



**COUNCIL OF  
THE EUROPEAN UNION**

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**NOTE**

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from : General Secretariat

to: Council

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Subject : EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS  
COUNCIL MEETING ON 9 AND 10 JUNE 2008

**Patient safety package**

- Information from the Commission  
(Other business item)
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With a view to the Council meeting (Employment, Social Policy, Health and Consumer affairs) on 9 and 10 June 2008, Delegations will find in the annex a note from the Commission on the above-mentioned subject.

**PATIENT SAFETY PACKAGE****INFORMATION FROM THE COMMISSION**

Patient safety, which aims to reduce medical errors and adverse events in the healthcare process, is one of the biggest challenges facing EU health systems. The precise extent and nature of the patient safety problem is not known in many Member States, but there are in the EU a few studies which provide us with some understanding of the scale of the problem. For example, the report from the Department of Health in England "An organisation with a memory" estimates that adverse events occur in around 10% of hospital admissions (about 850 000 adverse events a year). Several other international studies, including in France and Spain, support the view that about 10% of hospital admissions or primary care interactions involve some kind of harm to patients.

Healthcare-associated infections (HAIs, also referred to as nosocomial or hospital-acquired infections) are a specific example of common adverse events that present a tangible threat to public health. On the basis of recent national HAI prevalence surveys in Europe and based on the results of hospital-wide surveillance programmes of in different EU Member States, the total number of patients acquiring at least one HAI in the EU27 every year can be estimated at 4.1 million. Approximately 37,000 deaths are estimated to occur every year as the consequence of these infections. Approximately 20-30% of HAIs are considered to be preventable by intensive infection prevention and control programmes, including surveillance.

Some important areas of patient safety are already being addressed at EU level in specific areas such as pharmacovigilance, eHealth and medical device safety.

The Commission is now taking an initiative to cover patient safety in an integrated manner, by developing a Communication and a proposal for a Council Recommendation on patient safety and quality of health services, including the prevention and control of HAIs, in order to add EU level value to Member States' efforts to improve safety in their healthcare systems. Choosing a Council Recommendation as a (legal) instrument will allow Member States sufficient freedom to organise health care nationally as they do at present, while addressing this major challenge of improving patient safety and reducing HAIs according to agreed best practice.

The section of the Recommendation addressing systemic patient safety issues will be partly dependent on the outcome of the public consultation which closed on 20 May, as well the areas of potential Member State and EU level action proposed by the patient safety working group, subsequently endorsed by Member States through the High Level Group on Health Services and Medical Care in 2007. However, it is expected to cover areas such as the need for a common patient safety taxonomy and indicators, reporting and learning systems, cultural issues and the EU-wide sharing of best practice and experiences.

The Recommendation will also cover the prevention and control of HAIs, and the Commission has developed, with the help of experts, some specific recommendations such as the implementation of control and preventive measures, the organisation of infection prevention and control programmes in healthcare institutions, establishing or strengthening surveillance systems, and education, training, research and information.

The Patient Safety package is planned to be adopted by the College late in 2008 after which it will be transmitted to the Council and to the European Parliament.

