MINISTÉRIO DA SAÚDE

GABINETE DO MINISTRO DA SAÚDE

Response from Portugal to the Commission Consultation on Community Action on Health Services

General comments

Portugal welcomes the opportunity to contribute with its comments to the consultation launched by the Commission on future Community action in health services.

Ministers of Health agreed, on June 2006, following debate in the Luxembourg EPSCO Council, on the values and principles that should underpin EU Health Systems.

While we could all agree on the values and principles underpinning EU health systems, Member States tend to differ, by cultural reasons, tradition and other, on the preferred organisational model for our health care systems.

Some of us have a preference for Bismarkian models of health care systems, while others tend to favour Beveridge-style health systems. But we have in common the same values and principles, meaning the use of health systems not based on the power of money but rather on need.

Health systems are a central part of Europe's high levels of social protection and make a major contribution to social cohesion and social justice. The overarching values of *universality*, *access to good quality care*, *equity*, and *solidarity* are widely shared across the EU. Beneath these overarching values there is also a set of operative principles referring to *quality, safety, and care based on evidence and ethics, patient involvement, redress and privacy* and *confidentiality*.

It is an essential feature of all our systems that we aim to make them sustainable in a way which safeguards these values into the future. In order to pursue this goal Member States need to have **genuine steering capacity** of their health systems.

Q1: What is the current impact of cross-border health care on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

This question refers to the broad scope of cross-border health care, involving the four modes of provision of services. While considering all of them relevant for future community action we will confine ourselves, in this answer, to mode 2 – "use of services abroad".

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Under mode 2 “use of services abroad” there are mainly five broad categories of patients who seek care abroad:

(i) temporary visitors abroad
(ii) long term residents retiring to other countries
(iii) people living in border regions
(iv) programmed medical care of people who are referred abroad by competent national institutions, and
(v) people who seek treatment abroad on their own.

As for *temporary visitors abroad*, increasing mobility within the EU, as a result of European integration and globalisation, will increasingly impact upon our health systems, in terms of emergency care of temporary visitors, travelling on business or pleasure (E111 and European Health Insurance Card). This represents a relevant number of treatments broad and interinstitutional work is underway to assess impact on the Portuguese health system.

Regarding *long term residents*, Portugal, like other Southern EU countries, is a preferred residence, permanent or semi-permanent, of pensioners from other MS. In the southern region of Algarve, we have around 6 000 EU nationals from other MS registered in primary health care centres. There are also significant numbers of Portuguese citizens, who worked abroad and return to Portugal, after retirement. There is a need for accurate data on permanent or semi-permanent residents (pensioners, foreign or national) who contributed to foreign insurance schemes, and established permanent or semi-permanent residence in Portugal with or without transfer of their social insurance entitlements. The evaluation of their impact in the Portuguese Health System will be the subject of a study commissioned by the Ministry of Health.

Cooperation in *border regions* is mainly developed in the framework of bilateral agreements and protocols with Spain. Bilateral agreements within border regions also exist, and allow the sharing and pooling of certain capacities. For regions with low population density, patient mobility in border regions can be the most cost-efficient way to grant people access to treatment. Geographic proximity, limited language and cultural barriers, familiarity with health systems are favouring factors in border regions. Targeted medical fields, circumscribed areas, defined terms and type of care, price setting and financial arrangements in the framework of bilateral agreements, are easier to manage.

As for *programmed medical care*, the average flow of patients referred abroad by competent national institutions (NHS) has been around 300 patients per year, in the last couple of years, but the initial figures for 2006 suggest a steep increase (314 in 2004; 287 in 2005, and 234, in the first semester of 2006).

The fifth category, of *people who seek treatment abroad*, includes both those who seek treatment not covered by the national health system, and therefore are not reimbursed (for whom there are no estimations) and those who seek care authorised by the competent health institution. An estimated number of 338 E112 forms were issued over the last three years (90 in 2004; 125 in 2005; and 123 in 2006)

It is this fifth category, of people who seek care for themselves, and subsequently demand reimbursement, which is often referred as patient mobility, following EJ Court rulings on this matter. This represents a very small, but potentially increasing, fraction of cross-border healthcare currently delivered.

