ITEM 05.02/C/05

Council meeting 1 & 2 February 2005   OPEN BUSINESS

CHRE Performance Review

Purpose
To inform the Council regarding the response made to the Council for Healthcare Regulatory Excellence as part of the 2004-05 performance review process.

Recommendation
Council is asked to note the response submitted by the Society to CHRE.

1.   Background
CHRE uses performance review as a tool to improve the effectiveness of professionally-led regulation in protecting the public. The main focus is the promotion of good practice and continuous improvement in regulation, but CHRE also uses performance reviews to highlight and disseminate good and transferable practice.

While regulators have a variety of statutory – and in the case of the Society non-statutory – functions and processes, CHRE's focus is public protection. CHRE also therefore intends to use the process of review to identify how to resolve any difficulties regulators may have if their existing legislation does not reflect the principle of public protection, or hinders the regulator's activities and desired programme of change.

2.   Principles adopted by CHRE for review of performance
The review is focused on outcomes. This means that while CHRE are looking for processes that protect the public best, they accept that regulation needs to be responsive to the different circumstances of the regulated healthcare professions. However, there may be cases, in CHRE's view, where consistency across regulators is desirable.

Through its questionnaire approach, based on the European Foundation for Quality Management (EFQM) Excellence Model, CHRE has sought to cover aspects of work that are likely to be consistently relevant. For this purpose, the EFQM Model's processes have been divided into the main activities of the regulators:

- maintaining a register of professionals fit to practise in the UK
- setting standards of conduct and ethics
- setting educational standards to create and maintain the right competencies for professionals and setting systems to maintain continuing competence
- addressing concerns about professionals who are unfit to practise because of poor health, misconduct or poor performance
- co-operation and partnership with stakeholders, including registrants, the public and other professions (this last activity has been added by CHRE as it appears in the EFQM Model as "resources and partnerships").

The information was requested under the following headings:

- Leadership and governance (the regulator's leadership and governance facilitate its mission of public protection)
- Policy and strategy (the regulator's policy and strategy support its aims)
- People (the regulator's human resources strategy supports its aims)
- Partnerships and resources (the regulator plans and manages its external partnerships and internal resources to support its aims)
- Processes (the regulator designs, manages, reviews and improves processes in order to ensure that they are effective and relevant to its aims)
- Results (the regulator monitors, evaluates and reviews the success of its activities, particularly in relation to public protection)

After the written information has been provided, CHRE may come back to focus on some particular aspects, either to seek more information or to pursue a thematic study. This year, the particular themes are complaints handling, screening and fitness to practise systems.

3.   The performance review process

This paper provides the Council with an update on the process so far – the completion of the questionnaire. The information was requested by CHRE on 26 November, was assembled by the office in December, and submitted to CHRE on 7 January.

The second stage of the review is a meeting with CHRE, which is scheduled for 3 February. At the time of preparation of this paper, the Society had yet to receive any indication of the particular focus of the meeting, or the agenda. A report on this meeting will be submitted to Council in due course.

Following the meeting, CHRE will draft its performance review report by the end of March. Comments on the report will be sought from the Society before publication on CHRE's website. Material may also be used subsequently in CHRE's annual report to Parliament, which highlights areas of good practice, and this year may compare regulators' performance across different areas.

As the main focus of the reviews is the promotion of good practice and continuous improvement, CHRE intends to keep information collected year-on-year to examine trends. CHRE has also adopted the five regulation principles defined by the Better Regulation Task Force for any regulator devising, implementing, enforcing and reviewing regulation: proportionality, accountability, consistency, transparency and targeting.

4.   The Society's response
In response to the CHRE's review documents, the Society submitted a completed questionnaire (attached at Appendix 1), together with 23 appendices, under a covering letter which itself had 3 annexes (Annual Report, Equal Opportunities Policy, Diversity statement – see agenda Item 05.XX/C/XX). The full list of appendices is included at Appendix 2 to this paper. These were mostly existing documents or extracts from documents, available on the Society's website. The document provided at Appendix x to the questionnaire, which provides an update on the Society's 2004 operational objectives, is attached here at Appendix 3.

5.   Risk Implications
None identified, though clearly the office has used the opportunity of the performance review process to date, and will use the review meeting, to highlight again to CHRE the continuing risks presented by the delays to the Section 60 process.

6.   Resource implications
No further resource implications at present. The production of the materials involved considerable work from a number of members of staff around the Christmas holiday period. While further resource may be needed if deficiencies requiring specific remedy are identified within the review process, these cannot be identified at this time.

7.   Recommendation
Council is asked to note the response submitted by the Society to CHRE.

Robert Darracott
Director, Corporate & Strategic Development

2004/2005 Performance review questionnaire

A. Leadership and governance

A(i)   What are the strategic objectives (ie vision, mission statement, values, aims, objectives where appropriate) of the Council? *If specified in your documentation please direct us towards the relevant document and section.* To what extent do they reflect your commitment to public protection?

2004 was a significant year for the Royal Pharmaceutical Society. The organisation still awaits the public consultation on a draft Section 60 Order, which will provide the Society, *inter alia,* with much needed powers to modernise its fitness to practise procedures, implement mandatory CPD and register pharmacy technicians. However the linked updating of the Society's founding document – its Royal Charter – was completed on 7 December 2004 and work to implement new regulations under the Charter has already begun. The Charter not only establishes the Society's purpose, but also provides for significant elements of the organisation's governance, including the make-up of its reformed Council, which is due to take office in May 2005.

In the light of this new Charter, and in the full knowledge of the likely key components of the Section 60 Order, the Council has gone on to reconsider its vision and mission for the organisation, in work over the past three months. This work is, as yet, unfinished and, in any event, will be subject to confirmation by the reformed Council as one of its first tasks later this year.

For Society's current vision, which was determined by the Council in June 2003 is:

> "The Society will be the integrated regulatory and professional body for pharmacy and will be equally effective in both functions"

while its mission, which is used on all current press releases is:

> *"*The primary objective of the Society is to lead, regulate and develop the pharmacy profession."

