Law Commission joint consultation paper LCCP 202/ SLCDP 153 / NILC 12 (2012):
Regulation of Health Professionals
Royal Pharmaceutical Society Response

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.
The RPS leads and supports the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.
Its functions and services include:
Leadership, representation and advocacy: promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.
Professional development, education and support: helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.
Professional networking and publications: creating a series of communication channels to enable pharmacists to discuss areas of common interest.

General Comments

The consultation process

The RPS has a long and proud history of commitment to professionalism and support for excellence, firstly as the Regulatory Body for pharmacy and more recently, since the establishment of the General Pharmaceutical Council (GPhC) as the new Regulatory Body in 2010, as the Professional Leadership Body for Pharmacists.

The RPS have engaged with the Westminster Government's agenda for modernising the Regulators of Healthcare providers since 2002 and are supportive of the ethos of the Law Commission's consultation to ensure the legal aspects of regulation are now fit for purpose for a modern regulator. However, from a pharmacy perceptive we are disappointed with the tone of the consultation and the timing of the review.

Whilst we appreciate this is a consultation on Law reform rather than broader regulatory reform it is important to engage with the stakeholders that are being regulated to gain their input in to the

practical implication of legal changes. Unfortunately, this consultation is not designed to achieve that outcome. The tone of the consultation is more appealing to those with an in-depth knowledge of the legal framework of regulation than those delivering the service within that framework. Additionally, the consultation is so voluminous, consisting of 13 separate chapters covering 257 pages of complex issues and asking 178 questions so that, overall, it has been difficult to read and has inhibited responses from our members ; both individually and those within specialist groups. We believe this criticism is equally applicable from the perspective of the public and patients, the very stakeholders the reforms are designed to protect.

More specifically from a pharmacy perspective, pharmacy regulation is currently still in a period of evolution. The recently established GPhC (Sep 2010) continues to update and develop standards; they are currently consulting on standards for premises and the principles for revalidation. Therefore, we have a very limited timescale and experience from which to: judge its performance, establish the degree of influence our consultation responses have had, and interpret any outcomes of changes already made.

The establishment of GPHC was a Government initiative designed to create a modern, responsive pharmacy regulator, providing confidence to the public and the profession in pharmacy regulation. Thus to review and recommend wholesale changes to this evolving body seems premature at best and destabilising to the development of GPhC and pharmacy regulation at worst.

Additionally, the pharmacy profession is currently in a period of transition to the acceptance of GPhC approach to regulation namely, risk-based system of regulation that will allow it to focus resources where they are most needed, and it is vital for the successful transition that a clear, transparent, simple process is developed and any additional changes to the regulatory process must not be disruptive and financially cumbersome to the profession.

The RPS has thus based their responses to the consultation on the major principles we believe should be considered in the overall themes of each chapter. This should produce a robust model of regulation that will ensure that the pharmacy profession is regulated according to the same principles as other healthcare professions, as well as ensuring public confidence in the regulation of the profession. We have not included any specific comments on the GPhC regulatory functions as we believe it is too early in the evolutionary process to be constructive.

Value of individual regulators

Modern regulation is not concerned solely with discipline and poor performance but embraces safety, quality, standards, behaviours and competencies. We believe that to undertake these functions in full, an independent regulator for pharmacy must be retained and allowed to evolve within an overarching framework of regulation. An independent individual regulator makes an essential contribution to maintaining and raising standards. The regulator has a duty to foster and promote the development of the profession it serves, should be responsive to new ideas and innovation from within the profession, and should encourage the pursuit of excellence through best practice that will help develop professional practice. This role cannot be delivered by an overarching regulator or a regulator that has responsibilities for differing professions: it can only be delivered by an individual independent regulator working in partnership with the professional leadership body whose members it regulates.

We therefore support strengthening the Individual regulators by bestowing broader powers and would be concerned if smaller regulators were merged, with the consequence of losing their unique identity. Pharmacy, as a profession, has a long history of individual regulation and we believe that the ethos of individual regulation for pharmacy should remain intact within a set of common overarching principles.

Financial considerations

The impact assessment included with the consultation paper states that there would be a transfer of costs from the Department of Health to the regulators, for functions such as the drafting of Rules that were previously their responsibility. Additionally it is proposed that the CHRE would now be funded through the individual regulators contributions. The impact assessment concludes that cost efficiencies in professional regulation (anticipated to be between 5%-15%) could be made by allowing regulators to introduce their own rules. The GPhC is a new regulator and we have been reassured, when responding to the fee setting consultation process, that it is adopting stringent financial management. It would thus be extremely concerning and disappointing, if this level of anticipated savings could be achieved by a regulator that has only been established for 18 months. We are therefore very concerned that the financial burden of change proposed by this consultation will fall on the individual pharmacy registrants, and correspondingly cause a raise in registration fees, we would like assurances that pharmacists will not be financially penalised by any Governmental reform.

Patient safety

Whilst we appreciate this is a consultation on Law reform for regulation, it is very disappointing that patient safety does not appear to be a factor being considered within the reform process. The RPS is supportive of the regulatory process to ensure safe practices for the pharmacy profession and increased patient safety when receiving their pharmaceutical care. As patient safety is paramount, it is disappointing that the proposed changes seem to be more concerned with processes than increasing patient safety and it is often difficult to interpret the increased patient safety value in the changes being proposed. This consultation should have taken the opportunity to look at Law reform to strengthen the regulatory process from a patient safety perspective not a process prospective.

Learning from concerns

The consultation does not appear to have made provision for the concept in Statue for individual regulatory bodies to review the outcome of any concerns that have arisen as part of an investigation process. There must be provision for the regulators to promulgate any deficiencies identified in investigations in order to learn lessons, avoid such deficiencies occurring again and to improve services. Additionally there must be provision for regulators to identify with professional leadership bodies and members any areas of malpractice occurring repeatedly so that awareness is raised and standards improved as necessary.

