
GMC Response
Public consultation on the future of electronic commerce and the
implementation of the Directive on Electronic commerce (2000/31/EC)
5 November 2010

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. There are currently over 235,000 doctors with a licence to practise on the UK Medical Register. Of those, around 22,500 (9%) qualified in other parts of the European Economic Area.
3. 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 with doctors practising in the UK whose fitness to practise is in doubt.
4. Our approach to medical regulation stresses the importance of professionalism in raising healthcare standards and subsequently reducing risks to patients. We believe that the development of this approach to medical regulation across Europe could make significant contribution to safe and high quality healthcare. It is with this remit that we make our comments on the Commission's consultation.
5. Our position as set out in this response, aims to balance the development of e-health and telemedicine services with the maintenance of patient safety and high levels of professional regulation, which must be at the centre of any review of the e-commerce Directive.
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GMC position

Promoting the principles of good medical regulation

7. Medical regulation in Europe must comply appropriately with the principles of good regulation. In this regard regulation should be targeted, proportionate, accountable, consistent and transparent. It should also take place at the level most able to maintain patient safety and to deal firmly and fairly with doctors whose practice falls short of expected standards.

8. The GMC recognises the increasing importance of exploiting eHealth and telemedicine services to address healthcare needs, particularly in the context of budget deficits and ageing populations. However, the development and growth of these cross-border services must go hand in hand with the right for patients to effective, fair and robust medical regulation – whether the patient is treated at home or abroad and wherever in Europe their doctor is located.

9. The e-commerce Directive covers services between enterprises or between enterprises and consumers which are paid for by the recipient. This distinction raises significant legal challenges for most telemedicine services which are professional-to-patient activities and also in situations where the service would be contracted by public health providers rather than private companies and paying individuals.

10. The legal framework is further complicated by other sector specific initiatives driven by different European Commission Directorates-General, specifically Health & Consumers (DG SANCO), Information Society and Media (DG INFSO), and Internal Market and Services (DG MARKT). The GMC would encourage the Commission to ensure coherence between the priorities for a revised e-commerce Directive, the forthcoming e-Health Action Plan, the patients' rights Directive, and the review of Directive 2005/36/EC on the mutual recognition of professional qualifications.

11. We would also encourage the Commission to carry out a thorough impact assessment before bringing forward a revised e-commerce proposal. This should focus on the implications for the registration and licensing of healthcare professionals as well as on liability, data protection and conflict of jurisdiction, patients' access to redress if treatment goes wrong and the effectiveness of professional regulation. Any new proposal must balance the need to develop e-commerce and information society services with appropriate safeguards for patients.

12. A review of the Directive should also consider that only a small number of patients are currently exploiting cross-border eHealth and telemedicine services. Therefore it must not impose disproportionate administrative burdens on medical regulators.

There must be legal clarity for cross-border telemedicine services in the e-commerce Directive.

The legal framework for e-commerce must be coherent and consistent with other European policies and legislative developments.

A revised Directive should propose proportionate solutions to the level of demand and need for cross-border eHealth and telemedicine services.

The review of the Directive must go hand in hand with patient safety and access to redress.

Regulatory responsibility and legal clarity

13. The development and growth of eHealth and telemedicine cross-border services, without appropriate regulatory and legal clarity, raises challenges to healthcare professional regulation, patient safety and access to redress.

14. The nature and approach to medical regulation in Europe differs from jurisdiction to jurisdiction. A patient's healthcare experience in another European member state and the process for regulatory redress if things go wrong, may not be the same as at home.

15. There must be greater regulatory transparency across Europe for patients, the public, professionals and other regulators. In the UK, we have a freely accessible web-based real-time list of registered medical practitioners – patients can check anytime that the doctor treating them is registered and has no disciplinary action against them. We make our standards and guidance freely available to the public via our website and on request, and we set out on our website the mechanisms for making complaints about a doctor and notifications of disciplinary hearings.

16. We have also developed an interactive site *Patients' help*, which helps patients in the UK to understand which organisation to complain to if they have concerns about their doctor. It enables users to listen to a range of case studies, view an 'at a glance' chart on the life cycle of a complaint and look up local contact details on an interactive map.

17. We strongly believe that there should be no ambiguity as to where regulatory responsibility rests in any case of healthcare, and particularly in complex situations, such as cross-border e-Health, where neither the patient nor professional physically moves.

18. The GMC cannot hold regulatory responsibility for doctors who are not on the UK Medical Register. It must be the responsibility of contracting bodies to assure themselves that any e-Health contractors are appropriately registered and qualified in the country from which they are practising.

19. To improve regulatory transparency, the GMC has for some time been calling on all countries to provide an online register of healthcare professionals and publish details about fitness to practise actions. That way, patients, employers and those commissioning telemedicine services could easily check a doctor's registration and fitness to practise status.

20. The GMC has also contributed to the development of a European dialogue on regulatory issues through the establishment of the Healthcare Professionals Crossing Borders (HPCB) Initiative. The informal network of healthcare professional

regulators developed the Portugal and Edinburgh agreements which seek to identify shared principles of regulation; promote transparent and accessible healthcare regulation, as well as competence assurance of European healthcare professionals. These agreements also include a commitment by regulatory authorities to make information about professionals publicly available.

Regulatory responsibility in the context of telemedicine and eHealth services must reside with the jurisdiction of the practising doctor. There should be no ambiguity as to where regulatory responsibility lies.

Medical regulators must only take regulatory responsibility for those doctors registered in their jurisdiction.

Medical regulators must supply information to patients about registered medical practitioners; regulatory processes and procedures; the standards to which doctors must practise; and notifications of disciplinary hearings and findings.

Assuring high quality professional standards

21. All patients in Europe must have the assurance that the doctors that treat them – whether at home or abroad – are practising in accordance with robust professional and ethical standards. These include standards relating to quality, professionalism, confidentiality, continuity of care, prescribing and the communication of patient information.

22. In line with the principles of subsidiarity and proportionality, it is important that professional and ethical standards are developed at the national or regional level in order to take account of cultural and practical considerations, including differences in national law. We do not believe the setting of professional standards at European level provides added value. It could result in greater risk to patients through the application of “lowest common denominator” standards or by confusing patients and professionals about the standards to be adhered to, to the detriment of safe and high quality healthcare.

23. Our professional guidance, including [Good Medical Practice](#), is developed in consultation with a wide range of UK stakeholder groups, and is increasingly embedded in health service delivery in the UK. Within the consultation there is a mention of ‘codes of conduct’ for online commercial communications and information society services. The GMC has produced specific guidance on [Good practice in prescribing medicines](#), which clearly outline what is expected of doctors who prescribe remotely, including for patients overseas.

24. It is essential that doctors providing cross-border services are familiar with the standards applicable in the jurisdiction in which they practise, including communication with patients’ general practitioners or others providing healthcare; information standards to support safe and effective care and clinical audit; and systems for reporting adverse drug reactions and other patient safety concerns.

The GMC believes that professional and ethical standards for high quality medical practice must be developed at national or regional level and have patient safety at their heart

We do not believe there is a role for the European Commission to set professional and ethical standards in medicine and a review of the e-Commerce Directive must not provide for this.