The Council will go on to discuss values at further meetings over the coming months, when it will also confirm its aims and objectives.   CHRE may, however, be interested to know that, as part of the development of work on the Society's internal culture, a set of values was developed in 2003 by staff for staff, and this work is currently being re-examined as part of work flowing from an internal reorganisation. These values are:

- Integrity - To undertake their roles to the best of their ability and in an honest, objective and fair manner.
- Commitment to the vision -To believe and to be able to explain to others, why and how what they do every day is helping to lead, develop and regulate the pharmacy profession
- Confidence of our worth - To demonstrate confidence on their worth and that they deserve the trust placed in them
- Respect - In the way that the treat people they will show consideration to the viewpoints and feelings of others.

- Innovation - To accept that the way we do things, and how we do things, should certainly improve and evolve.

Within the context of the Charter process, the Society reaffirmed its overall aims, through the Charter objects, which are now all confirmed as being delivered within the context of the public benefit:

(1)   to advance knowledge of, and education in, pharmacy and its application, thereby fostering good science and practice
(2)   to safeguard, maintain the honour, and promote the interests of pharmacists in their exercise of the profession of pharmacy
(3)   to promote and protect the health and well-being of the public through the regulation and professional leadership and development of the pharmacy profession and the regulation of other persons engaged in related activities; and
(4)   to maintain and develop the science and practice of pharmacy in its contribution to the health and well-being of the public.

The full text of the Charter, including all of the Society's Charter powers, is included at Appendix A (Royal Pharmaceutical Society of Great Britain 2004 Supplemental Charter).

The Society's Council will develop and agree specific strategic objectives for the next few years as part of the process outlined above. The reformed Council will agree these in the second half of 2005.

The Society's planning runs on a calendar cycle. As part of the internal reorganisation of the Society, the Corporate & Strategic Development Directorate was created at the beginning of 2004 with one of its specific responsibilities being to instill an annual planning process into the organisation. As outlined in the covering letter to this documentation, the 2005 business plan is not yet available, but should be presented to the Society's Council in February, after which time we can make it available to CHRE. The work on the 2005 plan, which has been a largely internal exercise, has been taking place at the same time as the Council has begun the process of reviewing the underpinning strategic objectives, as described above. This Council process is the first stage in the production of a Plan for the organisation covering the years 2006-08.

With regards to performance in 2004, however, the key objectives for the organisation were produced for last year's Performance Review exercise. A copy is attached for ease of reference as Appendix B (RPSGB/CRHP1/06 Priorities 2004/05). An updated progress report on these objectives is attached to this document as Appendix C (Priorities 2004/05 – January 2005 update).

B. Policy and strategy

B(i)   How are your policies in relation to public protection developed?

The most significant step taken by the Society in 2004 has been the introduction of a mandatory declaration as part of the registration and retention fee cycle. This compels all registrants – pharmacists and pharmacy technicians - to declare convictions, cautions, letters of warning from the Procurator Fiscal and proceedings and findings from other regulatory bodies that could impact upon fitness to practise. The declaration also extends to cover any proceedings which may be pending. The disclosures which have resulted will be considered by the Infringements Committee and a determination reached on each individual case.

More generally, policies related to public protection are deals with by the Society's Law & Ethics Committee, one of the Council's four main policy implementation committees. Comprising 11 Council Members, including two of the Privy Council (lay) nominees, the Committee, like the others (Practice, Education, Science), take decisions within policies on behalf of the Council, generate ideas for work on new policies, and monitor the implementation of established policies. In doing this, the Committee considers policy development work either produced in-house or through specific time-limited working groups established for a particular purpose. These time-limited working groups tend to have a membership wider than that of the Committee, and can include lay representation.

Most recently, the work coming through the Law & Ethics Committee has included updated statements within the Code of Ethics on whistleblowing and on internet pharmacies. Details of these changes can be found at Appendices D (Whistleblowing) and E (Internet Pharmacy). Whistleblowing is covered further in the answer to question E.D(ix).

The exact nature of the supporting structures for the Council is currently being re-examined and will be formally determined in 2005 by the reformed Council when it takes office. It is likely, for example, that the Law & Ethics Committee will not survive in its current form. In the internal reorganisation of the Society, standard setting and the development of the profession's Code of Ethics (Practice & Quality Improvement) have been separated from enforcement and discipline (Fitness to Practise & Legal Affairs). There is, looking forward, a general recognition within the Society that much work needs to be done both before and after the Section 60 Order by some form of specific "fitness to practise policy committee".

At the same time, the time-limited working group approach is increasingly being used for policy development across a range of the Society's activities. As an example, the Society's response to the 4th Shipman Inquiry report (attached at Appendix F; Response to the Recommendations of the Shipman Inquiry Fourth Report), which focused largely on the management of Controlled Drugs in the community, was drawn up by a working party chaired by Elizabeth Filkin. The working party membership reached across pharmacy, the health professions and the NHS. Patient/public interest groups were included in a wider reference group. A full list of those who served on the Society's Shipman Working Group is included at Appendix G (RPSGB Shipman Inquiry Working Group), and those organisations consulted as part of a wider reference group at Appendix H (SIWP(04)15). The Society has also been an integral member of all of the Department of Health's Shipman Working Groups.

B(ii)   What mechanisms are there to secure feedback between the activities of education, registration, standards and fitness to practise?

The Society's internal reorganisation set about, in part, to bring together some of the areas of work that were clearly closely related. For example, our Education & Registration Directorate brought together two areas of work that were previously part of separate management structures. These teams are now housed together, and in some areas directly share staff across functions, particularly in those areas where work follows a (different) annual cycle.

However, as has already been described, the reorganisation also split, for all the right reasons, some functions that were previously together, and work is now going on to ensure that, where appropriate, feedback between activities and across the organisation work effectively.   In the short term, this process has been facilitated, fortuitously, by the promotion of staff from one area into the other.

Again, as the supporting structures for the new Council emerge over the next six months or so, some of the necessary feedback mechanisms will be institutionalised in formal structures. At present, all Council Members receive the minutes of the two main Committees in this area – Education and Law & Ethics, and the work of committees is co-ordinated where appropriate, so that information and work can, and does, flow between them.

The Society currently publishes Law & Ethics Bulletins. The material for these bulletins comes from a variety of sources – cases within the disciplinary processes, inquiries to the legal and ethical advisory service, or direct from the Society's Inspectorate. The Bulletins are widely circulated and are published to the profession in *The Pharmaceutical Journal.* An example is attached at Appendix I (Law and Ethics Bulletin). These Bulletins also appear on the Society's website.

