



The Commission's Proposal on Patient Safety

Katja Neubauer
Health and Consumers Directorate-General
European Commission

Brussels, 17 June 2008



Original basis

■ Commission Legislative and Work Programme 2008

■ Strategic initiatives

8. Health package

a) *Communication and Council Recommendation on Patient Safety and Quality of Health Services*

b) *Council Recommendation on health care associated infections*

Merging

Communication and Council Recommendation on Patient Safety and Quality of Health Services

+

Council Recommendation on health care associated infections



Communication and Council Recommendation on patient safety and quality of health services, including the prevention and control of healthcare-associated infections



Timing

- Impact Assessment paper submitted to the Impact Assessment Board (IAB) **13 June**
- IAB meeting **2 July**
- Interservices consultation **September**
- Adoption of the Council Recommendation **end of November 2008**



Policy options

- I. **No additional EU action – *status quo***
- II. Strengthened cooperation with the Member States and other bodies, supported by technical guidance
- III. Strengthened cooperation with the Member States and other bodies, supported by soft law instruments, such as a Commission Communication and a Council Recommendation**
- IV. Strengthened cooperation with the Member States and other bodies, supported by a regulatory instrument, such as a Commission Decision



Advantages of Option III (1/2)

Commission Communication:

- A Communication would provide an overarching structure for the Community's diverse initiatives on patient safety.
- It could address the overall cultural, leadership, systemic, communication and process barriers to improved patient safety. In consequence, morbidity and mortality due to patient safety issues could decrease substantially.
- It would present findings and good practice principles on patient safety to be applied in the EU and highlight the need for actions.



Advantages of Option III (2/2)

Council Recommendation (CR):

- A CR could include recommendations on patient safety and specific recommendations on the prevention and control of HAIs.
- A CR would represent a strong political commitment to address patient safety and HAIs.
- The literature and this impact assessment show that improved prevention and control of HAIs is highly cost-effective.
- A CR allows for monitoring and evaluation of the recommended measures.



EU initiative vs MS actions

- A 'soft law' Council Recommendation, 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 according to agreed best practice.



Legal basis

Article 152 (public health)

- *"Community action, which shall complement national policies, shall be directed towards [...] preventing human illness and diseases, and obviating sources of danger to human health. [...]"*
- *The Community shall encourage **cooperation between the Member States** in the areas referred to in this Article and, if necessary, lend support to their action. [...]"*
- *Community action in the field of public health shall **fully respect the responsibilities** of the Member States for the organisation and delivery of health services and medical care."*



Commission sources for PS initiative

- Recommendation on Patient safety by patient Safety Working Group (October 2007)
- Public consultation on patient safety (May 2008)
- 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 (May 2006)



The Consultation - Summarized Results

■ Respondents overwhelmingly ranked as important or very important the need for (continued) action on:

- **Budgetary commitment** to patient safety;
- **Patient and public involvement**;
- Local healthcare **management engagement**;
- **Education and training of health professionals**;
- A common **taxonomy** and set of **indicators**;
- **Reporting and learning systems**;
- **Standards and external assessment**;
- More **Research**;
- More information on **Redress** for patients.