

Perspectives on Healthcare, the Medtech Industry, and Digital

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Perspectives

1. About medtech and MedTech Europe
2. Facts and figures about the medtech market
3. Market access for medical technologies
4. Digital in healthcare
5. Q&A

1. About MedTech Europe

What is medical technology



Stents

1 every 5 secs



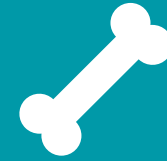
Hip replacement

1 every 15 secs



Pacemakers

1 every 20 secs



Knee replacement

1 every 20 secs

What is medical technology

Medical technologies are products, services or solutions used to save and improve people's lives.

In their many forms, they are with you all the time, from prevention, to diagnosis to cure. There are three main categories of medical technologies: medical devices, in-vitro diagnostics and digital health solutions.

There are more than **500,000 medical technologies** available in hospitals, community-care settings and at home.



MedTech Europe

from diagnosis to cure

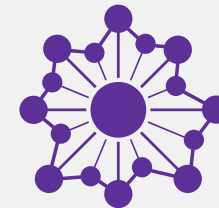
The European trade association
for the medical technology industries
including medical devices, diagnostics and digital health

OUR MEMBERS



120+
Corporations*

*medical devices, diagnostics and digital health



50+ medical technology
associations

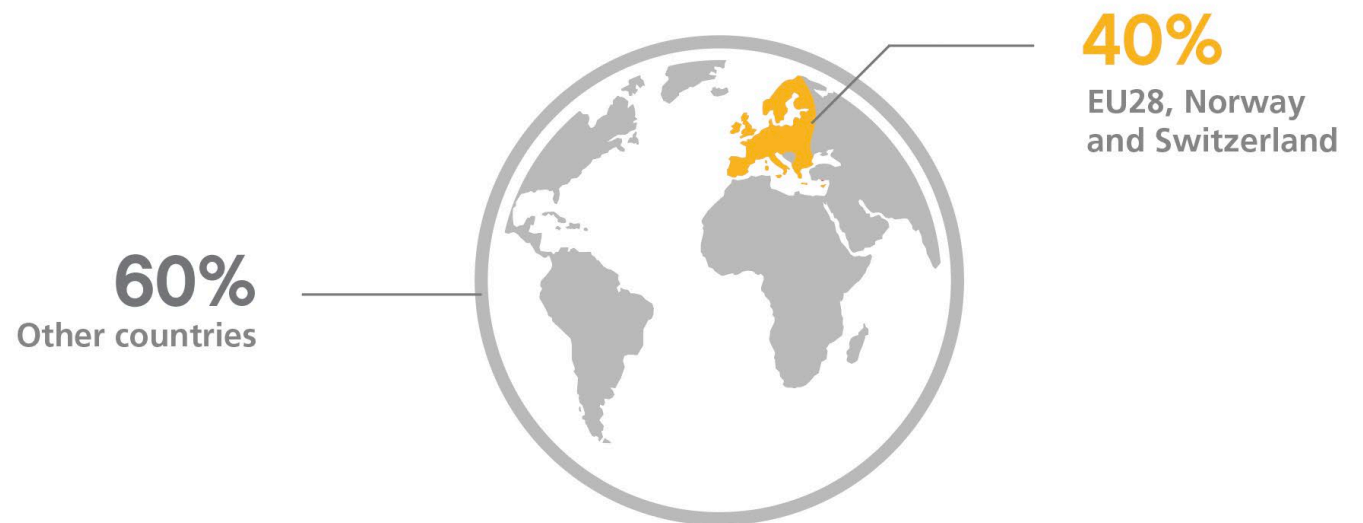
2. Facts and figures about the medtech market