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Q2. What specific legal clarification and what practical information is required by whom (authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

The existing EU broad legal framework provides different and contradictory solutions for similar situations regarding access to medical treatment in another Member State, depending on the invoked legal basis (Treaty or Regulation). This entails some uncertainty and confusion both for citizens/patients and competent authorities (e.g. rules applied to prior authorisation and reimbursement).

Provision of health care services in a Member State other than the competent one, has been dealt with, on the one hand, in article 22 of Community Regulation n.º 1408/71 (E112), replaced by Regulation 883/04, which requires implementing Regulation to enter into force (there is an ongoing process of formulation of implementing Regulation to replace Regulation n.º 574/72) and, on the other, through direct application of articles 49.º, 59.º of the Treaty, by the European Court of Justice.

a. need for legal clarification

ECJ rulings and proposed principles left much legal uncertainty for MS authorities, providers, health professionals and patients. This refers *interalia* to:

- **MS's degree of flexibility to plan, manage and regulate their own systems**
  Future provision of health services requires the definition of community legal instruments, which will be respectful of the principle of subsidiarity, while promoting solidarity among Member States. MS need to know which barriers to freedom in the internal market are considered unjustified.

- **how to reconcile individual entitlements with collective needs and equity in universal access to care**
  There is a need to discuss the question of prioritisation among principles (e.g. Treaty provisions on free movement in the internal market, applied to patient mobility, versus universal access, equity and solidarity, as fundamental values and principles enshrined in EU health systems)

  Recent Court rulings recognised the need to balance the patients' right to look for care in another MS with the need to prevent wastage of financial, technical, and human resources.

  With regard to reimbursement procedures, we sustain that the amount reimbursed to the patient should be equivalent to the cost of care in either the country of treatment or in its own competent state, whichever is the least. Technological advance and efficient management may lead to lower cost for higher quality and safer standards of care. Lower costs and higher savings for NHS can be achieved without necessarily commissioning services to low-cost health systems, regardless of quality and safety standards.

- **the essential concepts on which there is a need for common understanding at EU level**
  Without prejudice of national specificities of MS health systems, future provision of cross-border health care requires specific legal clarification of terms used in

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community regulations and case law, regarding concepts such as: *hospital care*, *non-hospital care*, *undue delay*, *clinical acceptable delay*, *prior authorisation*, *prior acceptance*, *comparable costs,* and how these can take into account the specific features and conditioning elements of different MS health systems.

Consideration should also be given to ongoing restructuring of health systems translated in movements from hospital to primary care settings and in innovation and technologic changes resulting in evolving concepts of hospital and non-hospital care with growing expansion of the latter. In this regard, jurisprudence should be reconsidered in order to make both ”non-hospital” and “hospital” treatment conditional to “prior authorisation”.

National health systems need to be the ones determining whether, given the patient specific conditions, ‘undue delay’ applies. Portuguese NHS uses referral processes to provide access to specialized care. These processes need to be respected in future legislative frameworks, which should enshrine the principle that “prior authorisation” mechanisms are justified for treatments abroad when these are accessed on referral in the patient home country.

The introduction of the “prior authorisation” mechanism is not a simple administrative and cost control procedure. It aims at referring the patient to an appropriate foreign health institution; providing guarantee for quality and safe provision of health care; ensuring that the competent national authority has the appropriate mechanisms to monitor the patient clinical process, and to evaluate outcomes and health gains resulting from patient mobility; setting mechanisms to ensure that access to health services and provision of care is made in the best possible conditions in terms of safety, safeguard of ethic values, informed consent, and confidentiality of health data.

Legal certainty is also required regarding prior acceptance of receiving country and obligation to treat patients who travel to seek treatment on their own.

