of insight'* as it is intrinsic part of some personalities. **MISCELLANEOUS** • The current criteria used by existing Infringements Committee is exhaustive. • Indemnity insurance should not be compulsory if the pharmacist is insured by his employer. Pharmacists often have to work within framework stipulated by employer, in this case the company

						superintendent should be prosecuted. *[DN: current definition of indemnity arrangements allows for this].*
Q7(iii)	Do you agree with the draft criteria in relation to performance cases?	**35**	**6**	**2**	**5**	**MISCELLANEOUS** • More detail could be added to the criteria so as to clarify each criterion more fully. • Set of clear standards & criteria to bench mark 'good performance'. These can then be used to judge poor performance. • How do you identify someone who '*is unlikely to comply with undertakings to Society?'* **ADDITIONS** • ADD: terms of service breaches. • ADD *repeated & unjustifiable failure to comply with advice* and *repeated & unjustifiable breachings of undertakings.* **CPD** • CPD criterion irrelevant – as it's a requirement for registration not a FTP issue. If CPD is a voluntary scheme then cannot be forced through FTP route. **INSIGHT** • Criterion *lack of insight'* is very subjective.
Q8	Do you agree with the draft criteria that the Investigating Committee should take into account when referring cases to the Health Committee?	**37**	**5**	**2**	**4**	**SUICIDAL** • How would Investigating Committee determine if individual is suicidal? • Concern about '*suicidal* 'criterion – possible change to '*member has attempted suicide'* • Change: *'member suicidal'* into a more general mental health statement. **HEALTH ISSUES** • Refusal by the registrant to undergo another medical should not count as a further disciplinary matter. **DEFINE** • DEFINE: '*no contact with the public'* should be qualified with (in a professional capacity) or something similar.

						AMENDMENTS • DELETE: *'whilst on the practising register'* • ADD: evidence that member's condition could be threat to public safety. • ADD: response of defendant to other investigations such as police or medicine inspectors.
Q9	Do you agree with the criteria for 'fast tracking' cases to the Disciplinary and Health Committees?	**27**	**13**	**4**	**4**	**ERRORS** • Definition of *large number of dispensing errors over short period of time* needs clarification. Large and short are open to various interpretations. • Dispensing errors should be based on error rate and severity of errors. • Error resulting in death needs to be fast tracked. • This has focused on dispensing errors. Not all pharmacists dispense so need statement that includes serious incidents that are not dispensing errors. **ADDITIONS** • Include serious violence against a person. • Fast tracking should apply only if there is a clear and on-going risk to public safety • Add serious fraud. • Add suspension under terms of service regulations. • Add serious criminal convictions resulting in custodial sentence. • Add alleged theft from employers or colleagues • Add addiction to drugs / alcohol. • Add individual's physical and mental health status. • Add child abuse and violent behaviour. **PORNOGRAPHY** • Need to provide definition of pornography, or degree of it. • Difficult to prove that pornography would affect individual's ability to perform professional duties. Perhaps the word *child* or *illegal* should be added to the word pornography. • Also stipulate no downloading during working hours. • Pornography is subjective to age, culture and religion. The issue is:

						are we subjecting the public to harm by allowing such a pharmacist to practise. • Presumably you mean illegal pornography? **MISCELLANEOUS** • Criterion for causing death or serious injury needs more consideration as the same error may go unnoticed in one patient and cause death in another. In pharmacists' new role of prescribing, death might be an unforeseeable outcome of what might otherwise be an accepted treatment for a condition. • Table 3 (aggravating factors) is much better template for judging severity of risk. • Why should all sexual misconduct be fast tracked. It should depend on the degree of severity and according to UK law.
Q10	Do you agree with the proposed definition of deficient professional performance?	**27**	**8**	**7**	**6**	**DEFINITION ISSUES** • Definitions too woolly and broad based. • This is too harsh- competency is related to experience in many cases. • The stated definition is ill-defined and open to subjective interpretation.. • This seems to parallel the Bolam test, but it is not complete, and not every aspect of practice is susceptible to well known and published standards. • Concern that as written, the Society would have to issue guidance on every potential area of practice. • Will specialist standards be applied to generalists? • Conflict in standards – they should be set against standards set by RPSGB and not other professional bodies. **DEFINITIONS - AMENDMENTS** • DEFINE: *'other relevant organisations'.* • DEFINE: when poor performance on a single occasion would result in *'Deficient Professional Performance'*. • DEFINE: a *departure from generally accepted norms of good practice….?*

