ITEM 05.04/C/19

Council meeting 5 & 6 April 2005 OPEN BUSINESS

The Shipman Inquiry Fifth Report - "Safeguarding Patients: Lessons from the Past-Proposals for the Future"

Formulating the response of the RPSGB - A report of the Shipman Working Party

Purpose
To consider a presentation by the Chairman of the Society's Shipman Working Group.

Action required
The Working Party asks the Council to consider the update on progress on the Fifth Report which will be presented to the Council by Elizabeth Filkin.

1. Background

The Government's response to the Fourth Report was published on 9 December 2004. On the same day, the Shipman Inquiry Fifth Report - *Safeguarding Patients : Lessons from the Past-Proposals for the future* - was published.

At the time of publication of the Fifth Report of the Inquiry, the Department of Health welcomed the broad thrust of the report and made it clear that much detailed work would be needed to consider the individual recommendations in the Report, in consultation with interested parties. Shortly afterwards, it was announced that the GMC's plans for revalidation of doctors were to be placed on hold pending a review by the Chief Medical Officer, Professor Sir Liam Donaldson. The terms of reference and membership of the patient safety review group were then announced. The RPSGB, in responding to the Fifth Report, will also need to consider how it may contribute to the Review. A further Review to deal with the other healthcare professions has been announced.

The Society's Working Party, chaired by Elizabeth Filkin, has had two meetings to consider the RPSGB's response to the Fifth Report and now presents the outcome to Council for consideration. The CMO Review is outside the remit of the Working Party.

The following issues were identified for discussion at the Council Strategy Day and the views, which emerged, were captured.

- The Role of CHRE
- The Single portal for complaints
- The raising of concerns
- Independent adjudication
- The availability of information to employers and the public

2. Risk Implications

There could be considerable risk to the Society if it fails to put the public interest first and embrace changes, which give the public greater protection. The Society will wish to contribute to the change agenda and may lose credibility if this is not achieved.

3. Resource implications

There could be resource implications if changes are adopted. A detailed resource paper will be compiled after the Governments response to the Fifth Report is placed in the public domain.

4. Action required

The Working Party asks the Council to consider the update on progress on the Fifth Report which will be presented at the Council meeting by Elizabeth Filkin.

Mandie Lavin
Director Fitness to Practise & Legal Affairs

05.04/C/19

Report of the Shipman Working Group

to

The Council of The Royal Pharmaceutical Society of Great Britain

Regarding Recommendations made in The Fifth Report of The Shipman Inquiry

6th DRAFT-17/3/05

INTRODUCTION

The Royal Pharmaceutical Society of Great Britain ("RPSGB") welcomes the publication of the Fifth Report of the Shipman Inquiry chaired by Dame Janet Smith.

The RPSGB supports the patient centred and public protection approach, which underpins the Recommendations in the Report. Although many of the Recommendations are necessarily specific to the processes and policies of the General Medical Council, the Working Group considers that many of the Recommendations have implications for the regulation of the Healthcare professions as a whole.

In particular, the Working Group fully endorses Dame Janet Smith's view of the principles and aims that should underpin the fitness to practise procedures of a Healthcare regulator.

> "For regulatory authorities like the GMC, the fitness to practise procedures are the public face of that authority, and the most likely point of contact with the authority for ordinary members of the public. (Paragraph 15.77, page 465)".
>
> At paragraph 25.352 (page 1023) certain basic principles are set out which underpin the fitness to practise procedures if their purpose of safeguarding the public interest, protecting patients and maintaining public confidence is to be achieved. These are that the procedures must be:
>
> a) " (subject to the requirements of medical confidentiality) capable of scrutiny;
> b) transparent;
> c) thorough, careful and of high quality;
> d) properly resourced in every aspect; and
> e) performed by persons who are suitably qualified and properly trained to carry out the procedures."
>
> Further, "in the interests of fairness and of the proper maintenance of standards, procedures must be followed and decisions made in a consistent, transparent manner."

"Protecting patients from harm must be approached in two ways. There must be measures designed to identify those who are not performing to an acceptable standard and there must also be measures that will help doctors who are performing satisfactorily to improve with time and experience and not slide backwards. (Paragraph 1.15, page 70)."

One of the methods by which patients can be protected is by the thorough investigation of complaints made by and on behalf of patients and also of concerns expressed by fellow professionals. In Dame Janet Smith's view, much can be learnt from complaints and expressions of concern. Unsafe practitioners can be identified, and poor practice and systems failures uncovered. All professional people should accept the need for the investigation of complaints as the right of the patient, as a learning experience, and as an important means of uncovering substandard care and protecting patients.
(Paragraph 1.17, page 71).

In responding to the Recommendations set out in the Report, the Working Group has taken into account the "Principles of Good Regulation" established by the Better Regulation Task Force. In particular, the Working Group has had regard to questions of proportionality, when assessing the recommendation made, against the risk of injury to the public. The Working Group has also been alive to the dangers of "gold plating" existing standards, and the risk of creating multiple layers of regulation. The balance needs to be achieved, Lord Warner at the recent CHRE

Regulatory Conference, in his keynote address, described a model of regulation that was *"light touch and fit for purpose".*

Nevertheless, in relation to fitness to practise issues, the main thrust of the Fifth Report is the pressing need to establish clear standards, thresholds and criteria. These key objectives of accountability, consistency and transparency form part of the principles of good regulation and are fully endorsed by the Working Group.

In terms of consistency, the Working Group has had regard to two essential themes arising out of the Recommendations of the inquiry into the Bristol Royal Infirmary. These are the need to work together with other Healthcare regulators to safeguard the consumers of health care services, and the need for transparency, openness and public involvement. The Society has adopted the wider view of regulation

> "Regulation of health professionals is not just about disciplinary matters. It should be understood as encapsulating all of the systems which combine to assure the competence of healthcare professionals: education, registration, training, CPD and revalidation as well as disciplinary matters."

The Working Group is also keenly aware of the need to keep abreast of emerging best practice and learn from professionally led regulation. The Working Group is aware that many of the professions are undergoing a period of self-examination and will continue to monitor developments in other regulatory fields.

Finally, in responding to the report, the Working Group has had regard to its own practical experience of some of the Recommendations proposed. In several key respects, the RPSGB already has in place mechanisms recommended by Dame Janet Smith. These include a trained and dedicated Inspectorate which performs a crucial role in the investigation of complaints; a legally qualified chair of the Statutory Committee; and the use of the civil standard of proof in disciplinary proceedings.

The Working Group has responded to most of the Recommendations in the report, with the exceptions of Recommendations 30,32,61-75,77-78 and 82-94, as these relate to technical aspects of FTP procedures of the GMC which currently do not have a comparator within the procedures of the RPSGB.

Overall Comments

- Many of the Recommendations in the report are directed at doctors and the GMC, in responding to the report we have identified where similar application to pharmacy and pharmacists could pose difficulties. Where the Working Group has chosen not to comment on the implementation of the Recommendations in a pharmacy context, no presumption should be made that the application would be appropriate. The impact of any new proposals should be considered in the context of the relationship between doctors, pharmacists and other members of the multidisciplinary team. Any changes to the arrangements for doctors will have implications for other professions. Benefits to patients should be the reason for imposing any additional requirements.

The Shipman Inquiry Fifth report examined primary care. Secondary care and the arrangements in hospitals also need consideration. If new procedures are to be put in place the implications should be carefully considered, to assess the impact on the delivery of Healthcare.

