EXPLANATORY MEMORANDUM TO

THE MEDICAL PROFESSION (MISCELLANEOUS AMENDMENTS) ORDER 2008

2008 No.

1. This Explanatory Memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. **Description**

2.1 This Order makes a number of amendments to:

- the Medical Act 1983 (the 1983 Act), and
- the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 (the 2003 Order).

2.2 The 1983 Act makes provision for the statutory regulation of medical practitioners. The amendments to the Act in this Order provide for the transfer of the statutory functions of oversight of medical education from the Education Committee of the General Medical Council (GMC) to the Council of the GMC. The Order also amends provisions relating to licences to practise for, and revalidation of, doctors in the 1983 Act. Revalidation is a process for evaluating doctor's fitness to practise after their initial registration, and the amendments:

- expand the regulation-making powers of the GMC in relation to what may be included in that process,
- include provisions relating to the handling of information obtained in the course of revalidation, and
- deal with some supplementary matters.

2.3 The 2003 Order provides for the regulation of postgraduate medical education and training for specialist medical practice and general medical practice. The amendments to the Order will allow the GMC to provide a mechanism to enable senior consultants who did not apply for inclusion in the Specialist Register at the time it was established (in 1997) to make a late application to the GMC. This will reinstate powers the GMC had prior to September 2005.

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

3.1 None.

4. **Legislative Background**

4.1 The White Paper "*Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century"* ("the White Paper") set out a programme of substantial reform to the system for the regulation of health care professionals. This was based on the results of consultation on two reviews of professional regulation published in July 2006: *Good doctors, safer patients* by the Chief Medical Officer for England, and *The regulation of the non-medical health care professions* by the Department of Health.

4.2 Orders in Council under section 60 of the Health Act 1999 can be used to regulate health care professions. This Order is one of a number of Orders in Council under that section (there have already been two others) that will take forward recommendations included in the White Paper.

4.3 The GMC is a statutory body governed by provisions set out in the 1983 Act. The GMC maintains a register of those who are fit and proper people to practise in the medical profession. It sets the standards for entry to their registers and runs disciplinary procedures for registrants who are alleged to have fallen short of the standards expected of them.

4.4 The 1983 Act requires the GMC to have an Education Committee. At the moment statutory responsibility for medical education lies with the Education Committee. This draft Order will transfer the statutory functions of oversight from the Education Committee to the Council of the GMC. The opportunity is also being taken to remove the anomaly created by the Health Care and Associated Professions (Miscellaneous Amendments) Order 2008 (the first of the three orders referred to in paragraph 4.2 above), which removed the role of the Privy Council in respect of the GMC's functions for graduate education, but did not address its role in respect of the postgraduate education functions covered in sections 10A(3) and 10(A)6 of the 1983 Act. That role has now also been removed.

4.5 Part 3A of the 1983 Act is to be inserted by the Medical Act 1983 (Amendment) Order 2002 but has not yet been brought fully brought into force. It provides for the GMC to make regulations for the issue and withdrawal of licences to practise and for the revalidation of medical practitioners. Chapter 2 of the White Paper included some of the important developments in thinking about how revalidation should operate that there have been since 2002 – in particular, that it should include 'recertification' of senior doctors (a process for determining whether or not they should remain on the General Practitioner Register or the Specialist Register, both of which are held by the GMC) and envisaging important roles in specialist recertification for the medical Royal Colleges. The evolution in thinking on the detail of how revalidation should operate, of which the White Paper represents the most significant step, is reflected in a number of technical changes to Part 3A of the 1983 Act.

4.6 The 2003 Order provides for a scheme for certain consultants to be entered on the specialist register. Article 14 of the Order provides the only route onto the register for those who do not hold a certificate of specialist training. Article 14 lists a number of grounds of entitlement, but before this came into force, the GMC had separate powers to allow late entry to the specialist register for doctors who were in post prior to 31st December 1996.

5. Territorial Extent and Application

5.1 The Order extends to the United Kingdom.

6. European Convention on Human Rights

The Minister of State for Health Services, Ben Bradshaw, has made the following statement regarding Human Rights:

"In my view, the provisions of the Medical Practitioners (Miscellaneous Amendments) Order 2008 are compatible with the Convention rights."

7. Policy Background

7.1 This Order makes a number of changes in order to meet the following policy objectives:

Transferring the statutory powers of the GMC Education Committee to the GMC from January 2009.

7.1.1 The 1983 Act requires the GMC to have an Education Committee and that Committee has statutory powers relating to medical education. The composition of the Committee is a matter for the GMC.

