General Medical Council

Regulating doctors
Ensuring good medical practice

GMC response
European Commission consultation on the legal framework for the fundamental right to protection of personal data
22 December 2009

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 250,000 doctors on the UK Medical Register. 22,000 (9.0%) of these doctors 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. The GMC believes the fundamental purpose of medical regulation is to ensure safety and quality of care for patients. Our approach to regulation is based on the fostering of professionalism. We believe that greater professionalism will drive up clinical standards and contribute to continuous improvement in patient safety. This makes effective regulation a vital component in achieving safe and high quality healthcare for all across Europe.

5. It is with this remit that we make our comments on the Commission's consultation. Our position as set out in this response, aims to balance the efficient free movement of doctors and patients with the maintenance of patient safety.

6. For more information contact Tanja Schubert, European & International Policy Manager, General Medical Council, 350 Euston Road, London, United Kingdom, NW1 3JN. Tel: + 44 20 7189 5346. Email: tschubert@gmc-uk.org

Mobility of health workers within the EU and exchange of information

7. The GMC supports the free movement of doctors in the EU. For decades the UK health system has benefited from overseas qualified doctors practising in the UK. However, in an environment where health professionals and patients are encouraged to move across member states a risk to patient safety in one member state is potentially a patient safety risk in another member state.

8. It is important that doctors and healthcare professionals, exercising their rights of free movement, are only granted registration when they are known to be fit and safe to practise. Patient safety and our knowledge of a doctors' fitness to practise relies on other competent authorities sharing the information they hold. If information is not shared efficiently and effectively a doctor could be erased or suspended in one jurisdiction while continuing to practise in another – such a situation is a serious risk to patient safety.

9. To this end, since 2005, the GMC, has coordinated, on behalf of all other European healthcare regulators, an informal initiative called Healthcare Professionals Crossing Borders (HPCB). HPCB's purpose is to contribute to patient safety in Europe through effective regulatory collaboration in the context of cross-border healthcare and free movement of healthcare professionals. The initiative developed two key voluntary agreements - the Edinburgh and Portugal Agreement - that set out a voluntary approach to regulatory collaboration and information sharing as a contribution to patient safety in Europe.

10. The initiative has been successful in raising awareness among all healthcare regulators of the importance of effective information exchange between regulatory authorities in the context of Directive 2005/36/EC. However our experience continues to show that the provisions of the Directive are open to varied interpretation based on national approaches to information management and privacy laws. Some regulators, for example, have expressed a desire to exchange information, but are impeded in the extent of that exchange because of national interpretations of data protection legislation.

11. Voluntary approaches provide some improvement but are inadequate in the context of data protection legislation and demonstrate the need for the European Commission to provide clarity as to when regulators should put patient safety ahead of data protection considerations and share information in a collaborative, efficient and transparent way. It is also imperative that regulators have a responsibility to act on such information so as to make patient protection and public safety their paramount concern.

12. Several cases of impaired healthcare professionals practising in a European jurisdiction after they have been stripped of their right to practise in another country have come to light and some have been brought to the attention of the European Commission in a number of questions tabled by MEPs in the European Parliament[1].

[1] Questions: P-3434/09 tabled on 5 May 2009; P-0690-09 tabled on 29 January 2009; H-0350/08 tabled on 28 April 2008.

13. These cases demonstrate that patient safety considerations may sometimes be overlooked as a result of interpretation of personal data protection legislation. They also highlight that it is imperative for competent authorities to be able to disclose, hold, request and act on full and up-to-date information about practitioners, such as simultaneous registrations, dual qualifications and registration and disciplinary history, and make this information available to other regulators. This is in line with Directive 95/46/EC which provides for the processing of data "necessary for the performance of a task carried out in the public interest" (Article 7) and disclosure where there is a public protection requirement (Article 13). Further guidance in this area may assist competent authorities with the disclosure of information.

14. For some time the GMC, individually and through the Alliance of Healthcare Regulators on Europe (AURE) has called on the European Commission to establish a legal duty on regulatory authorities in Europe to reactively and proactively exchange disciplinary information about the health professionals they register[2]. The diversity of domestic approaches to the implementation of privacy legislation throughout Europe means that public safety concerns, for some regulators, might be secondary to maintaining the doctors' right to privacy. Therefore the most effective way of ensuring information is exchanged, including on proactive basis, is through establishing a legal duty in European legislation. A legal duty would ensure that patient safety is central to the free movement of health professionals in Europe.

We call on the European Commission to propose the establishment of a legal duty upon national and regional authorities to reactively and proactively exchange regulatory information about doctors in the interest of patient and public safety.

We call on the European Commission to produce guidance for healthcare professional regulators about their rights and obligations with regards the exchange of personal data under Directive 95/46/EC.

Internal Market Information System

15. In our view the Internal Market Information System (IMI) is a useful tool for competent authorities to share information and is working well within its current remit (in support of cases of justified doubts). It helps us to build to build a network of contacts and assists with any queries at the point of registration.

16. However we have not yet had contact with all competent authorities though IMI as its use is not mandatory. We call on the European Commission to encourage all competent authorities to use IMI and eventually to make registration with IMI compulsory for all.

[2] To date the European Parliament has supported the GMC's and AURE's call for an EU legal duty on regulatory authorities to exchange information. This has been adopted within the texts of the Braghetto opinion in the Employment and Social Affairs Committee (adopted on 2 March 2008), the Vergnaud opinion in the Internal Market and Consumer Protection Committee (adopted on 9 March 2009), and the Bowis first reading report on the draft Directive on patients' rights in cross-border healthcare (adopted on 23 April 2009).