- The Working Group is concerned that throughout the Report it is suggested that relevant provisions should be subject to primary legislation and rules. In the Working Group's view this is contrary to the aims of trying to achieve simple and flexible legislation and reserving operational matters to guidance documents.

- Since the Kennedy Report some Healthcare regulators have spent considerable effort on improving governance arrangements. It would be a retrograde step if the outcome of these Recommendations resulted in a fragmentation of current arrangements.

- The Working Group supports the view expressed in the *Government's response to the Fourth Report of the Shipman Inquiry, Safer Management of Controlled Drugs, Cm 6434,*:

  "The emphasis should be on supporting Healthcare professionals to do things right first time, rather than on catching them out and punishing them when they do things wrong. Better systems will not only help the vast majority of Healthcare professionals who want to provide the best possible care for patients, but will also deter the small minority who may be tempted to abuse their professional position."

- The RPSGB has put forward its initial views. If some of the changes outlined in this report were to be proposed to the RPSGB they would need detailed consideration by the membership and decision making structures, some might also need legislative change.

RECOMMENDATIONS AND RESPONSES

Handling Complaints and Concerns

The Lodging of Complaints

Dame Janet said:

1. "I endorse the provision contained in the draft National Health Service (Complaints) Regulations (the draft Complaints Regulations), whereby patients and their representatives who wish to make a complaint against a general practitioner (GP) will be permitted to choose whether to lodge that complaint with the GP practice concerned or with the local primary care trust (PCT). I recommend that the time limit for lodging a complaint be extended from six to twelve months. "
   (Chapter 7, paragraphs 27.15-27.16 and paragraph 27.18)

The Working Group supports this proposal as it enables the public to more readily resolve complaints at a local level. The new complaints system should provide a mechanism for liaison and co-operation between the GP and the PCT; GPs working in private practice should also be included. Notification to PCTs of the outcome of complaints to the RPSGB will be part of the RPSGB's complaints handling process. The application of these arrangements for pharmacy is set out in the Regulations and guidance supporting the new contract, which the RPSGB has recently reviewed. The RPSGB has made representations to the Department of Health in England about some key areas of concern, which are currently being addressed. As the new pharmacy contract comes into force on 1 April 2005, the RPSGB will need to monitor the arrangements for liaison and reporting from PCTs. The RPSGB is currently seeking an assurance from Government that the new arrangements will adequately safeguard the public and that the new Regulations have adequate reporting requirements to the regulator.

The extension of the time limits will allow patients who may be vulnerable or find difficulty in deciding whether to complain, more time. There are no time limits for complaints to the RPSGB, however passage of time often makes investigation a more complex and time consuming process with the potential risk of loss of evidence. People should be encouraged to complain as soon as possible after the concern has arisen.

2. Steps should be taken to improve the standard of complaints handling by GP practices. (Chapter 7 and paragraph 27.17)

The RPSGB is in the process of reviewing its own complaints handling processes. The extent to which pharmacists need to strengthen complaints handling should be built into the new contractual arrangements. As the new contract comes into force on 1 April 2005, amendments may be needed to the Regulations, which underpin the Contract; an opportunity for these amendments may exist in the 'Performer' Regulations, which will be in force from October 2005.

Primary Care Organisations (PCOs) have the opportunity to impose more stringent requirements and for these to be monitored at local level. Representatives of the RPSGB have recently participated in a working group organised by the Council for Healthcare Regulatory Excellence ("CHRE") which was aimed at defining principles and best practice in the handling of complaints by regulatory bodies. The RPSGB will need to examine carefully the Recommendations of this working group, once endorsed by the Council of the CHRE. It appears that CHRE may issue guidance in this area for all health professionals.

3. Draft regulation 30 of the draft Complaints Regulations, which would require GP practices to provide PCTs with limited information about complaints received by the practice at intervals to be specified by the PCT, should be amended. GP practices should be required to report all complaints to the PCT within, say, two working days of their receipt. The report should comprise the original letter of complaint or, if the complaint was made orally, the practice's record of the complaint. The PCT should log the complaint for clinical governance purposes and, if it considers that the complaint raises clinical governance issues, it should 'call in' the complaint for investigation. (Chapter 7 and paragraphs 27.19-27.23)

The Working Group supports this proposal. Difficulties may arise if multiple parties are involved in an investigation simultaneously. The Working Group considers that, in such cases, there needs to be clarity on which party will have responsibility for the investigation. Where the complaint is handled by the practice, there should be a responsibility to inform the PCT of the outcome of the investigation. There should also be a central log of all complaints received. Similar arrangements for pharmacy are envisaged in the operation of the new contract. The requirement for all complaints to be reported to the PCT could cause some practical difficulties.

In some circumstances it may be appropriate for the regulatory body to be involved at an early stage, especially if evidence emerges which may call into question the ability of the practitioner to remain in practise during the investigation taking place. The public may also directly approach the regulator with a complaint about a practitioner; it may be difficult to capture all employers of practitioners especially if they work across borders of countries in the UK. Guidance should be formulated for PCTs to assist them in making appropriate regulatory referrals. The guidance will need to be developed with all regulators and this work could be coordinated by CHRE.

The Investigation of Complaints

4. There should be statutory recognition of the importance of the proper investigation of complaints to the processes of clinical governance and of monitoring the quality of health care.
(Paragraph 27.26)

The Working Group supports this proposal. The inclusion of a statutory duty to investigate complaints is a key development in public protection. A statutory duty of collaboration on all inspectorates and agencies involved in Controlled Drug issues has been agreed as a result of the Fourth Report of the Inquiry.

The First Triage

5. On receipt by a PCT of a complaint about a GP, a 'triage' (the first triage) of the complaint should be conducted by a member of the PCTs staff who is appropriately trained and experienced and has access to relevant clinical advice. The object of the first triage should be to assess whether the complaint arises from a purely private grievance or raises clinical governance issues.
(Paragraphs 27.27-27.30)

It is at this early stage that complaints, which raise fitness to practise issues, should be passed to the regulatory bodies or, where the matters relate to potential criminal offences, to the police. Local guidance will be required to enable staff with responsibilities for dealing with complaints to identify cases of a more serious nature. Staff at an appropriate level of seniority need to be engaged in this process. A decision to refer to the police or the regulator should be taken in consultation with others. A consolidated first and second stage triage would resolve this difficulty. A definition of what constitutes a "clinical governance" issue will be required. A timeframe needs to be set for completion of the first triage stage. Some complaints may require more than one type of response, e.g. a referral to the police as well as a review of clinical governance arrangements.

'Private Grievance Complaints'

6. 'Private grievance complaints' should be dealt with by appropriately trained PCT staff. The objectives in dealing with such complaints should be the satisfaction of the patient and, where possible, restoration of the relationship of trust and confidence between doctor and patient.
(Paragraph 27.31)

If an individual practitioner is to be held to account for their conduct or practise it is important that patients have the confidence to pursue their complaint. The principle of fairness to the practitioner complained against should be protected. Patients should be provided with clear information about the complaints process. This duty should be imposed on all regulators and could be monitored by CHRE. The PCT should also ensure that the regulatory bodies are involved if it seems likely that proceedings for misconduct may follow or if there appears to be a fitness to practise issue. A definition of what constitutes a "private grievance" will be required. Many patients will choose to complain after completion of a course of treatment due to concerns about the impact of the complaint on their care. In pharmacy some complaints may be in a category of a consumer or product complaint, it is unclear how this would fit with new complaints categories.