7.1.2 The White Paper set out the Government's intention to shift the Education Committee's responsibilities to the Council of the GMC. This will allow the GMC to consolidate responsibility for all four of its interlocking statutory functions, including promoting high standards of medical education, under the auspices of the Council. In doing so the GMC will be able to demonstrate that its responsibilities for medical education are central to, and not isolated from, its other regulatory functions.

7.1.3 Taking this step now will coincide with the establishment of the re-constituted Council in January 2009 and allow for an orderly transition to the new arrangements. The removal of the residual role of the Privy Council in relation to the first year of postgraduate medical education is as part of a process of giving the health care regulators greater independence in relation to how they perform their functions.

Providing an updated legislative framework for the GMC to be able to introduce a licence to practise for all doctors who require one in 2009.

7.1.4 The purpose of revalidation is to ensure that all licensed doctors are up to date and fit to practise. As is mentioned in paragraph 4.5 above, plans for the development and introduction of revalidation have been in place for some time. However, the publication of Dame Janet Smith's fifth report *Safeguarding Patients: Lessons from the past –Proposals for the future* and subsequent reviews of the issues arising from that report meant that this legislation has not yet been fully brought into force.

7.1.5 Patients and the public have made it clear that this wish to see progress on the introduction of revalidation, and this view is shared by the Government and the GMC. This Order amends some of the provisions of Part 3Aof the 1983 Act to bring them into line with the reforms outlined in the White Paper and with up-to-date thinking on how revalidation should operate.

7.1.6 The White Paper changes, which are outlined in paragraph 4.5, are essentially facilitative measures, expanding the GMC's regulation-making powers in the areas identified. In addition, there are measures relating to referral of doctors through the GMC's fitness to practice procedures where information obtained during revalidation calls into question their fitness to practise, and relating to making public, on public interest grounds, information obtained during revalidation when that ceases.

7.1.7 These changes place on a statutory footing the arrangements for handling adverse information about a doctor obtained in the course of revalidation, about which the Government considered that the legislation needed to be clearer in the interests of all concerned – and that there was a potential gap in the scheme in circumstances where a doctor was not referred through the GMC's fitness to practise procedures.

7.1.8 The new powers of public interest disclosure of adverse information will also apply in relation to revalidation pilot schemes. It is anticipated that the licences to practice will be introduced in 2009 before the statutory scheme for revalidation is rolled out, allowing the GMC to issue licences to practice as an important preparatory step towards the revalidation of all doctors. This will also help to identify those doctors in active medical practice who will need to participate in revalidation.

Reinstating the GMC's previous power to allow late entry on to the Specialist Register in certain circumstances.

7.1.9 Since 1997 the GMC has held a register of doctors who hold a specialist qualification (the Specialist Register) in addition to the Medical Register. Inclusion on the Specialist Register allows registrants to take up NHS consultant posts and is a requirement in the NHS consultant contract. Between 1997 and September 2005 any doctor who was in post when the Specialist Register was established could apply direct to the GMC for late entry onto the Register.

7.1.10 The vast majority transferred onto the Register when it was created, but some, for various reasons, did not. When the Postgraduate Medical Education and Training Board (PMETB) was established in September 2005 the GMC lost the power to grant late entry to the Specialist Register. At the moment, the only route onto the Register for those who do not hold a Certificate of Completion of Training (CCT) is through application under Article 14 of the 2003 Order. Doctors who became consultants before the CCT or its predecessor were created would fall into this category.

7.1.11 The existing grounds for entry on to the Register under article 14 were not designed for this group of doctors; rather, article 14 was essentially designed to provide a route for overseas doctors who had completed all or part of their specialist training abroad. An application by this route can be a lengthy and costly process. The additional route for entry on to the register which is to be added by the draft Order would not involve a lengthy scrutiny process, although the exact details of the process will be set out in a formal scheme.

7.1.12 As indicated in paragraph 4.5 above, revalidation is expected to include, in due course, recertification for those on the Specialist Register. The current situation where some consultants are not on the Register means that there is the potential for a small number of consultants to avoid recertification. The first step in correcting this is to ensure that there is a quick and easy route onto the Specialist Register by reinstating the GMC's power to accept late applications from this particular group.

Consultation

The Medical Profession (Miscellaneous Amendments) Order was published in draft for public consultation on 6 March 2008. Consultation closed on 5 June 2008. 34 responses were received, showing a majority support for the amendments set out in the draft Order. A report on the consultation has been laid before Parliament and is attached to this Memorandum.