17. In addition it would be helpful for the ad hoc IMI system to become more flexible in the future and we call on the Commission to explore whether it could become a tool for both the reactive and proactive sharing of disciplinary information. Currently the legal base for IMI restricts it to reactive information sharing. We understand that legal provisions in Directive 2006/123/EC on services in the internal market allow for an alert mechanism which would be helpful in relation to Directive 2005/36/EC and would make IMI a more useful tool.

We call on the European Commission to encourage all competent authorities to use IMI and eventually to make registration with IMI compulsory for all.

We call on the Commission to explore provisions in Directive 2005/36/EC for an alert mechanism about healthcare professionals that are no longer fit to practise. As an existing direct communication system, IMI could provide a secure and password protected direct communications tool between competent authorities which will satisfy those with data protection concerns.

Transfers of patients' data

18. The transfer of data about patients seeking medical care outside their home state or in order to provide e-services is an obvious and increasingly important change in the way health data is being processed. The challenges involved in this include the diverse implementation by nation states of Directive 95/46/EC, and the permissible variation in national law and societal norms that underpin different approaches to data protection, respect for privacy and rules for professionals.

19. The use of commercial sites for storing 'patient held' records[3] suggests a transfer of responsibility for the security and safe use of sensitive personal data from health organisations (such as the National Health Service or its constituent parts) to the individual. While there are obvious attractions to this and some precedent within and outside the EU, there are significant risks to patient safety if the data is not stored in a consistently uniform way, so that records may not be as interoperable or useful for secondary purposes without strict governance controls.

20. There is some tension between (a) Directive 95/46/EC and (b) the UK common law of confidentiality and Article 8 of the European Convention on Human Rights. The latter generally propose that medical information should be kept private and confidential unless there is a good reason to disclose; whereas the Data Protection Act[4] (DPA) is generally regarded as allowing sharing (usually justified by reference to the widely drawn 'medical purposes' condition in Schedule 3) unless there is a good reason not to. The first principle in the DPA is sometimes overlooked in this regard, with data controllers and third parties more concerned with satisfying a condition in the Act than with considering the individual's common law and Article 8 rights. Some integration of those rights into a revised data protection Directive (and

[3] For example the UK Conservative Party proposal to use Microsoft or Google as service providers for e-health records.
[4] Visit: http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_1

national data protection law) might help data controllers better to appreciate these rights and to balance the widely drawn right with some more narrowly drawn exceptions.

21. The move towards centralised databases of electronic health records[5] marks a fundamental shift in the paradigm of professional responsibility for the security of patient data and about decisions to share such data. Doctors have traditionally acted as custodians of health information, sharing relevant details with others providing care and making decisions to share information with others, including the police or researchers, with or without patients' consent. The centralisation of data on shared-access databases shifts many of these responsibilities onto the person accessing the data.

22. It is inherently more difficult for the person accessing records to know what is relevant to their role, and so restrict or avoid unnecessary invasion of the patient's privacy. Various initiatives to limit access through technological and role-based restrictions, to audit access and to allow patients to control who can access their records, to shield parts of their records from view, or to opt-out of having a shared record are advanced as means to mitigate the risks to privacy. The challenge for EU law makers is to develop legislation that reflects the new paradigm without unnecessarily stifling initiatives that promise improvements in the quality, safety and timeliness of healthcare services.

23. A difficulty with the existing Directive lies in the definition of 'consent'[6] and how consent is used within the Directive itself. Consent is qualified in a number of ways in the preamble and the Articles, including ‘unambiguous’, ‘explicit’ and ‘free and informed’. This raises questions about whether in each case a different meaning is intended, and creates the impression that where there is no qualifying adjective, a different, and lower threshold may be used when assessing whether a person has given consent to the processing of data. For example, in the UK the Information Commissioner’s guidance suggests that patients’ consent to disclosure of identifiable data to researchers may be signified by the patient continuing to seek medical care, provided that they are given necessary information about disclosures at the first consultation[7]. The patient’s actions in seeking care are regarded as ‘signifying his agreement’.

We call on the European Commission to consider the specific challenges of electronic databases of health information and the responsibilities that go with recording data in a uniform manner to ensure safety and interoperability.

We call on the Commission to consider a revision of the definition of ‘consent’ and the use of this term in Directive 95/46/EC.

[5] This is well advanced in Scotland and developing in England and Wales.
[6] Article 2(h): “...any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed”
[7] Use and disclosure of health data: Guidance on the Application of the Data Protection Act 1998 (May 2002) - opt-outs as a means of obtaining consent (see page 19).

Data transfer outside the EEA

24. Articles 25 and 26 of Directive 95/46/EC relate to the transfer of data to countries outside of the European Economic Area. The rapid development of information technology has led to the increasing use of overseas service providers. Most organisations, including professional regulators like the GMC, are likely to directly or indirectly transfer data to countries outside the EEA. This is particularly the case where organisations outsource some or all of their back-office functions including human resources, finance and payroll. It is also utilised in the interpretation of health data, such as radiographic images. This is an increasing reality of modern service delivery.

25. Articles 25 and 26 provide a high level framework to support such transfers. The distinction made between EEA countries and those outside the EEA seems to be increasingly arbitrary. A simplified approach might be appropriate, where any transfer outside of the originating jurisdiction is treated in a consistent manner, regardless of the EEA status of the recipient.

We call on the European Commission to develop simplified guidance on the assessment of recipient countries and organisations.