EXPLANATORY MEMORANDUM TO

THE PHARMACY ORDER 2010

2010 No. 231

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty. This Order is being laid simultaneously before the Scottish Parliament.

2. Purpose of the instrument

2.1 This Order establishes a new regulator, for pharmacy, the General Pharmaceutical Council (GPhC) and sets out the arrangements, in Great Britain, for the professional regulation of pharmacists and pharmacy technicians. This Order also makes provision in respect of the registration and regulation of pharmacy premises together with consequential amendments to existing primary and secondary legislation that are necessary as a result of the establishment of the GPhC. Provision is also included in this Order in respect of the education, training of pharmacists and pharmacy technicians, for the establishment of a new scheme relating to the continuing professional development of pharmacists and pharmacy technicians and regarding the regulator's capacity to address fitness to practise issues. .

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 This Order is one of a series of Orders that have been made under the powers given to Her Majesty under section 60 and 62(4) of the Health Act 1999, as amended by the Health and Social Care Act 2008, to modernise the regulation of healthcare professionals. The arrangements for pharmacists and pharmacy technicians replace those set out in the Pharmacists and Pharmacy Technicians Order 2007 which is repealed when this Order comes into force. The arrangements for registered pharmacies amend and supplement those which are contained in Part 4 of the Medicines Act 1968 and section 9 of the Poisons Act 1972. The purpose of this Order is to give effect to the Government policies described in section 7.

5. Territorial Extent and Application

5.1 This Order applies to England and Wales and Scotland..

6. European Convention on Human Rights

6.1 The Parliamentary Under Secretary for Health, Ann Keen, has made the following statement regarding human rights:

"In my view the, the provisions of the Pharmacy Order 2010 are compatible with the Convention rights."

7. Policy background

7.1 This Order takes forward recommendations in the Government's White Paper *Trust, Assurance and Safety – The Regulation of Health Professional in the 21st Century* ("the White Paper") which are designed to modernise and strengthen the regulation of healthcare professionals,

to ensure patient, public and professional confidence in the regulatory bodies and make the protection of patients and the public a priority.

7.2 The new regulatory body for pharmacy established by this Order replaces the RPSGB which, from 1841, was the professional and regulatory body for responsible for pharmacists in England, Scotland and Wales. The statutory regulation of pharmacy technicians by the RPSGB was introduced as from 1st July 2007, but not commenced till 2009.

7.3 In addition to establishing a new pharmacy regulator for Great Britain, the purpose of this Order is to enhance the development of high quality practice at a critical time for the pharmacy profession, with its increasingly clinical focus. It also aims to ensure that pharmacy regulation is proportionate and does not get in the way of good patient care. In particular it:

- Establishes the new pharmacy regulator and sets out its main objective to protect, promote and maintain the health, safety and well-being of members of the public;

- Establishes the GPhC's statutory duty in line with that of other professional regulators to ensure it considers the interests of stakeholders in its deliberations;

- Sets out the framework for the constitutional and governance arrangements for the GPhC;

- Sets out arrangements for accountability to the UK and Scottish Parliaments, covering annual reports (including arrangements to ensure that the regulator adheres to good practice in relation to equality and diversity, and a report on the effectiveness of its Fitness to Practise procedures) and strategic plans;

- Establishes GPhC's key functions which include:

    a. registration of qualified and competent practitioners;
    b. temporary registration and annotations during emergencies;
    c. setting and securing standards of practice, education and training, continuing professional development and conduct;
    d. operating fitness to practise procedures to deal with registrants where there are concerns about their fitness to practise and protect the public from registrants who become unfit to practise;
    e. registration, regulation and inspection of pharmacy premises and enforcement responsibilities**;**

- Establishes arrangements for the GPhC to set fees;

- Sets out transitional arrangements.

7.4 There are no plans to consolidate the legislation amended by this Order.

8. Consultation outcome

8.1 The Health Care and Associated Professions (Pharmacy): The Pharmacy Order 2009 was published in draft for public consultation on 8 December 2008. Consultation closed on 9 March 2009. 195 completed questionnaires were returned showing overall support for the proposals for the GPhC set out in the draft Order.

8.2 During the consultation period 5 stakeholder events were held to raise awareness of the consultation and to set the establishment of the GPhC in the context of the wider programme of Government led reforms to modernise and strengthen the regulation of health professionals. There were 4 national and regional events as well as an event specifically for organisations and groups representing patients and the public.

8.3 The *Health Care and Associated Profession (Pharmacy): The Pharmacy Order2009: Consultation Report* is available at:
http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_100891

8.4 There was broad support among respondents for the overall approach to establishing the GPhC set out in the consultation document. In particular, respondents supported the key underpinning principles of:

- The overriding interest being the safety and quality of care patient receive;
- A proportionate, risk based approach to the regulation of both pharmacy professionals and pharmacy premises that the proposed legislative framework for the GPhC seeks to facilitate;
- Including broad provisions in the draft Order to allow the regulator flexibility to adapt quickly to developments in pharmacy practice in the future and to reflect these through its standard setting and other functions.

9. Guidance

9.1 The Department of Health and the Scottish Health Department have not issued any guidance in relation to this Order.

10. Impact

10.1 The impact on business, charities or voluntary bodies is minimal in terms of its monetary implications. These and the more general impact issues arising out of this Order that relate to Pharmacists, Pharmacy Technicians and Pharmacy Premises are discussed in the attached Impact Assessment.

10.2 The impact on the public sector is minimal in terms of its monetary implications. The impact issues for the public sector which arise out of this Order are also explained in the Impact Assessment.

10.3 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business. The Pharmacy Order 2010 is designed to modernise and strengthen the regulation of healthcare professionals to ensure patient, public and professional confidence in the regulatory body and make the protection of patients and the public a priority. However this is a transfer of existing legislation rather than a new burden and the GPhC will have new powers to share information with other regulators to avoid duplication and move to a more risk-based methodology

12. Monitoring & review

12.1 This legislation will be subject to internal review by the Department of Health, together with the Devolved Administrations, in 2011.

13. Contact

Diana Kenworthy at the Department of Health Tel: 020 7972 2820 or email: diana.kenworthy@dh.gsi.gov.uk can answer any queries regarding the instrument.

.Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health - Medicines Pharmacy and industry (MPI)	**Full Impact Assessment of the Pharmacy Order 2009.**	
Stage: Final IA	**Version:** V4	**Date:** October 2009
Related Publications: Draft Pharmacy Order 2009 consultation, partial impact assessment and response to consultation, Lord Carter of Coles Report on professional regulation/leadership in pharmacy & the White Paper, Trust, Assurance&Safety- The Regulation of Health Professionals in the 21 Century		

Available to view or download at:

http://www.dh.gsi.gov.uk.

Contact for enquiries: John Roberts **Telephone:** 0207 972 5922

What is the problem under consideration? Why is government intervention necessary?

The Royal Pharmaceutical Society of Great Britain (RPSGB) is currently both the statutory regulator and professional leadership body for pharmacy. Government intervention is necessary to ensure the appropriate separation of roles and to ensure that modernisation of the regulation of pharmacy reflects the changing role of the pharmacy. Consequently powers were taken in the Health and Social Care Act 2008 to separate the functions.

What are the policy objectives and the intended effects?

The policy objective is to ensure that the public has confidence in the governance and the regulation of the pharmacy profession and that the regulation of the profession is effective and proportionate. The intended effects are greater transparency and accountability in the regulation of the pharmacy profession, and greater public confidence in the safety and quality of care. This could potentially lead to faster detection of anomalies and greater attention to the degree of fitness to practise of pharmacy professionals.

What policy options have been considered? Please justify any preferred option.

Option 1.: No change in existing policies.
Option 2.: Set up a new independent regulatory body to operate alongside the RPSGB.
Option 3.: Set up a new regulatory body that takes over the existing regulatory functions of the RPSGB, operating independently of any public leadership body but in close partnership.

The preferred policy is option 3 and this has been the subject of consulation and received broad support from all stakeholders.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

2011

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:

Ann Keen .....Date: ***22nd October 2009***

Summary: Analysis & Evidence

Policy Option 3 Description: Set up a new regulatory body that takes over the existing regulatory functions of the RPSGB, operating independently of any public leadership body but in close partnership.

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' Costs to regulator from increased operating costs: £3.2mn. Transitional set up costs: £3mn. Potentially significant benefits to patients from prevented loss of life and ill health. To break-even, between 2-3 deaths would need to be prevented per annum.
One-off (Transition)	**Yrs**	
£ 3mn	1	
Average Annual Cost (excluding one-off)		
£ 3.2mn	10	**Total Cost** (PV) **£ 29.5mn**

Other **key non-monetised costs** by 'main affected groups'

Strengthened regulation of the pharmacy profession could result in cost savings from prevented misconduct and resulting ill-health.

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'
One-off	**Yrs**	
£		
Average Annual Benefit (excluding one-off)		
£		**Total Benefit** (PV) **£**

Other **key non-monetised benefits** by 'main affected groups'

Main benefits are increased accountability, transparency and public confidence in pharmacy professionals.

Key Assumptions/Sensitivities/Risks. Conservative estimates used for all costs and benefits. The increased costs of the regulator will be, at least in part, met by fees charged to pharmacists, which amounts to a transfer. Therefore, there are unlikely to be significant disbenefits overall to the private sector. The costs/benefits of changes to registration fees have not been monetised as there is uncertainty as to the resulting deficit/surplus.

Price Base Year 2006	Time Period Years 10	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£**

What is the geographic coverage of the policy/option?			GB	
On what date will the policy be implemented?			1 April 2010	
Which organisation(s) will enforce the policy?			The new regulator	
What is the total annual cost of enforcement for these organisations?			£ N/A	
Does enforcement comply with Hampton principles?			yes	
Will implementation go beyond minimum EU requirements?			yes	
What is the value of the proposed offsetting measure per year?			£	
What is the value of changes in greenhouse gas emissions?			£	
Will the proposal have a significant impact on competition?			no	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for summary sheets)

1. Introduction

The White Paper, *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* (published in February 2007), set out the programme of reform to the UK's system for the regulation of health professionals. Specifically, the strategic direction of reform was based on consultation of the two reviews published in July 2006: "*Good doctors, safer patients"* (Donaldson review) and "*The regulation of non-medical healthcare professions"* (Foster review), as well as to the Government response to the recommendations of the Fifth Report of the Shipman Inquiry and the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries. A key principle emerging from these inquiries is that professional leadership and regulation should not sit in the same body. The current Royal Pharmaceutical Society of Great Britain (RPSGB) performs both roles. Following a review of the pharmacy specific professional issues by Lord Carter of Coles in 2007, provision was sought in the Health and Social Care Act 2008, to create a separate pharmacy regulator. The draft Pharmacy Order 2009 was the subject of full public consulation between December 2008 and March 2009. The Pharmacy Order 2009 is the seconary legislation that underpins that provision.

2. Purpose and intent

The policies promoted in the Pharmacy Order 2009 are intended to benefit all the population in Great Britain. The key aim is to modernise the regulation of pharmacy to take account of the changing role of the pharmacist and ensure that the pharmaceutical regulatory and clinical leadership arrangements are synchronised with the pharmacists' increasing levels of professional responsibility to patients. The key objectives of the policy options assessed in this Impact Assessment include making the regulation of the pharmacy profession more focused on patient safety and ensuring that the professional regulation of pharmacists remains independent, transparent and accountable to the public. It is also intended that the associated health outcomes following the transition will improve public and professional confidence in pharmaceutical services. In addition to improved health outcomes for patients, this should result in a more efficient performance of the pharmacy profession in the wider health system within which pharmacists operate. The provisions in the Order focus on setting standards so that the public can be clear about what they can expect from the profession and the profession is clear what is expected of it. The separation of leadership from regulation would offer pharmacy the opportunity to create a strong voice, which can speak on behalf of the profession and take forward its development. **However, the focus of the proposals and the evaluation of options in this impact assessment are to reform the regulatory structure for the**

pharmacy profession. The evolution of a professional leadership body for the pharmacy profession, from the RPSGB, does not fall under the scope of these proposals and will be for the profession to determine.

3. Background

Pharmacy is the only self-regulated profession with its own inspectorate. Since 1841 the RPSGB has been the professional and regulatory body responsible for pharmacists in England, Scotland and Wales. It has regulated pharmacy technicians from 1 July 2009. As a professional body, the RPSGB leads and develops the profession. As a regulator, it is responsible for the following functions:

- Setting standards for education and training;
- Maintaining a register of pharmacists, pharmacy technicians and premises;
- Setting standards for the conduct and ethics expected of registrants;
- Setting standards for practice and performance;
- Setting standards for the content and frequency of monitoring of continuing professional development;
- Approving courses, institutions and qualifications;
- Determining initial fitness to practise of potential registrants; and
- Investigating impaired fitness to practise and adjudicate fitness to practise cases.

