The Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006

Report on consultation

May 2006

Summary

1. In November 2005 the Department of Health published a consultation paper, *Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006 ; A paper for consultation* as part of the consultation exercise on the draft Medical Act (Amendment) Order 2006. The consultation period ended on 31 January 2006 and produced almost 70 responses. The Department is grateful to those who responded to the consultation exercise. Some of the comments made were not directly relevant to the issues raised in the consultation paper so do not feature in this summary.

2. The draft Order covers:-

    - new registration arrangements for medical practitioners qualifying outside the EEA, including the abolition of limited registration;
    - new training and supervision requirements for recently qualified practitioners;
    - further developments in respect of new fitness to practise procedures and licensing arrangements, introduced in the Medical Act 1983 (Amendment) Order 2002[1];
    - more streamlined decision making and procedures within the GMC; and
    - unconnected amendments to the Opticians Act 1989 and the Nursing and Midwifery Order 2001.

3. Around 350 copies of the consultation paper were distributed and it was also published on the Department of Health's consultations website. In addition a link was provided from the General Medical Council's website.

4. This document is the report on consultation as required by paragraphs 9(2) of Schedule 3 to the Health Act 1999. It discusses the main points arising from the responses received, and indicates where changes to the draft legislation have been made as a result.

Introduction

5. In 2000 and 2002, the Department of Health implemented the first and second phases of the reform programme proposed to them by the General Medical Council (GMC) to modernise the regulation of medical practice in line with the wider reform of the regulation of the health professions being undertaken by the Government. These enabled the GMC to modernise the Council structure and introduce far reaching reforms of their Committee and registration arrangements... The current proposals build on consultation with a range of stakeholders including the medical professions.

6. The Government welcomed the GMC proposals as consistent with its overall aim of reforming all regulatory bodies of the health professions so

[1] S.I. 2002/3135

that they become more streamlined, with greater public and patient involvement and with faster and more transparent procedures.

Responses

7. The respondents included 47 organisations representing medical practitioners, NHS bodies, professional associations, Royal Colleges, statutory regulatory bodies, health and social services councils, educational bodies, patient representative organisations, insurance and law companies with particular interest in the draft Order and public consultation paper and government departments. There were around 20 responses from individuals, including doctors. Lists of all those organisations and individuals who responded to the consultation are attached at Annex A.

8. The consultation document posed a series of questions and responses are discussed below in relation to each of these. We have also proposed a small number of technical changes to the Medical Act, which reflect improvements in the drafting of the Order and make provision for the addition of a number of new medical schools. These do not reflect changes to the policy or the intended effect of the Order, and have been the subject of detailed discussions with the GMC.

9. No respondents identified a difficulty with the provisions of the Order in relation to Scotland, Wales or Northern Ireland.

Conclusion

10. Overall, the majority of respondents supported the document. There was widespread support for the abolition of the register of practitioners with limited registration. Most respondents welcomed proposals for the establishment of the concept of an approved working environment (now referred to in the Order as an “approved practice setting”). The proposals for streamlining the internal operation of the GMC were generally approved. Proposals to clarify the GMC’s power to release fitness to practise information in specific situations and to remove practitioners from the register for failure to declare at the time of registration if an applicant’s fitness to practise was impaired were also endorsed by the majority of respondents.

11. Most respondents welcomed the proposals to introduce mandatory professional indemnity/ insurance against clinical negligence liability claims. Almost all endorsed the proposed penalties for failure to maintain the mandatory cover. There was endorsement from the appropriate professions and regulatory bodies for the proposed amendments to the Opticians Act and the Nursing and Midwifery Order.

12. Areas of debate and discussion included:- the abolition of limited registration; temporary registration for certain overseas doctors and eminent specialists; revised Education Committee arrangements;

mandatory indemnity insurance cover for practitioners; disclosure by the GMC of certain fitness to practise information; and streamlining of some of the GMC's internal procedures

13. Below is a summary of consultation responses received, as they referred to key questions asked in the consultation document. Where reference is made to an article or paragraph or to the Order, the reference (except where indicated otherwise) is the version of the Order published for consultation. Because of the amendments we have made these references may not be identical in every case to the articles in the version laid before Parliament.

Key Questions

Q1 Do you agree with the proposal to abolish the register of medical practitioners with limited registration? If not, can you suggest an alternative approach?

Q1.1. Over 69% of those respondents who expressed a view supported this proposal whilst just under 6% opposed it. The views of those supporting the proposal were typified by the comment of the Royal College of Physicians, "The International Office views the current system of limited registration as making life unnecessarily difficult for international Medical Graduates and in particular for refugee doctors. In particular, we would welcome the abolition of the requirement that a doctor must have obtained employment before their limited registration can be granted for those using the PLAB and Basic Specialist Training routes."

Q1.2. Amongst those who were opposed to the proposal there was concern that changes were being made for reasons other than the paramount concern for patients and their safety. There was also concern that it had not been adequately established that the new system would be as good as, or better than, the existing arrangements in dealing with inadequate medical practice. Some concern was expressed about the difficulty of monitoring the new arrangements and that the sort of inquiries that would be necessary if inadequate performance were be identified in a practitioner who was already fully registered would require additional time and work in order to discontinue the registration. However, it seems that this argument fails to do justice to the requirements for fairness and equality for international medical graduates since it operates on the basis that such graduates have less entitlement to due process than everyone else. Some respondents felt that it would have been helpful to have had definitions of the sort of "knowledge, skills and experience" which the GMC would consider appropriate for registration purposes although this is the sort of detail that would be better set out in guidance and rules arising from the Order.

