

IN SEARCH OF HEALTH CARE ?

Response to the European Commission's "Consultation regarding Community action on Health Services"

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SUMMARY:

Nobody is fully in charge of the development of health policy in the EU. Health service delivery and funding is an exclusive national competence but it is subject also to the Treaty principles of free movement as developed by the jurisprudence of the European Court of Justice - a jurisprudence that is sometimes hard to reconcile with the principle of national competence. Against this background, patient mobility is one of many aspects of health policy on which it is difficult to develop a coherent strategy. If coherence is to be achieved, agreement on the overall needs and rights of patients must be the starting point, which will then provide a basis for the work of the different institutions and decision making processes. Without a wide and clear agreement on patient rights, health policy will be driven by the agendas of different institutions and, worse, by the demands of specific interest groups and/or their institutional sponsors.

The lack of information about health care possibilities in other Member States and the lack of a transparent framework act as a deterrent to access health care abroad, even if it would be appropriate to do so. The current situation leaves too much uncertainty about cross-border health services and that's why an action at EU level is necessary.

What citizens need now is to move on from the patchy framework defined by the ECJ rulings and have legal certainty about their rights and entitlements when seeking health care treatment abroad. They need clear statements on what they may reasonably expect in terms of information, access to care, quality of care, redress in case of malpractice, access to records and reimbursement and they should be enabled to identify, compare and choose between providers in other countries.

Patients all need reliable, accurate, transparent, independent, comparative information about the treatment and the quality of care they will receive abroad.

An EU-wide patient's charter could help raise the standards and serve as a guide to consumers of health services both if they stay in their country and if they seek health care abroad as well as a guide for health professionals and decision makers.

It is essential first to define clear goals in respect of patients' rights and access to safe and high-quality health care for all, and only then decide the best institutional, legislative, non-legislative and judicial means to achieve these goals, taking into account the unique nature of health services, the issues of competences, the principle of free movement of people, goods and services, the European Court of Justice rulings and solid scientific evidence to assess different policy options. Without a clear set of overall goals, policy will develop in a piecemeal and haphazard way within the different institutions.

This is the BEUC response to the “Consultation regarding Community action on health services”¹ launched by the European Commission on the 26th September 2006.

Introduction

In the context of the EU as a whole there are two principles that govern the provision of health services. The first is that of national competence, by which Member States each retain exclusive competence for health service policy, delivery and funding. The second principle is that of free movement of goods, services and people, which applies to health services, according to the jurisdiction of the European Court of Justice.

In particular cases, or on particular issues, these two principles may conflict with each other. This conflict has existed for a long time but is becoming more acute in recent years. On the principle of national competence one might suppose that the distribution and supply of medicines is a matter for national health authorities. Apart mainly from the issue of pricing and re-imburement, however, it is in large measure European law that applies, even to the regulation of the manner in which medicines can be advertised and promoted. Within the European Commission, for example, the lead Directorate General (DG) dealing with medicines is not DG SANCO the health policy DG but DG Enterprise, the DG with responsibility for supporting the development, competitiveness, and economic wellbeing of the European pharmaceutical industry.

In more recent years, the issue of patient mobility has raised new questions as to how best to reconcile the two principles of national competence and free movement, and, crucially, how best to ensure patient welfare in cases with a cross border element.

There are two important developments relating to patient mobility. In the first place, more and more patients (called here “active patients”) choose or decide to travel to another Member State for medical treatment of one kind or another. Secondly, the Court of Justice has enumerated certain rights that all patients potentially have to travel to another Member State for treatment and to be reimbursed at least in part by their national authorities for such treatment. The impact of these two developments overlap in practice but for policy purposes it helps to consider them separately.

The decisions of the Court of Justice posed particular challenges. The Court has enumerated certain rights and, as is normal, it is the duty of public authorities to ensure that these rights are respected.