The Second Triage

7. 'Clinical governance complaints' should be investigated with the dual objectives of patient protection and satisfaction and of fairness to doctors. They should be referred for a further triage (the second triage) to a small group comprising two or three people - for example, the Medical Director or Clinical Governance Lead, a senior non-medical officer of the PCT and a lay member of the PCT Board. The object of the second triage should be to decide whether the complaint is to be investigated by or on behalf of the PCT or whether it should instead be referred to some other body, such as the police, the General Medical Council (GMC) or the National Clinical Assessment Authority (NCAA).
(Paragraphs 27.32-27.33)

The Working Group is concerned about the potential for dual investigation and that the primary sources of evidence may be undermined if the process is not clear to those operating it and subject to it. The second triage model may also result in delay in responding to complaints thereby exposing other patients to potential harm. Definitions of clinical governance complaints and fitness to practise complaints would help. In the future, the RPSGB will need to clarify which complaints are dealt with in each setting, to prevent inconsistent sanctions. This could be a source of protracted legal cases and undermines the objectives of CHRE. Timeframes for each stage need to be agreed. The possibility of this occurring will be reduced if Triage1 & 2 are integrated.

The Investigation of 'Clinical Governance Complaints'

8. The investigation of 'clinical governance complaints' should not be undertaken by PCT staff. Instead, groups of PCTs should set up joint teams of investigators, who should be properly trained in the techniques of investigation and should adopt an objective and analytical approach, keeping their minds open to all possibilities.
(Paragraphs 27.35-27.49)

The Working Group supports appropriate investigation and enquiry at local level. Much will depend on the quality of the training, support and resources allocated to the investigation teams and whether they are sufficiently impartial and independent of the practitioners they may be investigating. The Health Service Commissioner has repeatedly been critical of local systems of complaints handling. Adequate resourcing of the investigation process is essential. The RPSGB in its regulatory process, often relies upon evidence and data collated at local level by its Inspectorate. The complaints process, as set out in these Recommendations would need some careful consideration in the context of pharmacy. The role of Superintendent pharmacists should be recognised in any new process for dealing with complaints. The RPSGB has jurisdiction over corporate bodies who are registered as well as the ability to take action against individuals in those bodies. Some clinical governance complaints arise because those corporate bodies may not have effectively assessed risks. Any new arrangements would need to be able to identify and address these issues with speed to prevent risk to the public.

9. All 'clinical governance complaints' (save those which do not involve serious issues of patient safety and where the underlying facts giving rise to the complaint are clear and undisputed) should be referred to the inter-PCT investigation team. The objects of the investigation should be to reach a conclusion as to what happened and to set out the evidence and conclusions in a report, which should go to the PCT with responsibility for the doctor. If the investigators are unable to reach a conclusion about what happened because there is an unresolved conflict of evidence, they should say so in their report.
(Paragraph 27.50)

There will need to be a clear understanding of the rights and responsibilities of the practitioner during the investigation process. These should be set out in criteria or rules. The principles of natural justice will require that, as a minimum, the practitioner should receive a copy of the report and be given opportunities to correct matters of fact and to comment on the findings. They should also be entitled to representation during the investigation process. Questions of admissibility of evidence should be resolved in the event that a practitioner is eventually referred to the Healthcare regulatory body, and that body seeks to use evidence gathered during the PCTs investigation.

Acting on the Investigation Report

10. On receipt of the investigation report, the PCT group, which carried out the second triage, should consider what action to take. It might be appropriate to refer the matter to another body, such as the GMC or the NCAA. Alternatively, it might be appropriate for the PCT to take action itself, e.g. by invoking its list management powers. If the report of the investigation team is inconclusive, because of a conflict of evidence, the case should be referred to the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission), under a power, which should be included in the amended draft Complaints Regulations when implemented.
(Paragraphs 27.52-27.54)

The Working Group is concerned that delay may ensue in referring the matter to the regulatory body. It may be that the regulator is the only authority with the power to remove the licence to practise pending final outcome of the case. Although an employer may suspend from employment a practitioner may secure employment elsewhere which could expose the public to risk. This particularly applies to locums, who may seek employment in another part of the country. Effective mechanisms for communication will need to be established between the PCT, the regulator and employers of locums.

There needs to be common standards for reports, data and information at PCT level and arrangements should be in place for preserving information in the event of the amalgamation of PCTs. There are also risks related to cross border movement of professionals who may wish to avoid action being taken against them. Reporting arrangements with Scotland and Wales and other countries will need to be robust. A timeframe for action needs to be defined at this stage in the complaints procedure. The Recommendations in paras 1-10, relate to primary care, the arrangements for complaints handling in hospital needs to be considered in the context of any changes to complaints handling in primary care settings. The differences between complaints, "serious untoward incidents" and "near misses" may be more pronounced in a hospital setting. Data will need to be monitored across the NHS in all countries to achieve a range of improvements.

The Effect of Concurrent Proceedings

11. Neither an intention on the part of the complainant to take legal proceedings, nor the fact that such proceedings have begun, should be a bar to the investigation by a NHS body of a complaint. In circumstances where the NHS body is taking disciplinary proceedings relating to the subject matter of the complaint against the person complained of, a complainant should be entitled to see the substance of the report of the investigation on which the disciplinary proceedings are to be based and should not merely be informed that the investigation of his/her complaint is to be deferred or discontinued.

The Working Group supports this proposal. Pending civil proceedings do not preclude action by regulatory bodies. Reasons should always be given for deferral or discontinuation of a complaint.

12. In some circumstances, it may be necessary for a NHS body to defer or discontinue its own investigation of a complaint if the matter is being investigated by the police, a regulatory body, a statutory inquiry or some other process. However, a NHS body should never lose sight of its duty to find out what has happened and to take whatever action is necessary for the protection of the patients of the doctor concerned. It should also provide such information to the complainant as is consistent with the need, if any, for confidentiality in the public interest. The relevant provisions of the draft Complaints Regulations should be amended to reflect these principles.
(Paragraphs 27.55-27.61)

The RPSGB always collaborates with the police forces involved and decides whether, in the circumstances and in the public interest, an investigation should be stayed. The Working Group supports the recommendation that all NHS bodies should adopt this approach.

The Role of the Healthcare Commission

13. The draft Complaints Regulations, when implemented, should include a power enabling PCTs to refer a complaint to the Healthcare Commission for investigation at any point during the first stage of the complaints procedures. Cases raising difficult or complex issues or involving issues relating to both primary and secondary care might be referred to the Healthcare Commission for investigation at the time of the second triage, or later if the investigation by the inter-PCT investigation team raises more complex issues than were initially apparent. Referral to the Healthcare Commission should also take place in cases where an inter-PCT investigation team has found that it cannot reach a conclusion because there remain unresolved disputes of fact. The purpose of the referral would be for the Healthcare Commission to carry out any further necessary investigation and, if appropriate, to set up a panel to hear oral evidence about the facts in dispute and to decide where the truth lay.
(Paragraphs 27.52 and 27.62-27.71)

The Working Group considers that any body charged with resolving factual disputes should adopt sufficiently formal and recorded processes to ensure effective and accurate communication between regulatory bodies. Onward referral of a complaint must always be an option.

The ability of PCTs to investigate complaints, which involve more than one PCT or Healthcare provider, will be constrained and the allocation of cases crossing boundaries should be defined and regulators should be involved where appropriate.

Referral to the Healthcare Commission may result in a practitioner evading accountability. The involvement of the Healthcare Commission could represent a more attractive option for the Healthcare professional as it would establish another forum in which a hearing could take place. It is not clear whether the evidence before the panel would be heard in public.