						• AMEND: to *deficient professional performance….**repeatedly or seriously** falls…* • AMEND: to *deficient professional performance……that would **fall below the standard expected by peers…***
Q11	Do you agree with the Performance Assessment Framework?	**33**	**6**	**3**	**6**	**DEFINITIONS** • Clarity is needed on the definition of underpinning knowledge **ASSESSMENT ISSUES** • Any assessment framework must be supported by a 360 degrees feedback and appraisal. **ADDITIONS / AMENDMENTS** • The framework should be structured to include the expanded roles foreseen for pharmacists. • ADD: Management and supervision of support staff. • Point 9 should read…'*proactive provision of advice….etc'*. **COMMUNITY PHARMACY** • Concern that the Performance Assessment Framework too related to community pharmacy. It needs to address the whole profession. **MISCELLANEOUS** • Registrar shouldn't be allowed to order a performance assessment, only investigating committee should be authorised to do this.
Q12	Do you agree with the proposed composition of the Performance Assessment Team?	**25**	**15**	**2**	**6**	**ADDITIONS / AMENDMENTS** • These people are not enough. • ADD: representative for employer or local health agency. • ADD: PCT and LPC representatives. • ADD: peer review member and a Society inspector or lay member. • ADD: independent managers who work in the same areas of practice. **MISCELLANEOUS** • A number of concerns about the inclusion of lay members.

						• What will an inspector add to the team outside the community pharmacy sector? • The team should not be just one person. • The team should comprise all those listed. • Assessment team too biased in favour of Society. Pharmacist should be permitted to nominate representative from own professional field. • Will the defendant know the composition of the team? Does the defendant have the right to challenge the composition of the team? • Devolution issues need to be taken into account. • Disagree strongly with the registrar making the decision on the composition of the Assessment Team. Case managers shouldn't be responsible for forming assessment teams. • More thought should be given to academic and industrial workers and how they might be assessed.
Q13	What do you think the role and function of a 'Specialist Adviser' should be?	**text**				**NO NEED FOR ADVISER** • Not necessary to have adviser if assessment team is selected carefully. **INDEPENDENT ADVICE** • Provide an unbiased final assessment if the Panel could not reach an agreement. **ADVICE** • Advise on good practice & professional standards and legal and ethical matters in particular field of work. • Providing advice in specialised areas of pharmacy practice. • Adviser should have specialist knowledge and understand the professional environment in which the pharmacist is working. • Definition in the relevant Rules seems adequate. **MISCELLANEOUS** • Non-voting resource for committee. • Adviser needs to add value. • To advise on remedial measures. • Role and functions should be subject to the same criteria as the

						Expert Witness. • Role is as set out in the draft rules. However Rule (6) (4) (b) should be amended so that the registrar can cross examine the specialist adviser on his evidence.
Q14	What qualities and skills should someone have, in order to be appointed a 'Specialist Adviser'?	**text**				**TYPES OF EXPERIENCE** • Experience in relevant field under investigation. • Experience and of good character themselves. • Outstanding clinical knowledge and peer respect. • Experience of investigations of poor performance. • Knowledge of the Code of Ethics and pharmacy law. • Experience in reviewing conflict situations. Investigative skills. Impact assessment. • Member of a specialised group. • Unbiased view, good communication and psychology skills. Reputable and circumspect. • Experience in advisory or audit work in the relevant specialities. **PROFESSION OF ADVISER** • Specialist lawyer. • Pharmacist with expert knowledge in field under investigation **NUMBER OF YEARS PROPOSED** • Number of years proposed varied from 5 to 15 years. • Ideally a fellow or with a higher qualification.
Q15	In what circumstances do you think it would be appropriate to impose an order for interim suspension or an order for interim conditions on a member's registration?	**text**				**RISK TO THE PUBLIC** • Pose a danger to themselves or the public. • Depends of nature and severity of misdemeanour and likely impact on patients. • In some circumstances where criminal proceedings are pending. **ALLEGATION OF INJURY TO PATIENT ETC** • Death or serious injury alleged in misconduct. **SERIOUS OR CRIMINAL OFFENCE**

