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CITIZEN'S SUMMARY

What is the problem the proposal is seeking to address?

Patient safety, defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare, is an issue of increasing concern all over the world. It is estimated that in EU Member States between 8% and 12% of patients admitted to hospitals suffer from adverse effects whilst receiving healthcare. Frequently occurring adverse events include healthcare-associated infections that affect an estimated one in twenty hospital patients on average every year, medication-related errors such as patients receiving the wrong medicine, or the wrong dose, surgical errors, medical device failures and errors in diagnosis or the failure to act on the results of tests. Much of the harm to patients is preventable.

The 27 EU Member States have varying levels of awareness of the adverse events occurring in their health systems and dedicate varying levels of resources to counter the problem. The Commission has already taken specific steps in many areas to address the issue of patient safety. However; efforts to address the challenges of patient safety have focused mostly on specific sources of risk such as the safety of medicines, medical devices and resistance to antimicrobials. Building on those achievements, this proposal aims to be an integrated approach that recommends firm actions to tackle patient safety at the EU level and attempts to improve measures to reduce *all* potential causes of harm to patients in Member States.

How would the proposal tackle the problem?

The Commission Communication and proposal for a Council Recommendation on patient safety, including the prevention and control of healthcare associated infections, are intended to bring about a political commitment from all EU countries to address the patient safety challenge. Member States will be expected to implement a series of recommendations either individually, or collectively, supported by the Commission, to take practical steps to improve patient safety.

Why is it right for the EU to act?

The EU can lend support to Member States in their efforts to increase patient safety and can coordinate their action. In particular, the EU can provide political weight and visibility to patient safety, achieve economies of scale by Community wide collection of data and sharing of best practice and can strive for sustainability of action on patient safety at Community level.

How would the proposal work?

This initiative does not take away any of the powers of Member States in the field of health. 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 the major challenge of improving patient safety and reducing healthcare-associated infections, as appropriate to their health systems.

When is the proposal going to come into effect?

The proposal will soon be submitted to the Council of Ministers and to the European Parliament for scrutiny and debate. At this stage, no accurate prediction can be made as to when this process will come to an end. The Commission hopes that matters can proceed quickly, so that the benefits can be gained as soon as possible.

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