¹ SEC (2006) 1195/4, 26 September 2006.

http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/comm_health_services_comm2006_en.pdf

The jurisprudence of the Court is not as clear as we might wish, perhaps because of the difficulty of reconciling the principles of national competence and free movement and this presents problems for public authorities. It presents even greater problems for patients who can hardly be expected to understand or know, let alone to pursue their rights on the basis of a number of complex court decisions.

What citizens need now is to move on from the patchy framework offered by the ECJ rulings towards a clear and coherent framework at EU level.

An EU-wide patients charter, describing patients rights, would help raise the standards and serve as a guide to consumers of health services both if they stay in their Country and if they seek health care abroad as well as a guide for health professionals and decision makers.

Assumptions used in answering the questions

Because of the complexity of the issue and for ease of discussion, in answering the questions of the consultation we focus on one aspect of cross border health care, namely patient mobility (see section 2.2 of the consultation document) and on those citizens who go abroad to receive care, those who are first patients and then “mobile” and not on those who happen to be abroad when in need for care. Thus we exclude from our analysis tourists, professional travelers but also students and long term residents such as migrants and pensioners.

Without investigating the variety of reasons for which patients seek health care abroad, to better discuss the policy options we notionally divide patients between those who seek health care abroad within the framework of their reimbursement system those “active patients” who seek health care abroad without seeking to rely on their social security system, and thus willing to pay out of pocket if necessary.

The first are usually “sent” abroad by their national authorities within an institutionalized framework and include those who receive care abroad with a prior authorization by the competent authorities according to art.22.2 of regulation 1408/71, cases of cross border contracting, providers cooperation, common infrastructure.

The latter, the “active patients”, are those who deliberately choose to seek health care abroad on a voluntary base and self manage their care. They usually seek treatments not reimbursed or not provided in their country like dental care, cosmetic surgery and fertility treatments. Some of them are enticed abroad by advertising in their country of residence or on the internet, an increasingly common phenomenon.

For the first group, treatments, quality, prices and conditions are agreed by the competent authorities and the foreign providers while those who go abroad on their own initiative establish a direct contractual relation with the (private) service provider in another Country.

Whichever groups patients may fall into, they are all patients and have similar needs.

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?

Accessibility

The available data on cross border health care are fragmentary and incomplete. Even if at the moment they indicate that patients' mobility across Europe is a marginal phenomenon, the number of patients going abroad (both within EU and outside the EU) seems to grow and we do not know how the phenomenon might evolve in the future. In any case, it is clear that many more patients are interested in cross-border health care in principle. However, as mentioned in the consultation document, the lack of information about health care possibilities in other Member States and the lack of a transparent framework act as a deterrent to access health care abroad, even when it would be appropriate to do so. Many patients may go abroad and pay out of pocket even though they may be entitled to reimbursement just because they do not know their rights. Some may not receive timely treatment because they are unaware of their right to go abroad. That is why we think that an action at European level is essential.

On the "active patient" side, accessibility problems arise in terms of health inequalities as those seeking care abroad seem likely to be younger, better educated, and with higher incomes.

From the perspective of the resident population, at the moment we don't have evidence of cross border health care impact on accessibility to the health system but in the "sending" countries the principle of equity could potentially be jeopardized if patients going abroad on their own initiative disrupt domestic priority-setting systems.

In the "receiving" countries, especially in some areas such as border regions and tourist destinations², the local health care provision and the local health care budget can be challenged by a considerable number of patients coming from other Member States and this can have relevant implications in term of access to health care for the resident population. In addition, for the receiving country, there is a risk that foreign patients will be given priority over domestic patients, especially if foreign purchasers are willing to pay above official tariffs. Especially in new Member States, patients from abroad can be a third of the total in some dental clinics and this might have significant impact in terms of access to care as this could exert upward pressure on tariffs and increase waiting times. Thus, it seems important to understand how waiting lists should be managed.

It is also essential to avoid the simplistic notion that providing health care for payment to foreign patients is simply an economic opportunity for a receiving country. At some stage, such care will impact on domestic health care priorities.