Role of Governmental in regulation

Effective regulation requires independent oversight and scrutiny; this is best delivered through a non political system. The Westminster Government has the role of providing policy and strategic intent for regulation, but there must be clear distinctions for both its role and that of the CHRE.

We support the regulatory framework of the Westminster Government setting the overall policy, and holding the CHRE to account through The House of Commons Health Committee. The CHRE has a UK wide remit to provide the overarching framework for the individual regulators and also has the remit to hold the individual regulators to account through its Councils.

The differing roles of Government, CHRE, and individual regulators need to be clearly defined in Statue to avoid confusion and challenge. We are therefore concerned that at times in the consultation the default position appears to be where the law commission is uncertain it defers to giving Government powers e.g. 2.14 Government should be given regulation- making powers on certain issues, and 2.4 a limited number of rules being subject to Secretary of State approval. This stance needs to be clarified as professional regulation should be non political and regulators must be free to exercise their roles and functions without political interference or pressure.

Addressing the devolution aspects of regulation

The National Assembly for Wales and Scottish Parliament are responsible for health service policy, and implementation, these function cannot operate in isolation from the professional regulatory framework. The RPS has offices across the home countries and is supportive of the devolved Government's involvement in the findings and outcomes of regulatory review and oversight of the regulators reports. To fulfil this function we are supportive of The House of Commons Health Committee acting as the oversight committee for the CHRE, with devolved Governments raising any issue either through this Committee or through members of the CHRE's governing council.

The CHRE Council must include at least one member from the devolved Governments. Having Council membership from a devolved Government should inform CHRE of the deliberations and approach of the devolved Governments, thereby ensuring two- way knowledge of policies and strategies.

We are concerned that if the CHRE is responsible and presents itself to each Government's Health Committees individually this would be over burdensome and ultimately expensive exercise with no apparent benefit for patient safety.

Regulation in respect to professionalism

There is an increasing trend to regulate roles where there is patient contact and therefore a concern of risk to public safety. This increasing regulation has lead to more roles being classified as professional occupations. However we are concerned that a "defined professional occupation" may not be underpinned with professionalism in the wider context of standards and behaviours, and, more importantly, may cause public awareness of what constitutes a professional to be further confused.

For regulation and professional status to be meaningful it must involve more than being regulated. Professional regulation must demonstrate to the public that those being regulated have the required competencies, standards and behaviours of a professional but also have meaningful accountability for their actions. The GPhC now registers pharmacy technicians but has not clarified the difference between the responsibilities of a Registered Pharmacy Technician and a non registered technician. Additionally, it is currently possible for a technician that has been removed from the register to return to work in the same role as a non registered technician, thereby, in this area of pharmaceutical practice, calling the process of regulation and professionalism into question.

We are, therefore, concerned about the increasing Governmental trend to regulate roles and confer professional status to those roles without considering the resultant effects of diluting public confidence in the professional status of members of the pharmacy profession as a whole. Additionally we are concerned with the growing trend in professional regulation that fails to recognise the hierarchical structure of the individual professions. Regulators through statue must pay recognition to the different professions they are regulating i.e. Register Pharmacist and Registered Pharmacy Technicians are different roles and pharmacists act in the more overarching function and often supervise the work of pharmacy technicians.

Furthermore we are concerned this trend of giving both professions equally status is seeping into the fitness to practise processes and procedures.

Role of professionals within the fitness to practise process

The RPS believes that maintenance of fitness to practise is one of the primary functions of a regulator: but to ensure the integrity of the process we strongly believe that a peer of the professional being taken through the process must be involved at every stage. In the case of pharmacy this must be a pharmacist when a pharmacist is being investigated; this distinction should be supported in the Rules of the regulator.

Part 2: The Structure of Reform and Accountability

2.1 We are supportive of the principle of repealing existing legislation and providing a single legal framework. This approach should aid patients and the public to engage and understand the regulation process and therefore have more trust in the regulators to uphold patient safety.

2.2. We welcome the principle of consistency across the regulators, and the establishment of core functions. To support this we believe the provision of giving greater autonomy to the individual regulator will lead to an agile, effective regulator able to understand the environment for which they are responsible but still acting within the overarching ethos of regulation.

2.3 2.4 We support the proposal of giving broader powers to the regulators to make or amend rules. However, we have concerns about losing the functions of the Privy Council without knowing the details of the alternative safeguards that would be put in place. We have had limited opportunity to measure the outcomes of Rules consultation and how the input of relevant professional bodies into this process has impacted on the final outcomes of the Rules. Hence we are cautious of the removal of the check and balance that the Privy Council represented.

2.4 The best practice in developing legal Rules requires a scrutiny process to act as a check and balance. The removal of the Privy Council leaves a gap in this process, so the involvement of CHRE in scrutinising new rules seems sensible. We are unclear why and what benefit would be gained by a limited number of rules being subject to Secretary of State approval as, this would simply add confusion to the process.

The CHRE would appear to be the best placed body to have a supervisory role as having a limited number of Rules being subject to Secretary of state approval does not provide arms length scrutiny and could be perceived as confusing the CHRE role as the overseeing body for regulation. The Government must have faith in CHRE to undertake it roles and functions in an effective manner and not add in “loop holes “of law that could be seen as confusing the separate roles of Government and CHRE.

2.5-2.6 we agree with the proposals

2.7 we are supportive of this proposal

2.8-2.9 The CHRE as the overarching body should be subject to scrutiny by Government to ensure it is effectively carrying out it functions. The other regulators are accountable to CHRE and as such CHRE should act as the arbiter for issues between Government and the individual regulators.