The RPSGB combines its regulatory and leadership functions with a statutory enforcement role, exercising law enforcement functions under the Medicines Act 1968 and the Poisons Act 1972. The RPSGB is funded through membership fees, with a contribution by the Department of Health towards the cost of enforcing certain provisions of the Medicines Act.

There have been a significant number of developments in the pharmacy profession and policy over the past five years (for example, pharmacies are increasingly providing enhanced and advanced services), which have brought the sustainability of the dual role of the RPSGB into question. The White Paper *Building on Strengths, Delivering the Future* set out how pharmacists will work to complement GPs in promoting health, preventing sickness and providing care that is more personal and responsive to individual needs. Pharmacists already play a vital role for local communities in dispensing medicines and providing health care advice and other services. However, as a profession, pharmacists are entering a new phase, which highlights the need to ensure that pharmacists' regulatory and clinical leadership arrangements are balanced with their increasing levels of professional responsibility to patients.

In addition to the expanding clinical role of pharmacists, a number of events and systems failures in the last 20 years have highlighted the importance of ensuring that the professional regulation of healthcare professions is of high quality, transparent, can safeguard public safety and has the confidence of patients and other professionals. In particular, the Fourth Report of the Shipman Inquiry (published in 2004) identified a number of systemic shortcomings that enabled Shipman to procure large quantites of controlled drugs from pharmacies. These events have highlighted the need to ensure that the regulation of the pharmacy profession is brought in line with other healthcare bodies. The reform of the regulations governing the pharmacy profession is intended to ensure that there are robust processes in place to detect and prevent poor practice and identify any individuals who pose a risk to public safety.

Recent high-profile cases of clinical and systems failures in the NHS have made it essential to develop methods for regular assessment of the clinical performance of health professionals, such as pharmacists. This is to assure the public that clinical care is safe and to require individual pharmacists to show that they can provide services that meet the appropriate standards. Thus, the Government brought proposals to Parliament in the Health and Social Care Act 2008 to enable it to separate the regulatory and leadership functions of the pharmacy profession and establish a General Pharmaceutical Council (GPhC) responsible for the regulation of pharmacists and pharmacy technicians, the inspection of pharmacies and the registration of pharmacy premises.

Following the publication of the landmark document *Trust, Assurance & Safety-The Regulation of Health Professional in the 21st Century*, the Government set up a short-term working party, chaired by Lord Carter of Coles which included representatives from the RPSGB and other stakeholders. The remit was to develop a robust, deliverable, cost effective plan for the establishment of the GPhC. The working group recommended the GPhC should be fully functional by 2010. The report also set out the functions of the proposed GPhC under four headings: setting and promoting standards, education and training, registration and fitness to practise. In closing, the new Pharmacy Order (2009) will give to the Council the required legal framework necessary to take over the regulatory role currently exercised by the RPSGB.

4. Rationale for Government intervention

The Department of Health and Scottish Government are committed to improving and protecting the health of the population. Recent systems failures in public safety and medicines management (for example, by Shipman/Allitt/Kerr and Haslam) combined with the future strategic direction envisaged for the pharmacy profession make it imperative that the

professional regulation of the pharmacy profession is of high standard and that patients have confidence in the regulatory structures and the quality of services they receive. Pharmacists are increasingly taking on clinical responsibilities and an increasing number of pharmacies are providing enhanced services to patients (on average two per pharmacy) and moving away from solely providing dispensing services. The reform of the regulatory arrangements is intended to ensure that conflicts of interest between the leadership and regulatory functions do not arise. The Government intends to ensure that the regulation of the pharmacy profession supports the high quality services pharmacy professionals already provide, while putting in place systems that identify problems or potential weaknesses in service delivery. The Government also intends to ensure that the regulatory burden for the pharmacy profession is proportionate to the risks the regulations seek to address.

5. Outcome of the consultation

The consultation was developed following close work with a range of stakeholders and advice from the Professional Regulation and Leadership Oversight Group appointed by Ministers to oversee establishment of the GPhC. It was a joint consultation of the Department of Health and Scottish Government and was open between December 2008 and March 2009. The consultation was widely publicised in the relevant media and professional journals and five stakeholder events were held.

195 full responses were received with a further 54 emails and letters giving general comments relating to one or two specific issues – 42 of these opposing the proposals on restricted titles/no non-practising register. All responses were reviewed as part of the consultation process.

Generally there was broad support amongst respondents for the overall approach to establishing the GPhC set out in the consultation document. In particular, respondents supported the key underpinning principles of:

- the overriding interest being the safety and quality of care patients receive;
- a proportionate, risk based approach to the regulation of both pharmacy professionals and pharmacy premises that the proposed legislative framework for the GPhC seeks to facilitate;
- including broad provisions in the draft Pharmacy Order 2009 to allow the new regulator flexibility to adapt quickly to developments in pharmacy practice in the future and to reflect these through its standard setting and other functions.

On the issues of restricting the title “pharmacist” and “pharmacy technician” to those on the practising register and maintaining a single register for practising registrants it was decided to

implement the proposals in the draft Pharmacy Order 2009 to continue to restrict the title to those who are on the register of the GPhC, in line with the GPhC's key focus on public protection and patient safety. Respondents also raised concerns about the proposal for standards for pharmacy premises. In response it was decided to engage and involve a wide range of stakeholders, including patients and the public, in developing the more detailed thinking underpinning the broad standard setting powers and other key functions of the GPhC.

The report on the outcome of the consultation was published on the Department of Health's website in June 2009.

6. Coverage of the Impact Assessment

This full impact assessment considers the options of the preferred ways forward for the regulation of the pharmacy profession. This document sets out the differences in costs and benefits (both the monetised and non-monetised) that result from different institutional structures dealing with regulatory requirements. The focus of this analysis is not about reform of the RPSGB, or an analysis of its current efficiency. This Impact Assessment does not assess what level of fees would be appropriate to cover the increased operating costs of the new regulator.