² See "Patient Mobility in the European Union – learning from experience", M.Rosenmüller, M. Mckee and R.Baeten,, World Health Organisation 2006

Quality

Difficulties in cross border health care relate to the development of shared approaches to quality assurance, continuity of care, patient safety, information sharing, liability, redress or compliance with regulatory systems. For those who are sent, quality standards are (or should be) agreed by the competent authorities and the foreign providers. In direct contracting by public purchasers, for example when sickness funds sign agreements with foreign health care providers such as in Germany and the Netherlands, the contracts are often based on an interpretation of European Court of Justice rulings that care provided abroad should be under the same terms and conditions as that provided domestically. Thus, a Czech provider contracting with a German sickness fund is expected to apply German quality standards. The principle of exporting domestic standards applied also in the case of English patients treated in Belgium and France, as part of a short-lived attempt to reduce waiting lists.

For those who choose a health care provider abroad on their own, it is often difficult to assess the quality of care offered. Even if in the health sector price competition is usually frowned upon, in some cases they may pay cheaper prices at the expense of quality.

Thus, a key issue for the patients/consumers is to be enabled to find information about the quality of care, the standards and the scope of practice they might expect in another Member State.

Financial sustainability

Knowledge of the scale of the phenomenon and the monetary implications is rather limited but according to the available data, the current impact of patient mobility on the overall public expenditure on health care is relatively low and estimated at around 1%.

Against the constant increasing public health care expenditure, cross border health care could potentially offer a way to reduce costs and improve quality by promoting the use of spare capacity, the exchange of knowledge and best practices between physicians established in other Member States, the achievement of economies of scale (eg. centres of references , cross border provision of services such as telemedicine) but at the same time, in some areas of Europe and in some specific cases, it could have relevant implications on the health budget.

How it might evolve

Patient mobility could provide an incentive for improvements in health care delivery in both sending and receiving countries, for example by creating pressure to reduce waiting times. Patient mobility can also reveal weaknesses in administrative processes, such as patient registration and data flows. In border regions, it can facilitate a more rational use of scarce capacities: the country providing care can have the opportunity to generate additional income to cover their fixed costs or to support new capital investments.

In small countries such as Cyprus or Malta, patient mobility can make available treatments that would otherwise be unavailable but at the same time, it can be very expensive, and it can also delay the inclusion of new treatments when patients can receive them abroad.

Cross-border health care is fostering innovation in the way health is delivered and managed providing new ways of thinking in terms of the provision, organization and financing of health care.

On the other hand, patient mobility can also entail risks for health care systems, especially if the process is not managed effectively.

Cost-containment policies everywhere are to a greater or lesser extent based on restriction of supply (leading to waiting lists). Increased patient mobility could threaten cost-containment policies in the sending (and receiving) Member State.

Patient mobility can also put pressure on established organizational arrangements. Examples include the corporate system of contracting in Germany, referral systems in the Netherlands, collective agreements between providers and purchasers in Belgium, changed relationships between local and national authorities in France, Spain and Italy.

A recent phenomenon to emerge in some settings is the use of brokers, actors familiar with the system in the providing country. Their main aim is to ease negotiations, clarifying tariff-setting systems, and managing invoices for sickness funds but they are now also involved in providing information directly to the patients about the available options for care, cost implications, administrative procedures, transport arrangements, etc. Regarding this issue we are inclined to believe that except in the most straightforward of circumstances, they might not be a transparent and independent source of information and that the public competent authorities (at European, national and regional level) should play a greater role in providing unbiased information to the patients.

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

For all patients, those who are "sent" abroad and those "active patients" who exit their social security system, the challenge is to ensure that they have clear consumer/patient rights and the means to defend those rights. This challenge is very difficult in relation to all services with a cross border element but it is particularly acute in the case of health services because of the unique nature of these services, including the question of after care. What citizens need now is to move on from the patchy framework defined by the ECJ rulings and have legal certainty about their rights and obligations when seeking health care treatment abroad. They need clear statements on what they may reasonably expect in terms of information, access to care, quality of care, redress in case of malpractice, access to records and reimbursement and they should be enabled to identify, compare and choose between providers in other countries.

