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Dear Commissioner Vassiliou,

The *International Network for Safe Medication Practice Centres* (INSMPC) takes notice of the European Commission's intention to strengthen patient safety, notably through the launch of a public consultation in March 2008 by the Health and Consumer Protection Directorate (1). The protection of European citizens is, as a matter of fact, one of the European Commission's remits (article 125 of the European Treaty).

In response to this public consultation, please accept the following information regarding the European Commission's project.

PREVENTING THE PREVENTABLE IN EUROPE

Patient safety in Europe: time for action!

Summary:
● Patient safety must be improved through immediate action.
● Many concrete proposals are simply waiting to be implemented. Yet the European Commission continues to procrastinate, this time by launching a public consultation in March 2008. What this means is that patients continue to be exposed to preventable adverse events.
● It is time for action, and notably the implementation of proposals made by the World Health Organisation and the Council of Europe.

All European Commission initiatives intended to improve patient safety are welcome, especially because the European Union has fallen far behind in this area.

The "Open Consultation on Patient Safety in the European Union" is of particular interest to patients and caregivers (1,2).

But what is the European Commission's perspective on actions designed to improve patient safety? And what contribution can European citizens make to patient safety by participating in this consultation?

Yet another survey!

In general, during consultations launched by the European Commission, the different stakeholders are encouraged to give their opinions on general principles and proposals listed in a consultation document (3). This is not the case of the "Open Consultation on Patient Safety in the European Union", initiated by the Health and Consumer Protection Directorate of the European Commission.

Hazy intentions. The consultation document says little of the project itself, which is to be ready later this year. Two global objectives are briefly stated (**a**):
"*- to support Member States in their efforts to minimise harm to patients from adverse events in their health systems, through appropriate policies and actions to improve safety and, therefore, quality of care;*
- to improve EU citizens' confidence that they will receive sufficient and comprehensible information available on levels of safety and available redress in EU health systems, including healthcare providers in their own country and in other Member States" (2).

An inadequate survey. A survey of perceptions of "*the kind of policies, strategies, systems and processes already in place*" and on desired actions is implemented in order to answer the question "*Are European citizens receiving the safest possible care?*" (**b**)(2). Yet, among a total of 61 questions, only two open-ended questions allow potential participants to make proposals to the European or local authorities (2). The preamble to questions 35-38 (section 8) claims that there is no appropriate terminology, despite work conducted by the Council of Europe within the framework of the SIMPATIE program (see below) (2). Subjects of very different natures are mixed together, and too little place is left for comments, with too few open-ended questions.

► **In summary.** This poorly designed survey is not suited to allow relevant contributions to patient safety in Europe.

European citizens' opinions on adverse events are already known

The launch of the March 2008 survey is at the least surprising. Indeed, it was only in 2006 that the European Commission published the results of the Eurobarometer survey on Europeans' perception of medical errors (4). The Eurobarometer survey was initiated by the European Commission's DG Press and Communication in 2005, and took place in the 25 EU member states, affiliate and candidate nations, and the Turkish Cypriot community. Nearly 25 000 responses were collected (4).

A problem clearly perceived by the European population. In the 2005 survey, 23% of respondents said they had experienced or witnessed a medical error; 18% said they encountered a medical error in a hospital, and 11% were prescribed a wrong medication (4). Victims of adverse events tended to consider this an important issue, worried about encountering a new medical error, and placed less confidence in their country's healthcare system (4).

Healthcare errors are already considered an important problem. Nearly four out of five EU citizens (78%) considered that medical errors posed an important problem in their respective countries (4).
Opinions varied widely across the EU. Inhabitants of southern European countries and new Baltic member states were more preoccupied by hospital safety than their counterparts in western Europe and especially Nordic countries (**c**)(4).

► **In summary.** The results of this survey are perfectly clear. It is difficult to see what a new survey could add, especially one that would be less precise and too "institutional". In addition, the method is different from the previous survey, ruling out any meaningful comparisons (**d**). It is astonishing that the European Commission failed to take into account the results of the Eurobarometer survey in its proposals on patient safety. Do we really have to start again from scratch?

The European Commission's project must be based on existing proposals

Several relevant European and international initiatives are not even mentioned in the preface to the open consultation organized in March 2008.

The patient safety "big bang": more than 15 years ago. In the United States, the Harvard Medical Practice Study, published in 1991, suggested that tens of thousands of patients died each year because of medical errors (5,6). The US Institute of Medicine then launched a thorough debate on quality of care that led, among other things, to the publication in late 1999 of a report entitled "*To err is human – Building a safer health system"*, that had major repercussions (**e**) (7).

Similar studies conducted elsewhere subsequently confirmed the extent of the problem, and led to government actions such as the creation or reinforcement of agencies charged with patient safety improvement, based notably on adverse events reporting and learning systems, in the United States, Australia, Canada, Denmark, the United Kingdom, Spain and Ireland (**f**).

