PGEU Response

Consultation Regarding Community Action on Health Services

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1. Introduction

The Pharmaceutical Group of the European Union (PGEU) is the European association representing community pharmacists in 29 European countries including EU Member States, EEA countries and EU applicant countries. Within the enlarged EU, over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision making process.

PGEU welcomes the opportunity to answer this consultation, which is of major importance for the health sector. The decision of the Parliament and Council to exclude health services from the Services Directive, a decision which reflects the fact that health services require special consideration, presents us with an opportunity to reflect properly on both the scope for EU 'added value' to national health systems, and the appropriate application of internal market principles to health.

We particularly welcome the opportunity to respond to this consultation given the role of Community Pharmacists not only in health systems generally, but in cross border provision of health services. Community pharmacists, through the wide network of community pharmacies in Member States, are the health professionals who European citizens see most often, and are deeply involved with the treatment of individuals moving across Member States. Tourists, short term residents, long term residents, or cross border care users often seek pharmacists for the provision of health information and advice before consulting with any other health professional. Pharmacists tend to be more accessible abroad than doctors, so frequently pharmacists will provide primary health care services to travellers.

In many cases the pharmacist is a key player in signposting the citizen to other health professionals and sources of information and care. Pharmacists are also responsible for the follow up of pharmaceutical treatment and an important asset for ensuring continuous care.

2. Preliminary comments

In the view of the PGEU, this consultation needs to take into account three principles:

First, that in accordance with Article 152, responsibility for the organisation of health systems lies with the Member States. Accordingly, the scope for EU action is circumscribed by legal and practical limitations. We need to ensure that future Community action, whether in the form of legislation or 'soft' law, focuses directly on bringing additional benefits to the provision of health services which cannot be achieved by Member States acting alone, while respecting and reaffirming Member State competence in connection with the organisation of heath systems.

Second, we need to bear in mind that the provision of health services does not fit neatly into traditional consumer orientated economic models. It follows that special care needs

to be taken when considering health services in the internal market context. It does not follow, for example, that maximising the effect of the 'fundamental' freedoms of the Treaty necessarily accords with the legitimate choices made by Member States in the provision of health care, and the values those choices reflect.

Third, if there is a specific European dimension to health care, it lies in the fact that the EU governments choose to ensure that health care is not reserved for those who can pay or who can afford insurance; in other words the European view is that the most rational way to provide health care services is on the basis of sickness rather than ability to pay. While the consultation does not refer explicitly to questions of values, in our view they cannot be avoided. We must ensure that the 'added value' of EU action, however well intentioned, does not benefit some patients at the expense of others, and that principles of solidarity underlying e.g. access to health care are enhanced rather than eroded.

So for PGEU, in replying to this consultation, three concepts are key: **subsidiarity, solidarity** and **added value.**

Finally in this section we would like to make a strategic observation: the EU has an extremely commendable track record in the promotion of public health, a good example of an area where it adds value. The new consultation needs to ensure that any initiative in the area of *health care* relates to and complements action in the area of public health.

In our reply to this questionnaire we will focus on the questions which are relevant to our sector.

3. Answer to the questions

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?

From a European perspective, PGEU agrees with the preliminary analysis and findings made by the study mentioned in the consultation "Patient Mobility in the European Union"[1]. However, in order to provide an accurate and comprehensive assessment of the accessibility, quality and financial sustainability of healthcare systems, a complete assessment of the concept of treatment should be considered which should not be limited to hospital treatment and specialized medical treatments such as dentist, cardiovascular services, etc mentioned in the study.

At present, although in certain areas of Europe there is considerable demand for health services on the part of individuals from other Member States, the specific phenomenon dealt with in the Watts case, where an individual travels for specific purpose of seeking treatment, is limited (we refer to this as "Patient Mobility").

There is no doubt that community pharmacists are the health professionals who treat individuals from other Member States most frequently. The majority of people have

[1] "*Patient Mobility in the European Union. Learning from experience"* edited by Magdalene Rosenmöller, Martin Mckee and Rita Baeten, published by the WHO 2006 (ISBN 92 890 22 87 6)

cause to seek pharmaceutical advice or treatment at some point during their travels. However, most treatment is administered to cross border patients who have not travelled specifically for the purpose of seeking treatment (we refer to this as "Incidental Treatment").

PGEU believes that both manifestations of cross border treatment are likely to grow in the coming years.

From the perspective of Community Pharmacy, one issue in particular must be highlighted.

In the case of both Patient Mobility and Incidental Treatment, the treatment may begin on one Member State, but continue in another. To give two examples: a patient may fall ill during a holiday trip and be prescribed or issued on a non-prescription basis a particular treatment. That treatment may continue to be administered once the traveller returns home. Second, a patient may travel abroad for a complex procedure which gives rise to the longer term need for pharmaceutical treatment and care. That treatment will take place in the home country.