The other major mechanism at present is through formal and informal networking within the organisation. In some areas this is well developed. For example, the Society's Inspectors produce a list of pharmacies that they consider to be suitable establishments for preregistration training which is shared with the Education Division. At the same time, the Inspectorate will also inform Education where a pharmacy that is on the list for a training place may no longer be suitable. Also recently, the Society's preregistration training handbook was changed in the light of the outcome of a case before the Society's Statutory Committee.

Elsewhere, the Society has in place a number of internal structures where information sharing and work planning takes place. The Executive Group meets twice a month, and now includes regular attendance from the Society's senior staff in Scotland and Wales. Bi-monthly senior managers meetings are a regular forum for information flow on activities across the organisation. The papers for these meetings are widely shared, and form the basis for cascading information down the organisation. Towards the end of 2004 the Society also instituted an internal e-newsletter that is sent to all staff. While this is ostensibly focused on the contribution staff make to the work of the organisation, it too will provide a useful vehicle for cross-functional information flow.

C. People

C(i)   What human resources strategy do you have in place to support your aims?

The Society recognises that one of its most important assets is its employees. The HR function directly supports the improvement of organisational capability and performance through people. In order to accomplish this remit the function's focus lies in four main areas which have been identified as core to the Society's overall strategic objectives:
• Organisational Development & Culture
• Employee Resourcing
• Individual Development
• Reward strategies

In order to maintain and develop a fair, progressive and effective working environment our HR strategy is aimed at encouraging the development of an atmosphere in which an equitable employer/employee relationship can advance alongside effective performance.   The Society subscribes to a confidential helpline that can assist staff in a counselling capacity.

As a corporate objective, the Society intends to achieved or be positioned to achieve the Investors In People accreditation within the next five years. Over 2005 and 2006 specific work will continue to support the Society's ongoing cultural change programme. Specifically the Society will be developing a values-based framework of what the Society expects of its staff. Subsequently, these behaviours will be incorporated and linked across the most important HR areas such as recruitment, workforce planning and performance.

In addition 2005 will see the Society changing its governance structure at the highest level and HR function will assist in ensuring that any transition is undertaken as smoothly as possible.

Specific HR objectives, which are contained within the 2005 business plan, are included at Appendix J (Specific HR initiatives agreed for 2005). The 2005 training plan is attached as Appendix K (Training Plan 2005).

D. Partnerships and resources

D(i)   What mechanisms do you have to plan and manage your external partnerships?

The Society has a wide range of external partnerships.

At the formal level, the Society is increasingly adopting a Memorandum of Understanding approach. The first of these, with the National Patient Safety Agency, was concluded some time ago and covers the sharing of information, the regularity of joing meetings, the ways in which the two organisation work. A copy is attached at Appendix L (The RPSGB and the NPSA: Working Together To Improve Patient Safety). We understand from NPSA that the MOU with the Society has genuinely led to effective joint working.   The Society also has an MOU with the National Treatment Agency for Substance Misuse (NTA).

The Society has formal partnerships with a number of Royal Colleges and professional bodies to develop clinical guidelines with NICE. We are partners in both the National Collaborating Centre for Primary Care and the National Collaborating Centre for Chronic Conditions. These centres are commissioned by NICE to develop NICE Clinical Guidelines. The Society also has a partnership with the Royal College of Psychiatrists and others to develop a prescribing observatory for mental health.

One other major area of partnership working is the work that the Society's inspectors do working alongside the Medicines and Healthcare Products Regulatory Agency (MHRA). This not only involves exchanges of information but, on occasions, joint investigations and related prosecutions. An MOU is in development between the Society and the MHRA, but has been delayed over the last year due to the reorganisation of the Agency. MOUs will be considered in due course for other organisations with whom the Society has close links or work, including the NHS Counter Fraud and Security Management Service, with whom joint training events have already been held.

The Society also has a range of formal and informal contact with many partner organisations across from across the pharmacy profession and outside it. Regular meetings are held with, for example, the Chief Pharmacists from the UK Health Departments (a meeting attended also by the Pharmaceutical Society of Northern Ireland), the UK pharmacy organisations, other regulators, other professional bodies.

The Secretary & Registrar maintains a list of all of the Society's formal representatives and contacts, be they Council members or staff, with a wide range of public, health service and other bodies, including working groups of, for example CHRE, and reviews. A copy of the current list is attached at Appendix M (Society Representatives on Outside Bodies).

With particular respect to CHRE, the Society's Council now includes as a standing item a report on the work of the Council. This can include the tabling of the minutes, a verbal report from the President on recent meetings, an update on the use by CHRE of its Section 29 powers, and so on.

One area of "partnership" that has been a specific focus for the Society's work in 2004 has been internal. In February the Council agreed to establish a Review Group under the

Chairmanship of Lord Fraser of Carmyllie to examine the Society's structure and functions in the light of devolution.

It is clear that, while regulation of health professionals remains a reserved power to Westminster, the environment in which pharmacists practise, particularly within the NHS in the three countries of Great Britain, is changing, and may well be very different in a few years time. The regulation of new health professions, including allied groups like pharmacy technicians, is not reserved, while recent Scottish proposals for changes to the NHS Tribunal system suggest the regulatory environments may diverge in time. Regulators also have to consider, particularly in relation to Scotland with its different legal framework, the relevance of geography when scheduling hearings.

The Review Group is due to deliver its recommendations to the Council in February this year. It is clear, however, from the submissions to the review, that the Society's Council will need to devolve some authority to act to its Scottish and Welsh structures if the profession is going to be effectively served in Edinburgh and Cardiff. One item has already been taken off-line from the review. At its December 2004 meeting, the Council agreed that the Society should establish a Welsh Language Scheme.

D(ii)   How do you promote transparency and accountability within your processes? *Eg lay involvement, public involvement, accessibility of processes, information about the diverse background of registrants and complainants.*

The Society's lay involvement will receive a major boost with the election/ appointment of the reformed Council in the middle of next year. The reformed Council will comprise 30 members. There will be 17 elected pharmacists, 10 lay members appointed by the Privy Council (the closing date in the public appointment process was 6 January), 2 pharmacy technicians elected from those technicians on the voluntary register when the electoral process begins, and one pharmacist appointed by the universities.

Elsewhere within the Society there is already considerable lay input to the major governance support structures. The Audit and Remuneration Committees are both chaired by lay Council Members, and have additional external specialist lay input. The Corporate Governance Steering Group also has additional external lay input.