In supporting this line of accountability the Commons Health Committee should act as fulcrum for the devolved Governments. The cost of regulation would be become disproportionate to the risk and accountability if too many tiers of accountability are put in place. A simple process should be put in place that provides the public with the necessary assurances needed and allows both individual regulators and CHRE to perform their functions in a cost effective manner.

2.10 We have reservations about supporting this proposal, as we believe the Government's role is more overarching and the suggested example would be better off served by the CHRE. The Secretary of State role should be reserved for instances of extreme public safety.

2.11 We would support this proposal; each regulator should be open and transparent in its work and governance**.**

2.12 The National Assembly for Wales and Scottish Parliament has responsibility for the implementation of health policy within their countries. As the practice of pharmacy is different across the home countries, it is therefore appropriate that the same level of regulatory accountability is delivered to the individual governments.

2.13 No view

2.14 We are unsure whether to support the broad scope of this proposal. Government involvement in regulation should be overarching and strategic, giving Government powers on "certain issues" is too vague.

2.15 We are concerned about whether to support the broad scope of this proposal. The document does not clarify the process for Government involvement and the criteria for establishing, merging or abolishing regulators and does not offer a robust process for such an important issue.

2.16. We support this proposal; the CHRE should take recommendations from the individual regulators, Government, or the public. However we strongly believe that regulation must be for valid patient safety reasons and not solely to confer professional status to a role.

2.17 -2.18.As per 2.15 the details of the process are missing from this consultation document. An effective regulatory system would give CHRE powers to monitor regulators against outcome measures consistent across the regulators. There should then be an early warning system in place to support poorly performing regulators which would negate the need for Government intervention.

2.19 we support this proposal

2.20 We would support this proposal

2.21-2.23 no view

2.24 We would defer to the views of the GPhC, but would suggest that transitional arrangements are put in place to hear cases under the two sets of Rules. Priority must be given to clearing cases heard under the old Rules first, so that registrants do not suffer an undue delay in receiving adjudication.

Part 3: Main duty and general functions of the regulators

3.1 Regulation is effectively a shared responsibility between professional leadership bodies setting standards for professional activity and the enforcement role of the regulator. This approach ensures that the regulator maintains public confidence in the regulatory process and achieves a safe environment for the public to access their pharmaceutical care. The professional leadership body has the role of demonstrating to the public that pharmacy is a trusted profession whose members deliver safe pharmaceutical care.

We are therefore supportive of the first statement: *protect, promote and maintain the health, safety and well-being of the public, by ensuring proper standards for safe and effective practice;* but we believe it should be strengthened by the inclusion of the wording, "*maintenance of accepted standards of behaviour".*

We are cautious of the wording of the second statement, in that we believe the regulator has a role to "*maintain confidence in the profession"* in conjunction with the professional leadership bodies, but we have no history to measure how this could be demonstrated, in a practical sense, by the GPhC.

3.2 -3.4 We are unsure of the benefits of removing the provision of general or principles functions of the regulator in statue**.** Whist we are supportive of consistency across the regulators, each regulator should have broad powers to undertake its function and be informed by *guiding principles* but should also be free to make independent decisions that reflect the health profession they are regulating. There is a danger; by adopting a one size fits all approach to the general functions of the regulators, that the individuality of each regulator could be lost completely.

Part 4: Governance

4.1-4.11. General principles of Regulatory Councils

- **Strategic role of Council:**

We believe that by giving broad based powers to the individual regulator it should then have the discretion to undertake those functions in the most cost effective manner to achieve its statutory function, including the establishment of any committees they deem necessary. The scrutiny for this should be through the overarching Council.

The day to day management of the regulator should be the responsibility of the Chief Executive and management team with the Council having collective responsibility for the performance of the organisation as a whole, ensuring, via the Chief Executive, that the organisation carries out its functions and acts in accordance with the requirements of the law and good governance.

The Council must have a scrutiny role before, and after any new Rules are made, monitor the efficiency and effectiveness of the organisation .The Council must operate in a transparent manner and ensure the Public and Stakeholders are aware of its activities and strategic plans. It must demonstrate to the CHRE and the registrant that it has operated in a cost effective manner and justify any plans to increase fees.

- **Constitution of the Council:**

Membership of the Council carries with it a collective responsibility for the discharge of the functions of the regulator, with all Council members being appointed for their skills, knowledge and ability to undertake this duty both in an impartial manner and in the public interest. The selection of candidates with the required skills may be considered a generic task but individual regulators should have overall responsibility for any appointment. This responsibility can be delegated in part, if the individual regulator is satisfied that another body is best place to find suitable candidates, but the responsibility cannot be discharged fully to another body.

The Council for the individual regulators must reflect the profession it regulates. Professional input at a strategic level is essential. Members of a profession have a unique body of knowledge and expertise, and, as professionals, will act in the best interest of their patients.

Additionally the Council must reflect its GB wide remit. Strategic health policy differs across the 3 countries and this must be acknowledged at the highest level by designated Council membership.

- **Size and composition of the General Council:**

There should be guiding principles for total numbers. Our view would be that 10-12 Council members is enough to offer efficient decision making and provide the spectrum of views that is required to ensure it fulfils its function. A Council needs plurality of expertise and perspectives if it is

to undertake its functions and this cannot be achieved with too small a Council. In bestowing border powers to the individual Regulator, the Statute should be supportive of the development of individual Regulators and not set restraints on the overarching Council but allow it to evolve through experience.

The Council should be balanced in its membership between the professional expertise needed to provide the environment and insight into the professions being regulated as well as ensuring that any decisions are made in accordance with the general function of promoting and protecting the public. It is vital that a degree of self-regulation is maintained with Council membership, as, without professional input, Ill-informed decisions could be made. In the case of the GPhC the professional input must reflect the need for a majority of professional membership on Council of Registered Pharmacists, who can provide the knowledge and overview of the practise of pharmacy both technically and clinically.