The point here is that it is important to recognise that treatment is ongoing. Normally, responsibility for continuing care will rest with health professionals in the home state.

This may give rise to a number of issues. In both of the cases referred to above, the patients may have received treatment which either:

I. is unavailable in the home state or subject to a different reimbursement regime which would discourage its prescription in the home state;
II. have received prescriptions in a foreign language;
III. have suffered adverse reactions to the medicine which did not emerge until after return;
IV. have received treatment which is incompatible with another ongoing treatment of which the pharmacist or prescribing doctor in the visited state was unaware; (v) have received treatment on a non-prescription basis which is subject to prescription in the home state.

If the phenomena of Patient Mobility and Incidental Treatment grow as we expect these issues will become more pressing.

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?

PGEU believes that to ensure a high quality, safe and efficient cross border health care service and to solve the problem of continuous care raised above, three instruments could be supported and promoted by any initiative arising from this consultation:

I. Facilitating recognition of European prescriptions

Continuous pharmacotherapy follow-up could be enhanced through the development of a system of recognition of European prescriptions, and perhaps ultimately a European

prescription. This mechanism would ensure the efficiency and the pharmaceutical follow up of the treatment in any Member State.

Such a system should be designed to guarantee:

- The authenticity of the prescription;
- The professional competences of the prescriber or the dispensing person;
- The correct interpretation of the prescription's content.

A system of recognition of prescriptions might be achieved through a standardised bar code system or other security measures. This could also allow potential benefits for administrative purposes at national level. Nonetheless we consider that the initiative of the Commission to promote ePrescribing systems and facilitate its interoperability within Member States could overcome in the future the problem posed by paper based systems.

Ultimately a standard European prescription might be adopted, although we would need to be satisfied that any resultant disruption of established and well functioning national prescription practices was justified by the benefits achieved.

In addition, a public register of health professionals should be put in place, (perhaps through access to national registers) including the list of prescribers and dispensing persons of EU Member States. From the dispensing point of view this information is relevant to verify, if needed, the author of the prescription or to contact him in case of further clarifications.

Finally, the correct interpretation of the prescription content could be promoted for example by setting common standards for filling in prescriptions, such as the use of the International Common Denomination of medicines (DCI).

II. A comprehensive European medicines data base

A comprehensive data base of medicines would certainly facilitate cross border pharmaceutical care.

European legislation has already envisaged a European data base of medicines to inform the public and health professionals[2]. But we think that this data base should also contain information on the following aspects:

- Legal status of medicines (clarification if the medicines are subject to prescription in the member state of destination);

- Reimbursement conditions of medicines.

Clarification on the status of medicines could ensure transparency and promote patient safety, as well as avoid inconvenience, as the classification between prescription and non-prescription medicines differs in Member States. One patient moving to other Member State could be asked to provide a prescription for a medicine that in his country of origin is dispensed without it. Such a data base could be used by health professionals

[2] Regulation No 726/2004 Articles 57§1 l) and § 2

to counsel patients when preparing to travel. We acknowledge however that such a system could not be put in place by EU action alone, and would require substantial co-operation from Member States.

III. A system to ensure the traceability of medicines

Many Member States are developing systems to trace medicines. Those systems are put in place to avoid counterfeiting and ensure the transparency of medicines distribution channels.

According to the WHO, 1 medicine out of 10 is counterfeit, and this is a growing phenomenon in Europe. In addition, the evolution in Internet sales presents real impediments to the traceability of medicines and thus increases the risk of counterfeit medicines penetration, with all the health risks that entails.

Consideration needs to be given as to whether there is scope to promote a European-wide system of traceability in order to enhance and build upon national initiatives in this area. Such a system should allow identification of all the actors in the medicine supply chain, and facilitate fast and effective batch recalls in case of, for example, counterfeit penetration.

Finally, PGEU is strongly supportive of initiatives to facilitate cross border provision such as the IMI initiative (see answer to question 7), and the Health Professional Crossing Borders project. Where appropriate, support should be given to other initiatives that promote cross border provision such as the European Health Professional Card.

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

PGEU believes that a distinction should be made between clinical and financial responsibility, but the distinction derives from a common sense application of the subsidiarity principle.

There are good reasons why Article 152 reserves the competence to organise heath systems to Member States. First, health systems are organised according to different national specifics such as demographic profiles. Second, the management of health systems involves significant choices regarding the allocation and distribution of resources and the relationship between health and other public goods. These choices are best made by Member States in close consultation with national populations, in response to national needs and subject to direct democratic redress.

Two consequences follow from this: first, matters such as clinical oversight are matters for individual Member States and should not be subject to any form of legally sanctioned intervention from other Member States. That is not of course to say that the EU does not have a role in developing best practice in clinical areas.