The Infringements Committee, operating under the old legislation and Charter, has been chaired by a lay Member of the Council for a number of years. The Committee will be radically reformed under the Section 60 legislation. The Statutory Committee has, since its current underpinning legislation, the 1954 Pharmacy Act, had a legally qualified chairman. Given the delays to this vital new legislation, we have been unable to modernise our procedures in the way we discussed extensively at the time of last year's review. The issues arising from the delay are well known to CHRE. The major deficiencies are the lack of a Health Committee, a restricted range of sanctions and no powers of interim suspension.

More generally, the Society is currently developing a formal Patient and Public Involvement Strategy to cover the whole organisation. As part of this work, the Society has joined the CHRE/regulators group on this issue. The Strategy should be agreed by the Council during the first half of 2005.

Over the last 12 months the Council has agreed a number of changes to its processes in the

interests of openness and transparency. From February 2004 for a trial period a transcript of the open session of Council meetings was placed on the Society's website (target: within 10 days of the Council meeting). Following the trial, this process was confirmed and, to further aid transparency, the Council has now agreed that the agenda, papers and minutes would also be placed on the website at appropriate times in the process (ie a short time after Council Members have received them). The options for extending this form of transparency to other Society structures will be reviewed in due course. Statutory Committee judgements are already placed on the website.

The Annual Review remains a major mechanism to publish statistics. The content of the document is reviewed each year.

The Society's website will continue to be used to provide information on the Society's activities and its policies. The website review continues as a long-term project. As CHRE's own scoping study revealed last year, the website is not as accessible as it might be. Specific changes were implemented following the scoping study to provide direct information for the public on the Society's role, the work of pharmacists, and how individuals might raise concerns over the fitness to practise of a pharmacist, and the work of the Society. Provision has been made in the 2005 budget for the total revamp the site requires.

As identified in answer to question E.C(ii), the amount of information available to the public about individual registrants is quite limited at present, but more extensive information about the register as a whole has been collected in both 2002 and 2003 through a census. Like all the Society's research reports, the census is published on the Society's website. A copy of the July 2004 report on the 2003 data is included at Appendix N (Pharmacy Workforce Census 2003: Main Findings).

On expert advice and in order to avoid respondent fatigue, and because the 2003 findings showed minor movement – though significant in some areas – from the 2002 data, it is not proposed to do another census in the immediate future. However, several questions related to the type of work undertaken by pharmacists have been included within the retention form in 2005 as a mechanism to update data for the Society's workforce model, which has been developed in conjunction with the GB Departments of Health over the last couple of years. The report of the Society's Pharmacy Workforce Planning Advisory Group will be available in the next couple of months.

The Society has also recently commissioned work on the career motivations of pharmacy students, the teaching, learning and assessment methods currently used in Schools of Pharmacy, and a major cohort study that will follow a year of current students through preregistration on onto the Register.

E. Processes

E.A. Standards of conduct and ethics

E.A(i)   How do you ensure that standards of conducts are achievable but challenging, focused on public protection and kept up-to-date?

To ensure that the pharmacists' Code of Ethics reflects and supports the developing roles and responsibilities of the profession, the Society's Law and Ethics Committee continually review the Code in light of changes within the profession, the healthcare environment and changing public attitude. The Law and Ethics Committee meets at regular intervals throughout the year and comprises practising pharmacists and lay representatives, helping to ensure that the requirements of the Code are attainable and patient-focused.

Changes to the Code of Ethics are also identified as a result of cases considered by the Society's disciplinary committees, queries dealt with by the Legal & Ethical advisory service or the Society's Inspectorate, and through issues raised by the pharmacists. The recent consultation process for the Code of Ethics for Pharmacy Technicians provided another opportunity to obtain valuable feedback, as much of the pharmacy technicians' Code mirrors the pharmacists' Code of Ethics.

All changes to the Code are agreed by the Society's Council and are published to the profession. Changes to the Code are formally accepted at the Society's Annual General Meeting in May each year, although changes made in the year are implemented immediately on the agreement of the Council.

A comprehensive revision of the Code of Ethics was last undertaken between 1998 and 2001, during which time there was extensive consultation with pharmacists, stakeholders and other bodies. The next fundamental review of the Codes of Ethics will begin later this year.

E.B. Education

Under the current legislative framework the Society has standards setting (and monitoring) powers relating to undergraduate and preregistration training programmes and supplementary prescribing for pharmacists. It is however seeking more general standard setting (and monitoring) powers in relation to post-registration (and specialisation) training and specifically in relation to continuing professional development (CPD) in the S60 Order, for which the public consultation is expected in the next month or so. This new legislation will provide an obligation and the authority to set health and character requirements for registration. Whether the Order will place a duty on UK Schools of Pharmacy to disclose any concerns about undergraduates' health and character is still for discussion. This discussion – and others – is likely to be informed by the outcome and recommendations of the Shipman Inquiry and of Chief Medical Officer's consequential consultation on the General Medical Council's scheme for revalidation of registered medical practitioners. (The Society had already asked the Department of Health for full appropriate jurisdiction over undergraduates and trainees prior to these developments).

In relation to pharmacy technicians the Society is establishing a voluntary register from January 2005 which will recognise a range of qualifications equivalent to NVQ Level 3 as the basis for entry.   Again as part of the S60 Order, which will make the technician registration

statutory, wider powers to set and monitor standards in education for technicians are being sought.

E.B(i)   How are educational standards reviewed and kept up-to-date? *(please summarise briefly)*

Undergraduate & Supplementary Prescribing programmes

An expert group reviews the Society's standards for the undergraduate pharmacy curriculum every five years. Reviews cover the literature relating to the future of pharmacy and pharmacy education in addition to consultation with relevant stakeholders. The last review included a wide consultation within the profession, with senior officers and managers in the NHS, other healthcare professional bodies and patient representative groups and was completed in 2002. The output of this process is attached to this response at Appendix O (Accreditation of UK Pharmacy Degree Courses).

The curriculum for supplementary prescribing programmes was set by a multi-professional working group and the standards were set using a similar process (including wide consultation) to that adopted for the 2002 review of the undergraduate programmes.