This impact assessment covers Great Britain. The review entitled *'The regulation of the non-medical healthcare professions'* called for closer working between the RPSGB and the Pharmaceutical Society of Northern Ireland (PSNI) and, in time, for the amalgamation of the two. Although provision has been made for this in the Health and Social Care Act 2008, Northern Ireland Ministers have decided not to join the GPhC at this stage. In light of these proposals, further consideration is being given to the future arrangements for pharmaceutical and professional regulation in Northern Ireland. The Government will review these arrangements over time.

7. Risk Assessment

Without Government intervention, there is a risk that public confidence in pharmaceutical services could fall should those rare occasions where individual or systems failures occur be uncovered. Reforms in the regulation of pharmacy professionals will better promote the interest of the public and patients and ensure the highest standards of professional practice. Without any reforms, the RPSGB's responsibilities towards pharmacists for professional leadership are potentially in conflict with this role as an independent regulator for the profession itself. This

need for reform and for much greater clarity about the RPSGB regulatory and leadership functions has been recognised by the RPSGB itself.

There are a number of risks involved in the delivery of the proposed changes to the current regulatory structure and existing leadership functions for the pharmacy profession. These risks relate to the period of transition that any changes would necessitate. However, the Department of Health has put in place a number of mitigating arrangements and has significant scope to influence these issues through a detailed design of proposed options. Currently £3mn has been allocated for the transition for 2008 and 2009 for safety (to maintain clear accountability for safety and quality issues, as well as clear arrangements for handling investigations which span the period of transition), legal, IT, human resource and other transitional costs arising from potentially running two organisations parallel to each other in the initial stages.

8. Options

The main aim of this Impact Assessment is to set out the preferred option, and contribute to analysis of preferred ways forward for regulation of the pharmacy profession. The assessment is undertaken in light of the key principles which regulation should seek to achieve, described in the White Paper, *Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st Century.*

Four options were long-listed for consideration:

Option 1: No change in existing policy.
Option 2: Set up a new independent regulatory body to operate alongside the RPSGB.
Option 3: Set up a new regulatory body that takes over the existing regulatory functions of the RPSGB, operating independently of any public leadership body but in close partnership.
Option 4: Strengthen the existing regulatory powers of the RPSGB.

During initial options appraisal, it was considered that Option 4 failed to deliver the required separation of regulatory and leadership functions, which has been determined as the key principle of ensuring that there remains no conflict of interest in performing these functions. As transparency and accountability are some of the key deliverables of the proposed reforms, it was considered that merely strengthening existing regulatory powers of the RPSGB without a further structural reform, would not be able to guarantee public confidence in the regulation of the pharmacy profession. Therefore the following three options were short-listed for consideration:

Option 1: No change in existing policy.

Option 2.: Set up a new independent regulatory body to operate alongside the RPSGB.

Option 3.: Set up a new regulatory body that takes over the existing regulatory functions of the RPSGB, operating independently of any public leadership body but in close partnership.

9. Preferred option

The option offering benefits within acceptable monetary and non-monetary costs, as indicated by the analysis carried out by NERA Economic Consulting, is Option 3. NERA considered the costs involved in undertaking current functions jointly, allocating them to each of regulation and professional leadership, and assessed the extent to which costs are replicated and inefficiency is introduced by dividing the functions.

It is considered that Option 1 is unsustainable given the future direction of developments in the pharmacy profession and the need to ensure public confidence in regulation. The need to demonstrate the independence of regulation from the leadership and professional functions will not be met by this option. NERA analysis of the incremental costs and benefits of options suggests that Option 3 is also preferred to Option 2, as Option 2 does not make use of the shared technical expertise that may be inefficient to duplicate. Therefore, the most cost effective way of establishing an independent regulator for the pharmacy profession is to utilise existing expertise at RPSGB to create a regulatory body that works in close partnership with a pharmacy professional leadership body.

10. BENEFITS AND COSTS

Option 1: No change in existing policies

There are no benefits to this option and it does not meet the objectives for regulation as outlined in the Foster review, White Paper and related documents, particularly that of demonstrated independence of regulation from the profession, and the separation of regulation and professional leadership functions. Given the increasing clinical role of pharmacy professionals, existing regulatory arrangements are considered untenable.

Option 2: Set up a new independent regulatory body to operate alongside the RPSGB.

This option has the benefit of separating the leadership and regulatory roles in a transparent and clear way. However, with two completely separate bodies there will be no benefits from

synergies or the existing knowledge base within the RPSGB, which are key to enable the two entities to function at strategic and operational level. Without close working, the regulatory arrangements might be at risk in keeping with their increasing levels of strategic and professional responsibility and the accompanied benefits and risks to patients. This could result in the isolation of the regulator, which could have an impact on its performance. Further, a management imbalance in the way the pharmacy profession is led and regulated could occur if the two bodies did not work in synergy. However, it is possible that patients could see improved health outcomes from increased scrutiny of the pharmacy profession and faster detection of any misconduct and a reduction in systems failures.

Option 3: Set up a new regulatory body that takes over the existing regulatory functions of the RPSGB, operating independently of any public leadership body but in close partnership.

As the profession takes on an increasingly clinically important and professionally demanding role in the treatment of patients, the RPSGB needs to separate its regulatory system from its system of professional and clinical leadership, allowing each distinct function to focus solely on its core role for the benefit of the public and the profession. To maintain effective regulatory function during the transitional period — fundamental in guaranteeing public protection — it is essential to ensure that there is an efficient transfer of the specialist skills of those currently managing and undertaking activities related to regulation as noted in the *Report of the working party on professional regulation and leadership in pharmacy.* A learned and authoritative organisation, supporting excellence, professionalism, and innovation in the science and practice of pharmacy will complement and reinforce the regulatory body's role in determining and securing initial fitness to practise. The Government considers that a 'close relationship' between a new Professional Leadership Body (PLB) and the GPhC would be of clear benefit for continuity reasons to both bodies and subsequently to patients, the public and the profession. It would also ensure that none of the existing knowledge and expertise at RPSGB would be lost. A strong and effective professional body can contribute to the overall quality framework, and specifically it can help to achieve the objective that regulation seek not only to control and root out the rare examples of poor practice but also to raise the standards delivered by the overwhelming majority of professionals. Overall, a close relationship between an independent regulatory and the leadership bodies is the preferred option as it will assure the highest safety and quality of care that patients receive from the pharmacy profession.