Innovation

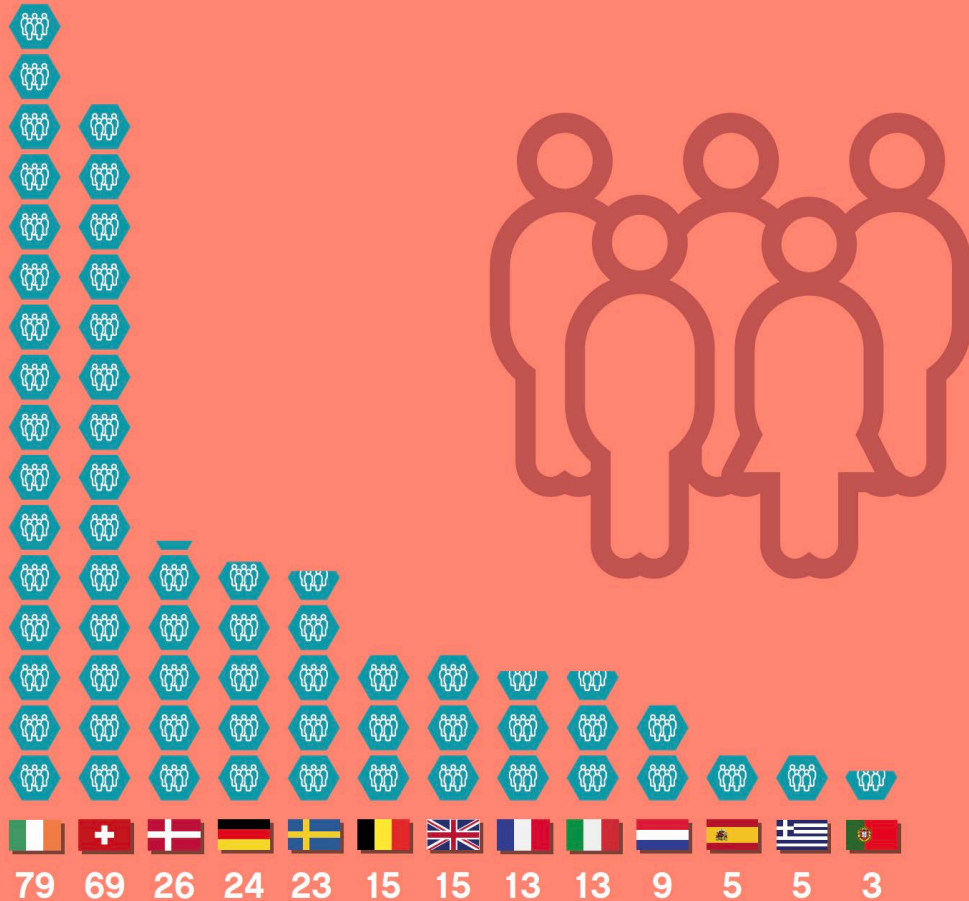
Medical technology is characterised by a constant flow of innovations, which are the results of a high level of research and development within the industry, and of close co-operation with the users.

In 2017, more than **13,000 patent** applications were filed with the European Patent Office (EPO) in the field of medical technology – **8% of the total number of applications in Europe** –, **more than any other sector in Europe**.

EPO patent application in 2017



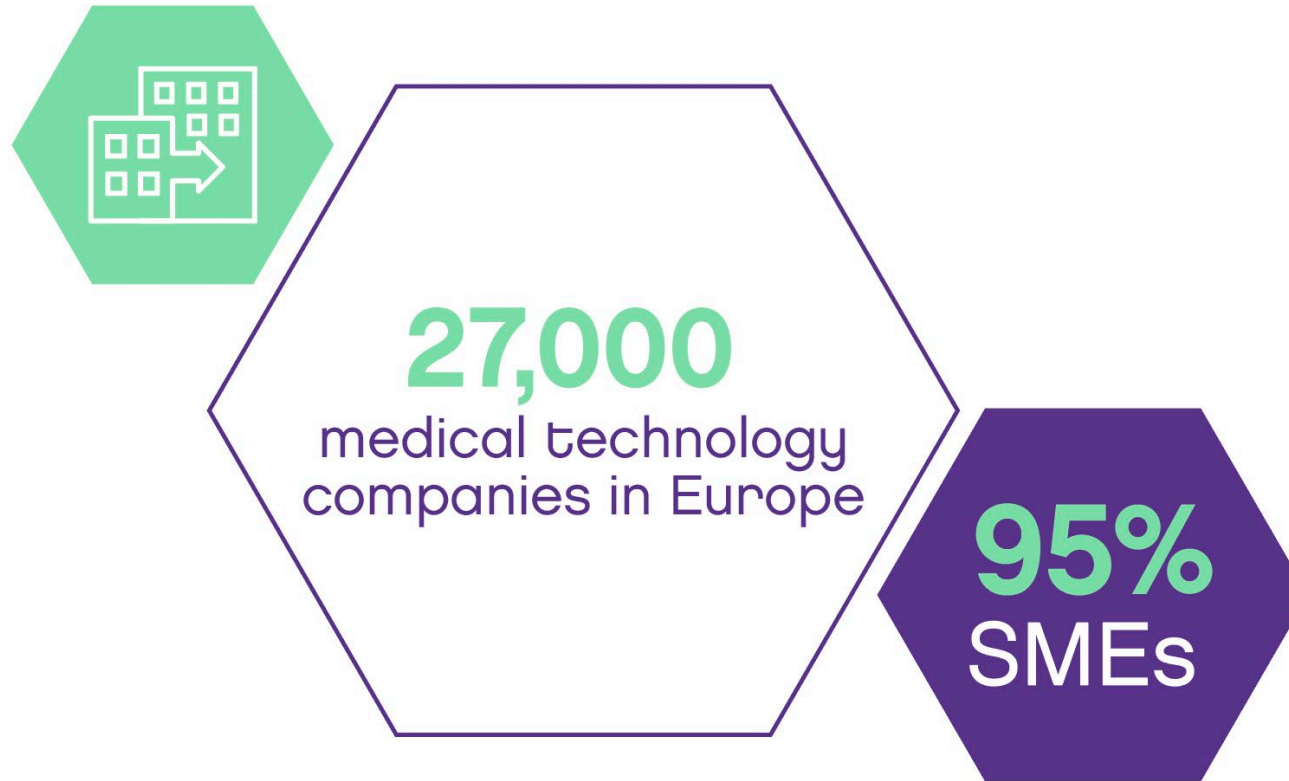
Employment



The European medical technology industry employs directly more than **675,000 people**.