Preregistration training

The Preregistration Performance Standards are reviewed every five years. The latest version is attached as Appendix P (Performance Standards). The last review was completed in 2002 and included consultation with a wide range of stakeholders. In addition the Society sets and marks a national exam, which is overseen by an appointed Board of Examiners made up of 11 members, one of whom is a non-pharmacy educationalist. The Board also sets the syllabus for the Registration Examination, which was last revised in 2001 following external consultation. Both the Performance Standards and the Registration Examination syllabus are kept under review within the Society and with external stakeholders.

Future education policy

As part of its forward plan the Society has recognised that its education policy needs to be reviewed and developed to reflect changes in the roles and responsibilities of pharmacists and, in the future, technicians. This review will inform development of new policy and the drafting of rules and standards under the new S60 Order. The planned review will focus on the following aspects of the regulatory framework as it relates to education:

* Setting and assessing educational outcomes – defining what needs to be taught, learned and assessed in relation to the career of a pharmacist (and technician).
* Quality assurance – how can the standards best be monitored and inspected.
* Infrastructure/environment – what framework is needed within the Society to support the standard setting and monitoring functions and externally to deliver appropriate teaching, learning and assessment in pharmacy.

Preliminary work to begin defining the knowledge, skills, attitudes and values needed is already underway. This will inform the setting of outcomes and assessments.

E.B(ii)   How is education provision inspected? *(please summarise briefly and/or highlight changes from the scoping study (p. 51-63 for all regulatory bodies - see extract provided))*

Undergraduate & Supplementary Prescribing programmes

The Society inspects all UK schools of pharmacy every five years while reserving the right to conduct interim visits if this is indicated by the conclusions of the quinquennial review. Teams of reviewers, which include pharmacy academics, practitioners from each of the main areas of practice and staff from the Society's Education and Registration Directorate, carry out inspections.

The process of accreditation is based on a comparison of the degree programme with the Society's published criteria for university facilities, resources and curriculum. The Society is currently in the process of implementing a new degree accreditation procedure in which a panel of reviewers will be established from which visiting teams will be drawn in the future. The panel will include lay members. In accordance with the current practice, all members will be required to undergo training for their role.

A similar process is applied to post-registration training for supplementary prescribers.

Preregistration training

The Society approves establishments that provide pre-registration training placements and approves the training programmes delivered in them. The process focuses initially on a self-assessment method (Appendix Q: Submission to Provide Preregistration Training) with providers asked to provide information about the training site and the training programmes that will be provided. In the case of community pharmacies the Society's inspectors visit preregistration-approved premises once every five years and all new sites before they are approved. Standards are set for the facilities required – a checklist of books, equipment and general questions covering suitability - and the experience needed to be a preregistration tutor. The Society publishes expectations of the preregistration tutors, which it hopes to be able to turn into standards under its new legislation.

E.B(iii)   What scheme of Continuing Professional Development (CPD) do you have or are you planning to develop? Is participation mandatory?

The Society completed the roll out of its scheme for CPD in October 2004. The scheme is based on the CPD cycle of reflection, planning, action and evaluation. Pharmacists are guided to identify learning needs through a process of reflection on practice, critical incidents, changes in practice, career development or other triggers and pursue these through the CPD cycle. The CPD scheme requires pharmacists to keep records of their CPD either on paper or electronically and to submit these to the Society on request. Every pharmacist will have their records reviewed by the Society against a set of good CPD practice criteria at least every five years.

Participation in CPD is currently a professional obligation. Pharmacists can choose to register with the Society as practising or non-practising. Non-practising members will not be required to do CPD but they will also not be allowed to practise or give professional advice. When the

Section 60 Order takes effect, CPD will become mandatory for all pharmacists on the practising register.

CPD will be mandatory for pharmacy technicians on the voluntary register from the point of registration with the Society. The CPD scheme for pharmacy technicians mirrors the pharmacists' scheme. The Society has invested considerable resources on an interactive web-based CD initiative and regional rollout exercise in CPD.

E.B(iv)   Have you put in place, or are working towards, a system of revalidation?
(whereby registrants are required to show on a regular basis that they are up to date and fit to practise)

The Society's CPD scheme will form part of a system for revalidation that is currently planned to be developed through to 2006. Development of a revalidation scheme will reflect development of post registration/ specialisation training. It is recognised that the current DH review of medical revalidation may necessitate a review of the current timetable for the development and implementation of proposals for a revalidation system in pharmacy.

E.C. Registration

E.C(i)   Have your entry requirements to the register for UK nationals, other Europeans and international applicants, and the evidence required, changed since the information was provided to the scoping study? *(see extract of scoping study provided)*

The Society is working with the other UK health regulators and the UK Health Departments to make changes, which will be beneficial to patient protection, in the requirements for EEA nationals holding EEA approved qualifications in pharmacy. These changes, however, can only be made at a European level.

There have been several important changes to the procedures for non-EEA national applicants holding non-UK degrees. These include:- testing for English, universal requirement to undergo the Overseas Pharmacists Assessment Programme (OSPAP) and a universal requirement to complete the preregistration year and pass the Society's Registration Exam. Table 3.2 in the scoping study could therefore be amended to show these as a cumulative process as follows:-

UK Applicants	International Applicants	Type of Registration
Qualification (Master of Pharmacy) + Successful completion of assessed experience + Good Health + Good Character + RPSGB Qualification	Qualification (Degree in Pharmacy) + GB qualification (OSPAP) + Successful completion of assessed experience + English + Good Health + Good Character + RPSGB Qualification	Full

E.C(ii) In respect of your register, what information on a registrant is publicly available and how?

The Society's register is available on the Society's website and is searchable by surname or registration number, with an optional use of forename. The information presented is:

- Registration number
- Title
- Surname
- Forename(s)
- Postal Town
- Date of registration date
- The fee paid – this will in future indicate whether a pharmacist (or pharmacy technician) is practising or non-practising
- An indication of whether a pharmacist is a supplementary prescriber.

The Registration Section also offer additional search services for which a fee is levied.

Until recently the Society's register was published as a bound volume. A limited number of this form of publication is still made, for internal use, and for the copyright libraries, but widespread publication was discontinued owing to rapid turnover of information and therefore its currency and relevance.

E.D. Fitness to practise (including handling of complaints against registrants and screening process)

E.D(i)   Please describe briefly your complaints handling and screening system.

The system is described on the two documents included as Appendices R (How the RPSGB deals with complaints) and S (Complaints Against Pharmacists and Owners of Pharmacies) which can both be accessed through direct links from the public side of the Society's website.