Costs

Option 1: No change in existing in policy

There are no additional costs in pursuing this option.

Option 2: Set up a new independent regulatory body to operate alongside the RPSGB.

There would be a number of transitional costs in setting up a new regulatory body from scratch. NERA estimates that ongoing operational costs of a regulatory body would be significantly higher as there would inevitably be a duplication of some of the functions already performed by the RPSGB at least during the transition phase to the new set up. A number of one-off costs would also arise in the process of culling duplicative functions, for example, the systems and IT infrastructure, which are currently in place at RPSGB, would have to be removed leading to additional costs for the PLB evolving from the RPSGB. They would also have to make alternative arrangements for a new tenant at their existing premises, which could potentially be more costly depending on the requirements of the new tenants. The new regulatory body would not have the monetary and human resources cost savings from utilising existing resources at RPSGB. Thus, this option is not considered cost effective nor risk-free.

Option 3: Set up a new regulatory body that takes over the existing regulatory functions of the RPSGB, operating independently of any public leadership body but in close partnership.

The overall costs of regulation are expected to increase due to its expansion in scope, and such an increase is likely to affect the costs of this option less than proportionately. A number of transitional costs would be incurred in setting up the new organisations. Such costs could include, for example, the cost of operating bodies in parallel during a transitional period, the costs of learning in a new organisation, and administrative matters such as the design and provision of stationery reflecting new organisational identities.

A close relationship between the two bodies will ensure continuity and create a synergetic and supportive relationship to move the new arrangements forward. Close working between the regulator and the professional body will help ensure that costs will be managed more effectively, especially since any technical or practice based knowledge support will be easily accessible and cost-efficient from the professional body. Stronger, more transparent and more accountable professional regulation for the pharmacy profession would be likely to result in better detection of any errors or anomalies in practice, which could result in significant cost savings to the Department from reduced public inquiries into misconduct and improved health outcomes for patients.

Summary of Benefits and Costs

Option	Benefits	Costs
1 – No change in policy	No additional benefits	No additional costs
2 - Set up a new independent regulatory body to operate alongside the RPSGB.	Increased public confidence in the regulation of the pharmacy profession. Greater transparency and accountability to the public.	There would be a number of transitional set up costs for the new body and potential duplication of functions.
3 - Set up a new regulatory body that takes over the existing regulatory functions of the RPSGB, operating independently of any public leadership body but in close partnership.	As above.	As above, but additional benefits of synergies between existing regulatory operations and proposed powers. This is likely to result in lower costs.

See also Annex B – Quantification of costs and benefits

Benefits

Separating the leadership and regulatory roles of the RPSGB is expected to lead to more effective oversight of the pharmacy profession. This is anticipated to have three main beneficial impacts: reduction in dispensing errors; avoidance of serious incidents of misconduct; increased public confidence in the pharmacy profession. These impacts are now evaluated.

The scale of these impacts, and the exact magnitude of the ensuing beneficial effects, is subject to great uncertainty and cannot be accurately forecast. To determine whether the level of benefits are sufficient to justify the costs of the policy, this analysis therefore evaluates a credible conservative scenario, which deliberately *underestimates* the likely benefits of the policy. This approach would therefore provide a lower limit of the expected benefits. If this conservative scenario leads to benefits that justify the costs of the policy, it is possible to have confidence that the true net benefit will be even greater.

Reduction in dispensing errors

Improving the oversight of the pharmacy industry is expected to lead to higher standards of pharmacy service, which should result in fewer dispensing errors.

A recent study found that over 3% of items dispensed in community pharmacy were subject to a dispensing error relating to labelling or content[1]. Of these, two thirds (2%) were of minor clinical

[1] Franklin, B.D. and O'Grady, K. (2007). "Dispensing errors in community pharmacy: frequency, clinical significance and potential impact of authentication at the point of dispensing." International Journal of Pharmacy Practice, 15 . pp. 273-281. ISSN 0961-7671

significance – and are not considered. If the effect of the proposed changes were to reduce this error rate by just **0.01%** - that is, from 1% to 0.99%, this would correspond to the elimination of **84,000** clinically significant errors[2]. If the average value of the health impact of a dispensing error is just **£5**, this would correspond to an annual benefit of **£420,000**, with a net present value over 10 years of **£3,500,000**.

Avoidance of serious misconduct incidents

Improving the oversight of the pharmacy industry is expected to reduce the likelihood that medicines could be used in serious incidents of misconduct.

If it is assumed that a serious misconduct incident would otherwise occur every **10 years**, and that it would involve **20 deaths** of patients, each losing the equivalent of **10 years** of additional life-expectancy at full health, then the average annual value of the lives lost would be calculated as **£1,000,000**. If the proposed measures were to reduce the likelihood of serious misconduct by **10%**, this would correspond with an average annual benefit of **£100,000**, and a net present value over 10 years of **£840,000**.

Any additional costs to the NHS of investigating serious misconduct incidents have not been reflected in this analysis. The impact of deaths on patients' relatives has also been ignored. To the extent that these effects will, in fact, result from serious misconduct incidents, the benefits calculated for the proposed measures will have been underestimated.

Increased public confidence in pharmacy profession

Improving the oversight of the pharmacy industry is expected to increase public confidence in the pharmacy profession – which can be considered as a valuable benefit it its own right.

Because it is difficult to determine the value which the public gains from any increased confidence in pharmacy profession, this impact has not been monetised. To the extent that this value is real and significant, the true value of the benefits of this policy will be greater than have been calculated in this conservative scenario.

11. Other qualitative issues

10.1 Pensions

The RPSGB maintains a now closed defined-benefit occupational pension scheme. As is common with many such schemes, the RPSGB's fund is currently in deficit. This is an important consideration for a range of reasons, including that it may have an impact on the cost of establishing any new bodies (that may employ at least some individuals currently employed by

[2] In 2008 there were 843m prescriptions dispensed in the community. Source: http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions

RPSGB and members of its pension scheme) and because its treatment could influence staff retention. It could ultimately have the potential to threaten the overall financial stability of the RPSGB, especially if doubts about the future viability of the RPSGB create pressure for the resolution of pensions issues to be accelerated. However, the Trustees of the RPSGB Staff Pension Fund have now established the technical provisions with the RPSGB and a repayment plan has been put in place over 5 years. The trustees will review this arrangement over the coming months. The Trustees will be monitoring factors that may have an impact on funding of the scheme including changes to actuarial assumptions and the specific issue of the split and when necessary commission a further full actuarial valuation. In addition, the Trustees will review the recovery plan and employer contributions once the current consultation on contributions and benefits is completed and the employer has decided on any changes. Another valuation will take place before there are any changes to the structure of the RPSGB and any new bodies are created.