Number of people directly employed in the medical technology industry per 10,000 inhabitants, 2017

Companies

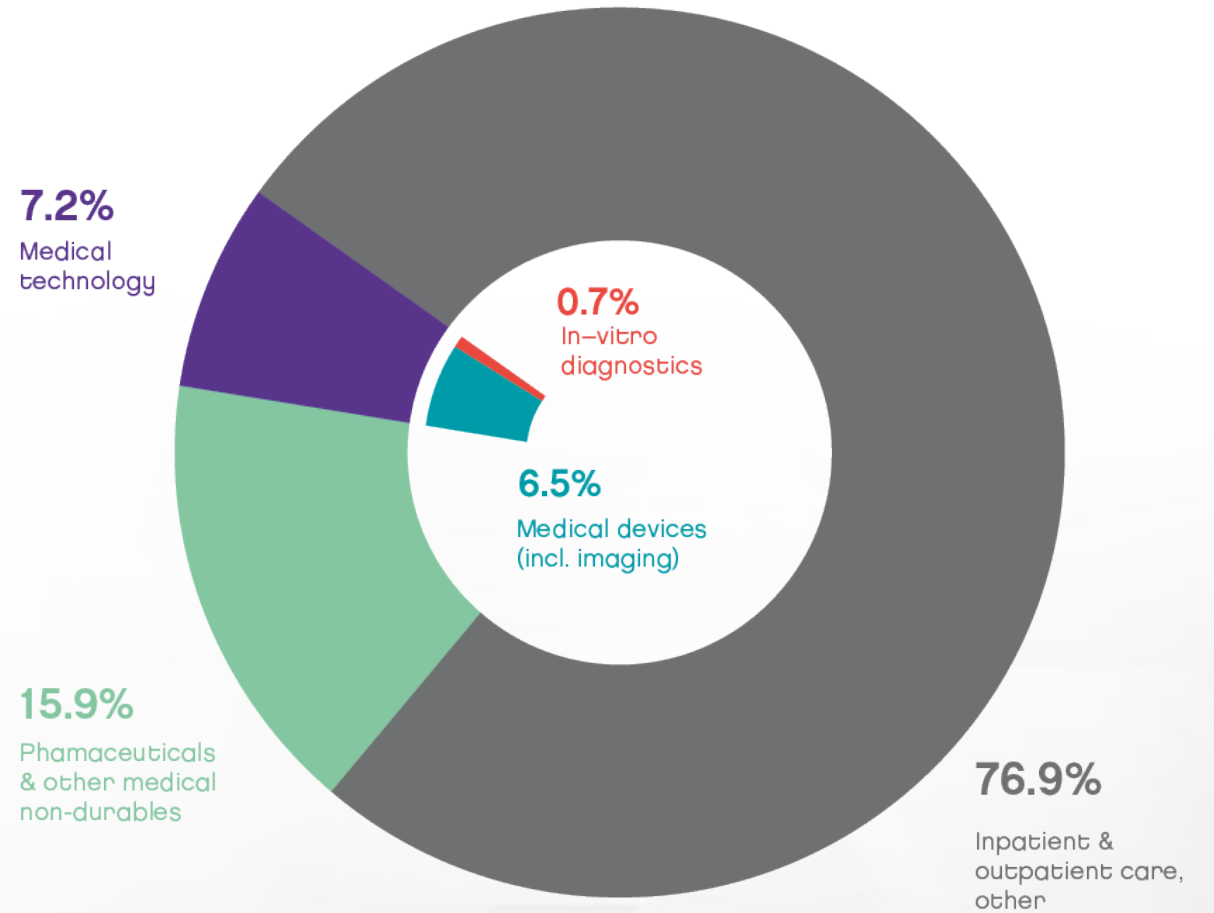


75% are based in **France, Germany, Italy, Spain, Switzerland, UK.**

Expenditure

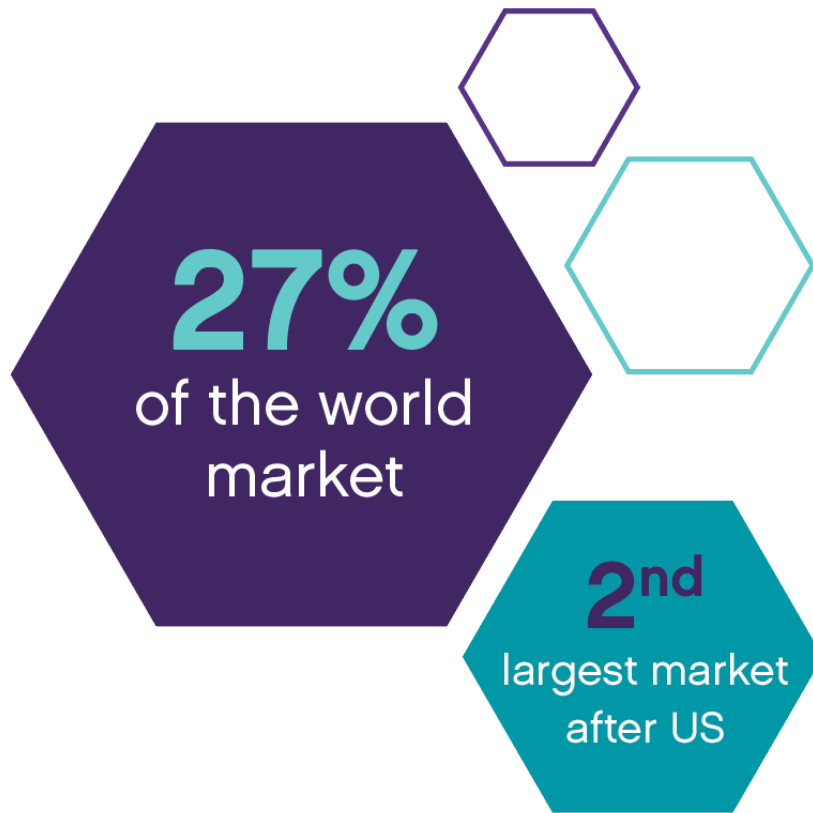


Breakdown of total healthcare expenditure in Europe (2017)

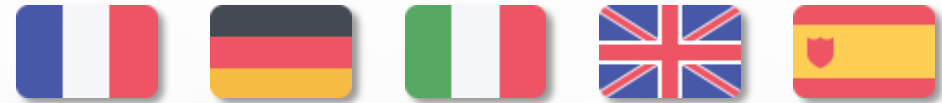


Market

The European medical technology market is estimated at roughly **€115 billion** in 2017.