Any proceedings or hearings initiated by the Healthcare Commission must be formally conducted and an accurate record of events captured to enable regulatory action where necessary. The different arrangements in Scotland and Wales will be significant,

especially where people have practised across borders. The liaison arrangements and information sharing between the different agencies should be agreed.

Complaints in the Private Sector

14. Complaints procedures in the private sector should be aligned as closely as possible with those in the NHS, so that a complainant who does not receive a satisfactory response to his/her complaint from a private sector body can proceed to a second stage of the complaints procedures to be conducted by the Healthcare Commission. (Paragraphs 27.72-27.74)

The Working Group supports this proposal and would like to see unified public access to a complaints system and a standard system of handling complaints across private and NHS sectors.

Handling Concerns

15. Concerns expressed about a GP by someone other than a patient or patient's representative (e.g. by a fellow Healthcare professional) should be dealt with in the same way as patient complaints. Such concerns should be investigated (where necessary) by the inter-PCT investigation team or, in a case raising difficult or complex issues, by the Healthcare Commission. Consideration should be given to amending the relevant provisions of the draft Complaints Regulations to permit the Healthcare Commission to accept and investigate concerns referred to it by a PCT or other Healthcare body without the need for a reference from the Secretary of State for Health. (Paragraphs 27.77-27.78)

The Working Group supports this recommendation and where a regulatory body receives a complaint about a practitioner, that regulator should not be inhibited from undertaking an investigation as soon as possible. A duty of collaboration with clear communication pathways should be established to ensure that all relevant parties know about the complaint and that there is an agreed procedure between them. The requirement for a referral from the Secretary of State seems onerous and unnecessary. The RPSGB has recently strengthened the procedures for pharmacists to make concerns known about pharmacy and other Healthcare professionals. . Guidance on raising concerns will be issued to the profession shortly. The outcome of a complaint should not be dependent on the route through the complaints process. Currently PCTs are able to refer matters to all Healthcare regulators, however, the regulator is under a duty to deal with all complaints it receives, rather than referring matters to PCTs for local resolution.

Standards

16. Objective standards, by reference to which complaints can be judged, should be established as a matter of urgency. These standards should be applied by those making the decision whether to uphold or reject a complaint and by PCTs and other NHS bodies when deciding what action to take in respect of a doctor against whom a complaint has been upheld. When established, the standards by reference to which complaints are dealt with must fit together with the threshold by reference to which the GMC will accept and act upon allegations, so as to form a comprehensive framework. (Paragraphs 27.79-27.82)

The Working Group supports this proposal. The RPSGB has defined criteria for referring cases for adjudication and indicative sanctions guidance. It should be emphasised that guidance only provides a framework for decision-making in individual cases. Individual circumstances must always be considered. It does not provide a prescriptive set of rules, or seek to fetter the discretion of the decision maker. The training of decision makers is essential to ensure consistency of approach. These quality processes could be introduced across all Healthcare regulators. The focus of standards must be to elicit lessons to be learnt and remedial steps to be taken. The experience of dealing with complaints must ensure feedback to the profession and the enhancement of professional practice.

Support for Complainants

The 'Single Portal'

17. In order to ensure that, so far as possible, complaints and concerns about health care reach the appropriate destinations, there should be a 'single portal' by which complaints or concerns can be directed or redirected to the appropriate quarter. This service should also provide information about the various advice services available to persons who are considering whether and/or how to complain or raise a concern, including advice services for persons who are concerned about the legal implications of raising a concern. (Chapter 11 and paragraphs 27.83-27.88)

The Working Group supports this proposal. A single portal model will need to ensure that patient choice is maintained, as many patients and members of the public have perceptions about the effectiveness of some complaint routes compared with others. The scope of the single portal model should be defined and decisions taken about whether it acts as a signposting and information service or adopts an advisory role. The interface between the single portal and other bodies involved in dealing with complaints from the public should be clearly defined, e.g. PALS, ICAS, Citizens Advice etc. Every opportunity must be given to resolve a complaint at local level. A single portal approach would allow trend analysis and greater public interface. The ability of the RPSGB to respond to a corporate complaint as well as a complaint about an individual will need to inform the setting up of the single portal.

The hierarchy of the NHS can make it difficult for junior staff or those employed directly by GPs to express concerns. These barriers must be overcome. An important element of the future arrangements will be the ability to learn from complaints and to take remedial steps to prevent recurrence and manage risk. Additional incentives are required to encourage action as a result of the complaints received. There should be robust monitoring to ensure that action has been taken on issues identified through the investigation of complaints. Where a complaint identifies an immediate and serious risk to other patients a fast-track system must exist to enable prompt preventative action to be taken in the public interest. Such action should still be taken even if the complainant decides not to pursue the complaint.

The New Arrangements

18. About two years after the Complaints Regulations come into force in their entirety, an independent review should be commissioned into the operation of the new arrangements for advising and supporting patients who wish to make a complaint. Any deficiencies identified by that review should be corrected. (Chapter 7 and paragraphs 27.89-27.90)

The Working Group supports this proposal

Disciplinary Procedures

19. The powers of PCTs should be extended so as to enable them to issue warnings to GPs and to impose financial penalties on GPs in respect of misconduct, deficient professional performance or deficient clinical practice which falls below the thresholds for referral to the GMC or exercise of the PCT's list management powers.
(Chapter 7 and paragraphs 27.91-27.102)

The Working Group is concerned about this proposal. This is because PCTs already have powers which could be mobilised in operating the contractual arrangements for GPs. GPs may hold legitimate views about treatment options for a patient, especially when considering NICE guidelines, any complaints system will need to have cognisance of this.

The Working Group considers that there should be a clear definition of the threshold for referral to the RPSGB and examples of what type of matter could be dealt with in this way. Safeguards would need to be imposed to ensure that a collective history of an individual practitioner's conduct was available for the regulator in the event of a more serious complaint emerging. Separate representations have been made to the Department of Health in England about the arrangements for pharmacists under the new contract and a response is currently awaited.

The Use of Prescribing Information as a Clinical Governance Tool

20. Steps should be taken to ensure that every prescription generated by a GP could be accurately attributed to an individual doctor. Only then will the data resulting from the monitoring of prescribing information constitute a reliable clinical governance tool.

The Working Group supports this proposal. The strengthening of the audit trail as recommended in *the Fourth Report of the Shipman Inquiry, The Regulation of Controlled Drugs in the Community,* should ensure greater safeguards. Prescribing information alone is not a particularly useful clinical governance tool unless it is linked to the patients' clinical condition. Prescribing and medication reviews may pose problems until the protocols are established to determine responsibility. IT solutions may assist in achieving this goal. Prescribing data should also be analysed in the same way for the private sector.

21. Regular monitoring of GPs' prescribing should be undertaken by PCTs. Special attention should be paid to the prescribing of controlled drugs. Doctors who have had a problem of drug misuse in the past or who are suspected of having a current problem should be subjected to particularly close scrutiny. When a restriction is placed on a doctor's prescribing powers, this information must be made available (preferably by electronic means) to those who need to know, especially pharmacists.
(Fourth Report, Chapters 5 and 12 of this Report and paragraphs 27.103-27.104)

The Working Group supports this proposal. When implemented this will enhance the ability of the pharmacist to identify and report problems more effectively. The RPSGB's *Code of Ethics* requires pharmacists to report concerns of this nature. When prescribing

arrangements change and pharmacists have powers to act as independent prescribers, monitoring arrangements should also be extended.

