AvMA's Response to the Department of Health Consultation Paper on the Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006

Action against Medical Accidents (AvMA) was originally established in 1982. It is the UK charity specialising in advice and support for patients and their families affected by medical accidents. Since its inception AvMA has provided advice and support to over 100,000 people affected by medical accidents, and succeeded in bringing about major changes to the way that the legal system deals with clinical negligence cases and in moving patient safety higher up the agenda. The legal reforms of Lord Woolf in the clinical negligence field and the creation of agencies such as the National Patient Safety Agency and the Healthcare Commission have followed after years of campaigning by AvMA.

The following is AvMA's response to the consultation 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?*

If it is the case that the system of limited registration is failing to adequately protect patients, then there is clearly an argument for change. If however the abolition of limited registration is primarily for the purposes of easing the entry of overseas doctors into the UK workforce, then AvMA would be concerned that this could be seen as a retrograde step if in so doing, it removed any added protection that limited registration and supervised probationary placements represents. Patient safety should be the underlying principle and any change in the system of registration should be with a view to improving standards and affording greater protection for patients.

It is important that any changes take into account lessons that can be learnt from an analysis of cases where overseas practitioners have been granted limited and/or full registration and have subsequently been removed from the register following conduct proceedings. Such an analysis may help to identify where and how our vetting and supervisory arrangements are failing. The level of complaints coming before the GMC in previous years would suggest that the system of limited registration did have significant flaws although there may well be more complex reasons behind the statistics.

In other words, more evidence is needed to determine whether the procedures require tightening up as opposed to what appears to be the case with the proposed reforms, relaxed. What is absolutely clear is that the imperative to

enable greater flexibility in the employment of overseas doctors and reduce the burden of regulation should not override or be at the expense of considerations of patient safety.

The current proposals suggest a move towards a more unified approach for all new registrants from the UK and overseas and whilst this may be the most pragmatic approach, does not appear to make particular provisions for the varying needs of overseas registrants. It could be argued that the 'one size fits all' approach' to registration of overseas doctors is inadequate in terms of the range of healthcare systems that doctors will be coming from and the different levels of support that doctors may need in order to adapt to practising effectively and safely in the UK. This is an important consideration in developing a system of registration and placement and the ability to identify potential problems before patients are put at risk. As discussed below, we believe that in the interests of patients, the same principles and regulations as apply to overseas doctors should apply to doctors from the EEA.

The concept of 'approved working environments' and to what extent they can provide the necessary induction, supervision and protection that patients would expect is a critical issue. This is discussed in our response to question 2 but is a fundamental issue in terms of whether the proposals to abolish limited registration and grant full registration and allow doctors to work in approved environments will provide an equivalent or more importantly, an improved system of regulation and supervision for new overseas registrants. AvMA is concerned that there will not be sufficient safeguards and that patients will be put at greater risk of harm.

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?

The system of limited registration in theory provides certain safeguards in terms of limiting employment to supervised placements and allowing a probationary period where a practitioner's skills can be assessed to ensure they meet acceptable standards. If working effectively, this sort of safeguard is essential on the basis that holding the requisite qualifications does not necessarily equate to safe and competent practice and the doctor may have significant gaps in their knowledge depending on the system of healthcare in their country of training. If this safeguard is to be removed, then the new system for full registration for overseas applicants would need a fundamental overhaul to provide equivalent if not substantially improved safeguards to ensure practitioners were safe to practise within UK health services and that there was still going to be the equivalent of a probationary period. Again, the requirements should be dictated by lessons learnt from past experience and the problems that have arisen.

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?

In our response to the GMC's consultation on the Draft Licensing and Revalidation Regulations, AvMA sets out our concerns with respect to 'approved environments'. It was at that stage being proposed that all NHS bodies and a large proportion of the main independent providers would potentially fall within the category of 'approved environments'. It was AvMA's view that this was a fundamental flaw in the proposals in that it appeared that any organisation which could demonstrate they had procedures for clinical governance and appraisal were likely to be deemed as having 'approved' status regardless of how these procedures might operate in practice.

