
GMC response to the Department of Health review of the balance of competences

February 2013

Introduction

1. The General Medical Council (GMC) is the independent regulator for doctors in the UK. Our purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine.
2. The law gives the GMC four main functions:
 - keeping up-to-date UK registers of qualified doctors
 - fostering good medical practice in the UK
 - promoting high standards of medical education in the UK
 - dealing firmly and fairly

Overall comments

3. We welcome the opportunity to respond to the Department of Health's call for evidence on the Review of the Balance of competences between the United Kingdom and the European Union (EU). Our response focuses primarily on those sections in the consultation paper that impact on our work as a regulator.
4. The fundamental purpose of medical regulation is to ensure safety and quality of care for patients. In this context, we believe that all European initiatives involving or affecting the health and healthcare of European citizens must, without exception, make the protection of the public and patients their first priority.
5. As highlighted by the call for evidence, EU action in health is of a supporting nature. However legislative and policy initiatives in other areas have implications for health policy and patient safety across Europe. This is complicated by the fact that a number of different European Commission Directorate Generals (DGs) have competence over matters that affect patient safety and may not always work jointly to consider the specific requirements and implications for the health of those living in

the EU. For example, DG Internal Market and Services is responsible for freedom of movement initiatives, rather than DG Health and Consumers, despite the fact that the movement of health professionals has significant implications for the health and safety of the public.

Section 12 – Implications of employment policy

6. The European Working Time Directive (EWTD) has an impact on patient safety and medical education and training in the UK.

7. Under the Working Time Regulations (WTR), which implement the EWTD in the UK, the UK's 55,000 doctors in training should not be working more than 48-hours a week, averaged over 26 weeks. They are also bound by another set of regulations from the UK government (The New Deal regulations) which also limit the hours they can work.

8. The interpretation of the regulations by the Courts has also had an impact. The Sindicato de Médicos de Asistencia Pública (SiMAP) and Jaeger rulings of the European Court of Justice have defined working time and compensatory rest respectively.

9. To help us understand and consider the effects of the WTR, in 2012 we commissioned research¹ into the impact of working time restrictions, and how they were working in practise. We have summarised below the main findings and implications for patient safety and education and training.

10. Following this research, we will write to employers and those responsible for training at local level to review how they manage and monitor working patterns. It is vital that rotas strike the right balance between training opportunities and clinical work. We will also highlight examples of what works well in designing rotas so that others can follow this good practice.

11. We have shared our findings with the European Commission Employment, Social Affairs and Inclusion DG as it reviews the EWTD and prepares for the adoption of a revised proposal

Implications for patient safety and education and training

12. The restriction of working hours in the last twenty years has brought benefits to many doctors in training and there is now a consensus that the very long working hours of the past were counter-productive, and dangerous.

13. Many (though not all) doctors in training believe that the 48-hour limit is appropriate and that they gain enough training experience within the current limit, although many were also frustrated by what they regard as a lack of flexibility within the current arrangements.

¹ [*The Impact of the Working Time Regulations on Medical Education and Training: Final Report on Primary Research. A Report for the General Medical Council*](#), February 2013.

14. However, many of the problems the WTR were intended to solve persist, and the evidence suggests that some doctors in training are still subject to tiring, and potentially dangerous, working patterns.

15. Educational opportunities vary with time of day, and with specialty. Many Foundation Programme doctors find that out-of-hours work provides them with useful experience, but with the caveat that at those times there is limited availability of consultants and other seniors to teach and supervise. Senior presence was felt to provide the best educational experience.

16. Increasing pressure to deliver service means that more educational activity, including reading and completion of e-portfolio but also attendance at some clinical opportunities (e.g. ward rounds, theatre, and clinics), takes place in the doctors' own time.

17. The WTR and the end of the 'firm' of junior and senior doctors working closely and regularly together have changed the educational relationship between consultant and trainee. This is seen by some as a considerable loss, with consequences for training, assessment and recruitment.

18. Acute fatigue and stress remain a significant concern both in terms of the welfare of these doctors and the patients they treat. There are differences in the issues faced by different specialties from working hours and patterns. Most medical specialties were reported to be more consistently intense than surgical specialties, even across shorter hours, with the result that more tasks build up during a shift. A shorter, more intense period of work was felt to be as fatiguing as a longer, less intense one. The same issues were present across nations and training grades.

19. The WTR are not, however, the sole cause of ongoing problems of fatigue. Other changes in medical training, and the composition of the medical workforce, have led to strains on medical rotas.