The Use of Mortality Data as a Clinical Governance Tool

22. The Department of Health (DoH) must take the lead in developing a national system for monitoring GP patient mortality rates. The system should be supported by a well-organised, consistent and objective means of investigating those cases where a GP's patient mortality rates signal as being above the norm.
(Chapter 14 and paragraphs 27.105-27.107)

The Working Group supports the creation of such a system. The signalling should take account of local demographic profiles, special local factors and public health indicators. The Working Group welcomes robust mortality data being more widely available.

23. Every GP practice should keep a death register in which particulars of the deaths of patients of the practice should be recorded for use in audit and for other purposes.
(Paragraph 27.108)

The Working Group is concerned about this recommendation. The maintenance of a register is only of value if there is audit and oversight of these arrangements. The scope of the registration information needs to be clearly defined and consulted on. The supporting evaluation and audit framework also needs to be considered and the added value of this requirement should be demonstrated. The Working Group questions whether the register should be accessible to the public, if so the public needs to be informed both of the existence of the register, and of their rights of access to it. Concerns about confidentiality and circumstances where the public will need help in interpreting the information in the register will need to be overcome. There is no clear parallel in pharmacy.

Appraisal in the Context of Clinical Governance

25. The purpose of GP appraisal must be made clear. A decision must be taken as to whether it is intended to be a purely formative (i.e. educational) process or whether it is intended to serve several purposes: part formative, part summative (i.e. pass/fail) and/or part performance management.
26. If appraisal is intended to be a clinical governance tool, it must be 'toughened up'. If that is to be done, the following steps will be necessary. Appraisers should be more thoroughly trained and should be accredited following some form of test or assessment. Appraisers should be trained to evaluate the appraisee's fitness to practise. GPs should be appraised by GPs from another PCT. Standards should be specified, by which a GP 'successfully completes' or 'fails' the appraisal. All appraisals should be based on a nationally agreed core of verifiable information supplied by the PCT to both the appraiser and the appraisee.
(Chapter 12 and paragraphs 27.110-27.116)

A clear and consistent definition of the term "appraisal" should be developed. The term appraisal is used in a developmental way in the context of staff appraisal (including NHS staff) whereas GP appraisal has explicit links to revalidation. In pharmacy, the term appraisal is used in the context of staff appraisal and is common place especially in larger companies. The RPSGB should contribute to the Review being conducted by The Chief Medical Officer, Professor Sir Liam Donaldson, which will take this recommendation forward.

The Use by Primary Care Trusts of Their List Management Powers

27. The Family Health Services Appeal Authority (Special Health Authority) or its proposed successor, the NHS Litigation Authority, should collect and analyse information relating to the use made by PCTs of their list management powers. Such analysis would assist the DoH in providing guidance to PCTs about the types of circumstance in which they might properly use their powers.
(Chapter 5 and paragraph 27.117)

The Working Group has received numerous calls asking for advice about the operation of lists at PCT level and how they may give an assurance of quality. An evaluation of the effectiveness of the List Management processes would inform the regulatory bodies' registration processes. Information collected must be of practical value. A method should be developed to identify poor performers, to enable swift action to be taken by employers, PCTs and regulators. The RPSGB has issued guidance on poor performance of pharmacists, for use by PCTs.

Practice Accreditation Schemes

28. The Government should consider the feasibility of providing a financial incentive for the achievement of GP practice accreditation by means of an accreditation scheme similar to that operated by the Royal College of General Practitioners in Scotland.
(Chapter 5 and paragraph 27.118)

The Working Group supports this proposal. Financial incentives should also be considered for other Healthcare professionals.

Support for Single-Handed and Small Practices

29. The policy of the DoH and of PCTs should be to focus on the resolution of the problems inherent in single-handed and small practices. More support and encouragement should be given to GPs running single-handed and small practices. In return, more should be expected of such GPs in terms of group activity and mutual supervision. The DoH should take responsibility for these initiatives.
(Chapters 9 and 13 and paragraphs 27.119-27.120)

It is not accepted that single-handed practice is, in itself, inherently problematic. Many pharmacists operate in a single handed manner. The RPSGB is keen to play its part in ensuring appropriate local professional networks through its branches and regional structures and to share good practice across the countries of GB. The RPSGB would be happy to work collaboratively with the DoH on these initiatives.

The Recruitment and Appointment of General Practitioners

31. A standard reference form should be developed for use in connection with appointments to GP practices. PCTs should insist that a reference is obtained from the doctor's previous employer or PCT. In the case of a PCT, the Medical Director or Clinical Governance Lead should sign the reference.
(Paragraph 27.129)

The Working Group supports this proposal as it provides a more reliable reference source. Any mechanism for checking references needs to take into account the use of locums, and the issues of devolution and workforce mobility.

General Practitioners' Personal Files

33. PCTs should keep a separate file for each individual GP on their lists. That file should hold all material relating to the doctor, which could have any possible relevance to clinical governance. If a doctor moves from one PCT to another, the file (or a copy of it) should be sent to the new PCT. It might be helpful if the DoH were to establish national criteria for the content of the files to be kept by PCTs.
(Paragraph 27.138)

The Working Group supports this proposal, and considers that a similar scheme might usefully be extended to other health care professionals. There would be some practical problems with implementation of this recommendation in pharmacy, because of the large numbers of locums. A data set should be established which would apply across all health professionals.

The Raising of Concerns

Facilitating the Raising of Concerns by Staff in General Practice

34. Every GP practice should have a written policy, setting out the procedure to be followed by a member of the practice staff who wishes to raise concerns, in particular concerns about the clinical practice or conduct of a Healthcare professional within the practice. Staff should be encouraged to bring forward any concerns they may have openly, routinely and without fear of criticism. In the event that a member of the staff of a GP practice feels unable to raise his/her concern within the practice, s/he should be able to approach a person designated by the PCT for the purpose. The contact details of that person should appear in the written policy. The designated person should make him/herself known to all practice staff working in the PCT area. PCTs should ensure, through training, that practice staff understand the importance of reporting concerns and know how to do so.

35. The written policy should contain details of organisations from which staff can obtain free independent advice. If the 'single portal' is created, in whatever form, the policy should set out contact details of that also.
(Chapter 9 and paragraph 27.139)

The Working Group supports this proposal. It is very difficult for staff employed by GP's to raise concerns about practice arrangements. Provision should be made at PCT level for reporting such concerns and the GMC reporting requirement will need to be factored in. Compatible arrangements could be made for pharmacy.

Facilitating the Raising of Concerns by Staff in the Private Sector

36. The Healthcare Commission should require all private Healthcare organisations to have a clear written policy for the raising of concerns. Steps should be taken to foster in the private sector the same culture of openness that is being encouraged in the NHS.
(Chapter 11 and paragraph 27.140)

The Working Group supports this proposal.

Support at a National Level for Those Who Wish to Raise Concerns about Health Care

37. Consideration should be given to amending the Public Interest Disclosure Act 1998 in order to give greater protection to persons disclosing information, the disclosure of which is in the public interest.

38. Written policies setting out procedures for raising concerns in the Healthcare sector should be capable of being used in relation to persons who do not share a common employment.

39. There should be some national provision (probably a telephone helpline) to enable any person, whether working within health care or not, to obtain advice about the best way to raise a concern about a Healthcare matter and about the legal implications of doing so. It might be possible to link this helpline with the 'single portal' previously referred to. (Chapter 11 and paragraph 27.141)

The Working Group supports these proposals. These changes should be complemented by a public awareness campaign to inform the public about the information and resources available to them. The RPSGB has been involved in a range of public awareness campaigns, e.g. *Ask about Medicines Week.* Any help-line should extend across the NHS and private Healthcare sectors.