Consolidation

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

8. Impact

8.1 An Impact Assessment is attached to this Memorandum.

9. Contact

Sean King at the Department of Health, tel: 0113 254 6898 or e-mail sean.king@dh.gsi.gov.uk

Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	**Impact Assessment of the Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2008**	
Stage: IMPLEMENTATION	**Version:** Final	**Date:** 24 **September 2008**
Related Publications: Trust, Assurance and Safety- The Regulation of Health Professional in the 21st Century; Medical Revalidation -Principles and Next Steps		

Available to view or download at:

http://www.dh.gov.uk

Contact for enquiries: Sean King **Telephone:** 0113 254 6898

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

The Government wants regulatory bodies to be more strategic. The GMC's Education Committee currently has statutory responsibity for education. This Order will transfer that responsibility to Council itself. The Government wants to make progress with revalidation to assure the public that doctors are safe and up to date. This Order will update part of the Medical Act to allow the issue of licences to practice and the piloting of revalidation projects. There is a contractual requirement for consultants working in the NHS to be on the Specialist Register and this Order simplifies entry.

What are the policy objectives and the intended effects?

Transferring the statutory functions relating to medical education to the GMC Council will consolidate responsibility for all the GMC's statutory functions, allowing it to act more strategically and cohesively. Updating the scheme for licences to practice and revalidation will enable these to be introduced which will improve patient safety. Reinstating the GMC's ability to accept late applications for entry to the Specialist Register will make it easier for a small number of doctors working in the NHS to fulfill contractual obligations to be on it and facilitate revalidation in due course.

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

The policy options for all three amendments were (a) to do nothing; (b) make changes but not on a fast track, and (c) to make the changes now, which was the preferred option in each case . The policy options for each amendment are discussed more fully in the evidence base.

Following consultation we have decided to proceed with the preferred option (c) and make the changes proposed in the draft Order now.

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

The evaluation of revalidation pilots is due in 2009/2010 and will provide an evidence base for assessing the wider cost and benefit of revalidation.

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

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Ben Bradshaw.....Date: ***9th October 2008***

Summary: Analysis & Evidence

Policy Option: C	Description: To make changes in draft order with immediate effect

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ £4m	1
Average Annual Cost (excluding one-off)	
£ 0	

Description and scale of **key monetised costs** by 'main affected groups' The estimated cost of £4 million for introducing revalidation pilots, which this Order will enable, was covered in the RIA for the white paper Trust Assurance and Safety based on an estimate of 5,000 sessions at an average of £400 to allow participation, plus development and administrative costs

Total Cost (PV) **£ £4m**

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

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ 0	0
Average Annual Benefit (excluding one-off)	
£ 0	

Description and scale of **key monetised benefits** by 'main affected groups' The RIA on the white paper noted that it would be difficult to cost direct benefits. Once revalidation is fully embedded clinical negligence costs (£592m in 05/06) and the cost of excluding doctors from work because of concerns (average cost£188k) should decrease over time. The pilots will provide evidence to assess benfits

Total Benefit (PV) **£ 0**

Other **key non-monetised benefits** by 'main affected groups' Amendment 1 consolidates the GMC's statutory functions under the auspices of Council. Amendment 2 allows for the introduction of a licence to practise as a first step in the process of revalidation (see annex) Amendment 3 will ease entry to the Specialist Register, which is a contractual requirement for NHS consultants .

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£ 0**	**NET BENEFIT** (NPV Best estimate) **£ 0**

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			2009	
Which organisation(s) will enforce the policy?			GMC	
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?			No	
What is the value of the proposed offsetting measure per year?			£ 0	
What is the value of changes in greenhouse gas emissions?			£ 0	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro **0**	Small **0**	Medium **0**	Large **0**
Are any of these organisations exempt?	No	No	N/A	N/A

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

Increase of £ 0 Decrease of £ 0 **Net Impact** £ 0

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

Introduction

1. This Impact Assessment updates the original assessment published when the draft Order was issued for public consultation in March this year. Some minor amendments have been made to the Order, but the three main proposals remain intact, with around 80% support in each case.

Summary of the White Paper Trust, Assurance and Safety- The Regulation of Health Professionals in the 21st Century

2. The White Paper sets out a programme of reform to the United Kingdom's system for the regulation of health professionals, based on consultation on two reviews of professional regulation published in July 2006: Good Doctors safer patients by the Chief Medical Officer for England and the Department of Health's The regulation of the non-medical health care professions. It is complemented by the Government's response to the recommendations of the Ayling, Neale and Kerr/Haslam Inquires, Safeguarding Patients, which sets out a range of measures to improve and enhance clinical governance in the NHS.

It can be viewed at http://www.dh.gov.uk/

Amendment to the Medical Act which will transfer the statutory functions of the oversight of medical education from the Education Committee to the GMC (Amendment 1)

3. The White Paper *Trust, Assurance and Safety- The Regulation of Health Professional in the 21st Century* described the interlocking nature of its four core functions: controlling entry to the register, fostering good medical practice, promoting standards of medical education and dealing firmly and fairly with doctors whose fitness to practice is in doubt..