Second it is essential that increased cross border care does not have an adverse effect on national budgets and their management, and that the degree of care supported by the fiscal framework of one state is not imposed on the fiscal resources of another.

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?

The question seems to address two different legal issues: first, the applicable law in case of cross border services: what rules would apply in the case of any legal liability to a patient; second liability for e.g. clinical negligence as a substantive issue in itself.

With respect to the first question, the determination of applicable law for non-contractual liability is currently being harmonised at EU level under the Rome 2 initiative. That initiative currently proposes that the applicable law should be the law of the country where the harm arises. In most cases that will be the country to which the patient moves for treatment, and not the home Member State. This is appropriate because it ensures that health professionals are not deterred from providing treatment to a cross border patient by unfamiliarity with the law of another Member State. There may also be implications for insurance of the health professional if this principle is changed.

Second, PGEU does not believe that there should be separate substantive rule on clinical negligence for cross border patients only. That would lead to severe confusion and complication. The more general issue of the rules of Member States with regard to clinical negligence for all patients is surely beyond the scope of this consultation given the limited extent of patient mobility at present and the need to satisfy a subsidiarity test.

In the specific case of pharmacy, the way the pharmacy coverage is organised, including in respect of liability issues, varies between Member States. In many cases, community pharmacists are obliged by national legislation to take out professional insurance to cover their services; in others there is a common practice to take such insurance. In addition, many countries establish in their legislation the personal responsibility of the pharmacy owner or the responsible pharmacist for the services provided in the pharmacy. Pharmacist's liability rules ensure the quality of pharmaceutical services and a high level of protection for the patient.

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

PGEU believes that this question is of utmost importance from the point of view of national health systems. Although the phenomenon of patient mobility is still relatively marginal, there may come a time that the balances referred to in the question are jeopardised. The balances referred to are of course relevant to both home countries and receiving countries (for example, where countries ration health care through waiting times, extensive outward patient mobility may have inequitable effects).

Systems of financial compensation are likely to be extraordinarily complex, legally and practically, and costly to manage. A simpler approach would be to codify the principle that the preservation of balanced medical and hospital services is an issue of overriding importance, and therefore that measures to preserve such balances, including the temporary suspension of patient mobility rights, are justifiable in terms of Community Law

Although the question refers to the provision of a balanced medical and hospital services accessible to all, and as it is not clear to us whether this includes health services provided in other healthcare settings than hospitals, we would like to point out that any action addressed to the issue of patient treatment and a balanced healthcare service opened to all, should also contemplate, among other things, the pharmaceutical follow up of such a treatment which is of key importance to ensure patient safety, adherence and compliance and therefore ensure the best therapeutic benefit for the patient while promoting cost effectiveness.

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?

In PGEU's opinion the current legal framework established by the Professional Qualifications Directive appears to offer an adequate framework to regulate the establishment and provision of pharmaceutical services. The relevant Directive has only recently been adopted, after a lengthy legislative process, and is currently in the process of being implemented by Member States. However, while in PGEU's opinion it would be inappropriate to reopen the complex issues in this area now, it is important that the interpretation, implementation and functioning of the Directive is monitored to ensure that an appropriate balance between free movement of professionals and the protection of patients is achieved. In particular, in those areas where there is degree of difficulty in the interpretation of the Directive, DG SANCO should take the lead in ensuring that Commission guidance makes a presumption in favour of health protection rather than free movement.

Finally, further consideration could be given to the possibility of automatic recognition for some specialisations.

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?

As indicated in question number 2, PGEU believes that a system of recognition of European prescriptions, a comprehensive medicines data base and a system to guarantee the traceability of medicines would facilitate the provision of pharmaceutical services across Europe.

In the design of those instruments the language to be used to facilitate the understanding of the parties needs to be considered. In this regard PGEU is aware of the efforts made by the Commission with the Internal Market Information system (IMI) and has been collaborating in order to facilitate its implementation within the framework of the professional qualifications Directive.

IMI will allow the translation of information required for migrant professionals to move to other Member States to provide services or to establish themselves. PGEU believes that such an innovative system would significantly improve the effectiveness of cooperation

between Member States. The knowledge acquired in the development of the IMI system could be used when implementing the ideas mentioned above. In particular, the approach of initiatives such as IMI may help to limit difficulties and complications arising from language differences.

In the context of the Services of General Interest dossier, PGEU is concerned about the exclusion of health services from the scope of the communication on social services of general interest in the European Union[3]. The introduction of the communication says that following the exclusion of health services from the services proposed Directive a specific initiative from the Commission will deal with health services, although the consultation as such does not deal with health as a service of general interest. Therefore PGEU believes that any future initiative coming out from this consultation should **carefully consider the specificity of health services as services of general interest**. Otherwise the Commission should reconsider this position and follow up with the approach proposed in the White Paper on services of general interest[4]. It would be regrettable if a lack of consistency between Commission approaches led to the neglect of this crucial area.