AvMA believes that a GMC 'approved environment' 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 those standards. To grant any form of blanket approval 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. If limited registration is to be abolished then it is essential that we already have in place an effective system of approved working environments and that only those approved environments that have been specifically accredited to receive new overseas registrants should be allowed to do so.

There is also the important question of whether it is realistic or safe to assume that appraisal in its traditional sense is going to be effective in fulfilling an ever increasing number of roles that are being placed upon it. As it is, there are already concerns about the role of appraisals in revalidation and perhaps we are now talking about a process which should in effect be quite different and distinct from appraisal as it is normally understood.

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

AvMA recognises and is very concerned about the problems posed by EEA legislation in relation to freedom of movement and the potential impact this will have on patient safety. This creates some serious anomalies in the way in which doctors practising within the UK are regulated with the apparent inability to apply

regulations to EEA doctors which are deemed necessary in relation to new or returning UK registrants and doctors trained outside the EEA. Any attempts to improve our system of regulation and enhance public protection is at risk of being fundamentally undermined by having to apply different standards to EEA doctors and in having to accommodate those differences, risks lowering the standards across the board.

On the basis that we are bound by EEA regulation, option C, but we believe this is an area where there is an opportunity for the regulators and patients groups to work together.

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?

As discussed above, we are concerned that organisations will be given 'approved' status without having reached a stage where they have the knowledge, skills and expertise to operate effective systems of induction, supervision and appraisal to ensure safe practice. In addition, with the abolition of limited registration and without the safeguard of revalidation, both employers and the GMC may face difficulties in being able to effectively identify and deal with potential fitness to practise issues.

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?

On the face of it, there would be an immediate concern as to whether the application process for limited registration was sufficiently robust to allow those same practitioners to be automatically transferred to the main register. This is particularly given the context referred to above that approved environments are still in development and there is a lack of evidence to establish that NHS and independent sector organisations are implementing clinical governance and appraisal to an appropriate and effective standard to meet the needs of new overseas registrants.

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?

It is unclear from the information provided whether this will provide adequate protection. We are concerned about the concept of a small category of doctors being registered with the GMC on the basis that they only treat non-UK nationals within the United Kingdom. Whilst there may be practical reasons for doing this, there is something very uncomfortable about the double standards this appears to represent. If a doctor is registered by the GMC, then they should be fit to practise in accordance with UK standards regardless of the patient's nationality or the context within which they are working.

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?

This is not an area where we have direct knowledge or experience. The only comment we would make is that flexibility should not be at the expense of political expediency or short-term gains that may have a detrimental effect on the profession and the provision of care in the longer term.

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?

AvMA would agree with adopting the concept of 'fitness to practise not being impaired' at the point of entry to the register. However, the requirements may need to be tailored to the particular overseas jurisdiction to ensure the procedures are capturing information from the most appropriate and reliable sources.

Q 10. 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?

Yes.

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?)

On the basis of the information provided, yes.

Q12. Do you think it reasonable that the GMC's power to disclose fitness to practice 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?

The guiding principle on this issue should be patient and public protection. Again, this is an area where it is important to learn from the mistakes of the past and the many examples where patients have been put at risk or harmed as a result of critical information about a doctor's practice not being shared.

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 handle their business? If not, can you suggest a better way to achieve those objectives in such cases?