- **what, if any, could be the health basket of common services at EU level**
  In face of the diversity of MS health systems, we wonder that patient mobility within the EU can evolve without agreement on a common list of health care services providing for comparable costs and prices associated with these services as well as common quality standards for the provision of health care services across the EU

In addition to the above items, it is of critical importance that a future legal instrument clearly determines, for the sake of patient safety and clear assessment of responsibility, essential information which should be provided by referral systems to patients, travelling abroad to receive treatment, and exchanged with health systems where treatment is provided.

b. Practical information made available to the following stakeholders

Needs of actors:

Authorities

- Information on patient flows, and projections of demand (*inflow*) for general specialised care in order to enable them to use strategic planning to determine medium and long term capacity.

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- Details on health care services provided in other MS by specialised type of care and projections of national institutional demand (*outflow*) by medical practice enabling them to estimate the type and size of institutional contracts or commissioning of services.
- Guarantees for quality and safety of care.
- Information on bilateral agreements between sending/purchasing and receiving countries, including conditions and tariff setting system for contracting – block and individual purchase - with providers integrated in the publicly funded system of the receiving MS.
- Guaranteed safety and quality standards of MS where the care is provided.

Providers

- Rules to observe on "prior authorisation", when applicable.
- Information about patient file and channels of communication with a referral system in the sending country.
- Sending country conditions for continuity of care.
- Prescriptions equivalence in the patient home country.
- Price of care applicable to patient and identification of funding institution.

Health Professionals

- legal framework beyond the issues already addressed by mutual recognition of qualifications, in particular over their clinical and administrative obligations to patients from other MS

Patients

- Clear, managed arrangements by purchasers or through provider co-operation, involving travel arrangements, translation services, funding and reimbursement Information.
- Information on quality and safety patterns, and on compensation for harm.
- Rights, duties and responsibility for consent, confidentiality of private information, access.
- Continuity of care, including validity of prescriptions when back home, transfer of patient files.

Funding institutions

- Transparency in tariff setting and costs
- Payment and reimbursement entitlements and procedures

Q3: Which issues (e.g. clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of CB HC described in section 2.2 above?

There is a need to define safety and quality criteria in the delivery of care to the European citizen at EU level. In this regard:

- As a general principle, clinical oversight should be the responsibility of both the sending referral country/institution and the receiving country/institution where medical treatment is provided, depending on the stage of the process.
- Sending country/referral institution should be responsible for timely diagnosis and treatment prior to care abroad, as well as for proper referral including relevant information of the patient's clinical file. Later on they should be responsible for clinical oversight regarding post surgery/care required by patient and prescribed by receiving country's care provider.

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- The receiving country/institution where medical care is provided should be responsible for clinical oversight, safety and quality of services, regardless of patients' or health professionals' citizenship (the same goes for institutions/right of establishment and concomitant responsibilities)
- Financial responsibility will depend on the arrangements through which patients receive care abroad and on the characteristics of the systems involved. Financial responsibility should vary depending on the conditions under which patient is sent abroad, in a programmed manner, through institutional contracting arrangement, or on his/her own.
- In self-managed patient mobility, patients can only rely on minimum guarantee regarding the professional rules applicable to the health care providers involved, and become victims of capture and induced care, since the country of origin cannot be held responsible for care delivered without proper referral and assessment of foreign provider.
- Responsibility for clinical oversight is different according to the four modes of service delivery: cross-border provision of services (mode 1), use of services abroad (mode 2), permanent presence of a service provider (mode 3) and temporary presence of persons (mode 4).

Special consideration should be given to mode 1 - cross-border provision of services or the delivery of services from the territory of one country to the territory of another (e.g. telemedicine, remote diagnosis). The allocation of responsibility is less clear than in others modes of provision of services. It is not regulated in most MS or at EU level, and is an area that is growing at global level that requires work at EU level for an effective and safe system to be put in place.

Regarding mode 3 – permanent presence of a service provider – authorities of the MS where the provider is established should be responsible for regulation and clinical oversight. Providers should be accountable to authorities of MS, where they are established (according to Treaty provisions, regarding the right of establishment).