12. Competition impact assessment

No competition assessment was deemed necessary for this proposal at this stage as the proposal does not directly or indirectly limit the number or range of suppliers of pharmaceutical services. Nor does the proposal limit the ability of pharmacists to compete or reduce suppliers' incentives to compete vigorously. As the main intention is to strengthen the accountability and transparency of the regulation of the pharmacy profession, rather than institute new regulations, it is unlikely that barriers to entry to the market, as a result of the proposed changes would be significantly affected.

13. Small firms impact assessment

Small businesses (independent community pharmacies and pharmacies with five or fewer chains) are important to the supply of pharmaceutical services in England and Wales. By March 2006, small businesses accounted for around 43% of all contractors. Small businesses are defined as independents and chains with five or fewer outlets (Source: The Information Centre). This represents a substantial decrease from two-thirds in 1991, resulting from a trend towards greater market concentration with take-overs and mergers, the entry of new low cost retailers and the expansion of supermarket pharmacies. This trend is likely to continue. By 2011, it is expected that around two thirds of pharmacies will be part of chains of six or more. The outline proposals will have the same positive impact across the pharmacy profession irrespective of the size of the business. There are therefore no adverse effects anticipated by the Government on small businesses.

14. Health impact assessment

The possible changes to amendments in legislation have been screened for their impact on the wider determinants of health, such as transport, housing, employment and lifestyle, as well as the demand they may cause on health and social care services. The changes are not believed to have a significant impact on transport and the environment. In particular, Option 3, where the GPhC and the PLB could be co-located in the existing premises of the RPSGB, is unlikely to produce any additional environmental or health impacts from the new physical arrangements. Other health impacts, for example improved health outcomes through better regulation of the pharmacy profession are considered as part of the formal cost and benefit assessment and can be found in Annex B.

15. Rural proofing

This was deemed unnecessary to assess, as the suggested changes will not affect rural areas and the services they will receive from the new regulatory and leadership arrangements.

16. Economic impact

In addition to the economic impact elements identified in the Competition Assessment, larger companies may better absorb the costs of these proposals. No additional economic assessment to the one presented in the Annex B was deemed necessary for this options stage impact assessment.

17. Equality impact assessment

Equality Impact Screening and Report attached in Annex A.

18. Enforcement and Monitoring

Council for Health Regulatory Excellence (CHRE) will monitor the performance of healthcare regulators

19. Implementation and Delivery Plan

The establishment of the GPhC will be implemented through the Pharmacy Order 2009 and subsequent, related Orders. A project plan for the delivery is attached at Annex C.

20. Review of Regulatory Impact Assessment

The Impact Assessment has been reviewed following public consultation and the analysis of the responses. The Department of Health commissioned further research into the costs and benefits of setting up a new regulator which has enabled assessment of the fee income that the regulator would need to generate to cover its operating costs.

21. Summary and Recommendation

Based on analysis by NERA Economic Consulting, it is at present considered that the preferred option is Option 3. It is the least costly and the most efficient way of delivering the objectives and desired outcomes of the policy.

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	Yes	No
Health Impact Assessment	Yes	No
Race Equality	No	No
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	Yes	No

Annexes

ANNEX A - EQUALITY IMPACT REPORT

The draft Pharmacy Order 2009.

This Order will take forward recommendations in the Government's White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*[1] to establish a General Pharmaceutical Council (GPhC) in Great Britain. The GPhC will be a new regulator for pharmacists, pharmacy technicians and pharmacy premises aligned with key principles in the White Paper that are designed to modernise and strengthen the regulation of healthcare professionals to ensure patient, public and professional confidence in the regulatory bodies and to make protection of patients and the public the first priority.

Background

The Royal Pharmaceutical Society of Great Britain (RPSGB) is currently both the regulatory and professional body for pharmacists. The RPSGB has commissioned regular census (including by employment grade and status) and analysis of its active register with a response rate of approximately 70% (latest census 2008 [3]) . It therefore has a detailed understanding of the ethnicity, gender and age of its members. Using this it has been able to understand areas of under and over representation.

The proposed General Pharmaceutical Council (GPhC) will have a statutory obligation to publish both an equality scheme and an action plan. It will therefore build on the excellent data and work produced by the RPSGB to look at whether any areas of over and under representation need to be addressed by the promotion of equality.

Disability impact assessment

The RPSGB started collecting disability data in March 2007 when all new pharmacists were asked to provide information, on the point of registration, in relation to sexual orientation and disability. To date, the Department is not aware that any pharmacists have registered as disabled with the RPSGB. It is a requirement that community pharmacy contractors, in fulfilling their responsibility to provide a range of essential services under the current contractual framework, comply with the requirements of the Disability Discrimination Act 1995. This includes a requirement that they assess and provide compliance support needed by those patients who fall within the protection of the Act and who have a need for assistance in taking their medicines.

Pharmacy contractors as service providers therefore have a duty to make reasonable adjustments to enable someone with a disability to utilise the service. Reasonable adjustment may include the provision of an auxiliary or compliance aid to enable a person, who is disabled, to take their medicines. In determining what is reasonable, consideration needs to be given to the individual circumstances of the patient and the pharmacy, and a judgement made by the service provider, the pharmacy. As such, it is not appropriate to determine and specify the nature of "reasonable adjustment" nationally, nor to set out different types of intervention and associated payments. Instead, the Department has made specific funding available within the overall contractual settlement (£2.2bn in 2008/09) as a contribution to contractors meeting the requirements of the Act. The changes proposed in this impact assessment are not expected have a negative or a positive impact on disability issues relating to pharmacy. The new

[3] Hassell, K, Seston, E. and Eden M. Pharmacy Workforce Census 2008. Main findings (2009 RPSGB)

regulatory and leadership bodies will continue to monitor disability issues and intervene where appropriate.

Race Equality impact assessment

From the Royal Pharmaceutical Society of Great Britain's (RPSGB) 2008 register of pharmacists, a greater proportion of pharmacists are from black and ethnic minority backgrounds (30%) than for the general population as a whole (9%), (drawing on 2001 Population and Census data). 20% are Asian, 4% Chinese, 4% black and 2% other or mixed race with 70% white.