Top 5 countries



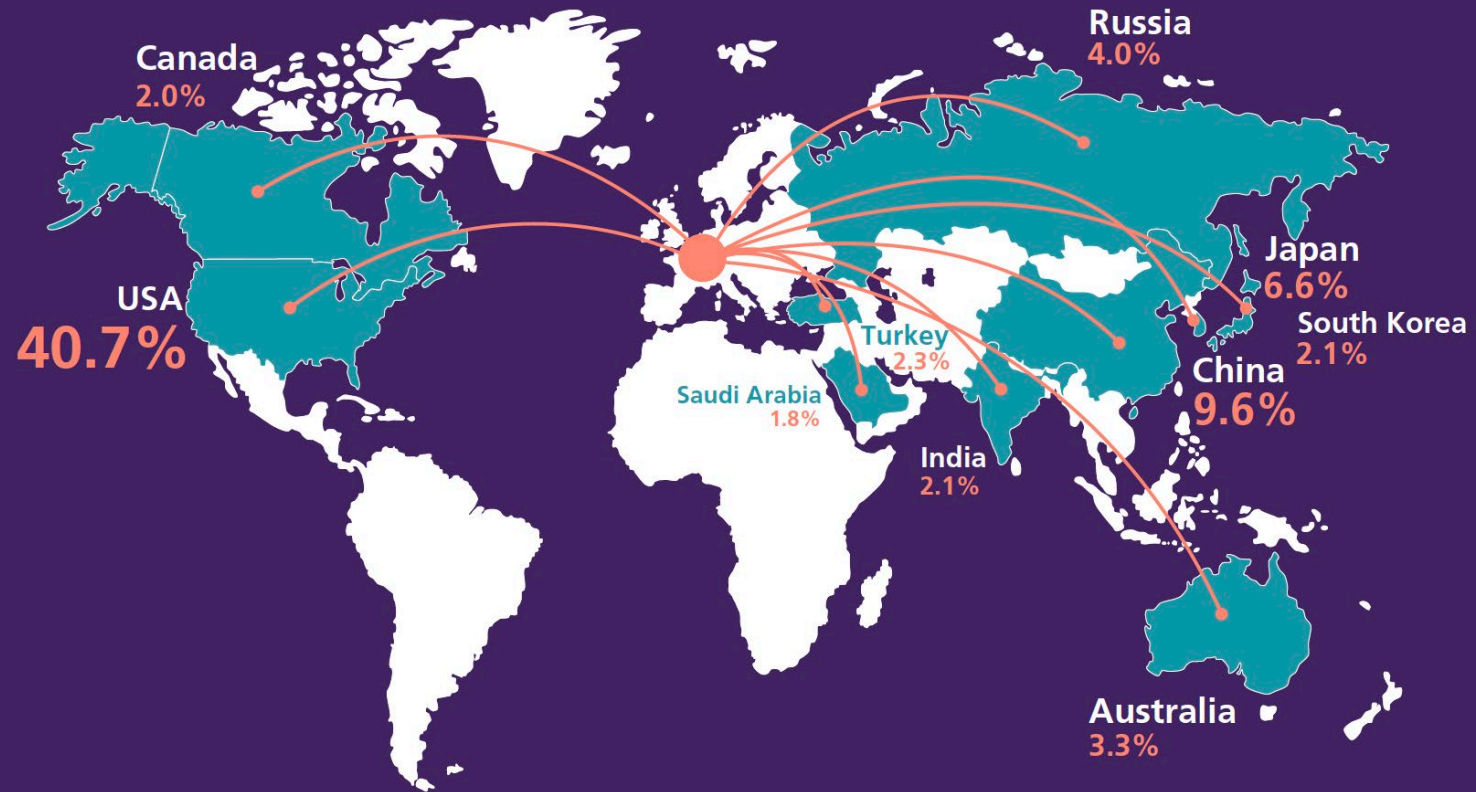
Trade



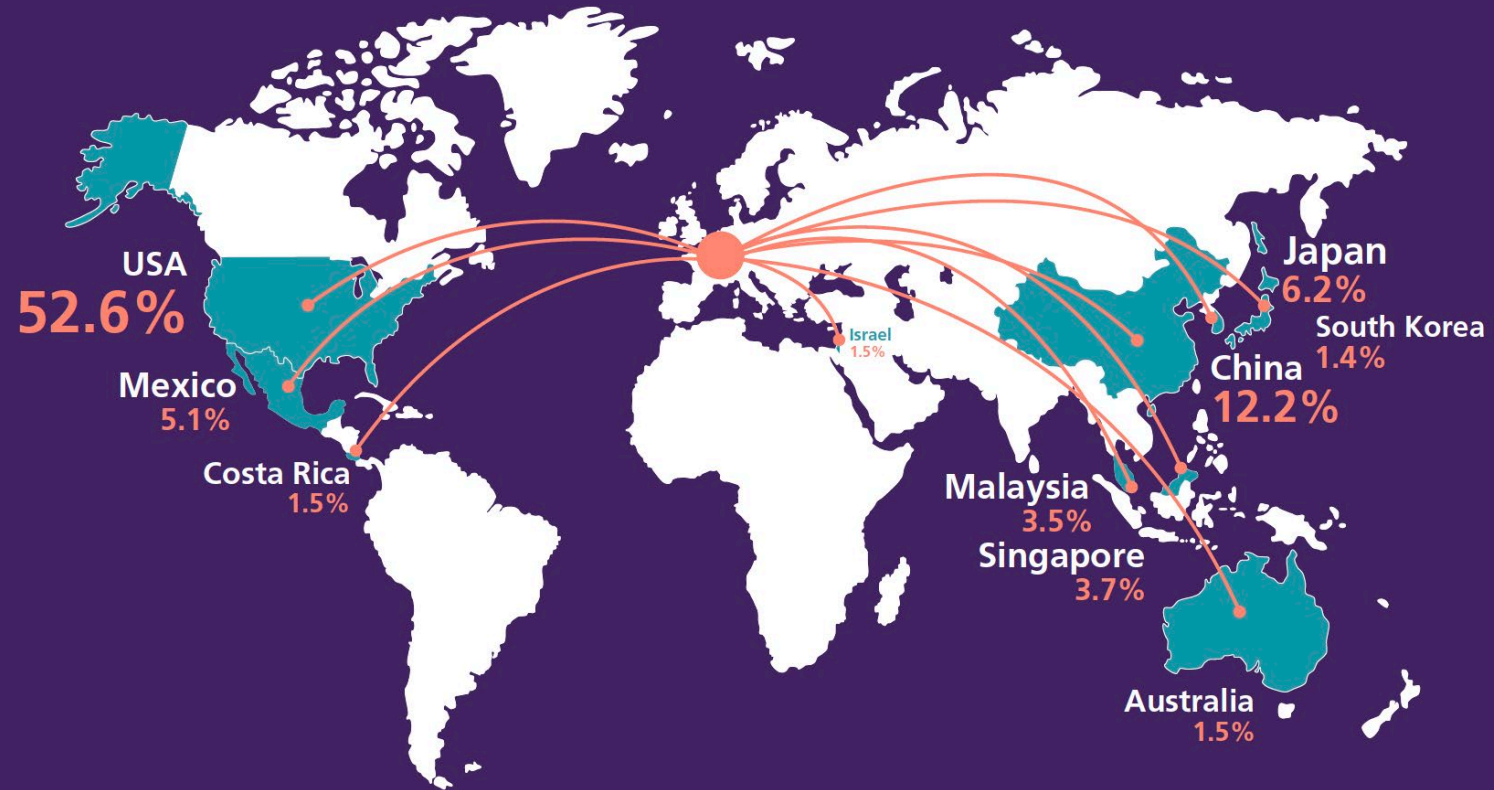
Europe has a positive medical devices trade balance of **€19.7 billion**.

In comparison, US medical devices trade surplus is at **€2 billion**.