						• Conviction for serious criminal offence. • Serious criminal investigations. • For Example: manslaughter, serious fraud, sexual & violent offences. **FAST TRACKING** • Cases meeting fast tracking criteria to Health or Disciplinary Committees, • Deficient performance. • As set out in draft Rules 22 (3) (e). – but where registrant is unable to work, such a case should be fast tracked. **HEALTH ISSUES** • Allegations of drug/alcohol abuse. • Mental health issues. • Evidence of health affecting ability to practise safely. **MISCELLANEOUS** • In extreme circumstances only. An order can have very negative effect on pharmacist, even if subsequently found innocent • Serious abuse of clinical relationship. Dishonesty. Knowingly working outside competence. • Evidence of major errors in practice • Unwillingness to respond to assistance. • Patterns of errors repeated. • When unsafe to continue to practise. • Where member's conduct is not at risk to the public but sufficiently unacceptable to warrant suspension if not corrected. • Not when the allegations are based on hearsay or uncorroborated evidence. • Definition in Rule 22(3) (e) of FTP Rules is good. • Inappropriate record keeping. • Not keeping up with CPD. • Professional who has been struck off by another professional body.
Q16	What sort of conditions do you think would be appropriate to	**text**				**SUPERVISION /SUSPENSION /TRAINING /ASSESSMENT** • Working under supervision.

	impose as part of an interim order? How would such conditions work in practice?					• Suspension – monitoring imposed conditions is too onerous/impossible. • Requirement to undergo further training followed by assessment. • To work only with one pharmacist. • Refrain from having direct contact with patients. • Undertaking to correct behaviour and evidence submitted to prove this. • Evidence of CPD with joint action plan provided by pharmacist and Committee. • Prevent undertaking duties that are likely to cause danger to the public. • Not to contact staff / patients. • Not to attend the pharmacy of work. • Refrain from working as superintendent. • Refrain from dispensing or supervising dispensing CDs. • Have second pharmacist work along side the defendant as a supervisor. • Restriction of professional activity. • Limitations in hours and location of works. • Requirements to urgently improve skills. • Requirements to seek treatment. • Not to work in an area where s/he is likely to harm a patient. • Branch support. • Inspector satisfied. • Medical clearance. • Not work alone with children. • Regular attendance at Occupational Health. **MISCELLANEOUS** • Conditions imposed must be based on risk assessment. They should be balanced, workable and consistent. Consideration to be given to practical effect of partial sanctions, eg CDs not to be dispensed. • Decided on a case by case basis. • Burden of monitoring should fall on Society or possibly NHS officials.

Q17	In what circumstances do you think it would be appropriate to require a registrant to give and comply with undertakings to the Society?	**text**				**HEALTH** • Mental health issues. • Only to be implemented for health/ performance cases. • Agreement to seek help for illness. • Agreement not to be in sole charge of pharmacy. • In health cases where there is a single and limited failure. • Pharmacist has to admit medical condition is impairing fitness to practise. • Be able to follow a course of action to restore health and fitness to practise. **SUBSTANCE ABUSE** • Drugs and alcohol addiction/abuse. • If registrant is receiving rehabilitation for drugs/ alcohol abuse. **RISK TO PUBLIC** • Where there is a risk or threat of harm to the public. • Where previous warnings have been disregarded. • Lack of competence observed. **PRACTICE ISSUES** • Where lacking in current professional knowledge. • Practice failures. • Poor facilities. **WRONG DOING** • Any circumstances that are governed by a suspension from the register. • Dishonesty. • Breach of confidentiality, • Failure to respond to complaint by patient. **MINOR ISSUES** • When problems identified have not caused death or serious injury to a person. • Low scale, low risk behaviour without any previous history.