Part 5: Registers

Purpose:

5.1- 5.2 Registers must not be a historic record of past registrants; they should only list practitioners who are competent to practise now, and can therefore be relied upon by patients and other practitioners as a meaningful quality check.
The Individual Regulator should hold and maintain the registers of the professions they regulate. Keeping and maintaining the registers is a primary function of the Regulator and as such there must be a dedicated person responsible for its maintenance and accountable for any failures. We can, therefore, see any justification for removing the duty to appoint a Registrar.

Types of registers:
5.3 We believe there is a need for Statue to empower Regulators to establish, maintain, and share the Registers of the professions they regulate. Registers should be annotated to include specialist qualifications where these qualifications indicate the competency of the professional to carry out specific functions. In respect to pharmacy, for example, the annotation of independent prescribing status could be recorded on the Register.

5.4-5.5 We do not support the introduction of student registration
Regulatory activity through student registration can be seen as a proxy for the real concern which is ensuring that the students are professional and, therefore, fit to be part of a regulated profession.

A priority for all health professions should be to strengthen any student's professionalism and understanding of their professional accountability. This can be achieved through more effective systems of supporting them to develop a professional ethos and dealing supportively with students who fail to demonstrate professionalism. We do not believe student registration will achieve this outcome.

However, we believe the Regulator does have a role in incorporating professionalism into the undergraduate and pre registration syllabi. Student learning and introduction to practice requires contact time with patients to demonstrate and develop skills, behaviours and competencies. This contact time can occur fairly early in their training, and we are therefore supportive of embedding professionalism within the core curriculum and learning syllabi of all students. This ethos should be applicable for university based courses and practical based teaching for pharmacy technicians.

5.6- 5.7-5.8 With regard to voluntary and non-practising registers, there seems little value in a register that is non-mandatory and fails to offer a safeguard to the profession that mandatory regulation applies.

These registers could also distract from the mandatory register and confuse the public as to the status of those professionals on these registers.

The Pharmacy Order no longer supports the need for these registers and we would consider their reintroduction as being retrograde in the modernisation of professional regulation.

Types of Registration

We are supportive of the need to adopt different types of registration and the ability to be agile in times of emergency.

Requirements for registration

5.13 We do not support the wording "fit and proper person" this is too abstract for professional registration.

5-14 Both forms of words are true: if (in pharmacy) the applicant has fulfilled the requirements to register, they have a right to apply to be registered. At the same time, the Regulator in pharmacy registers applicants who fulfil the criteria. We therefore do not have a opinion on which set of words are more appropriate.

Processing of registration applications

5.15 We believe this should be left to the individual Regulators, but should be consistent and appropriate across the professions, and within a timely manner. Additionally there should be sanction if a Regulator does not proceed appropriately when processing registration applications.

Restoration to the register

5.17- 5.22 We support these proposals in principle.

5.23 Professionals must be competent before returning to practise, patients should be protected from professionals whose knowledge is not current and /or whose professional skills have deteriorated through absence from practice. However, patient interests are not served by creating unnecessary time barriers to resumption of practice by competent professionals through proscriptive time frame sanctions.

When a regulator erases someone from a Register they are in possession of the facts as to why that erasure is a proper and just sanction. They should then decide the timeframe required to resolve the issue, or provide a timeframe that would impose a sufficient sanction on the individual. This cannot be determined by overarching legislation.

The periods of erasure issued by individual regulators should be reviewed, as at present, by the CHRE for consistency and an individual Regulator held to account by the CHRE for too hash or too lenient an approach to the erasure sanction.

Content of the register

5-26: To avoid confusion, we believe there should be only one register per profession with the Regulator having the power to decide when to annotate this register**.** Registers should be annotated to include specialist qualifications where these qualifications indicate the competency of the professional to carry out specific functions. For example, with respect to pharmacy the annotation of independent prescribing status should be recorded in the main register for pharmacists.

5.27 We support the requirement for all current fitness to practise sanctions appearing in the Register, however where a case is pending, this should not be in the public domain. Additionally, there should be a limited timeframe related to the publication of a sanction against a registrant's name on the Register.

5.28 The decision to make publically available warnings and interim orders must be considered very carefully .The decision must be taken that **not** to share the information would be a public safety

issue, i.e. In the case of someone being suspended from practice and awaiting a hearing, this stance must be consistent across the regulators.
Furthermore there should be a timeframe for these warnings to appear in the Register, as it seems unjust to have an annotation of a warning appear indefinitely, or even after a sanction has been served and remedial action taken.

5.29 This would seem appropriate, given that the role of the regulators is to ensure patient safety through minimum standards of profession practice and qualification.

5-30 The publication of all previous sanctions seems unjust and we would question if this offers any greater patient safety protection than having a sanction appear for a stated time. It seems unjust to have an annotation of sanction appear indefinitely, or even after a sanction has been served and remedial action taken.
The publication of sanctions demonstrates that a Regulator has acted and upheld standards; however the public should be made more aware that action was taken and the professional is now fit to practise again. This can be demonstrated by having the sanction removed within an appropriate time frame and definitely within 5 years.

Protected titles and functions

5.31 We strongly support and recommend the transfer of the protected titles contained within the Pharmacy Order into any new legislation. We would ask that this is strengthened by Regulators proactively taking action against breaches in use of protected titles, as failure to adopt this approach lessens confidence in the protected title.

5.32 The role of issuing or removing protected titles should sit with the body whose function it is to decide which a regulated profession is. We believe this sits with the CHRE and should be subject to scrutiny through reports and hearings by the House of Commons Health Committee.