The Department does not believe the proposed measures will affect any of the three parts of the race equality duty i.e. to eliminate unlawful racial discrimination; to promote equal opportunities or to promote good relations between people from different racial groups. Our assessment is therefore that a full race equality study is not required.

Gender impact assessment

Women are well represented in the pharmacy workforce. According to the RPSGB's register, in 2008, there were 48,794 pharmacists in Great Britain, of whom 57% are women. The number of community pharmacists in England is estimated at 22,000. The proportion of female pharmacists working in the community sector is similar to the proportion of female pharmacists on the register as a whole. Information on the number of transgender pharmacists is not reported.

NHS employed Pharmacists in the hospital and primary care sectors are approximately three times more likely to be women than men. However, with analysis by grade, this turns into over representation of males in senior posts. The proposed GPhC, as part of its role in promoting equality, would be able to examine this anomaly with NHS employers.

The Department does not consider the proposals set out here would have any impact on contractors owned or run by women. Nor does the Department consider this measure will impact on the availability of contractor services to those users who are women. A full gender assessment is therefore not indicated.

Age impact assessment

Over two-thirds of pharmacists in the 2008 register were aged 49 or less. A higher proportion of female pharmacists are in the younger age groups.

Older people are more likely to be regular users of pharmaceutical services. A study conducted for the Office of Fair Trading in 2002 found that 22% of the sample of 1,434 households who had pharmacies make their prescriptions up were aged between 60 and 70, and 17% were over the age of 70, compared with 10% and 11% of the UK population generally.

The Department does not consider that the proposals set out in this consultation would have a different impact on pharmacists across the age range. Neither does the Department believe that the proposals would impact in the availability of contractor services across different age groups in the population generally.

Sexual orientation

The RPSGB began collecting data in March 2007 when all new pharmacists were asked to provide information, on the point of registration, in relation to sexual orientation as well as disability. Information from this source is therefore relatively new and will be built up over time.

The Department does not consider that the proposals set out in this consultation would impact on pharmacists sexual orientation. Nor are they viewed as impacting on the services available to service users on he basis of their sexual orientation.

Religion or belief

Religion or belief of pharmacists is not recorded and there is no anecdotal evidence to suggest the proposals set out in this consultation will have any effect related to religion or belief.

Future work and monitoring

The new regulator, as well as working with NHS employers would also be able, in its Equality Scheme and Action Plan, to promote good practice in the equality of pharmaceutical provision within both NHS and contracted pharmaceutical services. This would be likely to be carried out in a similar way to the other healthcare professional regulation councils (for example, the GMC).

Conclusion

The proposals set out in this consultation are unlikely to result in an adverse impact on pharmacists, pharmacy technicians, pharmacy services or users of pharmacies, but positive impact is also unlikely. As no negative impacts across the equality strands have been identified a full impact assessment is not required.

Sign-off for Equality Impact Assessments:

Based on the information set out above I have decided that a full equality impact assessment is not necessary.

Signed: Sir Bruce Keogh

Business area: NHS Medical Directorate **Date: 16/10/2009**

ANNEX B – QUANTIFICATION OF COSTS AND BENEFITS

Discounting

All costings are for a period of 10 years and all costs are discounted at 3.5%.

Valuation of Financial Costs

Currently £3 mn has been allocated for the transition for 2008 and 2009 for safety (to maintain clear accountability for safety and quality issues, as well as clear arrangements for handling investigations which span the period of transition), legal, human resource and other transitional costs arising from potentially running two organisations parallel to each other in the initial stages. The transitional costs have been estimated by the RPSGB, but the nature and detailed allocation of these costs is yet to be determined.

NERA Economic Consulting analysed how the costs under the Options differed from the baseline of no change in existing policy by allocating costs from RPSGB's accounts into regulatory and leadership functions. NERA's analysis indicates that core regulatory activities (for example, registration of practicing professionals, supporting professional standards, monitoring compliance with regulations and enforcing compliance or taking disciplinary action against a registered practitioner who does not meet the standard) are relatively well defined but that there are also a number of activities that currently jointly support both the leadership and regulatory functions. Allocation of these shared activities depends on the proposed structure of the regulatory body and also sets out the cost differences for the different options. NERA estimates that the running of shared activities, indirectly attributable to regulation, cost approximately £10.5mn at present. In addition to the indirectly attributable regulatory activities, there are a number of direct costs arising from regulation. These costs are assumed to remain the same under all options, and therefore are excluded from the baseline. Under Option 3, where the GPhC is formed from the functions of the RPSGB, NERA estimates that the indirect regulatory operating costs would rise to £13.7mn per annum. They estimate that allocation of costs under Option 2, a structure where a separate body is formed to operate alongside RPSGB, would result in total costs of £15.3mn per annum. This is largely due to duplication of functions and higher operational costs as synergies from the current structure of the RPSGB cannot be utilised. Table 1 below indicates how the options compare with the baseline of no change in existing policy.

Table 1: Costs under the Options considered

	Costs	Difference from baseline
Option 1	£10.5mn	-

Option 2	£15.7mn	£5.2mn
Option 3	£16.7mn	£3.2mn

The difference in costs between Options 2 and 3 arise from differences in operating costs for the GPhC, under the difference scenarios. It is intended that the costs of the GPhC will be covered from registration fees.

It is also possible that there may be a number of cost savings coming out of the regulatory reform due to improved regulatory oversight. It is estimated that in 2008, there will be on average 758 cases pending investigation for the Fitness to Practise committees of the RPSGB. The major drivers for Fitness to Practise are Inspectorate and Conduct and Investigations. During 2007, the Investigating Committee referred 10% of all misconduct cases for the attention of the Disciplinary Committee and handled the remaining itself (using warnings, advice etc.). It is estimated that the total cost of fitness to practise hearings during 2008 will amount to £1.5mn. It is possible that the cost would fall if the improved regulatory framework acts as a deterrent for further misconduct cases. However, it is also possible that costs would increase if strengthened professional regulation leads to a larger number of cases being referred to the investigating committee. Due to the uncertainty over which way the case load will move as a result of the regulatory reform, this cost (or cost saving) has not been monetised for this options stage Impact Assessment.