						• Undertakings for all minor or single isolated misdemeanour cases where registrant acknowledges that FTP is impaired and is willing to address the issue. **REMEDIAL ACTION** • Where defendant can adequately demonstrate that they comply with undertakings. • When the registrant and Society agree on a course of remedial action.
Q18	What sort of undertakings do you think would be appropriate for the Society to accept?	**text**				**RETRAINING /ASSESSMENT /SUPERVISED PRACTICE** • Remedial actions e.g. re-training. • Regular supervision by a mentor; training and education. • Undertaking not to practise for a specified time; not to be in charge of pharmacy. • Evidence of CPD. • Employer's support • Reduced stressed workload • Remedial behaviour and evidence of compliance. • Provide a portfolio of evidence of good practice. • Evidence of effective treatment in health cases. Undergo re-assessment in a specified number of months. • Undertake specific training. • Refrain from working unsupervised. • Refrain from dispensing or supervising dispensing of CDs. • Refrain from having direct contact with patients. • Improved facilities. • Not to engage in any field of work where opportunity to re-offend arises or could cause harm to the public. • When it is appropriate to resolve matters by Branch support. • Attendance at remedial programmes. • Work as second pharmacist. • Re-sit pre-registration exam. • Resign form being a superintendent. • Retire from the register.

						HEALTH MATTERS • Counselling, attending support groups such as AA. • Medical review to confirm fitness to practise. • To seek medical help or treatment • Restricted practice on health grounds. • Agree to abstain from substance abuse. • Random testing. **MISCELLANEOUS** • Move to non-practising section of register if danger to public safety. • Society to recommend sanctions in line with other healthcare bodies. • Breach of undertaking should escalate severity of offence.
19	In what circumstances do you think it would be appropriate to impose conditions on a member's registration?	**text**				**DEFICIENT PROFESSIONAL PERFORMANCE** • Poor performance / competence / knowledge. • Where pharmacist needs support to function. **RISK TO SELF / PUBLIC** • Where there is a clear risk of harm to self or to the public **HEALTH** • Previous history of substance misuse • Health issues, • Requirement for pharmacist to receive health treatment and required to attend meetings. • In the likelihood of rehabilitation through a period of limited or controlled practice. **CRIMINAL ACTIVITY** • Fraudulent or indecent behaviour. • Sexual misconduct. **FAILING OF UNDERTAKINGS OF REGISTRATION** • No evidence of CPD. • Failure to comply with undertakings for registration. **MISCONDUCT & SUSTAINED MISCONDUCT** • Disregard for advice given by inspectors.

						• Sustained misconduct. **RESOLVABLE MINOR ISSUES** • If problem resolved and won't happen again. If agree commitment. Individual agrees to be monitored.
Q20	What sort of conditions do you think should be imposed on a member in: a) a health case b) any other type of case in order to protect the public?	**text**				**HEALTH** • Peer support / mentoring. • Supervision. • Undergo necessary treatment & assessment. • Cease practising until issue resolved. • Regular monitoring. • Psychiatric assessment in mental health cases. • Regular reports from health professional and regular evidence of continued rehabilitation. • Agree not to be in charge of a pharmacy. • Willingness to accept treatment. **CONDITIONS APPROPRIATE TO BOTH HEALTH & NON-HEALTH CASES** • Both should involve an agreement relating to supervision and appropriate re-training. • Reassessment at regular intervals. • Supervision. • Prevent from working in specified areas. • Refrain from working as superintendent. • Refrain from dispensing of CDs. • Refrain from direct contact with patients. • Additional CPD. • Branch and / or inspectorate support.
Q21	Do you think the employer should have a role in monitoring and enforcing undertakings or conditions?	**32**	**8**	**1**	**7**	**PROBLEMS RE EMPLOYER INVOLVEMENT** • Not always appropriate as pharmacist could be self employed or be a locum or family business. • Practical problems if registrant wishes to change employer. • Society has no power to impose conditions on employer. • It may depend on a particular case.