Finally, while the consultation rightly focuses on possible future initiatives, we must not forget that current legislation promoting crucial health objectives needs to be reaffirmed and where necessary defended. We could point in particular to two examples: distance selling (as it might apply to medicines), and direct to consumer advertising of prescription medicines. The provisions in 1997/7/EC and 89/552/EC respectively offer the possibility of protection in these areas, and Directive 2001/82/EC on the Community code relating to medicinal products for human use (amended by Directive 2004/27/EC) is also relevant in this context. All are currently under revision.

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?

PGEU believes that EU action should follow the current strategy of streamlining open coordination of health policies introduced by the open method of coordination in the field of social protection[5]. This initiative proposes mechanisms such as guidelines and indicators, benchmarking and sharing of best practice to improve the coordination of Member States' policies in the field of social protection.

In addition, we consider that the "Health in all policies initiative" should be further promoted, developed and implemented as proposed by the EU Finnish Presidency and endorsed by the Health Council on 30 November 2006.

Moreover, activities on patient safety will need to be properly addressed within the general health services framework, and the creation of an European Network for Patient

[3] COMMUNICATION FROM THE COMMISSION Implementing the Community Lisbon programme: Social services of general interest in the European Union COM (2006) 177 final

[4] COM(2004) 374, 12.5.2004

[5] COM (2003) 261 final. Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions Strengthening the social dimension of the Lisbon strategy: streamlining open coordination in the field of social protection

Safety as proposed by the Patient Safety Working Group of the High Level Group on Medical Care and Health Services, targeting both hospital and primary healthcare, could be an additional area where EU action would add value and would support health systems of the 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?

The EC Treaty establishes that the organisation and delivery of health care services to the citizens remains a responsibility of the Member States. Therefore in PGEU opinion the EU action should be focused on facilitating the coordination between EU health systems to solve the problems of health care reimbursement costs and to encourage the exchange of good practices between Member States (as referred to in question number 8). We think this action would help to ensure the quality of health care systems within Europe.

PGEU believes that a European Directive codifying the principles of ECJ case law on patient mobility would be an adequate way of bringing clarity to some of the uncertainties in this area. This Directive could also be used to clarify some concepts such as hospital and non hospital treatment, reasonable delay to get an authorisation for treatment abroad etc, although care must be taken to ensure that legitimate choices made by Member States in respect of fiscal priorities are not made unlawful by EU action.

In relation to information to patients, PGEU fully supports the current approach of EU institutions. Through several legislative initiatives the EU Institutions have decided to support a high level of protection in relation to the public advertising of medicines.[6]However we recognise that if patient mobility in its various forms is to be effective, safe and efficient, the provision of information in relation to different health systems will need to be facilitated. Regulatory intervention may be required to promote accuracy and objectivity this area.

One other aspect of information needs to be considered. There will no doubt be pressure for EU action to promote substantive comparisons of relative health outcomes in Member States. Care must be taken to ensure that any comparisons are properly reflective of the relevant context in each state, and to ensure that the objective of e.g. benchmarking is to assist in the gradual raising of standards rather than the generation of unnecessary and possibly injurious competition to achieve certain predefined outcomes.

As indicated in question number 6, PGEU supports the current framework in relation to the provision of professional health services and establishment in other Member States. In addition PGEU believes that following the Commission initiative of better regulation and simplifying legislation EU action should also encourage the adoption of codes of conduct developed by professional organisations.

[6] Article 88 Directive 2001/83/EC ; article 14 Directive 89/552/CEE

4. Conclusions

PGEU believes that any future health initiative as a follow up of this consultation should at least support the following proposals:

- a system of recognition of European prescriptions, a comprehensive medicines data base and a system to guarantee the traceability of medicines;
- the development of a strategy of streamlining open coordination of health policies;
- health services considered as services of general interest;
- rules facilitating the reimbursement of medical treatment and the cost of medicines received in other Member States;
- facilitation where possible of the continuing care of returning patients.

In addition, any health initiative undertaken by the Commission should carefully evaluate the balance between internal market objectives and health and social objectives. Any initiative should also be preceded by an impact assessment both on health systems and citizens' welfare.

Fundamentally, any EU initiative on health should fully respect Member State competences, and ensure that the values of solidarity underlying European health systems are not compromised. It needs to ensure that it genuinely complements national initiatives, rather then unnecessarily complicating them. As we pointed out in our preliminary remarks, **subsidiarity, solidarity and added value** are the key concepts we need to bear in mind.