Section 13 – Implications of free movement of persons: healthcare professionals

20. We are responsible for implementing the recognition of professional qualifications Directive (2005/36/EC). The Directive lays down the rules for how we register doctors that have qualified in other parts of the European Economic Area (EEA).

21. There are currently more than 250,000 doctors on the UK Medical Register; 25,000 (10%) of these doctors qualified in other parts of the European Economic Area (EEA). In 2012, we granted registration to more than 3,200 doctors under the provisions of the Directive.

22. The GMC supports the principles of free movement. The UK has significant experience of absorbing doctors both from Europe and internationally. This has contributed to a more diverse medical profession, and sustained our national health system. UK doctors have also benefited from the training and work opportunities available to them outside the UK.

23. However, the Directive has created a number of challenges to patient safety in the UK. While we recognise that the EU institutions are trying to address many of these through the proposal adopted by the European Commission in December 2011, we believe there are further measures that could be taken to improve the current legislative framework.

Administrative simplification and cooperation

24. Our interaction with competent authorities in other EEA countries have benefited from the introduction and use of the Internal Market Information System (IMI). IMI has helped us to build a network of contacts that is able to assist with more complex recognition queries and has helped to improve our understanding of medical regulation in other countries. We hope the Commission will continue to fund and improve this system in the coming years.

25. In addition, we have benefited from our role in key networks operating in the EU.

- a. We convene the Alliance of UK Health Regulators on Europe (AURE), which brings together 10 of the UK health and social care regulators to work on European issues affecting patient and client safety. The group shares information, agrees positions and responds to relevant European initiatives, particularly the recognition of professional qualifications and data protection Directives.
- b. Over the past three years, we have also built and consolidated relationships with other medical regulators across the EEA through the European Network of Medical Competent Authorities (ENMCA). ENMCA has enabled us to share experiences with the recognition Directive and present a united response to the proposals to reform it. This has led to increased recognition of ENMCA's role by the EU institutions and the inclusion of many of its suggestions in the Commission's recognition proposal published in December 2011 and the European Parliament first reading report adopted in January 2013.

26. Our involvement in AURE and ENMCA has helped us share best practice with other regulators, and contributed to a number of GMC projects including:

- a. The structure of specialties and progression through training.
- b. The GMC's *State of Medical Education and Training in the UK* reports.
- c. Building an evidence base for an induction for doctors new to UK practice by asking international regulators what the challenges are for new doctors in their countries and whether they have any arrangements in place to support them.
- d. Our review of the way in which we quality assure medical education in the UK.
- e. The review of our Professional and Linguistic Assessments Board test which doctors from other parts of the world are required to pass before gaining entry to the UK register.

Transparency of regulatory structures

27. Although IMI and our informal networks have significantly improved our communication with other competent authorities, practical difficulties remain. There is wide diversity of regulators and competent authorities with a range of structures, approaches, and emphases. Some are government bodies and some are self-governing, while others are professional associations with a regulatory function.

28. However, we do not believe a harmonised regulatory model would be beneficial or desirable. Each approach, is arguably, appropriate to each individual jurisdiction and is a member state competence. But we do believe that public and patient protection should be at the heart of all regulatory approaches and that more could be done to improve our understanding of these.

29. We would also like to see greater clarity over main contact points, particularly in federal jurisdictions, where there is more than one organisation holding information about a health and social care professional's registration history. Confusion and complex organisational relationships and structures can make sharing fitness to practise information between member states, and even within member states, time consuming and ineffective.

30. We believe that the Commission could encourage greater transparency of regulatory structures which could facilitate the free movement of professionals while supporting competent authorities to share information and communicate in a timely and effective way. Initiatives such as IMI, and ENMCA have already helped our understanding of how medical regulation is defined and organised in other countries and we hope the Commission will continue to encourage and support these activities.

Fitness to practise information sharing

31. Currently there is no legal obligation on competent authorities to share information immediately about disciplinary findings against doctors and other health professionals. This means that competent authorities such as the GMC are not routinely informed about doctors who may not be fit to practise in the UK.

32. The flow of information between competent authorities is often hampered by domestic data protection legislation in member states. Given that doctors are one of the most mobile professions in Europe and have powers of life and death over their patients, this is a serious concern.

33. There should be a clear obligation upon competent authorities to disclose details of disciplinary actions they have taken against doctors within their jurisdictions to other competent authorities. This should be done routinely and proactively by issuing the details to all other competent authorities in Europe. This would prevent doctors from avoiding or evading regulatory sanctions and posing a risk to patients by moving across jurisdictions with impunity.