4. The Medical Act 1983 requires the GMC to have an Education Committee, which currently has statutory responsibility for oversight of medical education. In view of the interdependency of the GMC's statutory functions, the Government wants the GMC itself, through its Council, to assume statutory responsibility for the oversight of eduction rather than the Education Committee.

5. The Government's programme for reforming the regulation of all health care and associated professions was first set out in *The NHS Plan - A Plan for investment, a plan for reform.* This made clear that regulation should be strengthened and specified that regulatory bodies should generally be smaller and more strategic with much greater patient and public representation in their membership.

6. This change will enable the newly constituted GMC to have the opportunity to decide the appropriate composition of any future Education Committee and to assist it in carrying out its statutory functions with regard to education. The GMC will be able to set and oversee the delivery of the standards for basic medical education in the UK.

7. No cost implications have been identified by the GMC. There will be no cost to the Department of Health. The main benefit of making this change is that the GMC will be able to consolidate all of its statutory functions under the auspices of the GMC Council.

Having all of its statutory responsibilities in one body will enable the GMC to develop coherent policy on revalidation in order to enhance public confidence and strengthen public protection.

8. The policy options available were:

(a) do nothing. Leaving the arrangements for education as they are would require no work but would not achieve the objective of placing the statutory education functions within the GMC Council.

(b) Make the change, but not on a fast-track. This would achieve the objective but any delay beyond the creation of the new council would make an orderly transition more difficult and leave the anomaly of one of the Council's key functions held by a committee rather than by the Council itself.

(c) Make the change now. This is the preferred option as the new Council will assume responsibility for all four of its interlocking functions from its inception and fulfil the objective set out in the White Paper. This is the preferred option.

Amendment to the Medical Act which will enable the General Medical Council to make regulations to issue a licence to practise and carry out pilots around the process of revalidation (amendment 2)

9. The Order will amend the Medical Act 1983 to update the powers of the GMC to make regulations to provide for the issue of a licence to practise to all doctors. The order will also enable the GMC to carry out revalidation pilot projects in a manner that reflects the updated powers. Issuing a licence to practise is an important first step in the work around revalidation. The purpose of revalidation is to ensure that licensed doctors are up to date and are fit to practise. Revalidation has three elements

* To confirm that licensed doctors practise in accordance with the GMC's generic standards (relicensing).
* For doctors on the specialist register and GP register, to confirm that standards appropriate for their speciality (recertification).
* To identify for further investigation and remediation where appropriate, doctors whose practice is impaired, or may be impaired- where local systems are not robust enough to do this or do not exist.

10. Revalidation presents a huge change to medical regulation. The Order takes this into account. It will facilitate piloting of revalidation, which ideally needs to take place before any final policy on revalidation takes place. Legislation may need amending at a later stage once the outcome of the pilots is known.

Licence to Practise

11. When a doctor first registers with the GMC they will simultaneously be issued with a licence to practise. The GMC have advised that currently they have 240,000 doctors included in the register of medical practitioners. Of these around 160,000 are thought to be in active medical practice. It will only be medical practitioners in active medical practice who will require a licence. All doctors who are registered at the time the licence is introduced will be entitled to receive one at no charge.

12. The main benefit of introducing a licence to practise will be, first of all, to identify those medical practitioners currently practising. This will be an important first step in the process of revalidation. Revalidation itself will deliver a range of benefits:

* it will sustain and enhance public confidence in the profession as a whole by providing periodic assurance that doctors continue to be fit to practise;

* It will provide a process through which doctors who may fall short of professional standards can be supported in addressing them
* It will act as a driver for raising standards of clinical governance locally
* It will give focus and energy to doctors' efforts to keep up to date and improve practice through continuous professional development
* It will identify a small proportion of professionals who are unable to remedy significant shortfalls in their standards of practice and remove them from the medical register
* It will allow patients and other professional colleagues to contribute to the evaluation of individual professional practice

13. The Partial Regulatory Impact Assessment for *Trust, Assurance and Safety- the regulation of health professionals in the 21st century*, published on 22 February 2007 estimated that the cost of pilots for revalidation to be £4million for 2008/09. This remains a current estimate – full costings on implementing revalidation nationally will be prepared in light of the outcome of the pilot projects.

14. The figure of £4m was based on an assessment of the number of professional sessions required to allow participation in the pilots, plus administrative and other costs. In April 2008, the GMC raised the annual retention fee to £390 to cover a number of risks, including the potential transitional costs that might flow from the White Paper.