						• What about self-employed people? Should PCTs have a monitoring role for community pharmacy? **MISCELLANEOUS** • The employer has a support role to play but it is the Society's role as regulator to monitor and enforce the undertakings. • Employer should support RPSGB by monitoring and supporting pharmacist, but should not be required to enforce.
Q22	In what circumstances do you think it would be appropriate to suspend a member's name for the Register?	**text**				**DANGER TO SELF / PUBLIC** • Clear risk of harm to self or to the public. **SERIOUS / SUSTAINED MISCONUCT** • Alleged serious misconduct • Re-offenders. • Fraud. • Very poor performance • Dishonesty. • Sexual misconduct. • Disregard of previous warnings. • Intentional activities to cause harm or damage. • Persistent or grave lapses in professional and / or clinical standards. • Violence in or outside the workplace. • Inclusion on statutory protection register. • Bullying. • Fraud • Child abuse • Misuse of drugs. **HEALTH** • Ill health that affects fitness to practise. **MISCELLANEOUS** • The aggravating factors listed. • Same circumstances as currently.

						• Similar to that for interim order. • When erasure for 5 years is judged to be inappropriate. • Evidence to show that defendant cannot undertake duties safely and professionally. • Power of suspension to be viewed as an interim measure and should not be used instead of erasing a member from the register.
Q23	We have set out some instances where it would be appropriate to remove a member's name from the Register. Do you agree with these cases?	**34**	**3**	**3**	**8**	• ADD: fraudulent behaviour. • ADD: when criminal prosecution resulting in a prison sentence. **MISCELLANEOUS** • '*Lack of insight'* is subjective and difficult to interpret. .
Q24	In what circumstances do you think that the Disciplinary Committee should exercise its power to award costs against a party?	**text**				**NEVER / HARDLY EVER** • A small number of responses stated that costs should never be awarded. • The remainder gave a variety of circumstances which included: **CIRCUMSTANCES** • Time wasting. • Lack of cooperation. • Obstruction of the investigation. • If pharmacist failed to appear or sought to disrupt the process. • Guilty. • Prolonged proceedings that are not considered reasonable. • Where party has been wilfully dishonest. • Not for health cases. • Not when defendant is ill. • Not if defendant is unable to meet the cost. • Not when defendant is found innocent. **MISCELLANEOUS** • To be considered on an individual basis and only if cases has been unduly prolonged
Q25	Do you think that costs should	**text**				Of the people who answered this question:

	include the cost of investigating the case (e.g. cost of an Inspector/administration time/cost of Investigating Committee etc) or simply the costs of the hearing before the Disciplinary Committee (e.g. witness expenses. legal fees, shorthand typewriter)?					All costs: 8 Cost of hearing: 16 None: 6
Q26	Do you think that the costs of the hearing should include the initial costs of medical examination/performance assessment and the subsequent costs of preparing the first report necessary to bring the case?	**10**	**23**	**9**	**6**	• This would give financial incentive to find all defendants guilty.
Q27	In what circumstances do you think that costs should be awarded against the Society?	**text**				Of the people who answered this question None: 2 Health: 2 Innocence: 20 • Time delays without suitable reason. • Where Society has brought a case with no reasonable prospect of success. • Society has handled the investigation incompetently, committed errors in process or brought a case frivolously or maliciously. • When suspension costs the employer's organisation if case cannot reach satisfactory completion. • Costs should always be awarded where an individual has lost earning or good standing as a result of delay and innocence. • Costs should not be awarded to other parties. • Committee errors in process or in fact.
Q28	What sort of evidence do you	**text**				• Employer & character references.