Patients all need reliable, accurate, transparent, independent, comparative information about the treatment and the quality of care they will receive abroad. Those who are “sent” abroad need clear information about the reimbursement mechanisms and timing in those cases where they have to anticipate the payment and they need to know since the beginning which expenditures will not be reimbursed. They also need to be informed about the support they will and will not receive by the “sending authority” to solve practical issues such as transportation, linguistic problems, accommodation for their relatives and especially after care.

Those who go by their own initiative must be able to exercise their consumers' rights and be enabled to make informed choices in identifying the provider in the foreigner Country. They should know if the health care provider is registered, if he/she is reputable or not and have access to his/her disciplinary records. They should be informed about the guarantee they should expect, about the difficulties linked to be treated in another country (e.g. informed consent and medical records in another language, after care) they might face.

A key issue in ensuring safe cross border care is *continuity of care*. While some minor problems can be managed as a single episode of care, many, especially those involving a pre-existing condition, require communication with the patient's usual doctor. This means that medical records must be accessible and understandable by different providers, there must be access to prescribed pharmaceuticals, and arrangements must be in place for follow-up assessments and rehabilitation in all its aspects.

Providers need more information about their own health care system given that studies show that one of the reason for which doctors send their patients abroad or patients ask to go abroad is because of a perceived low quality of the national health care system.

Providers involved in cross-border contracts need more legal certainty about what they are allowed to do, which procedures they should use, what prices they can charge, and which is the applicable law when things go wrong. Furthermore, they should also have ready access to patients' past medical history to guarantee a safe treatment and this requires effective systems for data management and privacy protection.

Referring providers play a crucial role in guiding patients in their choice of treatment abroad. The information needs of the referring providers are thus similar to those of patients.

Providers who actively offer to treat foreign patients for non emergency care should consider ethical issues if they are not able to provide the patient information about the treatment (and informed consent paper) in a language the patient can understand.

Purchasers need transparency of tariff-setting, guarantees of accuracy of invoicing, and systems to assure quality. This will require specific mechanisms to be put in place.

Authorities shall enable safe, efficient and high quality cross border healthcare by providing a clear legal framework and information to the relevant stakeholder and to the citizens covering issues such as patient safety, reimbursement, privacy, records management, quality assurance, freedom of information and data protection.

Question 3: Which issues (e.g.: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country?

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?

Health care and social security are exclusive competences of Member States. According to the existing legislation, the competent (national, regional or local) authorities, are responsible for ensuring the safety of all treatments provided within their country both by public and private providers, not only for national citizens but also for those coming from foreign countries. They are also responsible for the clinical oversight and for the financial sustainability of the system. The applicable law both for health professionals and patients is that of the Country where the care is provided.

In those cases when the patient is “sent” abroad by its own health care system (e.g. undue delay) the competent authorities should put in place specific mechanisms to ensure quality standards, clinical oversight, financial coverage and the right to redress in case of malpractice. They should be responsible for all these aspects together with the authorities of the Country where the care is provided. The currently discussed proposal on applicable law to non-contractual obligations may support this solution but explicit sector specific rules could help clarifying the need for joint liability.

For those who choose to go abroad there is a contract between the single patient/consumer and service provider but in the cases under discussion here it is not remotely possible to offer any hard and fast rule on such issues as the applicable law, choice of court, patients, liability for mal-practice or negligence etc. Currently, the applicable law may depend on whether the patient responded to an advertisement or positively sought out the service provider. The rights of patients in such cases should not be left to the vagaries of private international law; given the unique nature of health services, sector specific rules are needed.

The provision of health services for payment to patients coming from another Member State almost certainly needs specific regulation by the relevant national authorities, including but not confined to such issues as marketing and advertising, provision of after care, arrangements for informed consent, liability, applicable law and the specific competences of the service providers.

Question 5: What action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services?

