Medical devices in TTIP

Working together better to approve, monitor and recall devices

In this chapter we want to:
- make medical devices more accessible and traceable
- while maintaining our high safety standards.

Reasons for negotiating medical devices

Medical devices include things like:

- pacemakers
- scanners
- x-ray machines.

They're a vital part of modern health systems.

Both the EU and US have strict rules for such devices. Sometimes these rules overlap or test the same things twice.

This can mean:

- extra costs for public health systems
- delays in making new devices available for patients.

We want to use TTIP to improve cooperation between EU and US regulators. This could benefit both the public and industry.

The EU and US have already removed customs duties on most medical devices, so TTIP's benefits will chiefly come from EU and US regulators working better together to ensure:

- faster access to life-saving devices streamlining approval procedures to - for example by having similar electronic forms in the EU and US for sending in data from trials
- better procedures for:
    - monitoring products
    - recalling them when necessary.

EU goals

We want EU and US regulators to:

- work more closely together on medical devices
- base their work on the International Medical Devices Regulatory Forum (IMDRF).

We want to:

- agree to base our national systems for identifying and tracing medical devices on the international **Unique Device Identification (UDI)** system
- make sure the EU's and US' UDI databases are compatible with each other
- harmonise forms for getting new medical devices approved, so EU and US regulators can work on approvals at the same time; this will make new devices available more quickly
- work towards recognising each other's **Quality Management Systems** (**QMS**) audits

- create a basis for jointly developing state-of-the-art regulations on new areas not yet fully regulated.

Sensitive or controversial issues

Sensitivity/concern	EU response
1. Approval process	
TTIP will harmonise the way a medical device is approved in the EU and in the US.	In TTIP we don't want to harmonise the approaches for the approval of a medical device in the EU and US. Although the two systems are different, both provide high level of consumer protection. In TTIP we want to streamline the approval processes, for example by having a common application form when applying for approval of a new medical device. Manufacturers could apply simultaneously for approval in the EU and US and make new devices available to patients more quickly.
2. Regulation	
TTIP will affect the revision of the EU Medical Devices Regulations	The revision of the EU Medical Devices Regulations is being discussed by the governments of the EU's Member countries and the European Parliament. TTIP does not, and will not, interfere with that internal process.