A copy of the Partial Impact Assessment prepared for the white paper, including proposals for revalidation for all doctors is available on the DH website at http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Regulatoryimpactassessment

15. On 23 July the Department of Health published a report of the work of a group chaired by the Chief Medical Officer to set out an approach for a programme of revalidation for all doctors. A copy of *Medical Revalidation –Principles and Next Steps* is available of the DH website at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_086430

16. The policy options available for this amendment were;

(a) Do nothing. No additional work would be required, however the GMC would not be able to start work on issuing a licence to practise and undertake revalidation pilots, because the existing legislation does not include key elements in how we want revalidation to operate, for example recertification.

(b) Make the change, but not on a 'fast-track'. This would delay the issue of the licence to practise and impose a further delay on the introduction of revalidation all doctors.

(c) Make the change as requested. This would allow the GMC to introduce the licence to practise and undertake revalidation pilot projects in preparation for the introduction of revalidation for all doctors. This is the preferred option.

Amendments to The General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 to allow the GMC to let a small number of practising senior consultants onto the Specialist Register. This will reinstate the powers the GMC previously had prior to September 2005 (amendment 3)

17. Inclusion in the Specialist Register is one of the requirements for an appointment to an NHS consultant post. When the specialist register was introduced in January 1996, the legislation contained a 'grandfather clause' enabling those already in consultant posts to apply to the GMC for their names to be included in the register. Although most consultants took advantage of this, some did not for a variety of reasons such as practising overseas or undertaking voluntary or academic work.

18. When the Postgraduate Medical Education and Training Board (PMETB) was established in 2005 the grandfather clause was removed from the legislation leaving a small but significant number of consultants without a straightforward means of obtaining specialist registration.

19. The only avenue now available to those consultants who wish to be placed on the Specialist Register who do not hold a Certificate of Completion of Specialist Training is to apply through the article 14 route via PMETB. Article 14 is a lengthy and costly process. It is intended to cover those doctors who have completed all or part of their specialist training abroad. It is not intended for consultants who have been working successfully in a UK consultant posts for many years.

20. The current situation whereby some consultants are not on the Specialist Register sends confusing messages to patients. It also means that those doctors are unable to comply with NHS contractual requirements to hold specialist registration and would be unable to recertify in their specialty as part of revalidation.

21. We are therefore proposing to amend The General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 to allow the GMC to let small number of consultants mentioned above onto the Specialist Register by way of a late entry. This will reinstate the powers the GMC had prior to September 2005.

Costs and benefit

22. The GMC have advised that there will be no extra cost for consultants applying to the Specialist Register by the way of late entry. The benefit will be a less costly and less time-consuming route for a number of senior consultants to join the Specialist Register. This will bring them into the process of re-licensing and recertification and ultimately the revalidation of their licence to practise.

23. The options considered for before taking this amendment forward were:

i) leave the arrangements as they are and require these doctors to apply to PMETB to be placed on the specialist register. There are an estimated 1000 to 1500 consultants currently not on the register. The only avenue available to consultants who wish to be placed on the Specialist Register who do not hold a CCCT or CCST is to apply through the article 14 route via PMETB. This route was never intended for consultants who have been working successfully in a UK consultant post for many years. The risk of leaving the arrangements as they are that some consultants will not apply to be on the specialist register as it is a lengthy and costly process.

ii) Amend the General and Specialist Medical Practice (Education, Training and Qualifications Order 2003 to allow the GMC to let a small number of practising senior consultants onto the Specialist Register by way of a late entry. This option will reinstate the powers the GMC previously had prior to September 2005. Consultants will be more likely to apply, as this is a quicker and less costly route onto the Specialist Register.

24. We decided on option ii as this should ensure that the consultants not currently on the register would be more likely to register, as it is a less costly and less time-consuming route. The current situation whereby some consultants are not on the Specialist Register creates a loophole where a small number of consultants may avoid recertification. If the register is not up to date then this process will not be completed successfully.

25. This does not represent a change of policy, which is that anyone holding a consultant level post in the NHS must be on the Specialist Register. This is a technical amendment which reinstates the GMC's powers to admit doctors who did not join the specialist register at the outset in order to meet their contractual requirement to be on it. The GMC will consult further on details of the scheme to ensure that it is fair and meets the standards required for entry to the specialist register.

Summary of Costs and Benefits

Amendment	**Costs**	**Benefits**
Transferring statutory responsibility for education to GMC Council	No costs have been identified	GMC consolidates all four if its interlocking statutory functions under the auspices of GMC Council resulting in a more strategic focus to its activity.
License to practise	The GMC has increased its fees in April 2008 in the light of a number of risks facing the organisation, including the potential transitional costs that might flow from the white paper. The annual fee was increased by £100	Introduction of the licence to practice will enable the GMC to identify doctors currently practising and allow them to be brought into the revalidation process. The overarching aim of revalidation is to ensure that doctors are safe and up to

	this year to £390 The cost of implementing revalidation nationally will depend on the outcome and evaluation of the pilot projects, estimated to be £4M in 2008-09	date, and public confidence in the profession is enhanced.
Late entry to the specialist register	No extra cost	A less costly and speedier route for a small number of doctors applying for late entry to the Specialist Register. This will reduce the risk of a small number of consultants avoiding recertification, and will enhance public safety