To ensure that treating foreign patients is compatible with the integrity of the health care system, a monitoring system of patients and financial flows at EU level should be put in place.

The High Level Group on health service and medical care should work closely with the Administrative Commission for Migrant Workers and health authorities should foster cooperation with the social security authorities to guarantee better coordination and information exchange also at national level.

Patient mobility should be based on prices set in a manner that is transparent and that minimizes perverse incentives and distortions of the market. Providers treating foreign patients must be reimbursed appropriately, where relevant taking account of any extra workload and costs involved. A more transparent system would address questions such as how should prices be calculated in benefit-in-kind systems, if they include costs of infrastructure or not, how to reconcile exchanges between systems with and without fees-for-service and how extra costs (e.g. translation) should be dealt with.

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?

A Database at European level is essential to monitor health professional flows, to gather data on the availability of health professionals on one side and the demand for them on the other, trying to match the two. Strict criteria should be applied in the mutual recognition of professional qualification. Health professionals moving in another Member State should be trained with some basic language tools and about the cultural differences of the hosting Country.

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 institutions – suggest in order to facilitate cross-border healthcare?

NA.

Question 8: In what ways should European action help support the health systems of the Member States and the different actors within them?

The European Commission has a crucial role in collecting and disseminating comparable information on health care data and health indicators across Europe. We strongly believe that a European action is essential to support Member States in the areas of Health technology assessment, health impact assessment, e-health, patient safety, exchange of data and best practices not only through the activities of the High Level group on health service and medical care but also through the projects funded by the DGSANCO Public health Programme. DGSanco should be the lead DG on health policy, working with other DGs as is the case for food policy.

We think that this action should be fostered by providing information also to the general public through the EU Public health portal.

To increase the knowledge about trends concerning cross-border care it is essential to build up comparable data concerning patient flows. The High Level Group on health services and medical care should cooperate with the administrative Commission on social security for Migrant workers on the issue of data collection.

Member States should consider appointing a clearly defined contact point for patients that seek information on access to health care across abroad and establish a network between them.

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?

At EU level, the single market requires health services to adapt to market rules, while at national level, governments fund their own health care systems and seek to adapt market rules to ensure the effective delivery of health services within a social model. This and the provisions of art.152 of the Treaty raise conflicting principles that must be resolved. If neither a total integration of health services at European level, nor the exclusion of health services from the EU are possible, policy makers should bring greater clarity and legal certainty in the “muddling through” situation European citizens are facing now.

Because of the complexity of the issue different tools should be used to address the very different problems linked to cross-border health care, but starting from a clear, coherent and comprehensive set of patients rights.

To provide clarity and legal certainty at least on technical and specific issues such as entitlements and reimbursement procedures, together with a clarification of the vocabulary used (e.g. definition of the key terms used such as “undue delay”), a binding legal instrument is needed. This could be done for example through an additional revision of regulation 1408/71 and 574/72.

More general and complex issues should be dealt through the Open Method of Coordination.

Having recognised the common values (universality, access to good quality care, equity, and solidarity) and principles (equity, safety, evidence and ethics based care, patient involvement, redress, privacy and confidentiality)³ underpinning all European health care systems, Member States should now try to make a further step towards a European charter of patients' rights.

Many Member States have laws or charters securing the rights of patients, but there is no common standard throughout Europe as a whole. An EU-wide patient's charter could help raise the standards and serve as a guide to consumers of health services both if they stay in their country and if they seek health care abroad as well as a guide for health professionals and decision makers.

It is essential first to define clear goals in respect of patients' rights and access to safe and high-quality health care for all and only then decide the best institutional, legislative, non-legislative and judicial means to achieve these goals, taking into account the unique nature of health services, the issues of competences, the principle of free movement of people, goods and services, the European Court of Justice rulings and solid scientific evidence to assess different policy options. Without a clear set of overall goals, policy will develop in a piecemeal and haphazard way within the different institutions.

³ Council Conclusions on Common values and principles in EU Health Systems, June 2006

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