



European Commission



EU-U.S. COOPERATION

Exploring trade opportunities, from medical devices to the Internet of Things

TRADE IN MEDICAL DEVICES

25 July 2019



“Already today, the United States and the European Union have a \$1 trillion bilateral trade relationship – the largest economic relationship in the world. We want to further strengthen this trade relationship to the benefit of all American and European citizens.

This is why we agreed today, first of all, to work together toward zero tariffs, zero non-tariff barriers, and zero subsidies on non-auto industrial goods. We will also work to reduce barriers and increase trade in services, chemicals, pharmaceuticals, medical products, as well as soybeans.”

Joint EU-U.S. statement following President Juncker's visit to the White House, Washington DC, 25 July 2018

Medical devices

Ranging from simple contact lenses and sticking plasters to sophisticated pacemakers and replacements, medical devices are important to our health and quality of life.

Both the U.S. and EU have strict rules for medical devices. Sometimes, these rules can overlap or require that the same device is tested twice.

By working together, we can **make it easier for medical device producers to export** their product and for patients to get the devices they need.

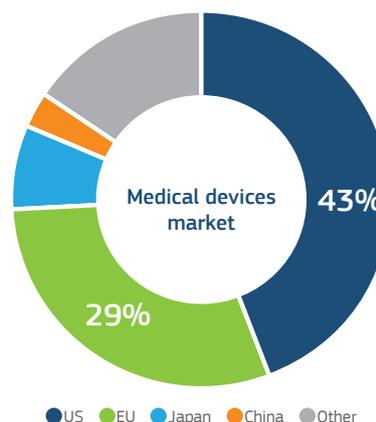


The EU and U.S. market

The U.S. and the EU are important producers of medical devices. This industry has successfully built a closely integrated transatlantic value-chain that makes the U.S. and the EU dominate this sector together.

The U.S. medical devices industry is a world leader, with total sales representing 43% of the global market.

The EU sales of medical devices represent 29% of the world market.



Balanced trade

There is a balanced trade between the U.S. and the EU that is a real win-win. The U.S. is the main supplier of medical devices to the EU – medical devices from **the U.S. represent over 55% of all devices imported** to the EU. The difference in trade-flow between the EU and the U.S. is **lower than 10%**. In 2017, the U.S. exports to the EU stood at **€15.7 billion**. The EU exports to the U.S. reached **€16.6 billion**.

Barriers



The EU and the U.S. rely to a large extent on the same international ISO standards, lowering adaptation costs for industry and facilitating the integration of the value chain. But there is **potential to do more**. In the area of approvals and inspections, our systems remain divergent, resulting in double controls.

There are two types of controls:

- Pre-market product approvals
- Controls of manufacturing sites

What are we doing to reduce costs for manufacturers?

EU and U.S. regulators are working together to ensure that conformity assessment bodies on both sides:

- Follow the same procedures as much as possible
- Recognise each other's work to avoid duplication of controls
- Engage in other trade-facilitating actions, such as compatible product-identification systems



MILESTONE REACHED IN MUTUAL RECOGNITION ON PHARMACEUTICALS



- On 11 July 2019, the EU and the U.S. achieved the full implementation of the Mutual Recognition Agreement (MRA) for inspections of manufacturing sites for human medicines in their respective territories. This will make it faster and less costly for both sides to bring medicines to the market.
- This Mutual Recognition Agreement is underpinned by robust evidence that the EU and the U.S. have comparable procedures to carry out good manufacturing inspections for human medicines.



As a result of the **Mutual Recognition Agreement (MRA)**, both the EU and U.S. **save resources and can put medicines faster on the market**. The **number of duplicate inspections has gone down considerably**. In the EU we have estimated that around **100 inspections in the U.S. will be waived by end 2019**. Patients will get **faster access to quality medicines**.

Current scope of the Mutual Recognition Agreement - Human medicines



The EU recognised the U.S. as having an **equivalent inspection system for human medicines in 2017**. On 11 July 2019 the U.S. recognised equivalence of **all 28 EU Member States**.



Both the EU and U.S. authorities in **charge of medicines** can now **rely on each other's inspection results to replace their own inspections**.



From 11 July 2019 **batch testing waver applies**. **Medicines imported from the U.S. do not need to be re-tested for quality** before being made available for EU patients.

Freeing resources for industry and public authorities

The MRA allows both side to free resources to inspect facilities in other large producing countries, notably China and India.

Resources for 1 inspection



€352 000 – 160 person days*
for industry



16 person days –
for a national authority

*Amount of work done by one person in one working day

The way ahead: veterinary medicines



A possible expansion of the **scope of the Mutual Recognition Agreement** to **veterinary medicines** would pave the way to **more cost savings by 2021**.

The EU and U.S. are among the biggest players on the **global veterinary medicines** market. According to the latest available figures, bilateral trade is worth nearly **€16 billion** and is projected to grow around **5% per year until 2023**.