As for mode 4, temporary presence of natural persons, MS where medical care is provided should be responsible for regulation and clinical oversight.

Q 4: Who should be responsible for ensuring safety in the case of CB HC? If patients suffer harm, how should redress for patients be ensured?

Redress should be directly linked to responsibility for clinical oversight and financial responsibility. The following general principles can serve as a basis for future action:

- MS where medical treatment is delivered should be responsible for safety and guarantee of quality of service, regardless of the citizenship of the patient or the provider.
- Health authorities of MS where medical care has been provided should have a right of return upon national providers, whose practice or omission of care resulted in harm suffered by the patient.
- In order to facilitate the right of the patient to redress, the competent MS could ensure redress to the patient and exercise the right of return before the MS of the provider responsible for harm caused to the patient.

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- In line with the rationale underlying answer to question 3, the sending country/referral institution should be responsible for ensuring proper referral including relevant information on the patient's condition and on the patient's clinical file.

Notwithstanding the above enunciated principles, this is also a matter of civil, criminal or administrative responsibility, which needs to be regulated by a future legal instrument. Mechanisms should be put in place to enable the determination of the actor responsible for the harmful act or fact.

Consideration should be given to the setting of a Common Fund for situations of "anonymous harm", where the source of the harmful act can not be determined.

Q5: What action is needed to ensure that treating patients from other MS is compatible with the provision of a balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in "receiving" countries)?

Building infrastructure and human capital is a long term endeavour requiring strategic planning. Treating non programmed, without prior acceptance, foreign patients can result in increased waiting list for national citizens. This is a matter that requires thorough analysis in terms of its potential impact on health systems.

There is a need to avoid adverse selection of better-off foreign patients at the expense of national citizens. Patient mobility can impact on several ways upon health systems:

- Patient mobility can result in more or less pressure on the **internal cohesion** and the basic objectives of national systems. The degree of pressure depends on the arrangements through which patients receive care abroad and on the characteristics of the systems involved.
- Allowing patients to move freely to another MS for treatment can thwart domestic **priority-setting** regarding rationalisation of demand. Patients on the waiting lists unable to pay the additional costs for treatment abroad, or to secure payment in advance and get reimbursed, may then have reduced access to care. This would endanger the overarching principle of equal access to high-quality and safe healthcare for all, underpinning our HCS.
- Patient mobility could also threaten **cost containment policies** of the sending MS whenever a managed supply of benefit-in-kind system, is confronted with either relaxed demand conditions in a fee-for-service system, or with provider induced demand receiving country.
- In receiving countries, foreign purchasers may put **pressure on the prices** and lead to providers giving preference to foreign patients, especially if they are willing to pay higher prices than the ones that apply to domestic patients or their funding institutions.
- On the other hand, market may impact positively on **efficiency** and **competitiveness** of National Health Systems, which rely too often on historic tradition of guaranteed financing. But one should be aware of the risk of capture of public systems by private operators.

Financial compensation is swifter in bilateral agreements than in EU social security mechanisms. The latter's reimbursement procedures are not as efficient, with consequent financial impact on health systems.

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Clear rules should apply to both sending and receiving countries (e.g. objective criteria for authorisation of treatment abroad by sending countries versus discretionary requirement /non requirement to treat non programmed patients in receiving countries).

Q6: 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 further issue relates to the perceived need for regulatory authorities to share information about current professional status on health professionals moving between MS.

Essential aspects regarding health professionals are already regulated by Directive 2005/36/EC.

Q7: Are there other issues where legal certainty should also be improved in the context of each specific health or social protection system?

Transparency in "prior authorisation" procedure is needed to ensure that this is a non discriminatory modality of patient access to care. It needs to be founded in objective criteria, non discriminatory, and known in advance. Conversely, it is important that prior acceptance of patient is considered for the receiving country.