Q1.3. Action against Medical Accidents (AvMA) believed there was a need for more evidence to determine whether the procedures require tightening up as opposed to what some would regard as being relaxed

under the current proposals. In their preparations and consultation in advance of the proposal to abolish limited registration, the GMC reviewed the likely effects of its abolition and concluded there would be no additional threat to the public and that simplification of the registration system would increase equity and remove unnecessary barriers to the flow of suitably qualified practitioners into approved working environments, to the benefit of patients and the public.

Q1.4. The Royal College of Radiologists, amongst others, were concerned about English language proficiency amongst EU graduates, and about establishing a system for ensuring that practitioners (e.g. teleradiologists) who were treating UK patients should be subject to the same standards as those who were located in the UK, wherever in the world they were located. These issues appeared to be outside of the remit of this Order although there might be some value in exploring how the objective could be achieved via the contractual or service level agreement routes.

Q1.5. Many comments were made about the mutual recognition arrangements for European graduates, set out in EC law, which do not include English language proficiency tests. Whilst many such respondents believed they understood the reasons for this, there was still a desire to see something done about this situation although the matter is determined at a European level and is essentially outwith the remit of this consultation exercise.

Q2 Are the requirements that applicants for registration will have to meet to secure full registration proposed in the new section 21B of the Act appropriate? If not, what do you think the requirements should be?

Q2.1. Just under 58% of those respondents who expressed a view supported the proposals whilst just under 8% opposed them. Something over 30% of those who responded had reservations about the proposals which fell short of outright opposition.

Q2.2. One individual stressed the need to ensure adequate standards of medical practice were maintained wherever the practitioner originated. He cautioned of the danger of allowing under qualified locums to practise simply because of shortages of appropriately qualified staff

Q2.3. There were concerns expressed about the GMC's ability adequately to assess the quality of training provided in other countries. The judgment of the GMC became more crucial in a situation where an employer had not had to determine the practitioner was worthy of employment before they were registered. The Royal College of General Practitioners (RCGP) considered that the definition of "an acceptable qualification" used in the draft Order was too wide and called for the GMC, or its agent, to have inspected any institution before its qualification could be regarded as acceptable. However, employers will still need, at some

point, to make a judgment about whether an individual is worthy of employment. In addition, it would not be practicable to expect the GMC regularly to inspect and to maintain up to date information on the thousands of medical schools around the world in countries where it has no jurisdiction. The GMC has addressed this situation, for many years, by focussing its main efforts on establishing the capability for practice of individuals at the point they seek registration (through, for instance, the PLAB test) rather than on the quality of institutions at which they originally studied, in some cases, many years earlier. The Royal College of Physicians believed that approved working environments would need careful selection for those providing assessments to be able to do so in a more robust way than at present. The Royal College of Pathologists feared that decisions on the suitability of an individual for sponsorship by one of the Royal Colleges could come to be regarded almost as an artificial limitation on registration.

Q2.4. The Royal College of Physicians observed that the proposals set out in the consultation document indicated that overseas doctors could obtain full registration by passing PLAB but there was no mention of whether there was to be a definite requirement for those overseas doctors to have worked at all in their own country before being awarded full registration. If post-PLAB doctors had not completed the equivalent of a foundation year 1 or PRHO post in their own country then they should be offered provisional rather than full registration. The new section 21C of the Act provides for international graduates who are unable to satisfy the Registrar that they possess the necessary experience for full registration to apply for provisional registration to enable them to secure the required experience.

Q2.5. Action against Medical Accidents (AvMA) made the point that holding the requisite qualifications did not necessarily equate to safe and competent practice. There was a need to ensure that the new system proposed provided all the safeguards necessary to identify and deal with such deficiencies in doctors who in future would be being offered full registration from the outset. The GMC recognises this, and, therefore, will not rely on an applicant's overseas qualifications as the basis for granting registration and will instead assess each applicant's capability for practice at the point registration.

Q3 Is the concept of "an approved working environment" a sensible approach which strikes the right balance between public protection and workforce flexibility? If not, can you suggest an alternative method of ensuring adequate supervision of newly registered or restored medical practitioners up to the point of their first revalidation?

Q3.1. Over 75% of those respondents who expressed a view supported this proposal whilst just under 7% opposed it. It was generally accepted as a vital pre-requisite to the abolition of limited registration.

Q3.2. The BMA said it, "*supports the concept of approved working environment and feels it will help many new doctors settle into the NHS before they practise independently.*

Q3.3. The Royal College of Physicians of Edinburgh was concerned that the "approved working environment" for newly registered doctors in service posts might not offer adequate supervision by comparison with the current limited registration and requirement for direct supervision. In their view, this could compromise patient safety. The Hospital Consultants and Specialists Association believed the proposals lacked clarity on this. The issue of the level of supervision that a particular individual requires has always been a matter for the employer to determine, even under the current system of limited registration. Under the new arrangements, an approved environment will be one in which there is 'provision for appropriate supervision' as well as a system for the appraisal or assessment of individuals.

