EUROPEAN COMMISSION: HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

EUROPEAN UNION CONSULTATION REGARDING COMMUNITY ACTION ON HEALTH SERVICES

The Royal College of Physicians of Edinburgh is pleased to respond to the above EC consultation. This is an area where the fundamental right to health care can clash with a market philosophy where health care is a commodity. In order for the market to limit adverse effects and protect the rights of all people in a Member State, the whole system requires an adequate regulatory framework at EU, Member State and local levels.

Question 1: What is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

In the UK the current impact is limited, as only in the south east of England does it appear that commissioners have purchased (in nearby France, Belgium and Netherlands) substantial packages of healthcare for their patients; in most of the rest of the UK only small numbers of individual patients have made their own arrangements for treatment elsewhere in the EU, and not in numbers sufficient to impact on UK-based health services, except in respect of fairly substantial UK populations (mainly elderly) resident in places such as Spain, who seek treatment there. Scotland and the North of the UK are relatively less affected, although this may also change in time. There is substantial cross-border flow of patients across the border in Ireland, mainly from the Republic into Northern Ireland. There are also anecdotal reports of substantial numbers of UK residents seeking dental treatment in other EU member states.

The extent and degree of change will be dependent on some or all of the following factors:

- the quality, accessibility and coverage of local health services;
- the coverage of local health policy as set out in the NHS in the UK;
- the willingness of people to pay to travel for treatment;
- perceived confidence in the national public health system;
- the extent of national solidarity towards the national public health system; and
- the strengths and compelling attraction of alternatives in health care provision.

Member States' policy towards long-term care and critical intervention will require to acknowledge the need for local systems to report on the continuing care of people where critical interventions take place elsewhere. Member States must be in a position to determine tariff or level of total health provision by agreed means and, by implication, limit the coverage of the health services, wherever provided, that they are committed to funding. Such systems will continue to be subject to appeal, but the principle of sovereignty in Member States for

their national public health service must allow discretion. A relevant Human Rights court case in South Africa relating to kidney transplantation refers.

If arrangements for quality control, accountability for treatment etc were to be clarified, treatment packages offered in the near-continent at lower cost than in the UK might become increasingly attractive to UK-based NHS commissioners across the UK; this might become a threat to some UK hospitals. Similarly, in the context of simplified and transparent arrangements, some major UK health service providers (both NHS and private) might seek to offer attractive healthcare packages to patients from elsewhere in the EU; this could affect accessibility to services for UK-based patients.

Question 2: What specific legal clarification and what practical information is required by whom (e.g. authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

At present, anyone (commissioner or individual patient) seeking to purchase healthcare in another Member State has to do so largely on the basis of faith and trust, without any clear guarantees regarding quality and with no clear understanding of entitlements.

Although we have mutual recognition of “medical specialists” across the EU, there is no agreed training pathway nor set of competencies needed to become a specialist, nor any system for the sharing of information on individual specialists regarding issues such as continuing professional development, revalidation etc. Basic standards applicable across the EU are needed, with systems for the sharing of information about them.

Similarly, purchasers (individual or collective) have no way of comparing performance (such as 5-year survival rates, postoperative complication rates, hospital infection rates etc) between alternative hospitals. The provision of information is also fundamental to the choice for patients. However, this information must be "adequate" with appropriate interpretation to information to make it of value. Member States should be responsible for requiring potential providers of care to residents and commissioners from other Member States to provide a basic information set. This could include:

(a) outcome-based evidence that the intervention is safe, efficacious and effective;
(b) the cost should be defined;
(c) expectations of other providers before and after the intervention should be defined;
(d) any peer-reviewed scientific evidence to back claims of innovative or novel treatments should be available; and
(e) the provider should be endorsed by the Member State for that specific intervention, or group of interventions.

Ideally, record systems should become compatible and there should be no bar to the movement of patient-based information between direct health care providers with the stated involvement and consent of the patient. However, the resource and confidentiality consequences of this would be significant.

Accountability and responsibility need to be clarified: it is suggested that health professionals treating patients resident in other Member States would remain accountable for their performance to the appropriate professional bodies in their own Member States, and that any legal action which might relate to alleged malpractice (for example) would be heard in the country of treatment, not the country of patient residence. This would also apply in respect of treatment centres based in one Member State but operating in another (eg if a major UK hospital were to set up a treatment centre in Netherlands, both this, and the professional staff working within it, would be accountable within Netherlands arrangements).

Accountability and responsibility in respect of provision of healthcare services by professionals operating temporarily in one Member State, but based in another, present a special problem. Such professionals should in such situations be accountable within the country of their (temporary) practice and regulators would need to facilitate this.

Question 3: Which issues (e.g. clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for different kinds of cross-border healthcare described in section 2.2 above?

The duty of care in a public health system should lie with the universal primary care system, if a country has one. Duties of care will be different for other systems including social insurance systems and others that may not offer comprehensive coverage.