Patient safety is a global issue, at an international scale. Adopted at the 55th World Health Meeting in May 2002, the resolution entitled "*Quality of care: patient safety*" invited member states to pay more attention to this issue and encouraged the World Health Organisation (WHO) to promote patient safety by establishing international standards, encouraging research, and supporting national programs (8).

Since then, the World Health Organisation (WHO) proposed, among other things, more patient and user involvement, an International Classification of Patient Safety (ICPS), and "solutions" to improve patient safety.

Guidelines for adverse event reporting and learning systems were distributed to member states during the London summit held in late 2005 (9), at which a program to involve patients themselves entitled "Patient for Patient Safety" was launched (10).

Council of Europe: long committed to patient protection. Within the Council of Europe, the European Public Health Committee (CDSP), created in 1954, is charged with encouraging closer European cooperation on health matters (**g**). The European Public Health Committee draws up recommendations based on work conducted by expert committees, that it submits for adoption to the Committee of Ministers (the decision-making arm of the Council of Europe). These recommendations are not legally binding but can help to foster change in the 47 member states.

In November 2002 the European Public Health Committee convened a committee of experts on management of safety and quality in healthcare (2002-2005) which, in 2006, led to a Council of Europe Recommendation on management of patient safety and prevention of adverse events in health care (see inset page 3) (**h**)(11).

The European Union does not have to reinvent the weel. The EU Health and Consumer Protection Directorate created the High Level Group on Health Care (2004-2006) through which member states could share their experiences, compare their policies and performance, and jointly develop concrete actions (12).

Organized in April 2005 by the Luxemburg Presidency of the European Union, the conference on "Patient safety - Making it happen!" adopted a declaration -- the Luxemburg declaration -- that included recommendations for national authorities, healthcare professionals, and European institutions (see inset below) (13).

Within the framework of the SIMPATIE program (Safety Improvement for Patients In Europe) for the period 2005-2007, exchanges took place with the Council of Europe during the preparatory phase of the Recommendation Rec(2006)7, and included work on the terminology of patient safety issues (14).

This project was supplanted in February 2008 by a European Network for Patient Safety (EUNetPaS), coordinated by the French National Authority for Health (HAS) (15). Its objectives are to promote a culture of safety, to help structure education and training in patient safety, to contribute to implementing reporting and learning systems by providing member states with the necessary tools, and to conduct pilot implementation of measures designed to improve medication safety in hospitals (15).

COUNCIL OF EUROPE

Main recommendations of the Council of Europe to member states (extracts)

The Council of Europe recommends that member state governments:

- ensure that patient safety is the cornerstone of all relevant health policies, in particular policies to improve quality;
- develop a coherent and comprehensive patient-safety policy framework (…)
- promote the development of a reporting system for patient-safety incidents in order to enhance patient safety by learning from such incidents (…)
- review the role of other existing data sources, such as patient complaints and compensation systems, clinical databases and monitoring systems as a complementary source of information on patient safety;
- promote the development of educational programmes (…);
- develop reliable and valid indicators of patient safety for various health-care settings (…);
- co-operate internationally to build a platform for the mutual exchange of experience and knowledge of all aspects of health-care safety (…)
- promote research on patient safety;
- produce regular reports on actions taken nationally to improve patient safety (1).

The appendixes to this recommendation on the management of patient safety and adverse event prevention in the healthcare setting describes prerequisites, the culture of safety and its systemic approach, the assessment of patient safety, data sources and reporting systems, medication safety, human factors, patients' empowerment and citizens' participation, patient safety education and training, research agenda, the legal framework, and implementation of patient safety policy (1).

1- Council of Europe "Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care" 24 May 2006.

EUROPEAN UNION

2005 recommendations of the Presidency of the European Union (extracts)

The Luxemburg Declaration already made a number of recommendations aimed at EU institutions, including the following:

- to establish an EU forum with participation by relevant stakeholders to discuss European and national activities regarding patient safety;
- to work in alliance with WHO Alliance towards a common understanding on patient safety issues, and to establish an "EU solution bank" with "best practice" examples and standards;
- to create the possibility of support mechanisms for national initiatives regarding patient safety projects, acknowledging that patient safety is in the programme of DG Health and Consumer Protection;
- to ensure that EU regulations with regard to medical goods and related services are designed with patient safety in mind;
- to encourage the development of international standards for the safety and performance of medical technology;
- to ensure that the European regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals (1).

1- European Commission "Luxembourg Declaration on Patient Safety: Patient Safety – Making it happen!" 5 April 2005; 2 pages. Available at: http://www.simpatie.org/Main/files/Luxembourg_Declaration_on_Patient_Safety_05042005.pdf/download

Protecting European patients from healthcare errors; immediate action needed!

The "open consultation" organized by the European Commission in March 2008 is out of kilter with previous and ongoing European initiatives on patient safety. In addition, it is conceived in a such a way that European citizens and organizations cannot respond constructively.

This "open consultation" is unnecessary, and its results will probably be difficult to interpret. Such initiatives, despite claims that they promote "participative democracy", must not be allowed to delay the implementation of measures already recommended by the World Health Organisation and by the Council of Europe.