Q3.4. Some respondents, including the National Clinical Assessment Service (NCAS) called for a clearer definition of what exactly comprised an approved working environment and a clearer statement of the advantages of this approach over the existing limited registration arrangements. The definition will be covered in GMC guidance. Approved working environments, together with the full registration of graduates who have demonstrated themselves to be fit to practise will deliver a system which is at least as safe for patients as previously and which is more equitable for international graduates to the benefit of patients and the NHS.

Q3.5. The National Clinical Assessment Service (NCAS) said that as described, the proposal suggested that responsibility for the supervision of new registrants was to be passed from supervising doctors to supervising organisations. If that was they case, they felt this should be set out in detail. They also asked whether the "quality assured support" available to registrants (para 9 of the consultation paper) was, in fact, anything more than a setting subject to an approved governance system? It is considered that the quality assured support will be provided by the clinical governance and appraisal systems required of approved working environments. The GMC will also be able to specify in more detail what other characteristics an approved environment should have.

Q3.6. The Royal College of Pathologists called for some degree of prescription as regards the time a doctor should spend in an approved working environment. It is considered that this is already provided by the need to work in an approved working environment until first revalidation. An alternative method suggested by the Royal College was some quality control at the point of entry over what posts sponsored doctors took, effectively creating artificial 'limitations' on registration.

Q3.7. The Royal College of Radiologists commented that the proposal relied on NHS appraisal and clinical governance, which in its view was not yet of consistently good quality and sufficiently robust.

Q3.8. The GMC will continue to ensure that only those doctors with the required knowledge, skills and experience are able to register. This will not change with the abolition of limited registration. The GMC are reviewing some of the existing routes to registration (such as Royal College sponsorship) to ensure that they remain robust and fit for purpose. It is not intended that the concept of the approved working environment for registered doctors should replace limited registration as limited registration and the approved working environments are intended to fulfil different purposes. Requiring newly registered doctors to work in an approved environment will help to ensure that they are located initially in a supportive practice setting where should problems arise they are most likely to be detected early. Even if it were true, as some had alleged, that the quality of clinical governance remained uneven in some parts of the country, that would not absolve employers from their responsibilities for ensuring that those they employ are and remain fit for purpose. Neither would it prevent those employers from taking action where it became apparent that this was not the case. Similarly, the GMC would continue to have responsibility for ensuring that those it admitted to the register had the necessary knowledge, skills and experience to justify their full registration. The GMC recognise that they it will have to put in place procedures to ensure that any environments approved for the purpose are sufficiently robust.

Q3.9. Action against Medical Accidents (AvMA) believed that approved working environments should be just that – an organisation that has been audited and assessed against set standards and been granted approval and that such approval could be removed if the organisation was found not to be meeting the standards. To grant any form of blanket approval, in their view, would make the concept of 'approved working environments' meaningless and in the present context, remove any safeguards that would have taken the place of limited registration However, any system adopted would need to be workable, economically viable and proportionate in relation to the overall policy of public and patient protection.

Q4 Which approach to the approved working environment issue do you favour? Are you able to suggest any other possible solutions?

Q4.1 Over 75% of those respondents who expressed a view supported option (c). Option (c) represented a combination of the other two alternatives and covered the GMC issuing guidance on what constituted a suitable working environment and giving the GMC a power to require newly registered and newly restored doctors to work in an approved environment unless the GMC decided to exempt them from the requirement. Of the remaining respondents, 4% supported option (a) 16% supported option (b) and 4% gave an indeterminate response.

Q4.2. The Royal College of Obstetricians and Gynaecologists supported option (c) and said that this "*where it is legally open to do so is advantageous. This would certainly benefit patients and the doctors will be aware of what is expected of them*." The Medical Protection Society

(MPS) observed with regard to the GMC's power to grant exemptions, "*as in all instances where the GMC is empowered to provide an exemption the process must be transparent and allow an appropriate means of challenge to any adverse decision*."

Q5 What problems, if any, do you foresee if the approved working environment approach is adopted in advance of the commencement of the appropriate articles of the Medical Act 1983 (Amendment) Order 2002 dealing with revalidation?

Q5.1. Just under 45% of those who responded to this question identified no specific problem. The same percentage identified specific problems without suggesting a solution whilst around 11% identified a problem and suggested their own solution.

Q5.2. A considerable number of respondents felt that the transitional arrangements set out in article 83 of the draft Order would be sufficient. Health Professions Wales stressed the need for consistency in all decisions. Hampshire and Isle of Wight Strategic Health Authority felt that if the transitional period was protracted there was potential for much confusion and it would be important to make sure that employers, as well as practitioners, were clear on their responsibilities.

Q5.3. There was a feeling from several respondents that if the approved working environment were to be introduced in advance of revalidation that it would represent a risk for patients and could be open to legal challenge.

Q5.4. Action against Medical Accidents (AvMA) expressed concern that organisations might be given 'approved' status without having reached a stage where they had the knowledge, skills and expertise to operate effective systems of induction, supervision and appraisal to ensure safe practice. The GMC acknowledges that that it will need to have put in place procedures for ensuring that any environments approved for this purpose are sufficiently robust.

