General Medical Council

Regulating doctors
Ensuring good medical practice

GMC response
Public consultation on the Commission's comprehensive approach on personal data protection in the European Union
15 January 2011

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 239,200 doctors on the UK Medical Register. 22,779 (9.5%) 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. That rests on trust between doctors and patients, which in turn relies on patients having confidence that the sensitive personal information they share with their doctors will be treated in confidence and that their privacy will be respected. It also requires the exchange of practitioner data between regulatory and other bodies where this contributes to patient safety and public protection.

5. The GMC welcomes the opportunity to respond to the consultation, which should be considered alongside our submissions in July 2010 and December 2009. Our response focuses on those issues that are most relevant to medical regulation and patient safety. It stresses the need for further clarity on the specific measures the EC is likely to bring forward in a revised Directive and assurances that the review will safeguard the public interest.

6. For more information contact 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: european@gmc-uk.org.

GMC position

Strengthening individuals' rights

7. The GMC has a statutory responsibility to hold a list of registered doctors wishing to practise in the UK. We collect personal data to update the register, administer and maintain registration and process complaints. In light of public interest and patient safety, we also hold information concerning past and present registration, including doctors no longer on the register for administrative or disciplinary reasons.

8. We are transparent in the information we collect and support the principle of maintaining individuals' rights in the processing of personal data. However, any proposal to revise the data protection Directive must balance the need for transparency with public protection. The "right to be forgotten" must be proportionate and clearly defined, with appropriate conditions, to ensure that data controllers are able to maintain any records required to protect the public and, in the case of medical regulation, safeguard patients.

9. We also believe that the Commission should focus on clarifying data subjects' rights to control the processing of their data rather than ownership issues. The question of ownership of medical records is complex and engenders considerable debate in the UK. Ownership of paper or computers in which data is recorded, ownership of data by the data subject, and even ownership of intellectual property by the record maker – particularly if the record includes diagnoses or analysis of some kind all need to be considered and are interlinked. We suggest that there is little to be gained from setting up a new legal framework to accommodate these issues. It is more important to strengthen and clarify data subjects' rights to control the processing of their data, irrespective of to whom the data belongs.

10. In healthcare, a right to have records deleted in total (for example when a patient wishes to transfer care to another provider) or to have data deleted from a record that is inaccurate, would also cause serious difficulties. It would be helpful to have a clear guide from the Directive about whether there were circumstances in which a data subject had the right to have data deleted or destroyed, rather than corrected, and how the potentially conflicting rights and interests of data subject and data controller should be resolved in a proportionate manner. The problem of shared genetic data means that data about one person might at the same time also be data about others the person shares genetic or other links with, and who may have a legitimate interest in the continued storage or processing of the data. The diagnosis of an illness in a patient might, for example, point to the likelihood or certainty to the same illness in a blood relative; or data about one person might be valuable in targeted tests for illness in a relative.

A revised data protection Directive must balance individual rights with the protection of the public.

The "right to be forgotten" must be proportionate and clearly defined. It should only apply to data no longer required to protect the public interest and maintain patient safety.

The Commission should focus on clarifying data subjects' rights to control the processing of their data rather than strengthening their ownership over it.

The right to have healthcare records deleted should be clarified in a proportionate manner.

Enhancing the Single Market

11. We welcome the Commission's intention to improve the harmonisation, implementation and enforcement of European data protection rules in its strategy.

12. As highlighted in our previous submissions, we believe that the fundamental right to the protection of personal data should not impede measures that allow regulatory authorities from sharing fitness to practise[1] information about healthcare professionals in line with Articles 7 and 13 of Directive 95/46/EC.

13. These provisions are essential in the context of Directive 2005/36/EC which facilitates the mutual recognition of professional qualifications and enables the free movement of doctors and healthcare professionals across the European Economic Area. The GMC supports this free movement. 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.

14. It is essential that doctors and healthcare professionals, exercising their rights of free movement, are only granted and maintain registration when they are known to be fit and safe to practise and have no conditions or limitations on the registration and right to exercise the professions. 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 disciplined or suspended in one jurisdiction while continuing to practise in another – such a situation is a serious risk to patient safety.

15. Over the past few years, the GMC together with other European regulators have developed voluntary approaches[2] to the sharing of fitness to practise information. However, our experience continues to show that national approaches to information management, data protection and privacy laws, impede their full adoption and implementation. Some regulators, for example, have expressed a desire to exchange information, but are impeded in the extent of that exchange because of

[1] Fitness to practise is the process by which concerns raised about a registered health professional's conduct, competence, physical or mental health, or criminal record, are investigated by a competent authority/ regulator. This may lead to a health professional being prevented from practising or restrictions being placed on their practise in order to protect the public.
[2] http://www.hpcb.eu/activities/documents/MoU_Master_2010.pdf

national interpretations of data protection legislation. This demonstrates the need for the European Commission to provide clarity as to when regulators can and should put patient safety ahead of data protection considerations and share information in a collaborative, efficient and transparent way.