Consultation

26. A draft Order was published for public consultation on 6 March 2008. Consultation closed on 5 June 2008. There were 34 responses and the majority (around 80%) in each case agreed with the proposed amendments. As a result, there were no changes to the main thrust of the proposals. However, provision has been added to provide a right of appeal to those doctors applying to the GMC for late entry to the register and there has been some redrafting to clarify the ability of the GMC to issue guidance on aspects of the process of revalidation. We have also decided to include a specific reference to consultants serving in the armed forces in response to a suggestion made in a consultation response.

27. The Order also provides an opportunity to correct an anomaly arising from The Health Care and Associated Professions (Miscellaneous Amendments) Order which removed the role of the Privy Council in relation to the GMC's undergraduate education functions. However it did not affect those functions in respect of Sections 10A(3) and 10A (6) of the Medical Act, and this Order provides for the removal of that anomaly.

Specific Impact Tests

28. This order will not impact upon the following tests: competition assessment, small firms impact test, legal aid, sustainable development, carbon assessment, other environment and rural proofing. The Order is compatible with human rights legislation.

Specific Impact Tests: Checklist

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

Annexes

EQUALITY SCREENING IMPACT ASSESSMENT

Initial scoping assessment and action plan for the Medical Profession (Miscellaneous Amendments) Order 2008.

This Order takes forward measures set out in the white paper *Trust, Assurance and Safety* published in 2007. The Partial Regulatory Impact Assessment which accompanied the white paper covered equity and fairness implications of introducing the revalidation of all doctors.

Summary of the purpose and aim of the proposal

This will enable the General Medical Council (GMC) to take forward some of the measures proposed in the White Paper *Trust, Assurance and Safety*. Proposals have been agreed by GMC Council. The GMC operates an Equality Scheme which sets out how it promotes equality and diversity through its functions and policies.

Assessment

The Order provides for the following:

1. It will enable the transfer of the statutory functions of the oversight of medical education from the Education Committee to the GMC. This shifts the statutory responsibility for medical education from the GMC's Education Committee to the GMC Council. There are no new functions and is not likely to impact differently upon people on grounds of their race, disability, age, gender, transgender, religion or belief and sexual orientation.
2. It will reinstate powers to the GMC to allow consultants onto the Specialist Register. This will apply to all doctors who did not apply to join the Specialist Register when it was established in 1997. The GMC will consult separately on the details of the scheme. This is not likely to impact differently upon people on grounds of their race, disability, age, gender, transgender, religion or belief and sexual orientation.
3. It will enable the GMC to issue a licence to practise and carry out revalidation pilot projects on the basis of the updated powers. All registered doctors will be able to apply for a licence to practise. This will allow the GMC to determine the number of doctors currently practising as a first step in the process of revalidation. Revalidation will help to maintain and improve patient care in all settings. Revalidation will be taken by all practitioners so should not impact differently upon people on grounds of their race, disability, age, gender, transgender, religion or belief and sexual orientation.
4. Ultimately, legislation will provide for the withdrawal by the GMC of a licence to practise if a doctor does not successfully complete the revalidation process. There is some evidence to suggest that the number of international medical graduates subject to the final stages of the GMC's fitness to practise procedures is disproportionate to the population of IMGs on the register. The GMC has undertaken some work to demonstrate that its internal processes are free from potential bias or discrimination and has undertaken a census on the ethnicity of registrants. The GMC has also commissioned

some external research to look into the patterns of referral of doctors to the GMC. This work will be relevant to any evaluation of revalidation pilot projects.

In drafting the Order we considered whether there were opportunities to promote equality of opportunity that could be taken. We have concluded that the answer is no because of the nature of the changes this Order is intended to make, which are enabling rather than prescriptive. Future consultation by the GMC on detailed licence to practise regulations and on a scheme to allow late entry to the register will provide an opportunity for further consideration. The GMC also operates its own equality and diversity scheme.

Health Impact Assessment

1. **Are the potential positive and/or negative health and well-being impacts likely to affect specific sub-groups disproportionately compared with the whole population**.?

   These measures should protect the public's health and well-being through improved surveillance of the medical profession. The amendments in the draft Order are intended to help facilitate the introduction of revalidation for all doctors, ensuring that they are up to date and safe to practise.

2. Are the positive and/or negative health and well-being effects likely to cause changes in contacts with and/or social care services, quality of life, disability or death rates?