Q6 Do you think the transitional arrangements proposed in articles 79-80 of the draft Order for dealing with those whose names are included, or who have applied for inclusion, on the register of practitioners with limited registration are fair and appropriate? Can you foresee any other possible eventualities which have not been addressed?

Q6.1. Around 68% of those respondents who expressed a view supported the proposed transitional arrangements for dealing with practitioners whose names were on the register of practitioners with limited registration or who had already applied for entry onto that register immediately before article 4 of the draft Order comes into force whilst just under 12% opposed them.

Q6.2. The BMA expressed the view that the transitional arrangements were acceptable and that they ensured safe practice and effective regulation and gave doctors the opportunity to move away from the process via revalidation.

Q6.3. Action against Medical Accidents (AvMA) had a concern as to whether the application process for limited registration was sufficiently robust to allow those same practitioners to be automatically transferred to the full register. The GMC believes that its mechanisms for assessing doctors' capability for practice at the point of registration, coupled with the concept of the approved working environment will be sufficiently robust.

Q6.4 Several respondents expressed concerns about the detailed outworking of some of the transitional arrangements but there is confidence that these arrangements will be suitably clarified in GMC policy guidance where this is required.

Q6.5. The Medical Defence Union suggested there was potential for some doctors to be disadvantaged if, for instance they were close to being eligible for full registration, and were then required to work in an approved working environment for a further specified period. However, in such a situation the GMC could consider bringing revalidation forward to the point where the practitioner would, in any event, have expected to get full registration. Medical Protection Society commented, in a similar vein, that it was not clear exactly what process the GMC would follow and what rights the contractor would have to contest an adverse decision or who would be responsible for adjudication. Article 67 of the consultation draft of the Order [now article 71] provides a route for appeal to a Registration Appeals Panel in cases where doctors disagree with the requirement that they should work in an approved environment.

Q7 Are the proposed new arrangements for temporary registration of overseas doctors in the circumstances described acceptable? Do they strike the right balance between public protection and the need for a rapid route to registration for eminent visiting specialists and doctors providing services for their own expatriate communities? How else might the same objective be achieved within the provisions of the Act and other existing legislation?

Q7.1. 60% of those respondents who expressed a view supported this proposal whilst just over 23% opposed it.

Q7.2. Several organisations that broadly supported the proposal made detailed comments. These and other issues will be clarified in guidance prepared by the GMC as a result of the Order .

Q7.3. Amongst those who expressed opposition to the proposals, The Hospital Consultants and Specialists Association believed there was a

danger that different standards would apply to doctors granted temporary registration than applied to others on the register. This provision is, however, not new. It updates an existing measure by putting the GMC in a better position to ensure that the circumstances in which they grant registration are more carefully defined and that the conditions under which such doctors practise are appropriately limited for the purpose of public protection.

Q7.4. There were various concerns expressed about the length of time a temporarily registered eminent specialist should be allowed to practise. Subject to the overriding maximum of 26 weeks in any 5 years, it would be for the GMC to determine this and to specify in its direction.

Q7.5. The National Specialist Commissioning Advisory Group (NSCAG) had responsibility for commissioning services for patients who needed access to treatment for investigation of a very specialised nature, or who had a very rare condition. This meant that services could be vulnerable if, for instance, a consultant decided to move on or became ill. NSCAG envisaged circumstances in which a consultant from overseas might need to be invited to come and work in one of their centres for a period exceeding 26 weeks in any 5 year period. NSCAG had suggested, therefore, that provision might be included in the Order to allow for extenuating circumstances to be considered on an exceptional basis. In such circumstances, however, consideration would need to be given to the possibility of the practitioner applying for full registration which would then be free of a time limit.

Q8 Do you support the proposed changes in the legislative framework? Do they strike the right balance between ensuring the accountability of the Education Committee and ensuring that it is able to be responsive to strategic change in this developing area of clinical training?

Q8.1. Around 80% of those respondents who expressed a view supported this proposal whilst 8% opposed it.

Q8.2. The Royal College of Physicians of Edinburgh sought confirmation that the GMC Education Committee would continue to consult over changes proposed to the education of medical students and Foundation Year 1 trainees/ PRHO if Orders of Parliament were no longer required. The GMC have indicated that they will continue to consult stakeholders in such situations.

Q8.3. A technical amendment, that did not arise directly from the consultation has been inserted as article 22 in the post-consultation draft of the Order. The number of medical schools is being increased and not all the new medical schools will necessarily be part of a university so it is proposed to amend section 8 of the Act to cater for this eventuality.

Q9 Do you agree that adopting the concept of "fitness to practise not being impaired" at the point of entry to the register will offer greater public protection and be more equitable than the current range of provisions for establishing doctors' standing? Are you able to suggest any approach which would be more effective?

Q9.1. Over 82% of those respondents who expressed a view supported this proposal whilst no outright opposition to the proposal was expressed.

Q9.2. In supporting this proposal, the GMC said the proposals would provide a clear separation between graduation and registration and would plug gaps in the existing powers to provide greater consistency in their approach to the registration arrangements for UK and other graduates. Most important of all, these proposals would put the GMC s in a better position to protect the public. The BMA supported the concept of fitness to practise not being impaired as a suitable entry test but felt that the terminology was rather negative.