The Society also publishes a booklet entitled "Complaints Against Pharmacists and Owners of Pharmacies", which details the system. From January 2005, the Society will send a copy of the booklet to each complainant.

The Society is also in the process of developing and implementing a questionnaire designed to evaluate customer satisfaction with the Society's complaint system. A copy of the questionnaire is attached as Appendix T (Satisfaction Survey on Patient Complaints).

E.D(ii)   Please give us the statistical for this year on:
- the number of complaints made

    A detailed breakdown of complaints and cases dealt with in 2003 can be found in the Annual Review. We are currently in the process of compiling and validating a detailed breakdown for 2004 for inclusion in the Annual Review for 2004, which will be published in May. When this information has been finalised, this can be shared with CHRE.

    - who made these complaints *(depending on the information you collect - eg member of the public, registrant, other professional, employer, public body)*

The Society is in the process of finalising a complaints form which will be sent to all complainants, and which will be available to download from the Society's website. The complaints form will have a section designed to capture this data.

- percentage of complaints progressing to various stages of your procedure (*depending on your own procedures – eg % of misdirected complaints, % of complaints progressing at the preliminary stages, % of complaints progressing to fitness to practise committees*) by category of complainants.

See above.

E.D(iii)   How are decisions made about which complaints you will investigate/refer?

From January 2005, the Society will investigate complaints in accordance with the referral criteria established by the Infringements Committee. A copy of the referral criteria is attached to this response as Appendix U (Infringements Committee Guidance on Referring Cases to the Statutory Committee).

The Society regularly provides training to its Inspectorate in the form of compliance with the Police and Criminal Evidence Act 1984 (and the Codes under the Act), the taking of witness statements, and covert surveillance. The Inspectorate investigate all complaints and have extensive powers in legislation of entry, search and seizure. In addition, the Society is the only healthcare regulator with explicit powers to order covert surveillance. In 2004, the Society was commended by the Office of the Surveillance Commissioner for all procedures in place to manage this process.

The Society intends to provide specific training on complaint handling and report writing in the first quarter of next year.

Screening staff have been trained in procedure, and relevant principles of regulatory and human rights law.

E.D(iv)   What are the committees, processes and sanctions currently involved in your fitness to practise processes, including informal (mediation, undertakings) or emergency processes? Please highlight areas of change from last year, or awaited changes (*eg through s60 orders*).

Complaints which meet the referral criteria are investigated by the Society's Inspectorate, and referred to the Infringements Committee. That Committee has the following options:

- (a) take no action
- (b) write a letter informing the registrant that no action will be taken on this occasion, but that should any fresh allegation be received by the Society within 5 years, the original allegation will again be considered, together with the fresh allegation;
- (c) write a letter of advice to the registrant;
- (d) where a registrant admits an infringement, issue a warning;
- (e) refer a case to the Statutory Committee; or
- (f) adjourn for further investigation.

Where the Statutory Committee has considered a case and found that a registrant has committed misconduct such as to render him unfit to remain on the register, it has a discretion as to whether to issue an admonishment or reprimand, or to order the removal of the registrant's name from the Register.

Before making its decision, the Statutory Committee may adjourn on terms agreed with the parties. As the Society does not have a Health Committee, this last process is used by the Statutory Committee in cases involving issues of ill health.

The Society is in the process of finalising with the Department of Health, a draft S60 Order for public consultation. The new legislation will provide for a Health Committee and a wider range of sanctions including interim orders, suspensions and conditions. This position has not changed since last year.

E.D(v)   How do you review, or plan to review, the consistency of the decisions of the fitness to practise panels?

The Statutory Committee has recently adopted Indicative Sanctions Guidance and Guidance on the Consideration of Applications for Restoration which will assist in ensuring the consistency of decision making. A copy of these documents is attached to this response at Appendix V (Statutory Committee Indicative Sanctions Guidance).

The Society provides regular training to all its fitness to practice panel members on issues of procedure; regulatory and human rights law; and provides feedback to panel members from issues raised by the CHRE and the S29 process. The rules of the Infringement Committee make training a mandatory requirement. This training also includes diversity training.

E.D(vi)   How do you publicise fitness to practise decisions?

Decisions of the Statutory Committee are published in the *Pharmaceutical Journal* and on the Society's website. Members of the Press are always invited to attend the hearings and do so on a regular basis.

E.D(vii)   What is your retention (or destruction) policy on documentation?

The Society has had in place for some time now a dedicated Records Manager who is, systematically, organising records management across the Society. A copy of the Society's policy is attached at Appendix W (Records Management And Archives Policy).

E.D(viii)   How would a member of the public find out whether a professional's registration is currently subject to restrictions or warnings (if applicable)?

The Statutory Committee does not have the power to impose restrictions on registration or to issue warnings. However, the Society is currently reviewing its policy on disclosure of voluntary undertakings and warnings issued by the Infringements Committee, in the light of the recommendations made in the fifth report of the Shipman Inquiry.

E.D(ix)   Do you encourage registrants to express their concerns about a professional's fitness to practise, and if so how?

The Society's Code of Ethics places a professional duty on pharmacists to act on any concerns they have about a pharmacist's, or other health professional's, fitness to practise for reasons of competence, conduct or health.   The Code of Ethics states that pharmacists must

'*act quickly to protect patients and the public from risk by reporting the matter to an appropriate person, authority or regulatory body if they have good reason to believe that they or a colleague from their own or another profession may not be fit to practise for reasons of health, conduct or competence. The safety of patients and the public must be the prime consideration, overriding any personal, professional or commercial loyalties*.'

The Code of Ethics for Pharmacy Technicians contains the same requirement.

The Society is currently producing further guidance to support this requirement and encourage responsible whistleblowing. The guidance will:
- advise pharmacists and registered pharmacy technicians who concerns should be reported to;
- highlight the importance of acting on concerns that may be considered 'mildly unethical' through to those that pose a threat to patient safety;
- encourage pharmacists to ensure all support staff are aware of local whistleblowing policies.

The guidance is expected to be available in the first quarter of 2005.

F. Results

F(i)   How do you monitor and evaluate your performance?

The performance of the organisation is monitored and evaluated at a number of levels.

At the Council, the implementation of action on decisions taken is monitored through a standing "Council update" item in the agenda. As highlighted earlier, as the Society's business planning process feeds through, the Council will be provided with a means to monitor progress of the Society against all the strategic objectives it has set.