	think that a person should be required to produce, in order to satisfy the Disciplinary Committee that his name should be restored to the register?					• Undergo assessment. • Evidence of re-training. • Certificate of good health. • Documentary evidence of the criteria described in table on page 40. • Documentary evidence of criteria for admission to the register • Evidence of attempts to improve performance. • Evidence of return to practise/ CPD undertaken. • Measurable evidence of change in behaviour / practice. The criteria to be identified at the disciplinary hearing. • Work under equivalent pre-reg tutelage for 6 months. • Supervised and assessed practice. • Evidence of Insight and / or remorse. • Absence of further offences. • Report by RPSGB inspector. • Abstinence. • Evidence of treatment and recovery. **MISCELLANEOUS** • The proposal on page 40 seems sound. • Will depend on reason for removal and should be specified at hearing
Q29	Given that a person can only be restored to the Register after the expiry of 5 years from the date of removal, what sort of refresher training do you think would be appropriate to require of such a person before granting his application for restoration to the Register? What form of assessment do you think would be appropriate to demonstrate that such a person is fit to return to practice?	**text**				• Evidence of retraining and updating of knowledge e.g. update on law & ethics, drug & therapeutic and pharmacy practice. • Return to practice course • Evidence of CPD. • Period of pre-registration training. • Registration exam. • Close monitoring by RPSGB inspector. • Evidence of up to date knowledge. • Supervision for 3 months, followed by competency assessment similar to pre-registration exam. • Medical examination if appropriate. • Competence assessment. OSCI, observation in practice. • Supervision by another pharmacist. • Declaration by a supervisor that the pharmacist is fit to return to

						practice. • Experienced pre-registration tutor to be supervisor. • Training tailored to individual needs with appropriate assessment. • At least 2 references. • Period of supervised practice in a placement approved by Society and achieve final pre-reg competencies.
Q30	We have proposed a set of matters that the Disciplinary Committee should consider when deciding whether or not to restore a person's name to the register. Do you agree with the list of matters to take into account?	**34**	**3**	**1**	**10**	**VICTIMS' TESTIMONIALS** • Weight given to representations received from patients and victims need to be taken into account on individual basis and dependent on level of grievance attached to the case. • A victim or victim's relative would never be able to provide an objective contribution. **MISCELLANEOUS** • ADD: where the investigation is such that it would be unlikely that the offences, if repeated, would be detected e.g. fraud, where the criminal learns from experience and is more successful at future attempts) • List not appropriate in case of voluntary removal.
Q31	What sort of evidence do you think that a person who has been off the Register voluntarily for a period of over 12 months should be required to produce to satisfy the registrar that his name should be restored?	**text**				**CPD / RETURN TO PRACTICE / UP TO DATE KNOWLEDGE** • Evidence of learning. • Character and other references. • Evidence of CPD. • Evidence of up to date knowledge, by certified attendance and exam. • Certificate of attendance/ training refresher course. • Period of retraining. • Regular reporting from mentor even if not practising as a pharmacist. • Evidence of competence to practise. • Evidence of insight. • A lighter version of that for restoration after 5 years. • Return to practise course with assessment. • Dependent on time off the Register. Undergo a structured programme to meet final pre-reg competencies.

						• Evidence of appropriate remedial action. • The collection of OSCE driven information evidence. . **HEALTH** • Medical assessment/ certificate. • Health references. **MISCELLANEOUS** . • Attendance at Branch meetings (However, difficult to produce evidence if you have not been practising.) • Provide evidence similar to that for initial registration • The first threshold should be 18 months. Beyond that but before 5 years: evidence of CPD in the last 12 months. Beyond 5 years CPD and a return to work refresher course.
Q32	What sort of refresher training do you think would be appropriate to require of such a person before granting an application for fresh registration? What form of assessment do you think would be appropriate to demonstrate that such a person is fit to return to practice?	**text**				**CPD / RETURN TO PRACTICE / UP TO DATE KNOWLEDGE** • Evidence of up to date knowledge, by certified attendance and exam. • Evidence of CPD throughout the period of removal from the register • Professional interview concept to be used. • Return to practise course. • Distance learning pack should be sufficient. • Similar to pre registration training. • Competency assessment. • Working under supervision for period of 3 months. Suitable assessment in form of interview. • Declaration from supervisor that the person is fit to return to practise. • Mentoring in practice. • Law & Ethics & therapeutics update. • Society to commission specific training package to include general competencies and relevant parts of pre registration examination for written assessment. • Returners to sign up to Code of Ethics. • Repeat of pre-registration exam is not appropriate.

