EUROPEAN COMMISSION

Citizens' summary

EU proposals on medical devices

WHAT'S THE PROPOSAL?

- The EU is proposing updated regulations on medical devices – from home-use items like sticking plasters, pregnancy tests and contact lenses to x-ray machines, pacemakers, breast implants, hip replacements and HIV blood tests.
- The aim is to ensure these products are safe, and can be freely and fairly traded throughout the EU.

WHAT'S THE ISSUE?

- Existing EU rules – dating back to the 1990s – have not kept pace with the enormous technological and scientific progress in the past 20 years.
- EU countries interpret and implement the current rules in different ways.
- It is not always possible to trace medical devices back to their supplier. New rules on traceability are needed.
- Patients, healthcare professionals and other interested parties do not have access to essential information on how medical devices have been assessed, and what clinical evidence there is to show they are safe and effective. The need for greater transparency has been highlighted by recent scandals about faulty silicone breast implants and problems with some metal-on-metal hip replacements.

WHO WILL BENEFIT AND HOW?

- **Patients and citizens** – all medical devices will have to undergo thorough, independent assessment of safety and performance before they can be sold on the European market. Controls will not block or unduly delay access to innovative, cost-effective devices for European patients/consumers.
- **Healthcare professionals** – better information on the benefits for patients, residual risks and the overall risk/benefit ratio will help them make the best use of medical equipment.
- **Manufacturers** – clearer rules, easier trading between EU countries and a level playing field, with penalties for those who don't play by the rules. The new rules support patient-oriented innovation and take particular account of the specific needs of the many small and medium-sized manufacturers in this sector.

WHY DOES ACTION HAVE TO BE TAKEN BY THE EU?

- People throughout the EU should enjoy the same high health & safety standards.

- Making manufacturers subject to the same rules encourages economies of scale so that they can reap the benefits of the EU single market.

WHAT EXACTLY WILL CHANGE?

- **Wider, clearer scope for EU legislation** on medical devices – extended to include, for example, implants for aesthetic purposes, and clarified as regards genetic tests
- **Stronger supervision of independent assessment bodies** by national authorities
- **More powers for assessment bodies** to ensure thorough testing and regular checks on manufacturers, including unannounced factory inspections
- **Clearer rights & responsibilities** for manufacturers, importers and distributors, which would also apply to diagnostic services and internet sales
- **Extended Eudamed database** on medical devices – will provide comprehensive information on products available on the EU market. Non-confidential data will be publicly available
- **Better traceability** of medical devices throughout the supply chain – enabling a swift and effective response to safety problems (e.g. recalls)
- **Stricter requirements for clinical evidence** to support assessments of medical devices
- **Updated classification rules** dividing medical devices into 4 different risk categories and health & safety requirements, including labelling rules – to keep pace with technological and scientific progress
- **Better coordination** between national surveillance authorities, with the Commission providing scientific, technical and logistic support
- **International guidelines to be incorporated into EU law**.

WHEN IS THE PROPOSAL LIKELY TO COME INTO EFFECT?

- Target for adoption: 2014.
- The new rules would then gradually come into effect from 2015 to 2019.