The Council also meets on a more informal basis at "strategic review days". These days are an opportunity for the Council to be updated on current activity, to receive presentations on the external environment, and to plan new work. In 2005, the format of this time is being changed to two-day sessions, allowing for more time for this activity. A variety of work-styles will be used to ensure effective engagement of the Council, and the use of external experts, in reviewing the work of the organisation and ensuring that activities are properly prioritised to deliver against strategic objectives.

The Society has a number of specific committees whose role is essentially monitoring. The Resource Management Committee ensures the appropriate application of the Society's resources and oversees the budgeting process. The Audit Committee monitors the financial and other governance arrangements. The Society has both external and internal auditors – tendering exercises for both were successfully completed in 2004. The four major committees (Education, Law & Ethics, Science, Practice) include the monitoring of policy implementation within their remit.

At the Management level, the organisation will be extending the set of measures used to monitor and evaluate performance across the organisation during 2005. These measures will be considered alongside financial performance in the bi-weekly Executive Group meetings. To this end, performance management systems are being developed across the organisation. The following are some examples.

Within the Fitness to Practice Directorate, performance will be monitored in future through an analysis of the satisfaction questionnaire. The Directorate have also established a series of Key Performance Indicators relating to the time taken to progress complaints. As well as this case management audit, in the light of continued absence of suspension powers (which will be included in the Section 60 Order) FTP has put in place processes to fast-track high risk cases through the system.

For pre-registration work monitoring is partly achieved through the interaction with stakeholders – the Society meets with senior executives from the major employers every six months – described above. The Society does not have any objective qualitative measures of performance as yet (and quantitative measurements are of no value in this context). What can be said, though, is that in developing its work so far on the workforce census data, the Society has found no evidence of undue attrition at the start of careers. An inference can be drawn that those successfully completing the preregistration year and the Registration Examination seem to be properly prepared for safe, competent and ethical practice and that they are also fit and ready to enter the employment market (in all sectors). Further research is planned to see if this inference can be confirmed.

The Society receives approximately 2500 advisory calls a month and the outcomes from those enquiries have been monitored on a random sampling basis during 2004 this programme of feedback, quality ,monitoring and review will be extended during 2005.

Staff performance is monitored and managed through a review process, including appraisal and objective setting at the beginning of each year, with a mid-year review linked to personal development. Salary increases can be both progression and merit-based, as assessed by line managers. The Society uses the Hay system of job evaluation.

The Society conducted its first ever staff attitudinal survey at the beginning of 2004, and established an action plan, covering internal communication. As a immediate result, the Society has developed an internal communications plan, has re-established it Employee Forum, and launched an internal e-newsletter. Further actions arising from the survey are planned for 2005.

The Society has a process for managing complaints about the performance of the organisation. Details of the process and of how to complain can be found on the Society's website. In the first full year of the system (to June 2004) 43 formal complaints were received – mostly regarding the 2004 registration process. All were resolved, the majority within the 10 working day target time. Statistics for the 2004 calendar year are still being compiled.

Appendix 2

Appendix Schedule

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Appendix 3

Priorities 2004/05 – January 2005 update

		Completion Date	Progress Report
Critical Success Factor 1 **The organisation must be an effective regulatory and professional leadership body**			
1.1	Implement the programme for reforming the Society	31.12.2006	Section 60 Order still being drafted by DH; New Charter sealed December 2004
1.2	Develop and implement procedures to take forward the disciplinary and fitness to practise procedures to ensure that the Society can fulfil its regulatory functions	31.12.2006	Preparatory work in progress. Requires Section 60 Order • Referral criteria agreed by infringements committee • Indicative sanctions agreed by Statutory Committee
1.3	Develop the inspectorate to promote high standards of professional practice and performance in pharmacy	31.12.2006	• Investigative and RIPA training now undertaken by all inspectors. • Inspectors' procedures manual in draft. • Revised standards for routine visits in progress. • Preliminary discussions on review of the inspectorate to take place in February. • Key performance indicators being finalised. • Meetings with key stakeholders held to foster joint working and training • Now looking at competency framework for inspectors together with NPC
1.4	Develop a strategy to raise competence in the use of professional judgement and awareness of professional values and ethics	30.6.2006	Date has been revised to enable strategy to take full account of Shipman.
1.5	Complete development work leading to effective implementation of the voluntary register for technicians on 1.1.2005	31.12.2004	Majority of development work completed. To enable outstanding work to be completed, implementation will be phased in by August 2005, commencing January 2005.
1.5a	Complete development work on the minimum competence requirement	31.12.2004	Achieved.
1.6	Achieve statutory powers to regulate technicians through Section 60 Order	31.12.2006	Voluntary register will be fully implemented by August 2005.

		Completion Date	Progress Report
			Statutory basis awaits Section 60 Order
1.7	Review the functions, internal structure and ways of working of the Society in the light of devolution, considering the specific implications for Scotland and Wales and the potential for any future regional devolution in England.	30.11.2004	Delay in recruitment of project manager led to timetable being shifted back 3 months. On schedule to deliver report to Council February 2005.
1.8	Develop and implement a strategy to facilitate and evidence-base pharmacists' learning and development needs for present and future practice	31.6.2005	Following the 2003 R&D Reference Group Report four projects commissioned: • TLA survey (March 2005) • Career expectations & motivations among undergraduates (June 2005) • Cohort study 2004-2009 (annual reports in June) • Occupations & Functions Map (with Skills for Health) (June 2005) Links with Schools of Pharmacy being strengthened through Academic Pharmacy Group. One-day seminars on student fitness to practise and developing professionalism through education planned for 2005. • Development of future academic workforce and research capacity being taken forward through the PhD Awards Scheme, which is currently supporting 8 students.
1.9	Develop and implement a policy development strategy to enable the Society to function as a modern regulator	31.12.2006	Preparatory work with directorates in progress.
1.10	Develop and publish a patient and public involvement strategy	30.9.2004	Work underway; RPSGB now member of regulators workgroup led by NMC
1.11	Fully implement recommendations contained in the practice research	31.12.2006	Projects commissioned in all three areas:

		Completion Date	Progress Report
	strategy by 31.12.2006 so as to ensure that decision-making by staff and the Council is evidence-based.		• Workforce (2 ongoing; 6 completed) • Education (2 ongoing; 1 completed) • Ethics (2 ongoing) • Responsive Grants (5 ongoing; 5 completed) Extended programme of dissemination with Council and senior staff.
1.12	Develop (by 31.01.2003) and implement (by 31.07.2010) a strategy to maximise the contribution of pharmacists to the implementation of the NHS Plans for England, Scotland and Wales.	31.07.2010	Major recruitment in Practice & Quality Improvement almost complete.
1.13	Develop a strategy to allow the Society to meet its chartered objectives and aspirations for the pharmaceutical sciences	31.12.2004	Strategy developed by Science Committee. Proposals to Council February 2005.
1.14	Conduct a policy review as part of the business planning process	31.3.2005	Phase 1 will be completed by end Q1 2005. Project now scheduled for completion Q2 2005.