34. We hope that the revised recognition Directive and the review of the data protection Directive will go some way to address these challenges.

Language skills

35. We strongly believe that the ability of the professional to communicate effectively with patients and colleagues in the language of the host member state lies at the heart of good medical practice and as such should be a prerequisite for access to the profession.

36. The language requirements in the existing Directive are not expressed clearly enough and have led to different interpretations and implementation across the EEA. We therefore welcome the European institutions' intentions to clarify Article 53 to enable competent authorities to assess the language competency of EEA doctors wishing to practise medicine in another member state. This would ensure that patients are fully protected while increasing trust and confidence in the recognition system.

Minimum training requirements

37. There are some inherent tensions between member states' exclusive competence in education and the minimum training times set out in the Directive under automatic recognition.

38. The mutual recognition of professional qualifications assumes comparability of medical education across the EEA. It is on the basis of medical qualifications that are deemed to have met certain minimum standards, that doctors can exercise their right of free movement within the EEA.

39. However the minimum training requirements in the Directive are so broadly drawn and general that they are of limited practical value in providing assurance about the standards of medical education and training of migrants. At the same time, the focus on time served in training rather than the outcomes of that training has imposed constraints which have impeded the UK sector from developing undergraduate medical education (of a shorter duration, for example).

40. To ensure public protection, competent authorities, employers and patients must have better assurances that the qualifications included in the Directive are genuinely comparable. In this context the lack of transparency on the nature and content of medical education and training or the skills, knowledge and competencies acquired means that the level of assurance that states can draw from the training obtained by migrants is limited.

41. We believe the criteria for automatic recognition and the minimum training requirements outlined in the Directive should be reviewed to reflect current practice in medical education and training and should over time be developed in terms of learning outcomes rather than inputs (hours and length of study).

Competence Assurance

42. The Directive as it currently stands does not allow competent authorities to assure themselves that the migrant doctors they register have kept their skills and knowledge up to date since the award of their professional qualifications. We do not consider that minimum Continuing Professional Development or

revalidation/relicensing requirements of the kind used in relation to medical education and training for the purposes of recognition should be imposed at Union level. However, the inability of member states to obtain assurance of an individual's competence inevitably weakens the level of confidence that competent authorities can have in the doctors seeking establishment in another member state.

43. We believe that there should be a requirement on doctors to maintain and improve their knowledge and skills throughout their careers and that only those doctors who have satisfied the competence assurance requirements in their home member states should be eligible for automatic recognition elsewhere in the EU.

44. Where a professional cannot provide proof of continuous competence, competent authorities should have the discretion to assess applicants under general systems and, if appropriate, apply compensation measures. This process does not need to be burdensome and would increase trust and confidence in the mutual recognition system.

45. In this context, we welcome DG SANCO's intention to publish a study reviewing and mapping national systems, governance and practices in place for the continuous professional development of healthcare professionals.

Review of the Directive

46. Despite the challenges highlighted above, the GMC welcomes the review of the Directive and the EU Institutions' attempts to address many of the public protection gaps we and other organisations have brought to their attention in recent years.

Section 16 – eHealth

47. The GMC recognises the increasing importance of EU initiatives aimed at advancing the implementation of eHealth to address healthcare needs while enabling entirely new modes of care in the context of budget deficits and ageing populations.

48. Any measures to encourage eHealth services must go hand in hand with the right for patients to effective and robust medical regulation. Legal clarity about regulatory responsibility in instances of cross-border provision of telemedicine is therefore essential to avoid ambiguity.

49. However, we do not believe that the current legal framework is a significant barrier to the uptake of eHealth services and would not support a European model for the licensing and accreditation of professionals carrying out telemedicine services. Any such move would be neither proportionate nor appropriate given the small number of patients and professionals accessing cross-border eHealth services.

50. In this context, a more appropriate solution would be for all member states to provide online registers of healthcare professionals and publish details about fitness to practise actions. That way, patients, employers and those commissioning eHealth services could easily check a doctor's registration and disciplinary status. This would

improve regulatory transparency and in turn increase confidence and trust in professionals providing cross-border eHealth services.

Section 20 – Non legislative action

Implementation of EU legislation

51. EU legislation, which is intended to govern action in the member states, is sometimes interpreted and implemented differently across the EEA. These discrepancies have the potential to jeopardise patient safety. We would welcome better coordination and sharing of good practice among member states when they implement Directives and other EU initiatives.

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