						• Peer review. • A lighter version than that given for restoration after 5 years. • References and testimonials. • Tutoring and assessment by accredited tutors on a par to those involved in pre-reg training. • Structured programme to meet final pre-reg competencies. • Portfolio assessment. **MISCELLANEOUS** • The first threshold should be 18 months. Beyond that but before 5 years: evidence of CPD in the last 12 months. Beyond 5 years CPD and a return to work refresher course.
Q33	Would you like to make any other comments?	**text**				**OTHER COMMENTS** • Unreasonable for person not to be paid whilst suspended. • If Society is seeking power to recover costs, then it should have to pay costs during suspension • How would the Society have the power to require employers to monitor undertakings and /or conditions imposed by a FTP Committee. • Consideration should be given to defining some terms used with greater precision. • Entry to a register should be dependent on an enhanced CRB check. We may need to consider CRB checks for those currently on the register. • There should be an option to provide a non-home address under specific circumstances. • Concern about requirement to return current certificates for destruction / overprinting with non-practising status. • Objection to civil standard of proof. (Single response) • General need for consistency across the healthcare professions. • Need to ensure liaison with PCTs during investigation process where appropriate. • Attention to be paid to rehabilitation processes. • There is confusion about the distinction between professional indemnity insurance and professional indemnity arrangements.

						• Electronic service of documents should only be by agreement between the parties. • Concern about disclosure of investigation to employer.

Appendix 3

Excerpt from Confidential minutes of Council, October 2005

05/100 2006 Retention form: criminal convictions declaration

Mr Philip Green, Deputy Registrar and Director Education & Registration introduced paper 05.10/C/43, which had been circulated.

At its meeting in August, Council agreed that the criminal conviction and fitness to practise declaration to be included on the 2006 pharmacist retention would be signed off by the Officers, in consultation with the Chairman of Infringements Committee, subject to guidance being prepared for Council to consider at its October meeting. The Officers had agreed a form of words which was incorporated in the proposal at Option 2 in the paper. A copy of the Schedule to the Officers minutes including the form of words was circulated.

The Council was advised that in order to ensure public protection and in order that the Society could withstand scrutiny by CHRE and judicial review, any element of self assessment of what ought to be declared should be avoided.

It was noted that at the recent Rules seminar the Council had discussed the criminal convictions declaration and the consensus view had favoured the declaration of all criminal convictions/cautions/conditional discharges/bindovers/etc that had not previously been declared to the Registrar.

The following points were raised in discussion.

- There was great potential for confusion on the part of members in knowing what constituted a criminal conviction and therefore a need for clear guidance.
- There was concern that if all convictions were declared the Infringements Committee would be overwhelmed in hearing cases brought because of declarations of relatively minor convictions.
- The Infringements Committee, at its training day in October, would develop guidance clarifying which convictions would require referral to the Committee.
- Reporting of one minor conviction might not indicate a problem, but repeat offending could be indicative of a situation requiring investigation.
- The pharmacy technicians' retention fee exercise had already begun and the form that had been despatched stated that guidance was available.

Council

agreed

i. that the criminal convictions declaration on the retention form should seek the declaration of all criminal convictions/cautions/conditional discharges/bindovers/etc that had not previously been declared to the Registrar.

Council

noted

ii. that guidance would be prepared to assist members in completing the declaration and widely published to ensure members had easy access to it, and

iii. that the referral criteria developed by the Infringements Committee would be published in order that members could be aware how certain types of conviction would be handled by the Committee.