Q9.3. The Royal College of Pathologists believed there needed to be some tightening of the term 'criminal offence'. This would be best dealt with by guidance/ rules drawn up by the GMC as a result of the Order. The Royal College also suggested that some offences may be minor, and arguably should not stand in the way of a doctor's progress. More severe offences would need to be judged accordingly. They also suggested that the term "serious matter" could usefully be more tightly defined. We do not believe that it would be helpful for the Order to go beyond the definition in article 12(2) of Directive 93/16/EEC.

Q10 Do you regard the power to erase from the register the name of a practitioner who is shown to have failed to declare an impaired fitness to practise at the time of their registration is an appropriate extension of the GMC's authority?

Q10.1. Over 87% of those respondents who expressed a view supported this proposal whilst no outright opposition to the proposal was expressed. The vast majority agreed that failure to declare such impairment should be dealt with by erasure from the register. The GMC observed that similar powers already existed under section 44 of the Medical Act which allowed the Registrar to remove an EEA doctor from the register where it could be proved the doctor was subject to a disqualifying decision in another EEA Member State at the time of registration and that decision remained in force. The proposed extension of the existing power was consistent with that arrangement. If the proposed approach were to be adopted the GMC would have comprehensive power to refuse registration to individuals who were unfit to practise and to remove the registration of those who could be shown to have concealed the impairment of their fitness to practise at the time of their registration.

Q10.2. The BMA agreed that the GMC should have the power to erase from the register the name of a practitioner who was shown to have failed to declare an impaired fitness to practise but had a number of caveats. The extension of the GMCs powers should be made clear to students at, or considering attending, medical school. The concept of rehabilitation should not be lost. The new power should not be applied retrospectively. Account would also need to be taken of whether the doctor knowingly and intentionally deceived the GMC. They observed there could be cases of doctors having had adverse fitness to practise findings in the past, but who had practised safely ever since. The GMC has taken these comments on board and, where appropriate, they will be reflected in guidance, rules and procedures arising from the Order.

Q10.3. The Medical Protection Society observed that the answer to the question depended upon the circumstances. Doctors whose fitness to practise was impaired due to ill health rarely had sufficient insight to assess their own fitness to practise and particularly with some psychiatric disorders insight was totally absent. If a doctor suffering from such a disorder subsequently underwent treatment and was then fit to practise it would, in their view, be inappropriate to erase that doctor's name from the register as a result of his or her actions when ill. If, on the other hand, a doctor had made a dishonest statement designed to mislead the Council that conduct would generally seem worthy of severe censure. The GMC's powers in this respect are discretionary. The GMC will need to ensure that through its policy guidance and rules it will exercise that discretion in a way that is sensitive to the circumstances of individual cases.

Q10.4. In similar vein, the Medical Defence Union observed, that such a power should be subject to a fair process to establish the facts

Q11 Is recourse by the GMC to a court order to enforce a request for necessary information related to a fitness to practise matter an appropriate extension of their information gathering power? How else might the same policy requirement be achieved?

Q11.1. Over 77% of those respondents who expressed a view supported this proposal whilst just under 5% opposed it. Of those who supported the proposal, some questioned whether 14 days was long enough for the process before an application was made for a court order.

Q11.2. The Medical Protection Society endorsed the proposal but suggested that it should be made clearer that the power to require disclosure did not apply to information given by a doctor to a medical protection or defence organisation. For the most part, the MPS and other similar organisations are likely to be protected from these provisions because of legal privilege. It would be extremely unusual for the GMC to take such action against a medical defence organisation and they have never made such an application under the general provisions in the Medical Act.

Q11.3. Amongst those who had reservations about the proposal, which fell short of outright opposition, the predominant feeling was that the alternative to an application for a court order was a move directly to erasure or a refusal of registration. It is a matter for judgment whether this would better serve the interests of the patient and the registrant concerned. This is, in any event, a permissive power and there will, no doubt, be occasions when the GMC would opt not to apply for a court order immediately if the circumstances indicated that was not the sensible approach. Automatic erasure of a practitioner because of the failure of a third party to comply with a requirement to produce a document would not be appropriate.

Q12 Do you think it reasonable that the GMC's power to disclose fitness to practise information should be extended and clarified in the ways proposed? If not, how else might the GMC secure the same measure of public protection and transparency?

Q12.1. Over 54% of those respondents who expressed a view supported this proposal whilst just under 21% opposed it.

Q12.2. Even some of those in favour of this proposal recognised that the GMC was being provided with a wide-ranging power and there were issues about whether the GMC would routinely release such information or only exceptionally do so. The Sick Doctors Trust supported the GMC's right to disclose, at their discretion, matters related to a doctor's health if it was absolutely necessary for the protection of patients but sought clarification whether the new fitness to practise hearings related to health were to be held in public and urged that they should be held in camera , as previously. They concluded "*there is a fine balance between safeguarding patients and ensuring that doctors are fairly treated*." They urged that any future changes to the regulation of doctors should be in line with European Human Rights legislation.

Q12.3. Some of those who were opposed to the proposal came at it from very different positions. Patient Concern, for instance opposed it on the grounds that there should never be a situation in which information about a doctor was not disclosed in the interests of their patients. In their view patients needed to know all the facts including details of the mental and physical health of their doctor to enable them to exercise their choice whether or not to be treated by that practitioner. However, sick doctors are also "patients" and deserve a degree of confidentiality unless there is an overriding public interest consideration in the information being released.