16. Several recent cases[3] 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 public, media, the European Commission and MEPs in the European Parliament[4].

17. 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). It is essential that provisions allowing competent authorities to share fitness to practise information are maintained in any new Commission proposal to ensure that patients and the public have confidence in the healthcare services they receive.

18. The GMC would welcome further European Commission guidance to assist healthcare professional regulators in exchanging personal data in compliance with their rights and obligations under Directive 95/46/EC. We also urge the European Commission to strengthen the information sharing provisions as part of its review of Directive 2005/36/EC and are encouraged that DG Internal Market and services (MARKT) is considering an initiative to introduce proactive information sharing between European healthcare regulators, either in its forthcoming Regulation on the Internal Market Information System (IMI) or as part of its evaluation of Directive 2005/36/EC on the mutual recognition of professional qualifications[5]. An "alert mechanism" is already provided for in the services Directive (2006/123/EC) through IMI, which requires member states to inform their counterparts about any service activities that might cause serious damage to health or safety of persons or the environment. However, we understand that the strict pre-conditions required for its use, particularly those concerning data protection, have limited its impact. Therefore, it is essential that any proposal to review the data protection Directive supports proactive information sharing, rather than constrain it.

19. We therefore urge the European Commission to ensure coherence between the priorities for a revised data protection Directive, the forthcoming regulation on IMI

[3] Please refer to the cases of Dr Marcos Ariel Hourmann (http://www.bbc.co.uk/news/uk-wales-11750857) and Dentist Ben Verlinden (http://www.ad.nl/ad/nl/1015/Gezondheid-wetenschap/article/detail/524852/2010/10/27/Horrortandarts-boort-vrolijk-verder-in-Spanje.dhtml)
[4] 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; P-1112/10 tabled on 8 March 2010.
[5] DG MARKT consultation on the recognition of professional qualifications Directive: http://ec.europa.eu/internal_market/consultations/2011/professional_qualifications_en.htm

and the review of Directive 2005/36/EC, to ensure that proactive information sharing becomes compatible with European data protection legislation.

We call on the Commission to improve the harmonisation, interpretation, implementation and enforcement of European data protection rules.

We call on the European Commission to ensure consistency between a revised data protection Directive and the revision of Directive 2005/36/EC on the mutual recognition of professional qualifications, in the interest of patient and public safety.

Consent

20. A difficulty with the existing Directive lies in the definition of 'consent' and how consent is used. It is qualified in a number of ways in the recitals and Articles, including ‘unambiguous’, ‘explicit’ and ‘free and informed’.

21. It is important that any distinction between the consent required for the use of personal data and of sensitive personal data is more clearly defined in a revised Directive. It may be helpful to consider and distinguish between circumstances in which the data subject takes a positive, relevant action to signify their consent (signing a form; giving a verbal agreement; completing an on-line form or tick box) (express consent) and those cases where their consent may be inferred because, having been given information about the use of the data, they have not exercised a clearly explained right to object to it being processed for a particular purpose (implied consent).

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.

Sensitive data

22. A fundamental principle of healthcare provision centres on patients having confidence that the sensitive personal information they share with their doctors will be treated in confidence and that their privacy will be respected.

23. The Directive refers to ‘data concerning health’ and the UK Data Protection Act 1998 (DPA) refers to personal information relating to ‘his physical or mental health or condition’. Close reading of these terms suggests that ‘sensitive data’ does not necessarily relate to either biometric and genetic data, or to family history, where they are not influencing or affecting ‘health’ or a condition.

24. In practice in the UK, however, all information stored in medical records is regarded as ‘sensitive personal data’ and therefore subject to greater controls. It may be helpful, nonetheless, to avoid any ambiguities or future challenge, to broaden the definition of sensitive data to include biometric and genetic data and a person’s family history, or to add a category which might be ‘data recorded by a healthcare professional in relation to the provision of healthcare.’ This would avoid any future disputes about whether information held in a health record, but not relating to a person’s health or condition, should be separately categorised as ‘personal data’.

25. In addition, some consideration might be given to the proportionate exercise of subject access rights by family members whose data (in the form of family history and genetic data) is shared with a family member (see paragraph 10, above) or stored in a relative's health record or disclosure by health professionals of such information for the benefit of those family members.

We call on the European Commission to broaden the definition of sensitive data to cover all information held in a health record.

Transfers of patients' data

26. 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 conditions in Schedules 2 and 3 of 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 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.

27. 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.

28. 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.