5.33 The protected title “pharmacist” is regarded as hugely important in our profession. Patients are assured that the person providing pharmaceutical care is appropriately qualified and regulated and will apply principles of professional conduct and ethics to their care. It overcomes the practising / non practising issue for our profession in that anyone practising as a pharmacist must be regulated. While this has been contentious across the profession, it is widely accepted and understood as good practice now and provides a unifying title for pharmacist members of the profession.

5.34 The Regulator should have a statutory duty to uphold the protected titles of its registrants. Ultimately, to fulfil this function it may be necessary to effect a criminal prosecution, but other sanctions should also be available. If a Regulator fails in its duty to uphold a protected title it will fail in its duty of maintaining trust in the profession and public confidence related to the maintenance of standards would be compromised.

PART 6: EDUCATION, CONDUCT AND PRACTICE

Overlapping responsibilities

We are supportive of the need for a more streamlined and coordinated approach to regulation in the areas of education, conduct and practice. In today's healthcare environment, a multidisciplinary approach is needed to achieve the best patient outcomes. This working approach should be fostered at an early but appropriate stage in professional development, by encouraging a multidisciplinary training environment where there are overlapping areas. The greater the exposure to fellow professionals, areas of education, conducts and practice the greater the understanding of roles, standards and competencies. This is not solely a regulatory function and should occur across professional leadership bodies and across the devolved countries.

We would however express a degree of caution on how far this co-ordinated approach should go. Multidisciplinary working is only successful if based on sound individual professional development. Each profession must bring its own expertise to the team and education, conduct and practice standards can have overarching elements, such as confidentiality, but must also be specifically developed for the individual profession.

Additionally, in respect of a streamlining and coordinated approach, the regulators should ensure their processes are not over bureaucratic and cumbersome but outcome driven.

We welcome the provisional proposal that the same regulatory principles should apply to pre-registration and post registration education and training.

Education

6-5: We support consistency in extending powers of national assessment of students at their point of registration. With reference to the pharmacy profession, there is already a national examination for pharmacy registration, delivered at the end of the pre-registration year. Additionally the Regulator provides a broad indicative syllabus for the undergraduate degree and Schools of Pharmacy are accredited against standards to ensure the quality of the degree.

6-6: We cannot support the extension of regulatory powers to the selection of those entering education. We can see no added patient safety value in extending the role of the Regulator into this area.

6-7: At the present time, we are cautious of supporting the proposal to provide a framework for the approval of multidisciplinary education and training; multidisciplinary working is only successful if based on sound, individual professional development. A level of professional autonomy should apply across the professions; this autonomy enables mutual professional respect to the contribution each professional brings to the team. We believe the benefits of multi- disciplinary education and training are best achieved through a structured approach of targeting to specific overlapping topics and not in the production of an overarching framework.

Guidance

6-8, We are unable to comment on this question as the GPhC is an evolving organisation .

We would however comment that guidance in itself is not always helpful and the Regulators need to co-operate with professional leadership bodies to ensure that registrants are able to interpret any guidance issued. This requires a collaborative approach between the two bodies.

6-10 We are unable to support the production of different levels of guidance, we believe it would be confusing both to the public and to registrants. The regulator should produce guidance documents that must be complied with: unless there are good reasons for not doing so.

6-11: In pharmacy, the Regulator provides guidance on standards that need to be attained: whereas the professional body provides supportive guidance on how to do so, with examples of best practice and support tools to help the pharmacist both in everyday practice and when dealing with difficult situations. This works well and seems to be a good balance between standards and support

On-going standards of practice

6.12 We support this proposal

Part 7: Fitness to practise: Impairment

7.1 Options for reform

Option 1 – We support the provisional proposal that this option should be discounted, we believe that fitness to practise is fundamental to professional regulation, should be specified clearly on the face of Statute and not open to interpretation by individual regulators .

Option 2 – We support the establishment of a single framework for determining impaired fitness to practise, but have reservations to the list of grounds that would be written into Statute and how evidence presented this way would be interpreted. This approach lacks the clarity and transparency that a professional would expect to see when receiving a judgement on their professional ability which may affect their livelihood.

Additionally we would ask for clarity of what is meant by 'relevant safeguarding body' before supporting the proposal.

Option 3 – We would support this option in principle as it appears to offer a more robust process in examining the evidence with a view to justifying the outcome. However we would suggest this could be strengthened by including the maintenance of accepted standards of behaviour. The public has an expectation of professional behaviour that can exceed that of the norm, and when professional behaviour is seen to be compromised, public confidence in the profession is invariably damaged.

Option 4 – This is a new concept and, whilst we acknowledge that it appears to have potential, we have no experience upon which to base an opinion and therefore cannot justify adopting an approach that has no evidence of offering better outcomes than those of option 3.

Currently, within pharmacy regulation, the Regulator takes into account all elements of option 3 but also the implications of option 2, and this system appears to produce a satisfactory outcome.

7.2 We are supportive in principle of a broader range of non-convictions but have grave reservations about how broad that list should be. It must only include elements that bring a professional's fitness to practise into dispute and not petty misdemeanours such as fixed penalty driving fines.

7.3-We have no experience of this so cannot comment.

However we are concerned that regulators have a full understanding of the environment in which they operate, especially in terms of the devolved administrations. There are now different processes for redress, complaints and for information sharing across the countries. All of these have to be aligned and co-ordinated when considering the delivery of professional regulation.

Additional Comments

As stated previously we acknowledge this is a consultation on the law and not health regulation. However, we are concerned at the tone and language within the chapters dealing with fitness to practise, as there seems to be too much emphasis on the definition of guilt from Criminal Law (beyond reasonable doubt) and not the Civil Law criterion of the 'balance of probability'.