Q12.4. On the other hand, the Hospital Consultants and Specialists Association (HCSA) observed, " *We do recognise and endorse the need to protect patients, but we are concerned that this proposal may contravene the rules of Human Rights.*" The GMC has responded that evidence that relates to doctor's physical or mental health will be heard in private.

Q12.5. The HCSA were concerned that leaving the decision on confidentiality to the GMC inevitably meant that there would be different rules on confidentiality for doctors than for other citizens and they found that to be an unacceptable principle. Their concern was that disclosure of history might make public allegations that subsequently were found to be unproven or to have been complaints which were without justification. The GMC believe that their current policy is clear on these issues. The GMC does not disclose or publish information relating to the physical or mental health of any practitioner. They do not disclose information in relation to historical complaints that were concluded without action at the investigation stage. There could be circumstances where it would be in the public interest to disclose such information, perhaps as part of a police or statutory inquiry. However, they do not make any public disclosure of such information.

Q12.6. The Medical Defence Union (MDU) felt that such a broad and unrestricted extension of the GMC's powers of disclosure and, presumably a corresponding extension of its ability to retain information, seemed unnecessary. They were particularly concerned about the proposals to permit the GMC to disclose information that arose before a doctor's registration, wherever that matter arose. There was no further qualification or explanation of the intent of these words in the consultation document and they assumed they referred to the proposal elsewhere in the document, that the GMC would be able to consider at the time of registration whether a newly qualified UK graduate was fit to practise. They felt this would benefit from clarification. "*While there is a duty to protect the public, this has to be considered in the context of a duty to consider a doctor's rights in deciding what is done with information that is retained or disclosed about him or her*" MDU expressed a hope that if the GMC received the extended powers proposed in the draft Order it would use them only in compliance with its own procedures and protocols and that there would be an opportunity for interested parties to comment on these in draft. The GMC intends to use these powers in compliance with their own procedures and protocols. Any proposed changes to those procedures and protocols would be subject to consultation.

Q12.7. The views of those who, although not definitely opposed to the proposal, had reservations are summed up by the comments of the Medical Protection Society who said that it was anticipated that there would be occasions when it was appropriate in the public interest to disclose historical information whenever and wherever it arose. Equally there would be occasions where it was not appropriate. Where it was proposed to do so, the doctor should be allowed the opportunity to make representations as to why such disclosure should not be made.

Q12.8. The GMC has observed in response to these comments that they currently disclose much historical information about a doctor's fitness to practise as a matter of routine. These are in situations where the information is already in the public domain, for example where a doctor has appeared before a Fitness to Practise panel, in public, and the panel

decided to erase, suspend or place conditions on the doctor's registration. These determinations will almost always be read in public and the GMC publishes them on their website. These determinations form part of the doctor's registration history and will continue to be disclosed to any enquirer, even when the doctor has subsequently been restored to the register or had any suspensions or restrictions lifted following a later review hearing. It would not be feasible for the GMC to go back to the doctor on each occasion when such a request was made. The policy intention is that these public decisions form part of the doctor's record in the list of registered Medical Practitioners that is published on the GMC website. Article 52 of the consultation draft of the Order (article 56 in the latest version) places a duty on the GMC to publish these decisions.

Q12.9. The BMA expressed concerns about the proposal and felt uncomfortable with the idea that any history given or known to the GMC could be disclosed at any time if the GMC thought fit. The BMA was particularly concerned that health issues would be revealed unless considered confidential. The GMC makes these kinds of judgments all the time and their current policy is not to disclose or publish information that relates exclusively to the physical or mental health of a practitioner.

Q13 Do you agree that the use of consensual disposal in cases before the Investigation Committee is an efficient and just way for the GMC to handle their business? If not, can you suggest a better way to achieve those objectives in such cases?

Q13.1. Around 88% of those respondents who expressed a view supported this proposal whilst no outright opposition to the proposal was expressed.

Q13.2. The National Clinical Assessment Service accepted that this might be an efficient means of disposal of cases but sought re-assurances that agreement to comply with appropriate undertaking required an admission by the doctor that the facts under consideration had been proved – analogous perhaps to a police caution. To have a practitioner accepting undertakings while not accepting that the charges against him/ her had been proved would be unsatisfactory. The GMC have yet to draft the guidance and rules in relation to this issue but will take the views expressed into account in framing the relevant provisions.

Q13.3. The Royal College of Radiologists observed that care should be taken in drawing up the guidance for the use of consensual disposal and it should incorporate explicit guidelines on matters which must be taken into account in the exercise of discretion to adopt this procedure. It is intended that the guidance/ rules prepared by the GMC as a result of this Order will reflect this intention.

Q13.4. Medical Defence Union sought re-assurance that, in line with the current rule 41(3)(b), it was not proposed to alter the Fitness to Practise Procedure Rules (SI 2004/ 2608) to provide for public hearings in health

cases. The GMC has advised that all evidence concerning a doctor's health is heard in private and it is not envisaged that this will change.

Q13.5. Action against Medical Accidents (AvMA) agreed with the use of consensual disposal in certain circumstances. They stressed the need for the patient or complainant to feel that they had been appropriately involved in the case (including having had the opportunity to express their views) and that the issue was not just being 'brushed under the carpet'. Consensual disposal should only be used selectively and monitored carefully to avoid pressures to use it inappropriately simply as a means of reducing a backlog of fitness to practise cases.