These measures are intended to enhance public confidence in the medical profession and safeguard the public. The process of revalidation should help to identify concerns about doctors at an early stage so that effective remediation can take place.

3. Are there likely to be public or community concerns about the potential health impact of this policy change?

No public or community concerns have been identified**.**

HEALTHCARE AND ASSOCIATED PROFESSIONS (MISCELLANEOUS AMENDMENTS) ORDER 2008

Consultation Report

Executive Summary

1. The draft Medical Profession (Miscellaneous Amendments) Order 2008 ("the 2008 Order") makes a number of changes to the Medical Act 1983 ("the 1983 Act") and to the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 ("the 2008 Order"). These changes will implement two of the reforms set out in The White Paper: Trust, Assurance and Safety –The Regulation of Health Professionals in the 21st Century. These are:

   - The transfer of the statutory functions of oversight of medical education from the Education Committee of the General Medical Council (GMC), and

   - Amendments to Part 3A of the Medical Act 1983 in line with revised thinking (since 2002) on the process of revalidation, which will facilitate the introduction of licences to practice and the development of revalidation pilot schemes.

2. The draft order also allows the GMC to provide a mechanism to enable senior consultants who did not apply for inclusion in the Specialist Register at the time it was established to make a late application to the GMC. This will reinstate powers the GMC had prior to September 2005.

3. The draft 2008 Order was published for public consultation on 6 March 2008. That consultation closed on 5 June 2008.

4. This document summarises the response to the consultation.

Introduction

This document sets out the outcome of a consultation to a number of changes to the 1983 Act and to the 2003 Order. All amendments relate to the General Medical Council. Some also relate to the functions of the Privy Council and the Postgraduate Medical Education and Training Board.

Background

The White Paper *Trust, Assurance and Safety –the Regulation of Health Professionals in the 21ST Century* set out a substantial programme of reform to the United Kingdom's system for the regulation of health care professionals. The changes proposed in the draft Order would implement two of the reforms proposed in the White Paper. These are:

- the transfer of the statutory function of oversight of medical education from the Education Committee of the GMC to the Council of the GMC , with amendments to the Medical Act 1983 to give effect to that transfer; and

- amendments to Part 3A of the Medical Act 1983 in line with revised thinking (since 2002) on the process of revalidation, which will facilitate the introduction by the GMC of licences to practice and the development of revalidation pilot schemes.

The draft 2008 Order also provides an opportunity to amend the 2003 Order to allow the GMC to provide a mechanism to enable consultants who did not apply for inclusion on the Specialist Register at the time it was established (in 1997) to apply to the GMC to be placed on the Specialist Register by way of a late entry. This will reinstate the powers the GMC had prior to 2005.

Consultation Process

The consultation took place over a three month period between 6 March 2008 and 5 June 2008. Respondents were asked to complete a form and submit it electronically or by post. A number of responses arrived in the form of a general letter rather than replies to specific questions.

35 Replies were received by the closing date

The responses represented a mix of professional bodies and organisations and individual health professionals.

A table showing all of the respondents is attached

Specific issues which arose in response to the consultation questions

Question 1 Do you support the transferring of the statutory powers of the GMC Education Committee to the GMC from January 2009 when the new council will be established.

Of those who commented on this proposal, 24 (80%) agreed, one (3%) disagreed and 5 (17%) were unsure. The majority agreed with the aim of consolidating all stages of medical education under the auspices of the GMC Council.

One respondent argued that the case for change had not been made in the consultation document and that in light of the proposed merger of the Postgraduate Medical Education Training Board with the GMC further, more detailed consultation on this matter was necessary.

Several of those who supported the proposal, and some of those who were unsure, said that policy for medical education should still sit within a specialist education committee to maintain a degree of independence. A number of respondents also commented that it would be important to retain the expertise of existing members of the GMC Education Committee. The GMC itself envisages a three board model for education (an undergraduate board, a postgraduate board and a continuing practice board) to advise Council. This model will have the scope to involve a wide range of expertise and will not preclude the participation of current members of the Education Committee.

Question 2: Do you agree with the amendments to Part3A of the Medical Act 1983 which will enable the GMC to begin work around revalidation including issuing licenses to practice.

24 (83%) of those respondents who commented on this question agreed with the proposed amendments. 2 (7%) were unsure and 3 (10%) disagreed.

Many of the comments raised questions about the details of implementing the licence to practice, and about the introduction of recertification and revalidation more generally. Two respondents were opposed to the principle of revalidation, but the majority of those who commented agreed that the introduction of the licence to practice and the establishment of revalidation pilots were an important step forward.