Other issues where legal certainty may be improved are continuing and long term care, more related to social protection than to cross-border provision of care.

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

European action could and should support MS in several concomitant ways: Continuing the work of the High Level Group on Health Services and Medical Care***;*** assisting MS to undertake studies on patient mobility impact assessment; promoting interoperability of EU information systems and technologies.

- ***High Level Group on Health Services and Medical Care***

  In line with the recommendations of the EPSCO Council, in November 2006, the Commission's High Level Group on Health Services and Medical Care should proceed with its work. The themes addressed in the various sub-groups are increasingly relevant: (i) *crossborder care, patient safety, health impact assessment, eHealth, centres of reference, movement of health professionals*.

- ***Pilot projects on patient mobility in the EU***

  At EU level, several pilot studies on patient mobility were conducted, financed under the Public Health Programme or the VI Framework Research Programme. Among those we single out the "*Europe for Patients Project - e4p*", the "*Access Project*" or the "*Health Basket Project*", which have been conducted in a limited group of MS.

  These pilot studies raised or increased awareness of both policy makers and managers of health institutions on how these issues impact upon their health systems. They also provided evidence for policy formulation and management of change. We believe that a

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second phase should be conducted for the MS that were not selected to participate in these pilot studies.

- ***Promote interoperability of MS health information systems & technologies***

The creation of common information and communication platforms, allowing for the fast and safe sharing of health data, between providers, health professionals and patients, could help overcome some of the shortcomings and hindering factors to patient mobility.

Member States are implementing electronic patient record systems that are often incompatible with each other. A worrying example of this, is the different technical supports which countries chose to incorporate electronic patient data in the European Health Insurance Card.

- ***EU Health Indicators***

Ongoing process for building, at EU level, a set of standard performance indicators could be speeded up and deepened. The *Health EU Portal*, launched by the European Commission, can be used as a privileged vehicle of information to the managers of health systems, to health care providers and, above all, to patients.

- ***Innovation and exchange of best practices on management of health organisations***

In order to improve quality and efficiency in the delivery of health care, consideration could be given to the possible use, of already functioning organisations (e.g. EHMA – European Health Management Association) in order to allow for a prompt response to perceived needs of MS.

Q 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?

This approach ought to be twofold: for some issues the instruments have to be legally binding, while for others they can take the form of cooperation between Member States, in the framework of the Open Method of Coordination.

With regard **to legally binding instruments** an EU Regulation is clearly not the adequate instrument to deal with the diversity of EU Health Systems. A directive has the advantage of providing legal certainty, leaving room to MS for adapting general provisions to the specificities of each health system, while avoiding casuistic approaches by the ECJ.

Hence, ongoing negotiations on Council's Group on Social Affairs regarding the implementing regulation for Regulation 883/2004 **should be led by health authorities** in order to ensure coherence of future EU law – primary and secondary legislation, in order to avoid existing tensions and contradictions between regulations and court rulings based on Treaty provisions. ECJ case law should not be transposed into the regulation, which ought to keep a **narrow scope** with regard to health issues.

A **broad scope** should be left for a future framework **directive** that, given the variety of health systems throughout the EU, could define the objectives to be achieved while leaving

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to MS the choice of instruments they see fit to apply to their health systems. Its content should encompass, *inter alia*, those issues referred to in answer to Q2 requiring legal certainty.

A framework directive concerning healthcare services will only be feasible with a careful managed political process, politically driven by Member States.

Cooperation among Member States, in the framework of the **Open Method of Coordination**, could allow for the debate of all the issues that do not require legal certainty, as well as promote convergence on essential issues for the development of health care systems.

Consideration could be given to the Council creation of a **Health Systems and Policies Committee**, the equivalent, for health systems, of the Social Protection Committee, for the coordination of social security systems and the mutual exchange of information. Such a body could foster debate on critical issues such as health systems' reform and the diversity of responses to common challenges, ensuring continuity of policy oriented debate and work on critical issues brought to the Informal Meetings of Health Ministers.

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