The Availability of Information about Doctors

Information Available to Employers and Primary Care Organisations

40. There should be a central database containing information about every doctor working in the UK. This should be accessible to the officers of NHS bodies and to accredited employers in the private sector, as well as to other bodies with a legitimate interest, such as the Healthcare Commission, the GMC, the NCAA and the DoH.

The Working Group supports this proposal and is keen to ensure that similar information is available about pharmacists and pharmacy technicians; this proposal may involve significant investment in Information Technology. The relationship between the current "register" and any new database will need to be clarified. There is a danger of multiple database development with incomplete information being held.

41. The database would contain, or provide links to, information held by the GMC, the Criminal Records Bureau (CRB) and the NHS Counter Fraud and Security Management Service. It would also contain records of disciplinary action by employers, details of list management action by PCTs, any adverse reports following the investigation of a complaint, any adverse findings by a Healthcare Commission panel or by the Healthcare Ombudsman and details of any findings of negligence in a clinical negligence action and settlement of a clinical negligence claim above a pre-determined level of damages. It should also contain certain other information. Doctors would be able to access their own entries to check the accuracy of the information held.

42. Private sector employers should be required to provide relevant information as a condition of registration with the Healthcare Commission. Deputising services should also be required to provide information and should be able to access the database through the relevant PCT.

43. Information about unsubstantiated allegations or concerns should not be included on the central database. Instead, the doctor's entry on the database should be flagged to indicate that confidential information is held by a named body. Access to that information would depend on who was asking for it and for what purpose and would have to be determined at a high level.
(Paragraphs 27.142-27.149)

Further Information to Be Provided to Primary Care Organisations

44. GPs should be required to disclose to the relevant PCO the fact that a clinical negligence claim has been brought against them, the gist of the allegation made and, when the time comes, the outcome of the claim. A failure by a doctor to make full declarations to a PCO as required by the National Health Service (Performers Lists) Regulations 2004 should be regarded as misconduct of sufficient gravity to warrant referral to the GMC.
(Paragraphs 27.150-27.154)

The Working Group supports these proposals, its current arrangements, which compel disclosure, are being reviewed. More robust registration procedures have already been implemented by the RPSGB, with requirements for disclosure of convictions, cautions and findings of other regulatory bodies as well as any proceedings that may be pending. There are concerns about the use of information relating to unproven allegations, however with appropriate safeguards, a workable solution could be devised. The declaration requirements for pharmacists are currently under consideration.

Information Available to the Public and Patients

45. The GMC should adopt a policy of tiered disclosure to apply to all persons seeking information about a doctor.

46. The first tier should relate to information which is relevant to the doctor's current registration status, together with certain information about his/her past fitness to practise (FTP) history. First-tier information should be posted on the GMC website and should also be disclosed to anyone who requests information about the doctor's registration. The periods of time for which information should remain at the first tier should depend on the nature of the information. When the relevant period expires, the information should be removed from the website. It should be replaced by a note indicating that there is further information which can be obtained by telephoning the GMC. That information should then be available at the second tier.

47. Disclosure of information at the second tier should be made to any person who makes a request about a doctor's FTP history. All information, which has at any time been in the public domain, should remain available to enquirers at the second tier for as long as the doctor remains on the register.
(Paragraphs 27.155-27.197)

The report lays great emphasis on the need to provide access to information for the patient. At paragraph 27.177 (page 1141) it is stated "All information about a doctor's registration is in the public domain and it should be made readily available. For those who wish to access the website, the full information including any history of erasure, suspension, conditions and warnings should be shown. For those who prefer to telephone, the full information should be volunteered, without the enquirer having to ask specific questions."

The report recommends, at paragraph 27.185-27.197 (pages 1143/1145) that the GMC should adopt a policy of tiered disclosure.

The Working Group supports these proposals, subject to appropriate safeguards to ensure confidentiality of a practitioner's medical history. Disclosure arrangements are currently under review. Current IT limitations may cause some delay to planned implementation of new disclosure arrangements.

The system of governance within pharmacy through the position of Superintendents is a unique feature. Superintendent pharmacists have responsibility for standards of pharmacy practice and are therefore key to clinical governance, any complaint made could result in a finding against the superintendent. By virtue of the position as superintendent, they may accumulate a substantial fitness to practise history, due to the scope of their responsibilities. In such cases special consideration will need to be given to disclosure of previous history, as there could be potential for injustice.

Information About a Doctor Which Should Be Given to Patients of a Practice

48. In all cases where a GP's registration is subject to conditions, or where s/he has resumed practice after a period of suspension or erasure, patients of any practice in which the GP works should be told. A letter of explanation which has been approved by the PCT should be sent to all patients. Patients should have the opportunity to refuse to be treated by a doctor who is subject to conditions or who has previously been subject to an order for suspension or erasure.
(Paragraphs 27.198-27.199)

The report considers that, in some situations, there is a positive duty to impart information to patients of a practice (paragraph 27.198, page 1145). This would include patients who are to be operated on by a doctor subject to conditions. In such circumstances, the patient is entitled to be informed at an early stage of arrangements for supervision of the operation.

While the Working Group recognises the need for patients to be as fully informed as possible, the public interest has to be the determining factor. The GP practice should assume responsibility for the supervision and rehabilitation of any doctor returning to practice or working within a restriction on practice. There may be practical difficulties in enforcing this obligation, particularly in relation to locums. In the case of a pharmacist it would be very difficult to convey this information in a community pharmacy context. There should be monitoring of the new arrangements to evaluate their effectiveness. The Working Group would wish the RPSGB to undertake a consultation with the membership on a recommendation of this nature, to elicit some of the practical problems, before submitting more detailed views.

The General Medical Council

The General Medical Council's Role in the Wider Regulatory Framework

49. The GMC should ensure that its publications contain accurate and readily understandable guidance as to the types of case that do and do not fall within the remit of its FTP procedures.
(Chapters 18 and 25 and paragraph 27.201-27.202)

The Working Group supports this proposal and the RPSGB should work with the other Healthcare regulators to achieve this. This area of work could be led by CHRE.

Separation of Functions

50. There must be complete separation of the GMC's casework and governance functions at the investigation stage of the new FTP procedures and this must be reflected in the Rules.
(Chapter 25 and paragraph 27.205)

51. The adjudication stage of the FTP procedures must be undertaken by a body independent of the GMC. This body should appoint and train lay and medically qualified panellists and take on the task of appointing case managers, legal assessors (if they are still necessary) and any necessary specialist advisers. It should also provide administrative support for hearings.
(Chapter 25 and paragraphs 27.206-27.209)

52. Consideration should be given to appointing a body of full-time, or nearly full-time, panellists who could sit on the FTP panels of all the Healthcare regulatory bodies.
(Chapter 25 and paragraph 27.207)

The Working Group recognises the need for separation of the functions of investigation and adjudication. The current arrangements for the Statutory Committee, which adjudicates on cases of misconduct in pharmacy, ensure that it is independent. To completely separate the Statutory Committees responsibilities would not pose any practical difficulties for the RPSGB. If any further changes are proposed, the RPSGB should review the Infringements Committee, which is responsible for investigation of complaints. The Working Group has some concerns about the recruitment of full time panellists, as this would fundamentally change the mindset of the Statutory Committee. It would become a professional full time tribunal as opposed to one which represented the public. This is an area on which the RPSGB would wish to consult the membership to elicit views. Council decisions and legislative change would also be required.