Trade - Export



Trade - Import



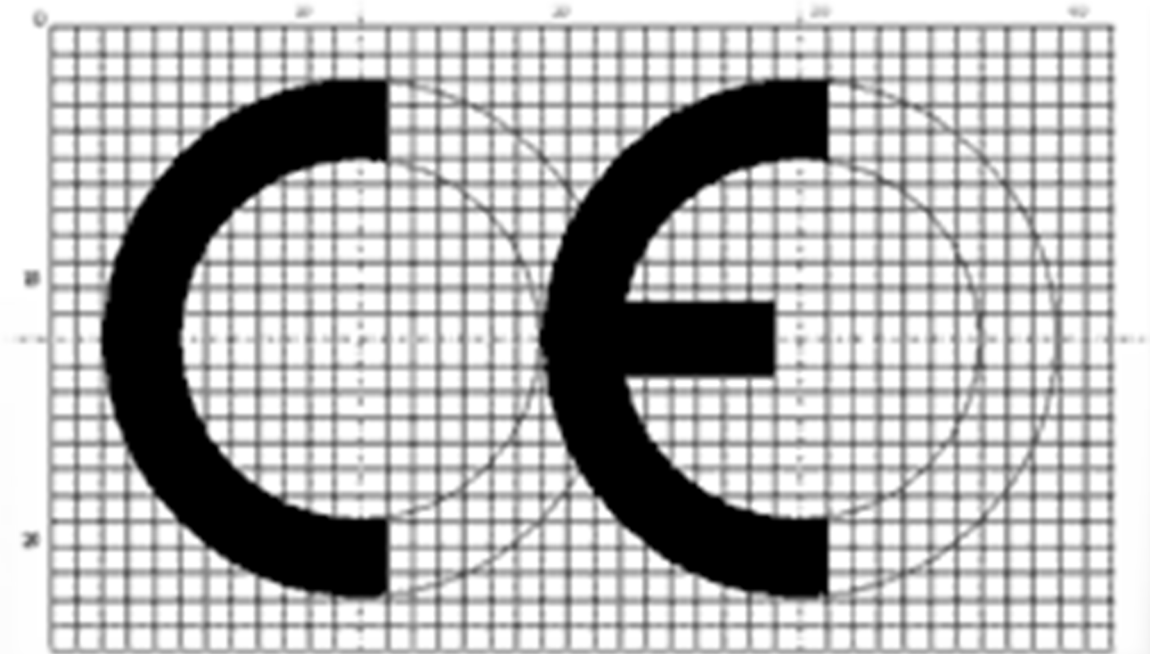
3. Market access for medical technologies

How medical technologies get to hospitals and patients



About CE marking...

- **The CE marking is a pictogram** affixed to various products regulated at EU level.
- **Manufacturers** affix the CE marking to **confirm their products' compliance** with the applicable EU rules when placed on the European market
- **In the case of medical devices**, the underlying requirement is to confirm:
 1. **That the device works**
 - I.e., it performs as intended and claimed,
 2. **That the device is safe**
 - I.e., its benefits outweigh any risks



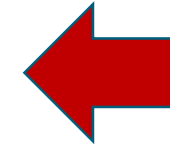
Many devices may only bear the CE marking after an expert third party appointed by the EU Member States (i.e., a '**notified body**') audits the manufacturer and certifies its compliance with the EU legislation.

2017 EU Medical Devices Regulation (MDR) raises the bar



**Former Directives
(from 1990s) = 95 pages**

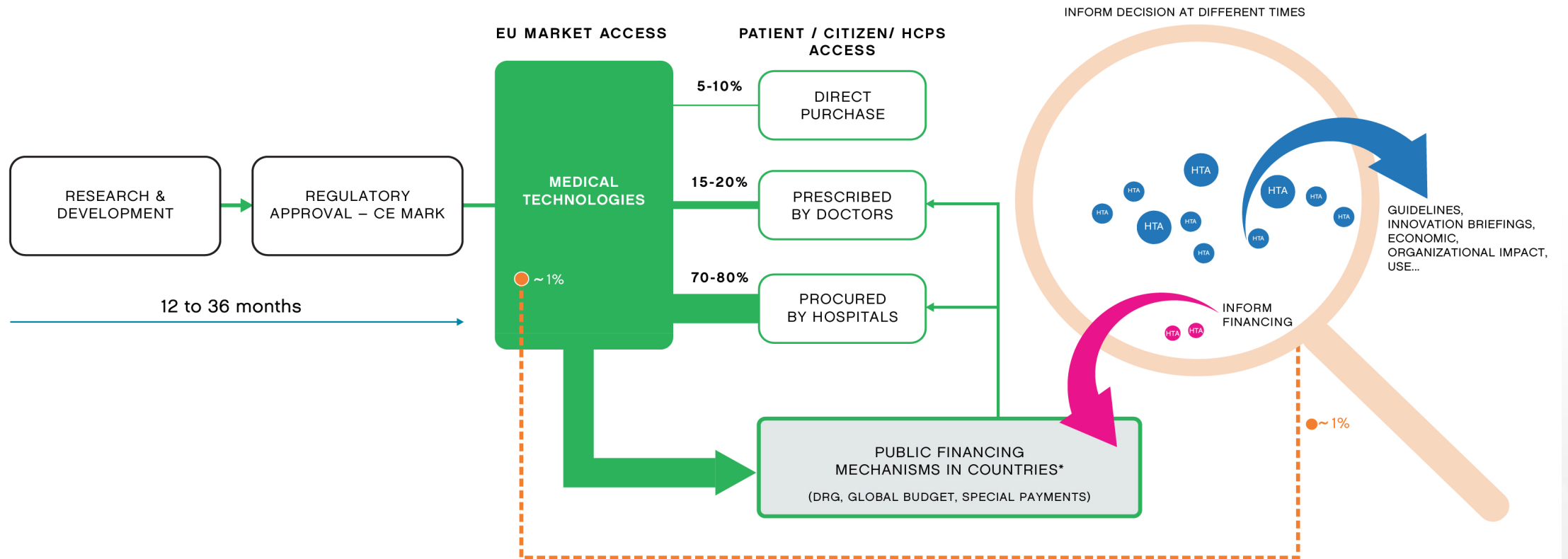
**CE marking
legislation**



**CE marking
legislation**  **New Regulation
(May 2017) = 175 pages**

... takes effect 26 May 2020

Patient Access to Medical Technologies




Open model: focus on competition and decentralization (fast innovation cycle)

