Johnson & Johnson

Johnson & Johnson response:

COMMUNICATION FROM THE COMMISSION
Consultation regarding Community action on health services

31/1/2007

Introduction

As the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services for the consumer, nutritional, pharmaceutical, medical devices and diagnostics markets, Johnson & Johnson is fully committed to playing its part in shaping the healthcare environment.

As part of this objective, we welcome the European Commission's Communication regarding Community level action on health services and the opportunity to share our thoughts in relation to this initiative.

This response will outline some general remarks in relation to the Commission's approach in this field, and then respond in greater detail to the specific questions set out in the Communication.

General comments

Johnson & Johnson maintains that health services should be approached in a holistic way. Activities in the area of public health should not only focus on health promotion and disease prevention; they should also take serious account of the care, treatment and services provided to patients. These should not only be safe and of high quality; they should also be timely. New therapeutic methods should be easily accessible. In this respect, high quality, comprehensive information is of vital importance.

While we recognise the differences between the various national health systems, the need for patients to receive high quality, safe, speedy and appropriate treatments as close to their homes as possible is universal, as is the need to be informed of their rights and entitlements when seeking healthcare elsewhere in the EU.

Engaging in dialogue with civil society (e.g. patient organisations, health advocacy groups, insurance companies and health care providers) and other stakeholders in this area is important in this respect, gauging their expectations and priorities before concrete activities for a future strategy are being decided. Furthermore, the evaluation of existing methods and practices should be taken into consideration in the development of a new framework for cooperation between Member States and health systems, embracing current strengths and addressing future opportunities.

As with any policy initiative, synergy with existing EU projects and programmes is of utmost importance in order to ensure continuity and consistency. Any new framework with regard to health services should take into account the outcome of the 2004 Commission Reflection process on patients' mobility and healthcare developments as well as the considerations of the High Level Pharmaceutical Forum, particularly in relation to information to patients.

We also recognize the need for alternative methods of legislation and we acknowledge the Commission's intention to address the issues, taking into account the Open Method of Coordination in relation to health and long-term care.

Specific responses to relevant questions of the Consultation

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?

As we recognize the lack of information and reliable data regarding the number of people moving across the EU seeking treatment as well as the number of citizens willing to do so, we believe that issues relating to accessibility, quality and financial sustainability pertain to "receiving" countries and smaller Member States in particular.

– Accessibility

The various difficulties faced by European citizens in accessing health services abroad are amply documented. One of the main barriers to seeking care abroad is lack of information. Patients are not aware of their rights, nor are they familiar with the formal requirements while moving across EU; moreover, they are not aware of the different therapeutic options available in different countries. Better information would support access to cross-border care.

Ensuring continuity of treatment is another issue. Whether the treatment or care provided is related to acute or chronic conditions, or on a short-term or on a long-term basis (e.g. citizens having relocated to another EU Member State), adequate follow-up of care is indispensable (not least in relation to pharmacovigilance). For instance, obesity surgery done in Belgium and not followed up in country of origin could be disastrous.

Needless to say, innovative medicines and procedures should be available as close to a patient's home as possible. Where this is not the case, adequate provision should be made for the follow up and continuity of care in chronic conditions or those that necessitate ongoing medical supervision for a period of time post surgical/procedural intervention.

In the case of citizens settling in another EU country, long-term treatment may be available, but is usually not reimbursed, while in many of these cases (e.g. people settling in another country after retirement) long term treatment and access to services will be required. Legal provisions cater for relocated or retired citizens to follow the procedure of form E121. However, differences within health systems, social protection schemes and bureaucracy form barriers to follow these specific processes. Johnson & Johnson supports a clear legal framework regarding the entitlements of patients and simplification of procedures, allowing patients easier access health care services.

As health systems vary, so does their quality. Many of the 'older' Member States are in a position to provide high quality treatment, and these countries are attractive to patients seeking the best possible health care. The new Member States, however, compensate the lack of advanced therapeutic services with small flexible units dealing with less complex diseases. Patients seeking care in these countries may have a negative effect on the sustainability of these countries' health systems.

– Financial sustainability

Differences in prices, costs or even reimbursement methods between new and old Member States (more particularly between Northern and Southern Member States) can apply different pressures on the financial sustainability of their respective health systems. While poorer countries providing health services at lower cost can also attract patients, movement of patients to more expensive health services providers, seeking nationally/public reimbursed treatments, can increase health costs within social protection systems which are already under pressure.

In respect to the above, we believe a clear framework for patient mobility can foster the cooperation between various health systems to share spare capacity, advance quality and retain financial sustainability while at the same time providing safe and high quality treatment and care to patients.

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?

Johnson & Johnson maintains that patients should be able to have speedy access to high quality treatment. In this respect, we support the cooperation between Member States, social security agencies and insurance companies through the Open Method of Coordination for the establishment of concrete criteria under which patients should be able to move across Europe for treatment, in line with the ECJ rulings. Such criteria might include the time frame of waiting lists, available treatment methods, reliability and quality standards.