VETERINARY MEDICINES

€454 million
R&D spending



In 2016 the European **veterinary medicines** industry spent almost **€454 million on research and development**.

Extending the Mutual Recognition Agreement to veterinary products would reduce the administrative burden and costs facing pharmaceutical manufacturers, including smaller producers.

CYBERSECURITY: MARKET OPPORTUNITIES FOR TRUSTWORTHY INTERNET OF THINGS (IOT) DEVICES

What is the Internet of Things?

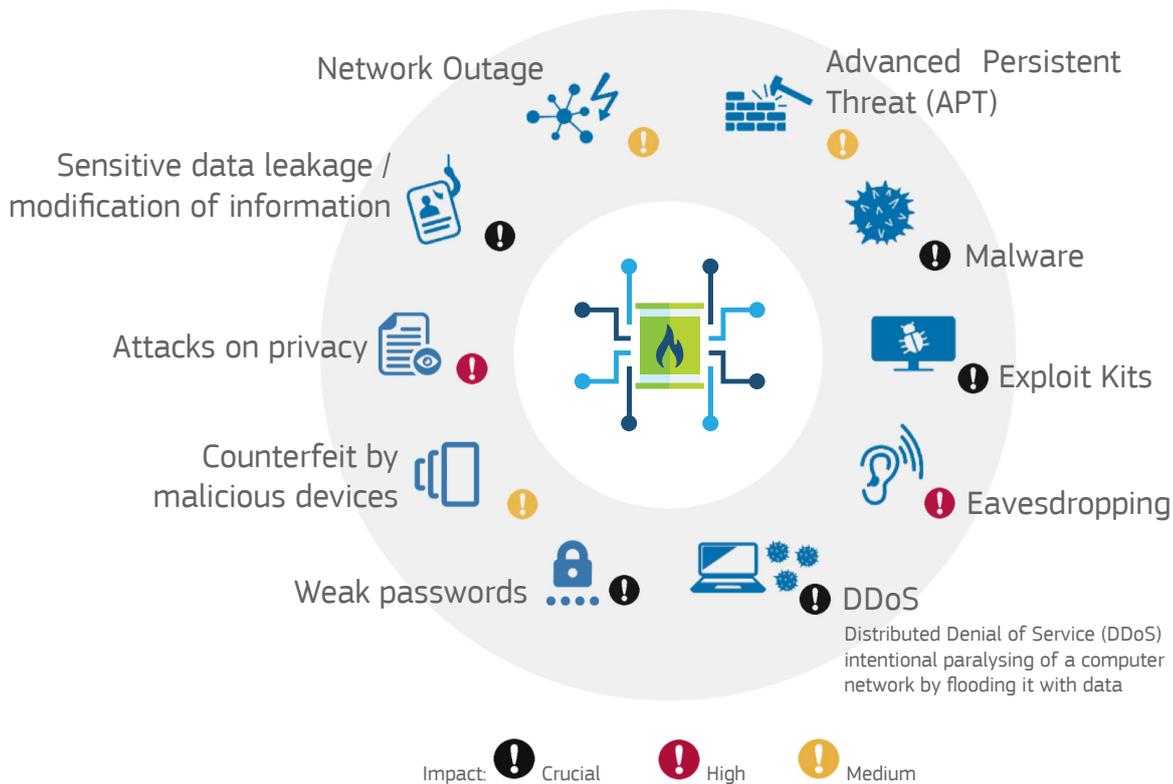
It is the future of the internet – connecting various computing devices embedded in everyday objects (wearable health and fitness monitoring devices, smart home appliances, etc.) enabling them to send and receive data.

Consumers on both sides of the Atlantic are already enjoying the benefits of innovation and digitisation, but are also facing increasing cybersecurity challenges resulting from insecure Internet of Things devices.

A common understanding on EU-U.S. baseline cybersecurity requirements will make consumer Internet of Things devices more secure.

Industry, consumer groups, regulators and standard setters in the EU and the U.S. agree that the bar needs to be raised on Internet of Things cybersecurity. This is why the EU and the U.S. are both looking at ways to improve cybersecurity in consumer Internet of Things devices.

IoT threats impact



Common EU-U.S. standards will provide new business opportunities and reduce red tape.

In a global consumer Internet of Things market expected to surpass \$1.5 trillion by 2020, cooperation between regulators and standard setters will indeed be a key factor of success.

Latest EU and U.S. efforts



U.S.



EU

- IoT Cybersecurity Programme of the National Institute for Security and Technology

- Cybersecurity Act – 2019 – European Cybersecurity Certification Framework

Next Steps

Last November, the U.S. and the EU agreed to intensify cooperation on standards and conformity assessment (including certification approaches) for connected devices.

The EU and U.S. regulators will continue to work towards common baseline cybersecurity requirements for Internet of Things devices that could greatly improve trustworthiness in this fast growing market while avoiding unnecessary burden on our innovative companies.