In the UK, therefore, the primary duty is for the provider of the current direct intervention. The hand-over of leadership in care should be explicit, and expectations by one health care provider of another should also be explicit. They should be agreed prior to transfer of care of the patient where possible. This would obviate possible conflict where a provider in another Member State prescribes treatment and follow-up care that is disputed by the health care provider in the host Member State. However, the doctor or primary care team in that host Member State should have the discretion to apply recommended treatment according to the notions of good practice locally.

If the Member State anticipates being unable to sustain follow-through care, this should be anticipated before referral. Systems of health policy should therefore restrict availability and referral only to interventions where follow-through care is available at an acceptable level. Otherwise, placing undue expectations on local Member States' health systems to live with decisions taken elsewhere is not a good use of resource.

Question 4: Who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

Commissioners and individual patients seeking investigation and treatment in another Member State must be expected to take some responsibility for such decisions, on a “caveat emptor” basis. However, as stated above, the general principle should be that professional accountability and legal responsibility should be located in the country of treatment. Legal aid arrangements might be adjusted to facilitate patients seeking legal redress in another member state.

Question 5: What action is needed to ensure that treating patients from other member states is compatible with the provision of balanced medical and surgical services accessible to all (for example, by means of financial compensation for their treatment in "receiving" countries)?

This is a challenging issue, especially for those host and receiving Member States that are relatively poor and may offer a more basic level of coverage in health care provision. A Member State must be allowed sufficient discretion under its principle of sovereignty to determine resource allocation for health care in total provision, and between different classes of provision. This principle of sovereignty must extend explicitly to differences of approach within the devolved administrations of the UK, given that Scotland, Wales and Northern Ireland no independent voice within Europe. By implication, this may require limitations on cross-border flow to protect health budgets for the local population and which would conflict with a free market model. Within each Member State, and relying on its democratically elected institutions, there should be transparent and exclusive criteria which limits clinical intervention and limits the financial provision to meet clinical commitments. Without such a system, and as currently seems to be occurring in dentistry (EU paper refers), the integrity of Member States' local systems is under threat, as is their ability to address nationally determined health care priorities.

Question 6: Are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

The competence of health care professionals is integral to patient safety and the quality of care. Competence and language problems continue to cause concern, particularly the ability of doctors to practice successfully with limited language skills. At present, language difficulties cannot influence regulatory rights to work in member states although employers have more discretion.

Question 7: Are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other member states – such as healthcare providers and social security organisations – suggest in order to facilitate cross-border healthcare?

The public and patients throughout the EU need to be aware of their rights to obtain healthcare, of the extent and limitations to such rights and the quality of healthcare in other Member States. Promotion of such information should be a shared responsibility between the EC, and all healthcare organisations within Member States. The quality and accuracy of this information must be managed to agreed standards.

Question 8: In what ways should European action help support the health systems of the member states and the different actors within them? Are there areas not identified above?

There should be a European framework for health care regulation. This could start at a fairly basic level and grow to reflect increasing sophistication of information and its interpretation; increasing the expectations by consumers and the need for assurance that providers are making authentic claims for the treatment, and living with the risks of health care provision. Each Member State should commit itself, where the treatment is innovative, unusual, high cost or high risk, to an approved programme of research. This research should be peer reviewed at its instigation, through to publication. It should have external scrutiny and, ideally, be achieved through a competitive grant system. In the absence of a feasible research programme, there should be a publicly available and transparent evaluation framework. It should be an implicit condition of participation and treatment that patients should consent to information relating to their care being made available to researchers in order to achieve maximum learning.

The consultation document refers to "European networks of centres of reference", "Realising the potential of health innovation", "A shared evidence base for policy-making", and "Health systems impact assessment". Legislation in these areas would permit subsequent developments under these headings, by agreement. Such developments could be of real benefit to health services in all member states.

Question 9: What tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means?

In general, the College accepts the inevitability of freedom for patients to avail themselves of investigation and treatment across the EU, provided adequate safeguards can be put into place. However, public and patients, and healthcare commissioners and providers, all need legal certainty concerning their precise rights and responsibilities. The regulatory framework should be statutory and would require legislation. This framework must allow the full principle of subsidiarity of national public health systems to operate, especially in areas that delineate the right of Member States to determine the level of comprehensiveness of care coverage, and care priorities. This accepts that "comprehensiveness" will be differently interpreted between Member States depending on choices they make using democratic means.

However, other issues discussed above, such as those concerning professional standards, professional accountability, information required for informed choices by commissioners, general practitioners and patients, are likely to be achieved best by agreement following open discussion of the issues.

The quality of research and evaluation should be non-legislative but reference to it should be legislative and the commitment of Member States to establish research and evaluation networks should be a legislative principle.

All College responses are published on the College website www.rcpe.ac.uk.

Further copies of this response are available from Lesley Lockhart (tel: 0131 225 7324 ext 608 or email: l.lockhart@rcpe.ac.uk) [31 January 2007]