There will be some less serious cases where consensual disposal of cases before the Investigation Committee could be an appropriate resolution but there are a number of potential problems with this approach. Firstly, from the patient's and/or complainant's perspective, if they are not involved and consulted in this process, it can be perceived as 'brushing a problem under the carpet' or the GMC 'siding with the doctor'. This has certainly been the perception in the past where cases have been disposed of with a letter of advice or where there has been an inadequate explanation as to why a case has not proceeded. There needs to be transparency of process and confidence that the procedures are robust in their operation. The legitimate interests and needs of complainants must also be recognised so that no case would be disposed of without the views and interests of the complainant being taken fully into account. Secondly, one would want to be assured by means of an effective investigative process, that the allegations did not represent 'just the tip of the iceberg' and that there were no underlying problems that needed addressing. Thirdly, it would be important to establish that the doctor had insight and that they were not simply agreeing to the conditions on the advice of their representatives. Consensual disposal should only be used selectively and monitored carefully to avoid pressures to use it inappropriately simply as a means to reduce a backlog in 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?

Yes. In the past, loopholes in the regulations have allowed, for example, an errant doctor to evade GMC action by voluntary removal from the register and then re-applying for registration at a later date. It would appear that this proposal would close one such potential loophole.

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?

AvMA strongly supports and agrees with the requirement for mandatory professional indemnity/insurance to be in place as a condition of registration. There have been many examples over the years where patients have not been able to obtain financial redress because the doctor has failed to obtain professional indemnity cover. There have also been some cases where the doctor has belonged to a defence organisation but cover for the particular claim has been refused. Therefore any indemnity scheme should not only be mandatory, but must also prevent any patient finding that the doctor's professional indemnity cover fails to provide indemnity for their particular claim leaving them without financial redress.

There are a number of problems with existing professional indemnity schemes and these need to be addressed to ensure mandatory indemnity cover is going to provide the protection intended. AvMA is not qualified to determine the most appropriate form of mandatory professional indemnity cover but in order to ensure that the proposed requirement for such cover is meaningful and that no patient is left without financial redress, we recommend that the GMC in conjunction with the Department of Health and other stakeholders, establish clear criteria for such cover with a view to producing a list of approved providers and products.

It will also be essential that patients and their representatives can freely access details from the GMC of the doctor's indemnity cover, regardless of whether the doctor is still registered with the GMC. This is particularly important in cases where the practitioner is no longer working within the United Kingdom and is not readily traceable – a scenario which is perhaps not unusual where a practitioner is facing a number of clinical negligence claims.

With increasingly complex contractual arrangements for the provision of healthcare between the NHS and the independent healthcare sector, and the

establishment of organisations such as foundation trusts and independent sector treatment centres, the issue of indemnity for clinical negligence is very much in the forefront at the present time. AvMA is concerned that the present arrangements may leave increasing numbers of NHS patients at risk of not being able to obtain financial redress. AvMA believes this needs to be addressed urgently and would strongly recommend joint discussions between the Department of Health, NHSLA, GMC and other interested stakeholders.

AvMA believes that all NHS treatment should be covered by NHS indemnity. This is regardless of whether this treatment is provided through independent providers such as general practitioners, NHS dentists, independent hospitals, independent sector treatment centres, as well as the new breed of NHS organisation such as Foundation Trusts and other such organisations as appear in the future. This is the only way to ensure that NHS patients are adequately protected in terms of financial redress but also in terms of monitoring the quality and standard of care provided under the NHS. This is very much in line with the Chief Medical Officer's report of June 2000, An Organisation with a Memory, and the need for a systematic approach to learning from mistakes. This cannot happen effectively within a fragmented system of accountability and redress.

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

Yes. However, this may come too late to protect the interests of patients who have a clinical negligence claim against a practitioner who is found not to have appropriate indemnity cover. In theory the number of cases in the future should be limited if the proposals for indemnity cover being a condition of registration are introduced but we would still recommend that a scheme should be established to protect patients who have a claim against a practitioner who is not indemnified.

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

Yes.

Q18. Do you support the proposal for the Registrar 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?

This is not within our experience to comment.

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?

From the information provided, this would appear to be a reasonable approach.

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?

From the information provided, section 46 should be retained and amended.

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

Not at this stage.

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?

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