Johnson & Johnson welcomes the Commission's European Public Health Portal and we believe that patients should be able to receive quality and appropriate information regarding both European centers of excellence as well as different providers and treatment availability and methods. We argue that effective and quality cross-border healthcare can only be safe when patients dispose of information enabling informed choices between multiple providers.

Johnson & Johnson welcomes the Commission's work on the development of a European health-related data transferring system; and we support the establishment of a European Health Card providing access to key personal health data when patients seek healthcare abroad. Furthermore, we believe that information on medicines should be an essential part of this information, and we support transparency about the use of medicines as part of the medical history of individuals. However, since the sensitive issue of data protection is gaining importance, we support the Commission's initiative to cooperate with the data protection authorities of the Member States under the umbrella of Directive 95/46/EC.

3. 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 cross-border healthcare?

The Communication lists various types of cross-border health care:
1. Cross-border provision of services (i.e. telemedicine)
2. Use of services abroad (i.e.patient mobility)
3. Permanent presence of a service provider (i.e. establishment of provider in another Member State)
4. Temporary presence of persons (i.e. mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).

In each case, there are two or more countries involved and clarity relating to which Member States' authority is responsible for supervising health services is of the essence. As in most of the cases regarding issues in relation to the internal market, Johnson & Johnson supports the notion of responsibility of the 'receiving' Member State for supervising the quality and the compliance to standards. Legal provisions, principles and values should be in line with specifications of the host country's specifications, which needs to monitor both the overall framework as well as the specific conditions under which health services are being provided.

As safety and quality of health services is a major concern, we support the Commission's efforts to bring together the views of all relevant stakeholders, to obtain a clear idea of the differences between the individual health systems in order to develop overarching guidelines.

We underline the need for the European Health Insurance Card (EHIC) to adequately address the issue of emergency health care. It should also include all family members and although emergency health care is already covered by Community law, this is not the case issues in relation to long term treatment. As citizens choose to relocate and retire in different regions across Europe, they face difficulties in relation to their rights and obligations. In this respect, we believe that advanced cooperation between Member States is of the essence to further develop the E121 form, allowing citizens to transfer their pension rights in order to be eligible for health care provided in and by the host country. Consequently, the use of a solid legislative tool such as Directive will secure the framework.

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 services should aim to improve the health, well-being and quality of life of patients. However, this is not always the case. In situations where patients suffer, due to clinical omissions or medical errors, we believe that patients should be directly compensated by their own insurance company, applying the laws of the country in which this agency works.

As a first step, patients should be compensated directly by their own insurance/social system. In second instance, insurance agencies/ organizations should resolve their differences under community law and bilateral agreements.

.

High quality and accessible information can make a huge difference to facilitate patients' choices, and therefore contribute to their safety. Information should be available on systems, quality assurance, costs and reimbursement mechanisms as well as on treatments and medication. European guidelines should be developed on the basis of universally agreed standards, with the aim to assure quality and reliability of health and treatment information in the broadest sense. The European authorities should be in a position to reinforce these guidelines.

Johnson & Johnson is not in favor of channeling all information exclusively via one EU public health portal, as this would create a heavy burden in administrative terms. A multitude of accredited information channels is acceptable, as these are easy to access and comply with the established quality standards.

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 accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

As it is stated in the report entitled "Patients Mobility in the European Union – Learning from experience", the number of patients seeking healthcare abroad is not evenly distributed across the regions. For instance, in Spain or Italy, during the summer period, more than 40% of patients requiring hospital care are from abroad. At this juncture, many Member States have established bilateral agreements to overcome bureaucracy and reimbursement issues. For instance, the UK has developed a formula to estimate the number of UK citizens visiting Spain each year in order to anticipate the number of patients requiring health services. In this way, the UK is reimbursing the Spanish central health system, not on the basis of the actual number of patients but on the basis of estimates. Lack of actual data about the number of citizens requiring health care abroad during the summer period is causing many challenges to health care providers.

In countries like Germany, Belgium, Netherlands and France, an increasing number of citizens living in border regions is seeking health care abroad, since in many cases, the care provided is more appropriate and more easily available. In these cases, many social protection agencies and insurance companies have established bilateral agreements with providers, again in order to overcome bureaucracy and to better serve customers.

In respect to the above, we support the Commission's initiative for the establishment of an Observatory reporting and providing data regarding the number of patients moving across Europe and the consequences of this movement. We believe that only by disposing of adequate data (enabling effective organization), healthcare providers can ensure high quality and safe health care services. Hence, as various health systems are already cooperating in various ways to share spare capacity and promote trans-national health care, we welcome the Commission's proposal to properly assess and evaluate these various arrangements as a means to educate and share best practise among Member States.

Furthermore, some of the new Member States face an increasing number of patients seeking dental care or other non-reimbursed treatments. Small flexible units and lower prices attract patients from 'old' Member States, resulting in an unbalanced situation for providers in these countries. We believe that the Open Method of Coordination can play a role in facilitating a framework for cooperation between new and old Member States so that patients as well as health systems can benefit from the differences in costs and capacity.

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?

Cross border health care does not only have consequences for patients but also for health professionals. Ensuring high quality and safe healthcare services automatically implies ensuring high standards of professionals as well. Yet again, the lack of data on the current situation in relation to the movement of healthcare professionals does not allow statements regarding future strategies on this issue.

