

PATIENT SAFETY AND QUALITY OF HEALTHCARE:

ACTIONS AT EU LEVEL

Background paper for a public consultation

November 2013

This document does not represent an official position of the European Commission. It serves as a tool to explore the views of interested parties on the consultation subject. The suggestions contained in this document do not prejudice the form and content of any future proposal by the European Commission.

Background and context

Quality of healthcare¹, and in particular its core dimension - patient safety² have been addressed at EU level in various initiatives, including quality and safety of [blood, tissues and organs](#), quality, safety and efficacy of [medicines](#), [medical devices](#), [cancer screening](#), [health professionals](#) or [patients' rights](#) in cross-border healthcare.

In 2009 patient safety has been addressed at EU level in a comprehensive manner, through adoption of an overarching strategy on patient safety, in the form of a [Council Recommendation](#).

The Recommendation included a series of actions to be implemented by EU Member States individually or in collaboration with others and with the European Commission. The envisaged actions covered: embedding patient safety as priority issue in public health policies, empowering patients and promoting patient safety culture among health professionals, through appropriate training and possibility of learning from errors.

In 2012 the European Commission initiated together with Member States and other stakeholders a 3-year EU collaboration on patient safety and quality of care. This initiative, in the form of a [joint action](#) has as objective to organise an effective exchange of best practice in the field of patient safety and quality as envisaged by the Recommendation and requested by the [Working Party on Public Health at Senior Level](#); and to propose sustainable EU co-operation for the period after the joint action, i.e. after March 2015.

The Recommendation envisaged for the Commission to assess three years after the adoption to what extent the proposed measures work effectively. To this end, the Commission published an [implementation report](#) in November 2012. Good progress was made in embedding patient safety in public health policies in the EU Member States. However, all other fields were insufficiently and unevenly implemented across EU.

Consequently, the Commission [working group on patient safety and quality of care](#) decided to produce materials helping mutual learning and providing guidance on how to effectively put in place the provisions of the Recommendation, related with reporting and learning systems and with education and training of health professionals. This work is on-going.

While reporting to the Commission about implementing the patient safety Recommendation, Member States stated that the financial crisis slowed down the implementation and that more time was needed to make work properly. Moreover, some hinted to a risk of patient safety being given less priority than needed because of financial matters taking over on political agendas. The awareness of such risk seems growing. This is why - within the [European Semester](#) exercise - the Commission encourages Member States to prioritise access to high quality healthcare while reforming their health systems.

Finally, the EU [Directive](#) on patients' rights in cross-border healthcare, which by now should be enacted in national laws, comprises a number of provisions about safe and high quality healthcare,

1 Healthcare quality is understood as healthcare that is effective, safe and responds to the needs and preferences of patients

2 Patient safety means freedom, for a patient, from unnecessary harm or potential harm associated with healthcare

such as obligation of being transparent towards citizens about safety and quality standards and guidelines or obligation of cooperate between Member States on the latter.

2014 will be an important year for reflection on future of EU action on patient safety and quality of care. Several elements will contribute to this reflection:

firstly, the Commission will publish a second implementation report on patient safety, in which it will assess progress with implementation of the Recommendation, will state whether the proposed measures work effectively and will consider need for further action;

moreover, the Commission will monitor implementation of the Directive on patients' rights in cross-border healthcare in view of a report due in 2015;

finally, the joint action on patient safety and quality of care will produce a sustainability plan of EU collaboration, to be considered by both Member States and the Commission.

Objective of the consultation

Results of this consultation would assist reflection on the future of EU policies on patient safety and quality of care. The specific **objective** of this consultation is to seek opinion of civil society on:

- Whether patient safety measures included in the Recommendation 2009 are implemented and contribute to improving patient safety in the EU;
- Which areas of patient safety are not covered by the Recommendation and should be;
- What should be done at EU level on patient safety beyond the Recommendation;
- Whether quality of healthcare should be given more importance in the future EU activities.