4. Digital in healthcare

Digital health presents opportunities

 **Real-time information** allows self-management, monitoring, and proactive care



 **Connectivity** enables remote monitoring and access to care

Care search & scheduling

Telehealth




 **Big data** powers real-time analytics and artificial intelligence

Clinical decision support

Clinical research with comprehensive patient data



 **Automation** improves patient experience, outcomes and provider efficiency

Hospital operations
Monitoring through algorithms

Collaboration and coordination
between providers and with patients

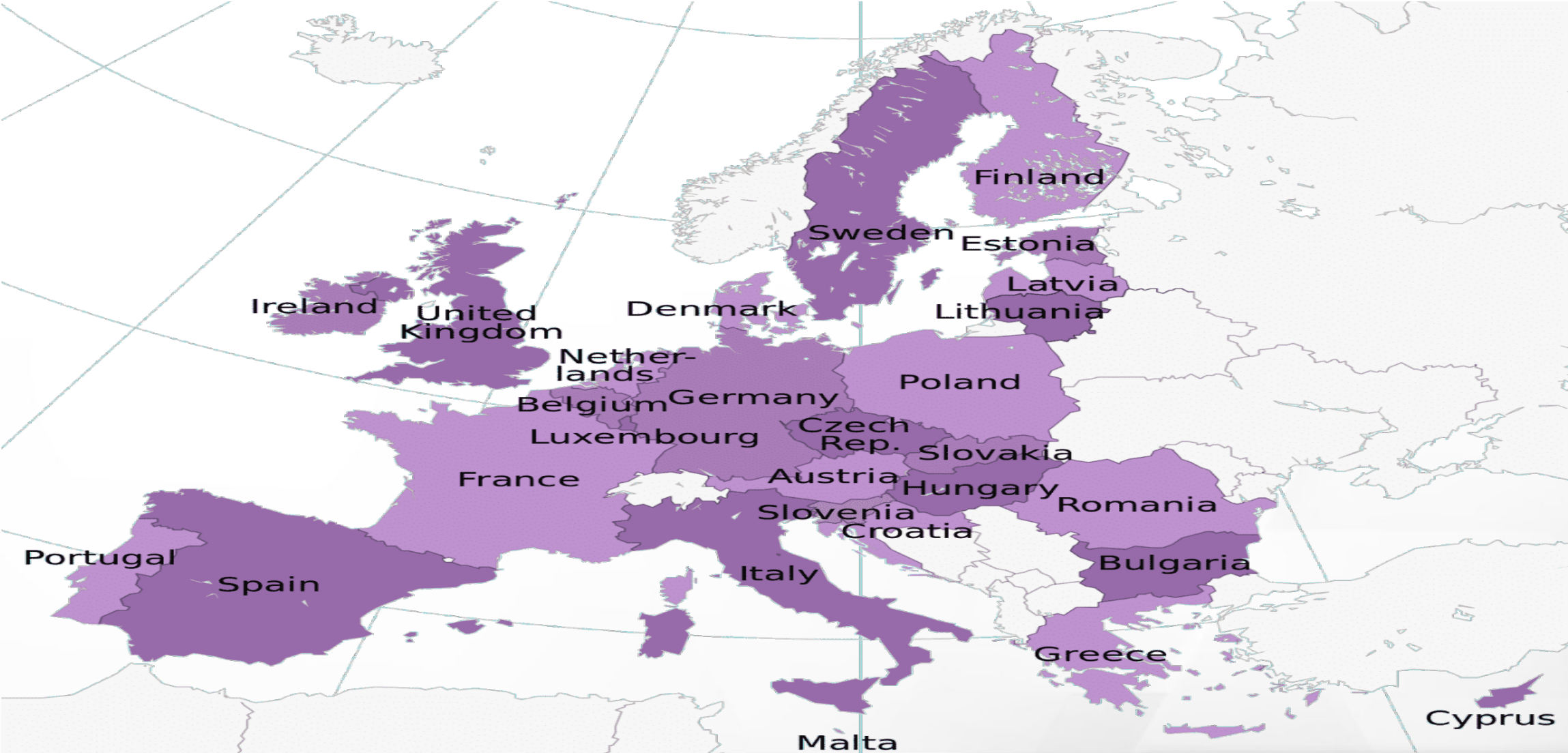


Free flow of data enables integrated, patient-centred care and big data/analytics and AI for personalized medicine, population health management, and research