Johnson & Johnson supports the Commission's efforts for the establishment of common criteria and rules on the mutual recognition of professional qualifications related to basic clinical training. In addition, Johnson & Johnson strongly supports appropriate and adequate training for health professionals choosing to offer their services in another country, bringing them up to speed on the host country's culture, practise, available equipment and clinical guidelines. Obviously, this will make a contribution to sound clinical practice and enhance patient safety.

Furthermore, Johnson & Johnson welcomes the Commission's efforts in bringing together Member States and international organizations to gather data regarding the movement of health care professionals. Sound data can support the Community's efforts in helping to ensure a balance in availability of health professionals and adequate services.

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?

We believe that EU health policy is an inherent part of a broader EU strategy for the well being of European citizens and economic growth, as reflected in the Lisbon Agenda. Prioritizing issues, in cooperation with health stakeholders, including the health industry is essential for facilitating EU health strategy objectives.

Johnson & Johnson supports the use of the Open Method of Coordination in order to facilitate Member States' exchange and cooperation in relation to the different trends and structures of the individual national social security systems. This will also contribute to exchanges and learning regarding patients seeking health care abroad and to the early identification of issues to be addressed as cross border healthcare will evolve and grow.

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?

Within the context of the High Level Reflection Process on Patient Mobility, it was stated that coordinated activities add value to health systems and promote positive developments with respect to the overall EU health agenda. Johnson & Johnson recognizes the Commission's commitment in developing a formal framework that fosters those activities to maximize its outcome:

– European networks of centres of reference

Johnson & Johnson welcomes the Commission initiative to cooperate with Member States in order to identify the various EU centres of references in relation to rare diseases. The requirement of concentrated resources and knowledge in tackling specific kind of diseases in a cost effective and flexible way is of utmost importance. We believe that a clear structure supporting the cooperation between various centres of reference could be a useful first step. Johnson & Johnson maintains that comprehensive and reliable information about these centres and the various treatment and care options is crucial.

– Realising the potential of health innovation

Johnson & Johnson believes that innovation will benefit patients and health systems. Therefore, innovation needs to be facilitated and supported, both at the EU as well as at national levels. We support the activities of the High Level Pharmaceutical Forum in relation to the identification of the various elements of innovation and we welcome any opportunity to share our thoughts and offer our cooperation.

– A shared evidence base for policy-making

Johnson & Johnson welcomes the Commission's initiative for the establishment of a European Observatory, which will gather data in relation to the implementation of different therapeutic methods and their outcomes. We agree that monitoring and comparing different mechanisms and techniques could provide a sound evidence base for improving health care across Europe.

– Health systems impact assessment

Johnson & Johnson supports the development of impact assessments for the proposed framework on health services.

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?

Community legislative initiatives regarding health services should respect the common values and principles of access, solidarity, equity and universality while at the same time meet patients' expectations and needs. Taking into consideration the various different health systems, Community objectives, threats/opportunities resulting from increasing patient mobility, as well as the lack of data regarding the current situation and future trends, we support that a step-by-step approach should be adopted. Clearly, legislation is needed regarding patients' rights and obligations; the cooperation between health systems, providers and national health insurance providers could be achieved through the use of alternative, softer methods of legislation.

Johnson & Johnson supports the use of a "minimum" Directive outlining up the rights of patients when they seek healthcare abroad. This should include patients temporarily moving across EU and those relocating on a permanent basis, as well as patients "sent" abroad for treatment by their national health system and those that choose to seek treatment abroad of their own accord. Furthermore, we believe that emphasis should be given to the upgrade of the EHIC to include all

family members and also to actions strengthening its effectiveness. The Commission's initiative should focus on the reduction of bureaucracy and the efficiency of the framework.

When patients choose to seek treatment abroad, the costs could be shared between the patient and the national systems that insure them. On the other hand, when patients are "sent" abroad for various reasons, the national system could bear the costs.

As patients constitute Johnson & Johnson's primary concern, we believe that, in case of harm or medical error, patients should be compensated from their own social protection system, even if they received treatment abroad, applying the rules and laws of their own country.

Furthermore, Johnson & Johnson supports the notion of developing a Directive setting minimum requirements for health professionals and providers. In this respect, the Community should establish minimum standards securing citizens receiving health services under an adequate framework.

As is stated above, appropriate and high quality information to patients is an essential requirement ensuring improved access to cross-border health care. EU initiatives under the future framework should ensure that patients are able to receive practical information regarding treatment methods, centres of excellence, innovative therapeutic techniques and verify the quality of the provider from a single, European, centralized information system. The health industry can play its part in providing reliable information on treatments, contributing to ensuring continuity of treatment when patients return to their home country after the intervention or care received abroad.

Lastly, Johnson & Johnson supports the Commission's proposal for the establishment of an Observatory that will gather data regarding health services and patients mobility. Obtaining a clear image of the current situation is the first step towards shaping the future healthcare landscape and we believe that the Commission's initiative regarding health services is a start for the development of a common health care culture across an enlarged Europe.