We consider fitness to practise to be one of the primary functions of the Regulator and to undertake this task effectively we would advocate that the Statute is more prescriptive and ensures individual regulators to fulfil this requirement themselves. They may merge to deliver some of the administration aspects involved within the process, for cost effective reasons, but must establish a panel /committee to undertake this function internally. Additionally, professional representation must be integral to **all parts** of the fitness to practise process from the initial phase of interpreting the findings through to the appeals stage. This professional representation must be through a member of the same named profession being investigated, in the case of a pharmacist this must be fellow pharmacists who is able to provide the ethical position and contextualise the professional environment that pharmacy operates in.

Furthermore, when needed, there should be access to someone who can provide any country specific contextualisation , that may have had an influence on a pharmacist's professional judgement.

Part 8: Fitness to practise: Investigation

Allegations

A previous analysis undertaken by RPS in 2008, whilst in the process of preparing to devolve its regulatory function to the GPhC, indicated that Pharmacy receives more allegations per registrant than some other regulators: 1.7% for RPSGB compared to 0.6% for the General Optical Council and 0.2% for the Nursing and Midwifery Council and the Health Professions Council. This may be due to the context within which pharmacy is practised, in particular community pharmacy; frequent financial transactions, easily verifiable mistakes and lack of alternative complaint routes. Furthermore, as a proportion of the registrant population, there are similar rates of referral of complaints to the adjudication process and similar percentages of registrants removed from the register as a result of the adjunction process. Thus indicating how important the investigation, and specifically the allegation stages are for cost effective regulation for pharmacy.

8.1, 8.2, 8.3. We support the need for Regulators to have broad powers and discretion to deal with all the information and complaints they receive, however this must then be supported by a formal process after an allegation has been made. The Regulator has a role to act as a "filter" for complaints and not as a stockpile for evidence against a professional. They should not stockpile minor complaints without advising the registrant because, whilst it may appear to be a method of building a body of evidence against a registrant it does not allow the registrant to build a defence against these complaints or to take remedial action to redress the issue.

Whilst we support the concept of having no set format for allegations we believe that, in principle, there must always be a mechanism whereby the person making the complaint/allegation knows that their name and address will be made available to the professional involved and any other healthcare body who may be approached for information relating to the case. This approach should minimise the risk of malicious allegations being made against any registrant.

8.4-There should be, across the professions, a defined time limit between the alleged offence and the receipt of the complaint, this should be consistent with any time limits set out in criminal law. However, we consider that there should be a caveat that this could be extended if other, relevant, information about the occurrence of a similar incident becomes available or the effects of the incident were not seen within the time period.

Initial consideration

8.5 Agree- as per general comments on allegations, there is a need within pharmacy regulation for a robust screening process prior to taking a case forward for adjunction.

8.6 Agree as long as there is a robust open/transparent process in place to justify the selection.

8.7 Agree as long as there is a robust open/transparency process in place to justify the referral.

8.8 -Yes, we would support consistency across the regulators in this important area of fitness to practise.

Investigation

8.9-8.10 As an overarching principle we believe that any investigation should be through an appropriately constituted investigation committee, with the Regulator having the broad Rule-making powers to undertake this task in a cost effective manner. Furthermore, we believe that investigating someone's fitness to practise is so important that Statue should dictate that the professional being investigated should be investigated by a committee that contains a member of his/her own profession, to provide context to the investigation. In the case of pharmacy that must be a pharmacist where a pharmacist is being investigated.

8.11- 8.13 -We accept the need to request full disclosure of information but would query where the balance between self incrimination under criminal law would be. It seems unjust that a professional should be made to disclose information and not be able to "refuse to comment" as it could open up a whole industry of redress through civil prosecutions.

Furthermore we would be concerned with unintended consequences of this policy on "whistle blowing". We acknowledge that the issues are different, but there could be overlap, and guidance would be needed to reassure staff that if they raise concerns about one member of staff that the issue is dealt with confidentially as per "whistle blowing policy".

8.12 -8.14 In general, yes but there does need to be some mention of significant penalties to be applied for non-compliance (by either side) within a specified timeframe.

Threshold test

8.15- We support the introduction in Statue of the real prospect test

Disposal of cases

8.16 We support the proposal in principle but would strengthen the proposal by asking for a check and balance on the power of the regulators through requiring the Regulator to issue Rules related to the composition of the bodies making the decisions, their remit, and a facility to consult/request further information/approve these decisions.

8.17 we support the need for oversight of the use of the powers suggested but are not reassured that the process proposed would improve public safety or confidence in the profession concerned but would instead introduce increasing costs and time delays.

8.18 Agree

8.19 We would suggest the wording voluntary removal is more clearly understood than voluntary erasure

Mediation

8.20, 8.21 We can envisage a very limited use for mediation within the framework for pharmacy regulation and would be cautious of its introduction. We have no evidence that this will achieve any better outcome than through the processes currently in place. Mediation can lack transparency and ultimately increase costs to the regulator and hence the profession being regulated without achieving any beneficial outcomes. Within the field of pharmacy regulation we would be concerned if the Regulator decided to explore this further without demonstrating evidence of cost effectiveness and improvement to the current system.

Reviews

8.22- Agree

8.23 8.24- We have reservations about this proposal. There must be a threshold to warrant a review of a decision, and that threshold must be the ongoing risk to public safety. Additionally the vagueness of wording "anyone who has an interest" is too overarching and empowering for anyone to request a review just because they are unhappy with the outcome. We believe one of the thresholds for review should be consideration of "is there an ongoing risk to public safety ". Reviews, by their legal nature, are costly and time consuming and should only be undertaken when the cost is proportionate to the public risk: otherwise it has the potential to introduce a significant legal bill to the regulators with implications for increases in future fees for registrants.

8.25 We support this proposal in principle but have some reservations. We ask for clarity as to whom, and what internal, and professional consultation, there would be for the designation of the proposed broad powers to make Rules on all aspects of the process. We ask for assurances that professional opinion will be sought and listened to with such an important area of innovation.