Digital health requires connectedness



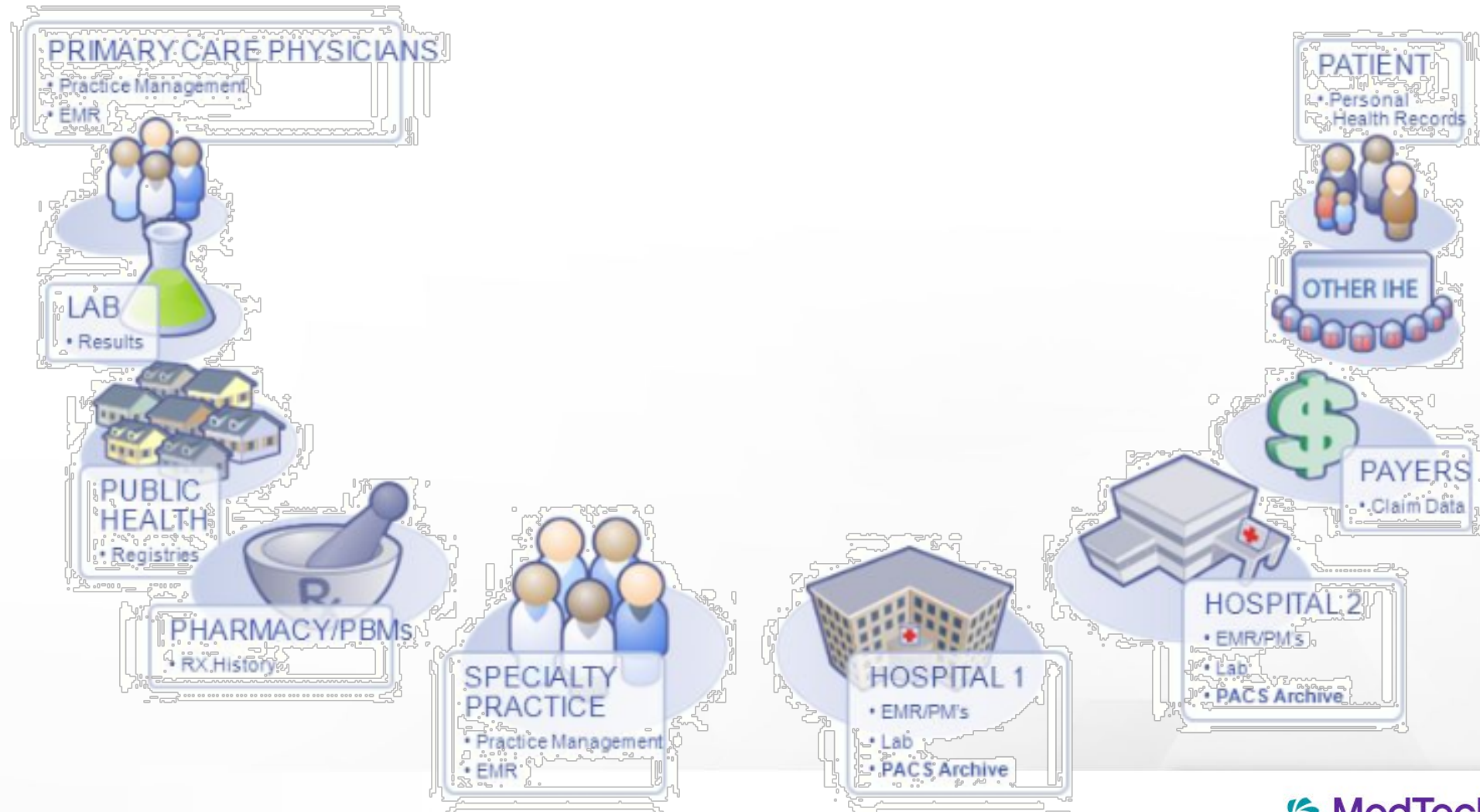
Health and social care are national competences...



... and connectedness often remains an aspiration

	Legal framework		Institutions		Infrastructure		Electronic Health Record Applications		Health services		Sum (10 total)
	Data protection	Legal certainty	National digital health agency	Enforcement of standards	Universal national patient identifier	Technical data infrastructure	Patient summary	Vaccination record	e-Prescription	Telehealth	
 Estonia	✓	✓	✓	✓	✓	✓	✓		✓	✓	9
 Denmark	✓	✓	✓	✓	✓	✓		✓	✓		8
 Sweden	✓	✓	✓	✓	✓	✓	✓		✓		8
 Austria	✓	✓	✓	✓	✓	✓	✓		✓		7
 Belgium	✓	✓	✓	✓	✓		✓		✓		7
 England	✓		✓		✓	✓	✓		✓		6
 Italy	✓	✓	✓		✓			✓	✓		6
 Portugal		✓	✓			✓	✓	✓	✓		6
 France	✓		✓								2
 Germany	✓	✓									2

... and health data silos prevail



2020 – a year of change?

- **Interoperability:** European Commission issued a recommendation for an *Electronic Health Record Exchange Format* (February 2019)
- **Member State push:** Many Member States are accelerating building digital health infrastructures and making legal/regulatory changes
- **New Commission:** Incoming European Commission is committed to a “European Health Data Space” and the deployment of artificial intelligence

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