Indeed, any delay would leave patients exposed to the same level of risk, and with no prospect of a tangible improvement in the foreseeable future.

INSMPC asks to the European Commission to act without delay to protect Europeans patient from medical errors, by encouraging action in individual member states.

INSMPC
The *International Network of Safe Medication Practice Centers* (INSMPC) is an international network involving the main programmes for safe medication practices, which aims are to prevent medication errors and contribute to safer care.
Acted by the "Salamanca Declaration to promote safe medication practices globally" in November 2006, this specific network aims at promoting the creation and reinforcing the cooperation between independent, multidisciplinary programmes for safe medication practices.

Our group, which is composed of some of the world's leading medication safety expert physicians and pharmacists, stands ready to communicate directly with the world's patient safety leaders to further the cause of medication safety.

Most sincerely,

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Notes

a- It is stated, rather laconically, that the European Commission's project would concern systemic issues such as "culture, leadership, education, information, reporting and redress" (2).

b- This survey comprises 61 questions divided into 11 categories: personal experiences of preventable adverse events, the political support for patient safety in each member state, the corresponding budgetary commitment, patient involvement in improving safety, management of local healthcare structures, healthcare professionals, reporting and learning systems, sharing of information, standards and assessment of safety practices, research and development, complaints and redress (2).

c- More than half of the Europeans surveyed (51%) thought that they could not avoid being victims of medical errors while in hospital, considering themselves incapable of exerting any influence whatsoever on decisions concerning their health, while 16% of respondents thought it was not even possible (4).

d- The European Commission is thus depriving itself of useful information on trends in European citizens' opinions on medical errors.

e- Several other reports followed, including "Crossing the quality chasm: a new health system for the 21st century" (2001); "Patient safety: achieving a new standard for care" (2003); "Keeping patients safe: transforming the work environment of nurses" (2006); "Preventing medication errors" (2007). Published almost simultaneously, this latter report is a useful complement to the Council of Europe's report on the prevention of medication errors (11,16,17).

f- The US Agency for Healthcare Research and Quality (AHRQ), the Australian Council for Safety and Quality in Health Care, the Canadian Patient Safety Institute, the Danish DanskPatientSikkerhedsDatabase, the UK National Patient Safety Agency (NPSA), the Spanish Agencia de Calidad del Sistema Nacional de Salud, and the Irish Clinical Indemnity Scheme (CIS).

g- With respect to patient safety, recommendations exist on blood transfusion and organ transplantation, as well as the European Directorate of the Quality of Medicines (EDQM).

h- Appendix E of this Council of Europe recommendation, entitled "Medication safety, a specific strategy to promote patient safety", summarizes the principles behind a complementary report on the prevention of medication errors (11). This report includes a thorough glossary of terms relating to patient safety (17).

References

1- European Commission "Launch of an Open Consultation on Patient Safety" 25 March 2008. http://ec.europa.eu/health/ph_overview/patient_safety/consultation_en.htm

2- European Commission "An open consultation on patient safety in the European Union" Http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=patientsafety

3- European Commission "Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission" Brussels 11 December 2002; réf: COM(2002) 704 final. http://ec.europa.eu/transparency/eti/index_en.htm#3: 27 pages.

4- European Commission "Medical errors" Special Eurobarometer 241 / Waves 64.1 & 64.3 – TNS Opinion & Social. January 2006; 66 pages.

5- Brennan TA et al. "Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I" N Engl J Med 1991; 324 (6): 370-376.

6- Leape LL et al. "The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II" N Engl J Med 1991; 324 (6): 377-384.

7- Kohn LT et al. "To err is human. Building a safer health system" National Academy Press, Washington 2000: 239 pages.

8- World Health Organisation "Quality of care: patient safety" Fifty-Fifth World Health Assembly, WHA55.18, 18 May 2002.

9- World Health Organization "WHO Draft guidelines for adverse event reporting and learning systems: from information to action" 2005; 77 pages.

10- World Alliance for Patient Safety "London Declaration: Patients for patient safety" 17 January 2006; 1 page.

11- Council of Europe "Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care" 24 May 2006.

12- European Commission "Documents of the High Level Group (2004-2006)" http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_documents_en.htm

13- European Commission "Luxembourg Declaration on Patient Safety: Patient Safety – Making it happen!" 5 April 2005; 2 pages. Available at: http://www.simpatie.org/Main/files/Luxembourg_Declaration_on_Patient_Safety_05042005.pdf/download

14- Safety Improvement for Patients In Europe (SIMPATIE project). http://www.simpatie.org.

15- European Network for Patient Security (EUNetPaS project). http://www.eunetpas.eu.

16- Aspden P. et al. "Preventing medication errors" National Academy Press, Washington 2007: 544 pages.

17- Council of Europe - Expert Group on Safe Medication Practices "Creation of a better medication safety culture in Europe: Building up safe medication practices" March 2007: 278 pages.