The Statutory Tests

53. The GMC should adopt clear, objective tests to be applied by decision-makers at the investigation and adjudication stages of the FTP procedures. The tests that I recommend are set out at paragraphs 25.63 and 25.67-25.68. The tests should be incorporated into the Medical Act 1983 and/or the Rules. The draft Guidance for FTP panellists should be amended so that it is consistent with the provisions of Section 35D of the Medical Act 1983 and rule 17(2)(k) of the General Medical Council (Fitness to Practise) Rules Order of Council 2004 (the November 2004 Rules).
(Chapter 25 and paragraphs 27.211 and 27.261)

The Working Group supports a statutory test. Dame Janet Smith considers that the "realistic prospect test" is "obviously set inappropriately high for a preliminary test." Paragraph 136, page 39). The realistic prospect test is the test used by the RPSGB's Infringements Committee, however if this test were to be replaced this could be implemented speedily and supported by training. A similar test should apply across Healthcare regulators as many cases may involve multiple professionals and they should all be judged by a similar standard to ensure the administration of justice and fairness to the individual.

A New Route to Impairment of Fitness to Practise

54. The Medical Act 1983 should be amended to add a further route by which there might be a finding of impairment of fitness to practise, namely 'deficient clinical practice'. (Chapter 25 and paragraph 27.212)

The report recommends (at paragraph 25.71, page 954) that a new category of deficient clinical practice should be added. This is to capture the isolated or nearly isolated serious error committed negligently. The Working Group supports this recommendation.

Standards, Criteria and Thresholds

55. Urgent steps should be taken to develop standards, criteria and thresholds so that decision-makers will be able to reach reasonably consistent decisions at both the investigation and the adjudication stages of the FTP procedures and on restoration applications.
(Chapters 17-25 and paragraphs 27.213-27.229)

56. The Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE)) should be invited to set up a panel of professional and lay people (similar in nature to the Sentencing Advisory Panel) which should assist in the process of developing the necessary standards, criteria and thresholds.
(Chapter 21 and paragraph 27.230)

57. Steps should be taken to ensure that FTP panels determining cases in which issues of deficient professional performance arise apply a standard which is no lower than that set for admission to general practice.
(Chapter 24 and paragraph 27.231)

The Working Group would welcome CHRE involvement especially in a sentencing advisory capacity. In due course, this should reduce the number of cases which need to be referred to the High Court for scrutiny and assist the public, the profession and the regulator in identifying cases which are likely to have similar outcomes. This would also provide greater consistency across the professions.

Clear standards should be established in this area, this will allow definitions of serious offences to be judged against the particular professional responsibilities.

The Investigation Stage

The Preliminary Sift: the Test for Jurisdiction

58. Rule 4 of the November 2004 Rules, which sets out the test to be applied by the Registrar on receipt of an allegation, should be amended to give greater clarity. The test that I recommend is set out at paragraph 25.115.
(Chapter 25 and paragraph 27.232)

Preliminary Discussions with and Disclosure to Employers and Primary Care Organisations

59. The November 2004 Rules should be amended to make formal provision for the GMC routinely to communicate with employers and with primary care organisations (PCOs)

before deciding what action should be taken in response to an allegation and giving the GMC power to require from the doctor the necessary details to enable it to make such communication. Communication should take place in all cases other than in the case of an allegation which is so serious that it obviously requires further investigation or in the case of an allegation which is plainly outside the GMC's remit.
(Chapters 18 and 25 and paragraph 27.234)

The Working Group supports this approach and the RPSGB will review arrangements when the Section 60 Order is in the public domain.

The Treatment of Convictions

60. Where a doctor has committed a criminal offence in respect of which a court has imposed a conditional discharge, that offence should be dealt with by the GMC in the same way as if it were a criminal conviction.
(Chapters 18 and 25 and paragraph 27.232)

The Working Group supports this approach.

The Adjudication Stage

Investigation

76. There should be an explicit power in the Rules to allow the GMC to undertake any further investigations it considers necessary after a case has been referred to a FTP panel and before the panel hearing.
(Chapter 25 and paragraph 27.250)

The Working Group supports this recommendation.

If changes are to be adopted across the Healthcare regulators, early discussions will need to take place to develop these proposals. In addition, the corporate jurisdiction exercised by the RPSGB and some other health care regulators should be retained.

Legally Qualified Chairmen

79. In the event that the GMC retains control of the adjudication stage, it should appoint a number of legally qualified chairmen who should, as an experiment or pilot, preside over the more complex FTP panel hearings. The results of the pilot scheme should be scrutinised to see whether there are benefits, whether in terms of the improved conduct of hearings, more consistent outcomes, improved reasons and/or fewer appeals.
(Chapter 25 and paragraph 27.254)

The Working Group supports this recommendation. The RPSGB's Statutory Committee has a legally qualified chairman and this remains Council policy.

Evidence

80. As part of their training, FTP panellists should be advised about their discretion to admit

hearsay evidence and other forms of evidence not admissible in a criminal trial. Panellists should also be advised, during training, that it is entirely appropriate for them to intervene during FTP panel hearings and to ask questions if they feel that any issue is not being adequately explored.
(Chapters 21 and 25 and paragraph 27.255)

The Working Group supports this approach and these matters are included in the training programme for the disciplinary committees. The report recommends, at paragraph 25.307 (page 1012), that members of fitness to practise panels should be "encouraged to ask questions and to explore issues which they think are of relevance, even if it appears that the parties do not intend to do so. The objective of the hearing is, after all, to enable the panel to reach the right decision for the protection of patients and the public." This is a key part of the training provision for those involved in investigation and adjudication.

Standard of Proof

81. The GMC should reopen its debate about the standard of proof to be applied by FTP panels. The civil standard of proof is appropriate in a protective jurisdiction. It is arguable that the criminal standard of proof is appropriate in a case where the allegations of misconduct amount to a serious criminal offence.

The report recommends that the question of the standard of proof should be revisited. "In general, in a protective jurisdiction, the civil standard of proof will be appropriate. However, it is certainly arguable that it would be appropriate to retain the criminal standard of proof where the allegation amounts to a serious criminal offence."(Paragraph 21.195, page 803; paragraph 25.97, page 1009)

The Working Group supports this recommendation and the RPSGB has adopted this in its procedures.

Reasons for Findings of Fact

83. FTP panels should be required to give brief reasons for their main findings of fact. (Chapters 21 and 25 and paragraph 27.258)

The Working Group supports the requirement for FTP panels to give reasons for findings of fact; this change in practise could be implemented speedily and supported by training programmes for panel members.

Applications for Restoration to the Medical Register

95. The arrangements set out in the 2003 draft Rules, whereby any necessary gathering of evidence in preparation for a restoration hearing should be undertaken by a specially appointed case examiner, should be reinstated.

96. Every doctor whose application for restoration to the register has reached the second stage of the procedure should be required to undergo an objective assessment of every aspect of his/her fitness to practise. The doctor should not be restored to the register unless s/he has met the required standard.

97. Doctors who are restored to the register should be required to have a mentor whose task

it will be to monitor, and report to the GMC on, their progress in practice.
(Chapters 24 and 25 and paragraphs 27.275-27.277)

The report recommends, at paragraph 27.276/7 (page 1167), that doctors must pass an objective assessment of their fitness to practise before being restored to the register, and those who are restored, should be required to have a mentor whose task would be to monitor their progress in practice and to report to the GMC on their progress. There could be some practical problems if this approach were to be recommended across community pharmacy as the ability to supervise practice is more limited, however this is an issue which needs to be addressed and in formulating the procedures for the operation of Section 60 the RPSGB will need to consider this. A probationary approach to restoration has been discussed at earlier stages in the development of the new provisions. The use of the term "mentor" in this context should be clearly defined. Case summaries would provide guidance to panels deciding whether or not to restore a person's name to the register. The Statutory Committee has recently agreed and published restoration guidance. The RPSGB would wish to do more detailed work and consultation in this area before formulating further views.