This consultation did not address a number of issues of detail that may arise during implementation of licences to practise. These issues will be for the GMC to address through detailed regulations that will support the introduction of the licence to practice, which in turn will be the subject of a further public consultation. The amendments to the regulation making powers of the GMC are permissive powers and the final content of the regulations will be determined by the GMC, although they will also be subject to approval by the Privy Council. The process of revalidation will also be subject to piloting and evaluation before it is introduced more widely.

In its response, the GMC argued that the provisions dealing with the disclosure of information by a licensing authority during the course of evaluating a doctor's fitness to practise for the purposes of revalidation (including pilot schemes) were unnecessary, as the GMC already had comprehensive powers to disclose information to specified recipients within their own fitness to practise procedures. However, given that the need disclosure could arise in circumstances where the GMC's fitness to practise procedures are not activated, the Government decided to move ahead with its suggested changes on this point, despite the GMC's reservations. The Government's position is that it is anxious to ensure that there are no technical bars to the release of information which in the public interest should be disclosed. It also considers that having more of the process of how adverse information will be handled on the face of the legislation (in outline) is clearer and therefore better for all concerned.

Question 3: Do you agree with the amendment to the 2003 Order which will reinstate the GMC's previous power to allow late entry onto the specialist register in certain circumstances.

29 (88%) of those who commented on this question agreed with the proposed amendment. 3(9%) were unsure and one respondent disagreed. The majority agreed that the GMC's powers to admit late entry to the Specialist Register should be re-instated. Some respondents commented that they would have liked more details on the scheme that the GMC intends to operate. Those details, including an appeals mechanism, will be subject to further consultation by the GMC.

Three respondents commented on the definition of 'consultant' and, as a result, we have broadened the definition to include those consultants who were serving in that capacity in the armed forces prior to 1997.

Other points raised were more generally directed at the fitness to purpose of the Specialist Register and therefore go beyond the scope of this consultation. This issue is likely to be looked at again as proposals for the recertification element of revalidation are considered in more depth.

Additional issues

In its response the GMC pointed out that the Health Care and Associated Professions (Miscellaneous Amendments) Order 2008 proposed removing the role of the Privy Council in relation to its education functions relating to undergraduate medical education, but did not address the role of the Privy Council in relation to the functions covered in Sections 10A(3) and 10A(6) of the Act. These relate to the first year of the foundation course that is the first part of a medical practitioner's postgraduate medical education. This Order has provided the opportunity to remove that anomaly.

At the request of the GMC, the Order now specifically allows the GMC to issue guidance relating to the information to be provided by doctors for the purposes securing the grant of a licence to practise. The Order also makes clear that information or documents that are covered by the GMC's licensing and revalidation guidance may in fact relate to standards set by, or documents issued by, another body such as a medical Royal College.

Summary and next steps

The majority of respondents supported the measures proposed in the draft Order. Some raised questions about implementation of the proposals and these issues are likely to be considered in more depth as detailed plans for implementation are developed in due course. The amendments to the regulation making powers of the GMC are permissive powers and regulations will be subject to consultation and approval by the Privy Council.

The draft Order will be subject to the affirmative resolution procedure in both Houses of Parliament. Subject to Parliament, part of the draft Order will come into force on 1 January 2009 as that is the date that the GMC is reconstituted by virtue of other legislation.

List of respondents

John Collins	Royal College of Physicians (Edinburgh)
Prof Andy Adam	Royal College of Radiologists
Rachel Noble	Postgraduate Medical Education and Training Board
Prof Vivienne Nathanson	British Medical Association
Claire Roberts	Queen's Hospital, Burton Hospitals NHS Trust
	Royal College of Paediatrics and Child Health
Dr C M Byatt	
Stephanie Croker	Medical Protection Society
Dr Maureen Baker	Royal College of General Practitioners
Sally Aldridge	British Association for Counselling and Psychotherapy
Dr Robert Reynolds	
	British Geriatrics Society
	Royal College of General Practitioners (Wales)
Kimara Sharpe	Dudley Primary Care Trust
Elisabeth Paice	Conference of Postgraduate Medical Deans
Dr Colin Geddes	
Dr Andrew Jones	Nuffield Health
Richard Smith	Royal College of Ophthalmologists
Dr Vincent Argent	
Dr Tahir Mahmood	Royal College of Obstetricians and Gynaecologists
Dr Don Sinclair	
J C Pollock	
	Faculty of Sexual and Reproductive Healthcare
Alan McLean	
Allan Henderson	
Dr John Stephenson	
Dr Julian Kenyon	British Society of Integrated Medicine
Stella Macaskill	Royal College of Pathologists
Sir Graham Catto	General Medical Council
	Independent Doctors Forum
	NHS Employers
Dr Rodney Burnham	Royal College of Physicians
Nicola Ryan	Bassetlaw PCT
	Royal College of Surgeons
Dr Judy Curson	NHS Workforce Review Team