Valuation of Financial Benefits

Reform of the regulatory arrangements is likely to lead to improved patient satisfaction, improved professional accountability, transparency and effectiveness of the pharmacy profession. While it is difficult to monetise the benefits of strengthened professional regulation of the pharmacy profession due to the significant uncertainty over the projected benefits, it is clear that there are a number of benefits to the public and the health care profession in general from improved regulatory framework. These benefits are likely to accrue from prevented ill-health and loss of life through misconduct by health care professionals. When misconduct does occur, the costs of public inquiries, in addition to the loss or damage to human life, can be significant. Assuming that strengthened professional pharmacy regulation would result in a 10% reduction in the probability of misconduct and a resulting public Inquiry (for a 1 in 25 year event), the annual savings would amount to £120,000 per annum. This excludes the benefits from potential loss of life or increase in ill health due to misconduct or poor professional service, which would increase the benefits significantly.

To achieve value for money from this policy under Option 3 in terms of health gains. At a cost per QALY of £25,000, we would need to see a saving of 128 QALYs per annum. For example, assuming the average life expectancy of 80 years for both men and women, this equates to around two full lives saved in full health per annum.

Assumptions for GPhC budgets

1. The base annual costs of regulation being incurred by the RPSGB have been assessed at £12,518,182 (base costs).

2. Non recurrent transitional costs of £4,384,559 incurred or planned for 2008/09 and 2009/10 have been included.

3. The additional annual costs of regulation through the GPhC have been assessed at £3,428,239. These costs were included in the calculation of the fee charges for 2010 consulted on by the RPSGB in 2009.

4. It is considered that there is a reasonable possibility of further additional costs, at an average of £790,454 per annum, over the ten-year period.

5. The additional annual costs of £3,428,239 include,

    5.1. Lambeth Road accommodation charge. It has been assumed that the GPhC will share accommodation in the current RPSGB Headquarters at Lambeth Road. The cost includes rent, service charges and insurance, based on expected occupied floor space and informed by advice from Chartered Surveyors.

    5.2. GPhC Council - a 14 member Council, meeting up to 12 times a year.

    5.3. The GPhC will appoint a Chief Executive. Additional costs will also be incurred on the supporting secretariat staff and non-staff expenditure.

    5.4. The additional cost includes provision for the appointment of a Director of Finance, deputy, two finance officers and supporting secretariat. It is assumed that basic accounting and transaction services will be shared with, and hosted by, the RPSGB. These are included in the Shared Service recharges in the base costs.

    5.5. The GPhC will need to develop transparent Corporate Governance processes compatible with its status as an independent legal entity. These will include reporting and audit. The additional costs include provision for a manager, and non-staff costs.

    5.6. The costs include provision for the development of an information service within the GPhC to undertake data analysis in support of more effective regulatory processes. The estimate includes a senior information officer and four data analysts, with an assumption of reporting to a main board director.

    5.7. Effective communications will be part of the core activities within the new regulator. Key relationships will include consumers, the wider public, Government, the professions and other regulatory bodies. The cost estimate includes provision for a director, two supporting managers and secretariat.

    5.8. The directorate will be responsible for facilitating and developing strategic and operational planning. The cost estimate includes provision for a director, three support staff and a secretariat.

5.9. Provision has been made for additional cost to be incurred in operating a resource dedicated to the ongoing development of ethics and standards.

5.10. The base costs include provision for a HR director and some shared HR services. The additional costs are for a HR Manager, one support officer and secretariat.

5.11. The GPhC will need to establish and maintain an independent website for transaction and information purposes. Additional costs will also be incurred for telecommunications, e-mail and other business applications. This will include hardware maintenance and applications licences. Some support services will be shared with the RPSGB and the estimate costs are included. The costs have been derived from paper prepared by the RPSGB head of information technology.

5.12. The costs of offices in Scotland and Wales are included. There is also provision for four staff.

5.13. A composite provision has been included for a range of possible additional costs that may be incurred, including aspects of shared services with the RPSGB.

6. The potential additional costs (£7,904,536) that may be incurred over the ten year period include,

6.1. Replacement or upgrading of Registration and Continuing Professional Development IT systems.

6.2. Increased annual running costs of upgraded IT systems.

6.3. Increased costs of pharmacists registration, support, investigation and conduct processes as a consequence of more effective regulation and enhanced standards. It is envisaged that much of the potential increased cost may be avoided through more effective working practices, increased use of technology, information and data analysis.

6.4. The additional costs of pharmacy technician registration, support, investigation and conduct processes as a result of the mandatory regulation of pharmacy technicians. Mandatory regulation of registered Pharmacy Technicians will increase costs in Directorates previously dealing with voluntarily registered pharmacy technicians. This will be as a consequence of an increase in the costs of maintenance and monitoring of standards and competencies. In addition the change from voluntary to mandatory regulation will substantially increase the number of registered pharmacy technicians. The Indicative fees for 2010 are based on 9500 registered pharmacy technicians, however there is the potential to increase to 15000 during 2010 and 2011.

6.5. No additional costs have been included for premises – inspection and enforcement. The GPhC will have the additional power to issue enforcement notices and fines. Notwithstanding this increase in scope there appears to be a consensus that the current number of inspectors is sufficient. It is considered that the processes for monitoring inspection will change to become more efficient, information driven and risk based. There will be increased resolution of potential problems at a local level and earlier in the process. There will be investment (see above) in an improved IT information system for inspectors.

7. It should be noted that, without changing the fee rate, the introduction of mandatory regulation for Pharmacy Technicians should result in an increase in income to the GPhC estimated to rise to £823,860 per annum. The total estimated additional income over the ten-

year period of £7,410,600. This is as a result of a projected increase in the number of registered Pharmacy Technicians from 9500 to 15000.

8. The recurrent additional costs are estimated to be £3,428,239 per annum with potential additional costs estimated at an average of £790,454 per annum.
   The range of additional costs is between £3,428,239 and £4,218,693 per annum.

   The non-recurrent transitional cost of establishing the GPhC is estimated to be £4,384,559.

   Assuming a discount rate of 3.5% over the ten-year period 2010/11 to 2019/20 the

   - **Net Present Value (NPV) of the current (pre GPhC) regulatory cost is £104,108,779.**
   - **NPV of additional GPhC regulatory cost is estimated to be between £28,511,311 and £35,030,040.**

ANNEX C – IMPLEMENTATION AND DELIVERY PLAN