Critical Success Factor 2			
The organisation must have the resources to deliver current and future operations			
2.1	To develop & implement a Management Information System to aid Directors & Senior managers in the effective running of the organisation	31.12.2004	Begun. MIS and capital budget for 2005 has addressed many of the Society's mission critical system as well as the establishment of a business recovery plan. 2005 Business plan will provide clearer details of Key Performance Indicators across the organisation that will form the basis of the system.
2.2	Ensure that standards of financial audit and probity are maintained through a process of internal and external management review. Implement material recommendations within six months of reporting.	Ongoing	External Audit put out to tender and current firm Horwath Clark Whitehill reappointed
2.3	Ensure that the Society has ready access to funds to deal with any reasonably predictable emergency / disaster that may arise.	Ongoing	Council decision on fees taken in August 2004 against background to build financial base and reduce reliance on publications.
2.4	A business planning process will be instilled in the organisation during 2004, in order to facilitate full implementation in the planning cycle for 2006-08, starting in Autumn 2004.	31.7.2004	Begun. 2005 Business Plan still to be presented to the Council. Work on mission, vision, values and objectives for 2006-08 begun by Council Q4 2004.
2.5	Have an efficient and effective budgeting process that ensures that all funded activities are necessary and represent value for money. Ensure that the annual budgets are consistent with the business plan.	31.12.2004	Detailed in depth budget prepared and approved for 2005 based on revised fee and reserves strategy.

	Critical Success Factor 3 **The organisation must have efficient and effective support functions**		
3.1	Develop the HR strategy to deliver the Society's change management programme. Fully implement	31.12.2004	Strategy in place. 2004 achievements include the establishment of the Employee Forum and the internal newsletter. 2005 training plan agreed and funding secured.
3.2	To formulate, plan and implementation of a fully integrated information management strategy for the Society, including a review of current systems and future requirements	30.6.2004	First draft of strategy detailing IM & T requirements to 2009 completed and awaiting approval.
3.3	To develop a cohesive security policy to ensure the integrity of the Society's existing systems and protect its intellectual property having due regard to Data Protection and Freedom of Information implications	30.6.2005	Security for all of the Society's networks have been upgraded and rigorous firewalls installed. All policies regarding use of data have been updated. Overall policy document being drafted. Data Protection registration renewed June 2004. Freedom of Information Publication Schedule added to Society website ready for 1 Jan 2005. Records Manager working with relevant groups on internal processes and procedures (on-going). Need for staff training identified.
3.4	Monitor the quality of customer service delivery across the organisation, including via the customer complaints procedure. Produce annual report by end of January 2005.	31.1.2005	In first full year to June 2004 there were 47 complaints (43 formal ones). Registration received the most. All resolved, with majority within the 10 working day target time. Feedback regularly given to Senior Managers and corrective actions identified where appropriate. Work being done now on internal customer service level agreements.
3.5	To develop, implement and test a Business continuity plan for identified key business processes	31.12.2004	Initial assessment of requirements being carried out. IT Disaster Recovery in place and subject to on-going review. Now extending scope to key business processes
3.6	To provide all geographical locations of the Society with an IT infrastructure	31.12.2004	Wide Area Network in place. Phase II now being rolled out -

	which guarantees every user a robust, secure, easy & fast access to the appropriate applications & information		will provide broadband connectivity to key remote workers.
3.7	Continue implementation of the recommendations of the Information Centre Review.	31.12.2005	Additional features of on-line library catalogue introduced such that demand for borrowing increased. Budget agreed for 2005 for investigating increased selective access to e-journals.
3.8	Review the provision of Society-wide information and advisory services	31.12.2004	Working Group established. First phase (shadowing and scope analysis) completed. Recommendations on a common framework by end of March 2005
3.9	Ensure current registered status of the Society's museum through maintenance of scheme's standards, working towards a new phase of registration from the middle of the year.	31.12.2004	Registered status retained under existing scheme. New phase of registration (now re-named Accreditation) launched nationally in November 2004. Museum is likely to have to comply by Q2 2006.
3.10	Continue to implement Access and Learning Policy for the Society's museum.	31.12.2004	Achieved to date, particularly through access measures to on-site displays. Full implementation of agreed measures reliant on reception refurbishment.
3.11	Complete the implementation of the new organisational structure.	31.3.2004	Achieved. Workforce planning will be undertaken during 2005 as part of ongoing structural review.

Critical Success Factor 4			
The organisation must be an effective influencer of the membership and public, other key stakeholders and opinion formers			
4.1	Implement a corporate communications strategy, aligning resources to external, internal and pharmacist communications. In particular for 2004, work across directorates to ensure that the corporate communications strategy is taken forward in management programmes. Further align public relations activity with policy implementation.	Ongoing	The first part of this objective was largely achieved in 2003.
4.2	Complete a review and relaunch the Society's website in line with principles of transparency and governance	31.12.2004	Entire site now being restructured to improve access and navigabililty, while still including the public focus pages launched March 2004 following CHRE's scoping study.
4.3	Develop and deliver the British Pharmaceutical Conference as the showcase for pharmacy science and practice.	30.9.2004	Achieved (annual objective).
4.4	Continue the work that started with *Shaping up for the future*, and support the development of the local RPSGB network in order that it can meet the needs of the profession.	Ongoing	Development continues to ensure network meets the modern day needs of the Society. January 2004 saw launch of 3-year *Future Branch* pilot project exploring new ways of working. In September 2004 a new CPD toolkit was launched to support CPD via the Branches. The Society has also appointed a network of trained facilitators to support this work.