Q14 Do you think the proposed arrangements to permit the GMC, in certain additional circumstances, to treat a doctor whose name is suspended from the register, and who is therefore prevented from practising, as if his/ her name was still on the register are sensible and just? Can you suggest any other way in which the policy objectives could be achieved?

Q14.1. Over 71% of those respondents who expressed a view supported this proposal whilst just under 5% opposed it.

Q14.2. The GMC commented that this proposal complemented an existing provision and represented a sensible reinforcement of their current powers. It would ensure that individuals could not escape the possibility of further action by the GMC simply because their registration was already suspended.

Q14.3. The Royal College of Paediatrics and Child Health said the proposed arrangements were probably sensible and just. However, they believed there were circumstances in which this could lead to the unnecessary pursuit of a doctor who was voluntarily willing to leave the register. Similarly, the BMA felt that forcing a practitioner to stay on the register so that he/she had to go through a hearing rather than be voluntarily erased could be seen as cruel and unfair especially when erasing themselves from the register could be punishment enough. The GMC will look at the circumstances in each particular case to decide whether further action may need to be taken, or voluntary erasure granted, where a doctor has already been suspended from the register.

Q15 Do you consider the requirement for mandatory professional indemnity/ insurance to be a sensible requirement for the protection of patients and the public? Could the requirement for professional indemnity/ insurance cover be more clearly defined, or satisfactory public protection be achieved in other ways?

Q15.1. Over 66% of those respondents who expressed a view supported this proposal whilst just over 3% opposed it.

Q15.2. Those supporting this proposal included the Medical Defence Union (MDU) and the Association of Personal Injury Lawyers (APIL) although they only wanted to see insurance based cover, the Medical Protection Society (MPS), who endorsed the requirement for any sort of indemnity or insurance and the Medical and Dental Defence Union of Scotland (MDDUS) who supported only the indemnity option. MDU and APIL proposed a series of criteria to determine an adequate and appropriate arrangement and a set of minimum terms and conditions. Guidance and rules prepared by the GMC as a result of this Order would be the place for these to be included if they were considered appropriate.

Q15.3. The Royal College of Radiologists supported the proposed introduction of a legal requirement for professional indemnity/ insurance together with robust sanctions to enforce it. They believed the required levels of cover would need to be reviewed regularly to respond to changing costs and to reflect the nature of individual's practice in the new mixed health economy. The draft Order gives the GMC power to make rules on what constitutes adequate and appropriate arrangements and the GMC will consult on any proposals that it brings forward.

Q16 Are the sanctions against practitioners for not having the necessary arrangements for indemnity/ insurance in place appropriate?

Q16.1. 88% of those respondents who expressed a view supported this proposal whilst just under 4% opposed it.

Q16.2. The vast majority of respondents supported this proposal unreservedly.

Q16.3. Because the Royal College of Obstetricians and Gynaecologists felt that the state should provide the indemnity/ insurance cover it followed, therefore, that they were opposed to this proposal. NHS Indemnity arrangements alreadycover doctors' NHS work.

Q16.4. The Royal College of Surgeons of England endorsed the proposal subject to the proviso that it could be shown that any failure to have insurance or indemnity cover was wilful and not the result of clerical or administrative error by the doctor, employer, insurance provider, postal service or any other party. The GMC's powers in this respect are discretionary (they 'may withdraw a licence' and failure 'may be treated as misconduct'). It will be for the GMC to develop guidance, protocols and rules which ensure that the power is exercised reasonably and proportionately in each case.

Q17 Do you support the GMC's discretion to vary an individual medical practitioner's revalidation date?

Q17.1. Just over 85% of those respondents who expressed a view supported this proposal whilst no outright opposition to the proposal was expressed.

Q17.2. The National Clinical Assessment Service said "*we view this as an important safeguard and strongly support the proposal*." Patient Concern supported the proposal provided the maximum time between revalidations was not violated. There is, in fact, no statutory maximum time between revalidations, though in general they will be once every five years. The policy intention, however, is to enable the GMC to bring forward an individual's revalidation date where appropriate and to target their activities to where there is greatest risk.

Q17.3 An amendment has been made to article 61 in the consultation draft of the Order (article 66 in the current version) as a result of the consultation, to clarify that the GMC has the power to make enquiries about scope of practice, as a medical practitioner, of registrants that will help them establish when and how revalidation of an individual practitioner should be carried out.

Q18 Do you support the proposal for the Registrar to be able to be the one to be satisfied with regard to provisional registration cases covered by section 21 and in determining whether a registration entry has been fraudulently procured or incorrectly made? Is there any other way that the same policy objective could be achieved more efficiently?

Q18.1. Over 85% of those respondents who expressed a view supported this proposal whilst just under 10% opposed it.

Q18.2. Patient Concern and Rethink believed that the proposals gave too much responsibility to a single individual and that the task should be performed by a panel. However, the Registrar would be making these decisions with the support and advice of the General Council or a Registration Panel.