Part 9: Fitness to practise: Adjudication

General comments

We consider fitness to practise adjudication to be a primary function of any Regulator and, to undertake the task of adjudication effectively, we would advocate that the Statue is more prescriptive and thereby ensure that individual Regulators fulfil this requirement. They can merge to deliver some of the administration aspects involved within the process for cost effective reasons but must establish a panel/committee to undertake this function internally.

Furthermore, this panel must be robust and comprise, as a minimum, a legally qualified chair, a peer of the professional being judged and a lay member. This would then provide expert knowledge, impartiality and context to the panel. In the case of pharmacy, it should be ensured that the professional panel member is a pharmacist where a pharmacist is being investigated.

9.1 We are unclear why this is required as the explanation within the document states the UK has the requirements of Article 6 aspect covered by existing legislation.

9.2 We support the provision for separating the processes of investigation and adjudication. This model is established within pharmacy regulation and operates effectively. If changes to the current system are deemed necessary then they must be to improve public safety and be balanced by any cost implications of introducing change.

9.3 We do not support this provision for the pharmacy profession. - as per general comments above

9.4- Agree

9.5- Agree

Composition of panels

9-6, 9.7 9.8 We support this proposal, but would ask that it is strengthened to include the standard provision for a legally qualified chair and a peer of the professional being investigated to provide knowledge and context to the panel: In respect to the pharmacy profession this must be a pharmacist where a pharmacist is being investigated

To reduce reviews, appeals and give credence to the fitness to practise procedures and outcomes, it is vital that all the regulators demonstrate consistency and have a robust panel in place that has legal and professional knowledge and is balanced by lay representation.

Conduct of hearings

9.9 We agree but would ask that this is strengthened to include in Statue the need for a basic framework of requirements i.e. minimum number of panellists, peer professional, lay representation in balance, and legally qualified chair.

9.10 This should not be a requirement but optional: based on cost effective regulation and legal implications of the Welsh Language Act and Scottish law

9.11 We cannot see the justification for applying different rules in different parts of the UK. Rules should be overarching and applicable across the UK and not where a hearing takes place.

9.12 We accept that a professional fitness to practise hearing needs to take into account behaviours and therefore seek evidence from sources that would not be applicable to criminal proceedings. However, we a cautious about the extent to which this would apply. We would need more assurance and transparency as to what individual regulators would consider “fair and relevant to the case”

9.13 The use of civil standard of proof must be monitored by the Regulator, CHRE and Government to ensure a fair outcome for the public, and registrant. It should not be used to develop harsh regulation but more to be able to assess professional behaviour and judgement.

9.14 We support the provision for public hearings

9.15, 9.16 We are supportive of this proposal in principle but are conscious of potential cost implications

Interim orders

9.17-9.21

We support the proposal in principle but would ask for clarity on what is meant by 'appointed by a body which is separate to the Council'.

9.20 We would refer to our response to 3.1, as we believe interim orders should also be for the *maintenance of accepted standards of behaviour*.

9.21 Agree

9.22 We support the need for registrants to give evidence at interim hearings; this should be consistent across the regulators.

9.23- We support this proposal

Final, sanctions and other disposals

9.24- Agree

9.25 - No view

9.26 We support the need for these powers, but only after the case has been heard and a decision reached.

9.27- Agree

9.28 We would refer to our response to 3.1, as we believe interim orders should also be for the *maintenance of accepted standards of behaviour***.**

9.29-9.33 – Agree

9.34 We do not support giving the Regulator these powers**.** The appointment of a legally qualified Chair should ensure that the hearings are conducted in a robust, lawful manner. Additionally, CHRE has an oversight role and reviews all decisions and make comments about the mechanisms used to reach decisions and have the power to refer matters back to the relevant regulator if they consider anything to be unsatisfactory or unfair. We therefore believe CHRE should remain in overall control, not the individual Regulator who may have a vested interest as far as the public is concerned.

9.35- Agree

<u>Part 10- Council for Healthcare Regulatory Excellence</u>

The role functions, powers and duties of CHRE

The current and future role of CHRE is the lynchpin to successful regulation. We are supportive of an overarching body that would have an oversight and audit role for the individual regulators and be responsible to Government, the public and health professionals, for ensuring a consistent approach to the regulation of health professionals. It should act as the intermediately between Government policy and the individual regulators implementation of that policy. It should provide oversight and scrutiny to the regulators through annual reports and promulgate, if considered necessary, any deficiencies identified in their investigation process. However it should be an arm's length body for individual regulators and not interfere with their daily operational mechanism unless deficiencies have been observed.

We would advocate that the oversight body would support an ethos of a fair and transparent culture for regulation and enable the individual regulators to deliver effective regulation.

Our concern for an oversight body would be that the body could grow disproportionately relative to its roles and function. The individual regulators should have the broad powers and the oversight body should be lean and strategic and not duplicate the role and functions of the nine individual regulators.

Professional regulation comes with a cost to its registrants and this cost must only increase when the public risk increases: not to support an ever growing regulatory governance structure.

Governance

The Governance structure of CHRE, as an oversight body, should be proportionate to its function and reflect representation across the devolved Governments.

In respect to the appointment of Board members we would stress this must be aligned with the Commissioner for Public Appointments current code of practice and be based on the Nolan Principles related to merit, fairness and openness.

Part 11: Business regulation

We are pleased to note that the Law Commission recognises the inherent tensions for professionals who practise in commercial settings and environments. Such settings will include community pharmacies. These inherent tensions can lead to professional conflict between the autonomy to practise as a professional and corporate profit making initiatives. However, there is a professional

responsibility to ensure these tensions do not affect patient safety and system regulation is vital in ensuring professionals have the legal support for the environment in which they work.