Cases involving Drug Abuse

98. A thorough investigation of the circumstances underlying allegations of misconduct involving drug abuse should be conducted. The full facts should be established, including the circumstances in which the abuse began.

99. The GMC should commission research into drug abusing doctors and the outcomes of their cases following supervision under the health procedures.
(Chapter 23 and paragraph 27.278)

The Working Group supports this Recommendation. The RPSGB does not yet have a Health Committee. However, when the Section 60 Order under the Health Act 1999 is in force, research into health issues will be undertaken. An early analysis and data collection exercise is currently underway. The suggested approach to drug abuse cases is in line with the RPSGB's early ideas on case handling. The powers of interim suspension, which will soon be available to the RPSGB, will provide additional safeguards in health cases.

Transparency

100. Every aspect of the FTP procedures in which either doctors or makers of allegations have a direct interest should be set out in the Rules. In addition, the GMC should publish an FTP manual, containing all its relevant Rules and its guidance for panellists, case examiners and staff, together with any relevant Standing Orders.

101. Clear statistical information should be collected and published by the GMC. The GMC should publish an annual report which should amount to a transparent statement of the year's activities in respect of the FTP procedures.
(Chapter 25 and paragraphs 27.279-27.280)

The Working Group supports these Recommendations. The report recommends, at paragraphs 25.356 and 27.279 (pages 1025 and 1168), that the GMC should produce a handbook containing all its fitness practise rules, guidance, and any standards, criteria and thresholds to be applied when making decisions. The handbook should also give a

clear and complete account of what can happen at each stage of the procedure. The handbook should include such documents as the indicative sanctions guidance and standard forms used in screening decisions. The Handbook should be readily available on the GMC's website.

The RPSGB has developed similar information and is in the process of publishing it. Changes to IT systems will make the data more readily available to support this statistical analysis. CHRE could specify a minimum data set for the regulators to publish every year and this could be linked to a set of performance standards against which each regulator could be required to report outcomes.

Audit

102. The GMC should carry out audits of various specific aspects of its procedures, in addition to its other routine auditing activities.
(Paragraphs 27.203, 27.232, 27.233, 27.240 and 27.241)

The RPSGB will review its procedures to ensure appropriate audit is in place. At the moment auditing of decisions of the Statutory Committee is conducted by CHRE, however, it is necessary for auditing of the Infringements Committee decisions to be conducted to ensure that a rigorous and consistent approach is being adopted. This work is at the planning phase and will form part of the RPSGB's Business Plan for 2006.

Revalidation

103. The arrangements for revalidation should be amended so that revalidation comprises, as required by section 29A of the Medical Act 1983, an evaluation of an individual doctor's fitness to practise.
(Chapter 26 and paragraphs 27.281-27.282)

104. The annual report referred to at 101 above should include clear statistical information about the number of applications for revalidation and their outcomes. It should amount to a transparent statement of the year's revalidation activities.
(Paragraph 27.280)

The report undertakes a detailed examination of the GMC's procedures for revalidation of a doctor's registration and concludes that the proposed arrangements "will not provide an evaluation of fitness to practise." The discussion is "GMC specific" at present but similar arrangements for pharmacy will need to be created. The Working Group notes that periodic revalidation may be expected of all self-regulating professions, and that revalidation should be seen as a positive assessment as to whether the practitioner is currently fit to practise, rather than a negative assessment on the basis that "nothing adverse" is known about him. The Working Group agrees that revalidation therefore goes further than the fulfilling of CPD requirements. The Review being conducted by the Chief Medical Officer encompasses patient safety and provides an opportunity for all the professions in Healthcare to collectively find a solution to the continuing licence to practice debate. Much of the scoping work and consultation conducted by the GMC in the preparation of the revalidation arrangements, which were due to come into force on 1 April 2005, has been considered by other professions. The RPSGB would wish to submit evidence and participate in evidence gathering sessions.

Independent Review

105. In three to four years' time, there should be a thorough review of the operation of the new FTP procedures, to be carried out by an independent organisation. This task should be undertaken by or on the instructions of the CRHP/CHRE.
(Paragraph 27.307)

The RPSGB is subject to annual review by the CHRE and to date this has been a valuable exercise. It is anticipated that this will be extended in the future. A more extensive review would be welcomed when the Section 60 Order under the Health Act 1999 is in force and regulatory changes have been implemented. Any review of new FTP procedures should engage with the views of the profession and the public as to its effectiveness.

Constitution

106. The GMC's constitution should be reconsidered, with a view to changing its balance, so that elected medical members do not have an overall majority. Medical and lay members who are to be appointed (by the Privy Council) should be selected for nomination to the Privy Council by the Public Appointments Commission following open competition.
(Paragraphs 27.310-27.312)

The report recommends that the GMC's constitution should be reconsidered to allow for the implementation of more appointed professional members. The Working Group supports this proposal for the GMC.

The RPSGB has already made considerable reforms to its constitution and further change is anticipated under the Section 60 Order, with clearer lines of accountability and a wider range of powers to protect the public. In the meantime, closer engagement with the public through a Public Involvement Strategy is anticipated.

Public Accountability

107. The GMC should be directly accountable to Parliament and should publish an annual report, which should be scrutinised by a Parliamentary Select Committee.

Closely linked to the questions of constituency and representation, is the question of accountability. The report recommends that the GMC should be directly accountable to parliament and required to publish an annual report of its activities, which should be scrutinised by a Parliamentary Select Committee. (Paragraph 165, page 46). (Paragraph 27.314)

The Working Group supports this proposal and accepts that similar lines of accountability may be applied across Healthcare regulation. In welcoming this recommendation, the RPSGB will ensure that its Annual Report for 2004, due to be published in May 2005, is sent to appropriate ministers, the Scottish Parliament and Welsh Assembly.

The Council for Healthcare Regulatory Excellence

108. Section 29 of the National Health Service Reform and Health Care Professions Act 2002 should be amended so as to clarify that the Act provides for the CRHP/CHRE to appeal against 'acquittals' and findings of 'no impairment of fitness to practise', as well as in

respect of sanctions which it believes were unduly lenient.

109. There should in the future be a review of the powers of the CRHP/CHRE with a view to ascertaining whether any extension of its powers and functions is necessary in order to enable it to act effectively to ensure that patients are sufficiently protected by the GMC. (Chapter 21 and paragraph 27.283)

The RPSGB works collaboratively with the CHRE in the discharge of its functions. The ongoing programme of activity being defined by CHRE is a crucial part of the development of regulation for the future. Some aspects of CHRE's work such as the regulatory conference, the annual performance review and scoping exercise have been of particular benefit. The powers of CHRE, as set out in the legislation, are very broad already, it seems unlikely that amendments to primary legislation would be required to enable CHRE to diversify activities. In the future, CHRE may play a key role in capturing and disseminating best practice and commissioning research into regulatory activities. Aspects of fitness to practise relating to ill health of health care professionals could be a subject of academic research. A pro-active role could also be adopted in relation to some of the issues emerging from Europe. The problems the RPSGB faces in ensuring language competence have already been shared with CHRE and they have been very helpful on this matter.

Elizabeth Filkin
17 March 2005