Q18.3. The Royal College of Physicians of Edinburgh expressed a hope that the GMC would introduce quality control measures to ensure the Registrar's proposed new role in registration decisions complied with policies and guidelines agreed by the full Council. Examples suggested included determining whether overseas nationals possessed adequate primary qualifications and whether fraudulent applications had been made. The GMC is currently developing systems for monitoring and auditing of decision making in these cases.

Q19 Do you support the proposal, for the sake of improved administrative efficiency, to break the automatic link between a medical practitioner's annual retention fee renewal date and the date of their first registration?

Q19.1. Over 86% of those respondents who expressed a view supported this proposal whilst just under 5% opposed it.

Q20 Do you consider section 46 of the Act continues to have a useful and necessary purpose? Do you think it should be retained and amended, as proposed in the draft Order, or repealed?

Q20.1 Around 91% of those respondents who expressed a view supported this proposal whilst no outright opposition to the proposal was expressed.

Q20.2. There was almost universal acceptance that section 46 of the Medical Act still had a value and should be retained but amended as suggested in the draft Order.

Q20.3. Hampshire and the Isle of Wight Strategic Health Authority concluded, "*It would seem prudent to retain the powers in section 46 of the Act at least until we have a greater understanding of the issues raised through increasing plurality of healthcare provision. The proposed amendments are reasonable*." The BMA said "*We believe that section 46 of the Act is still relevant and should not be repealed, but we accept that it should be amended. If it is amended as described it could provide useful protection to the public against impostors*."

Q21 Is there anything else covered in this consultation document on which you would specifically like to comment?

Q21.1. There were some general expressions of welcome for the proposals contained in the draft Order and consultation document . These included the Parliamentary and Health Service Ombudsman and the General Medical Council. A respondent to the Royal College of Physicians Patient and Carer Network said "*As a lay person I am not confident about responding to the majority of the questions as I feel you need knowledge and understanding of the process, but I have a real positive feeling about the thinking behind it as it appears to have patient safety and well being at its heart*."

Q21.2. There were a number of comments about the unrelated amendments to the Opticians Act 1989 and the Nursing and Midwifery Order 2001, including expressions of support from the General Optical Council and the Federation of Ophthalmic and Dispensing Opticians in respect of the former and the Nursing and Midwifery Council and the Royal College of Midwives in respect of the latter.

Q22 Is there anything that you would have expected to see in this draft section 60 Order which has not been included? If so, what is it and why do you think that it should be included in this Order?

Q22.1. There was a small number of comments made regarding issues which had not been raised in the current draft Order and public consultation paper. Several of these were issues that were more appropriate to the internal administration of the GMC or to legislation other than the Medical Act and are, therefore not covered here. However, the Nursing and Midwifery Council made a general point that the consultation had been conducted in advance of the publication of the findings of the two major reviews into Medical and Non-medical Regulation and that it was possible that further amendments could flow from one or both of those reviews. We have noted this comment but feel that the changes proposed in the Order are of a nature that they may proceed independently of the progress of the reviews into medical and non-medical regulation.

Annex A

Responses were received from
Organisations
Action against Medical Accidents (AvMA)
Administrative Justice Division Department for Constitutional Affairs
Association fro United Kingdom University Hospitals
Association of Personal Injury Lawyers
Board of Community Health Councils in Wales
British International Doctors Association
British Medical Association
Caerphilly Local Health Board
Cardiff Community Health Council
Department of Health - National Specialist Commissioning Advisory Group
Dorset and Somerset Strategic Health Authority
Eastern Health and Social Services Council
Equality Commission for Northern Ireland
Federation of Ophthalmic and Dispensing Opticians
General Medical Council
General Optical Council
Hampshire and Isle of Wight Strategic Health Authority
Health Professions Wales
Hospital Consultants and Specialists Association
London IRYO Centre
Medical and Dental Defence Union of Scotland
Medical Defence Union
Medical Protection Society
National Clinical Assessment Service - National Patient Safety Agency
National Specialist Commissioning Advisory Group - Department of Health
North Bristol NHS Trust
Northern Ireland Practice and Education Council for Nursing and Midwifery
Nursing and Midwifery Council
Parliamentary and Health Service Ombudsman
Patient Concern
Postgraduate Medical Education and Training Board
Rethink
Royal Berkshire and Battle Hospitals NHS Trust
Royal College of General Practitioners
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Physicians
Royal College of Physicians - International Office
Royal College of Physicians of Edinburgh
Royal College of Radiologists
Royal College of Surgeon's of England
Sick Doctors Trust
Swansea Trust
The Administration of Radioactive Substances Advisory Committee
The Royal College of Pathologists
Welsh Consumer Council

Individuals
Anonymous response #36
Anonymous response # 37
Mr Basik Ashihabi
Concerned Overseas Doctor
Dr Anirban Gupta
Dr Prakash Harischandra
Dr Wilbur Hughes
Dr Gulam Jilani
Dr Saeed Khan
Dr Syed Khan
Dr Wisam Khidir
Dr Pragnatha Komaravolu
Dr Robert Kramer
Mal 951
Dr Sadat Muzammil
Dr Ansar Humera Siddiqui
Royal College of Physicians - Patient and Carer Network - Response 1
Royal College of Physicians - Patient and Carer Network - Response 2
Royal College of Physicians - Patient and Carer Network - Response 3
Royal College of Physicians - Patient and Carer Network - Response 4