We therefore believe that system regulation should be consistent across the regulators. Independent contractors operate within a businesses environment but they operate out of physical premises. These premises must be regulated in accordance with public risk.

Provision of a professional environment should be one of the standards for public safety and a more consistent approach across the regulators should be achieved. In respect to dispensing medicines, there is currently an anomaly between pharmacy premises and dispensing doctors' premises, where different regulatory standards apply. This inconsistency of approach should be addressed as part of this consultation process.

The GPhC has recently consulted on draft standards for registered pharmacies, which recognises the importance of systems based and risk based regulation. We would like to refer the Law Commission to our response to this consultation as it adds detail and experience to the question of business regulation

RPS response can be found at: http://www.rpharms.com/consultation-responses-pdfs/consdoc120501.pdf

11.1 We believe that regulation within a commercial setting does make a difference. The individual professional is often not in a position of genuine authority or influence and, therefore, is unable to affect decisions made in relation to systems and processes established within the commercial setting. In pharmacy this is particularly apparent with the recent establishment of the Responsible Pharmacist role, where by the responsible pharmacist is taking responsibility for an environment they may not be in a position of influence to change.

11.2 We would support the proposal that the GPhC retains the existing premises regulation of pharmacies. We believe that the system of pharmacy inspection needs to be updated so as it is based on risk and that the GPhC needs to move towards a systems regulation approach. However, this is part of the recent consultation from the GPhC and they will be providing amended standards for registered pharmacies towards the end of 2012.

11.3. We believe that the move towards a systems regulation approach is the right one. Equally the move from Rules based, to risk based regulation, we believe, is a move in the right direction. However, the data and evidence to support this and the processes which will be used to implement it need to be developed further. Within pharmacy, we believe that the Superintendent Pharmacist

needs to be given genuine authority in order to be able to make decisions to ensure patient safety throughout the organisation.

11.4 We believe that all Regulators who register bodies corporate should provide a consistent approach to the regulation of processes and systems. Currently there are differences between the Regulators and this seems inconstant with the public risk of accessing services through these premises.

11.5 We believe the role of the Regulator is to uphold patient safety in respect to professional standards and behaviours: this does not incorporate consumer complaints. Dealing with consumer complaints would cloud professional regulation and have the potential for the Regulator to become embroiled in financial redress rather than upholding public safety. (Please refer to our comments on Part 8: allegations in a community pharmacy setting.)

Additionally, this would involve a financial cost for the registrants that could not be reconciled with the role and remit of the regulator.

11.6 We support the proposal for extending regulation making powers to regulate business to any regulator. We believe this extension is within the ethos of consistency that this review of law is aiming to achieve.

Part 12: Overlap Issues

We are fully supportive of the need for clarification of the landscape of regulation. As stated previously, it is often complex and unclear for both the public and the profession. We are, however, not in a position to advise how this could best be achieved.

We would support the harmonisation of some administrative functions across the Regulators if it leads to greater understanding of the regulatory process within each Regulator and reduces the cost of regulation. However, joint working should not extend to interpreting evidence, outcomes and adjudication in fitness to practise cases, which requires professional input from the individual Regulator and registrant. Furthermore, joint working should not occur to such an extent that the identity of an individual regulator is lost and regulatory function has merged in everything except name.

We can see value in establishing greater co-operation between relevant organisations and are disappointed that the need to foster relationships between professional leadership bodies and the Regulator is not referred to as an important overlap issue.

With respect to providing a transparent system where joint working is operational within an individual Regulator, this should be highlighted to the public, registrants and CHRE as part of an annual report.

Part 13: Cross border issues

Registrant entering from within and beyond EEA

Whilst we acknowledge this is not a review of the EU Professional Qualifications Directive, we strongly believe that the issue of language and practice based competencies should form part of the Statue, or, alternatively, the need to write Rules pertaining to these issues should form part of the Statue.

Patient safety must be the focus of pharmaceutical care and not free movement of professionals. The issues of language/communication and professional competence to practise must be assessed before a pharmacist is allowed to fully register and practise in the British Islands. This assessment should be through a period of supervised working where fitness to practice is assessed by a competent independent peer and should only include a formal examination-type assessment if deemed necessary.

All health professionals operating in another Member State should undergo a period of adaptation to the host country's health care systems. This should include legal, ethical and practice matters, national policies and procedures as well as supervised learning to understand the nuances of practising as a pharmacist in that country

The issue of language competence is of utmost importance for the pharmacy profession and all healthcare professionals working in within and beyond EEA. Within the pharmacy profession there is concern related to language standards and professional mobility. The ability of the patient, pharmacist, doctor, nurse, to understand one another and to communicate effectively is integral to the delivery of safe and effective care. Pharmacists must be able to communicate with both technical vocabulary and with language in the context of patient care. This includes the various colloquialisms and expressions with which migrant health professionals may be unfamiliar.

Many medicines are sold over the counter for minor ailments and pharmacists are required to have communication skills that include both everyday expressions and health- related expressions: such as euphemisms for parts of the body and different words for expressing particular types of pain. These language competencies are difficult to assess in a formal manner and require communication skills in addition to language fluency.

13.4 We would support the introduction of the same regulatory arrangements applying in the Channel Islands and the Isle of Man. We are not however in a position to comment on how this could be achieved.

13.8 We believe that distance service provision should adhere to the same regulatory standards as those being for UK based service providers. Patient safety is paramount; and enforceable measures should be put in place to ensure that pharmaceutical supply via a distant service provision is regulated to the same standard as conventional supply models. Internet sites should be registered with the GPhC, premises should adhere to premises standards, and patients must have access to pharmaceutical advice with every transaction.

In respect to distance provision of health care services, all the Regulators should take a proactive approach to ensure patient safety and regulate internet sites accordingly.