MEETING WITH DG GROW

Medical Devices: EU Investments in R&D

Challenges and opportunities

THE EU CHEMICAL STRATEGY

aims to achieve a toxic-free environment with a high level of protection of human health & the environment

Key messages

- The medical devices industry is aligned with the CSS objectives of a high level of protection of human health and environment
- The medical devices industry employs 500K workers, generate 100 billion revenue with production facilities in Europe and invest 8% of sales volume in R&D.
- Our investments in innovation save lives
  - ✓There are about **500 million radiological/imaging procedures** in Europe every year (15/s)
  - ✓About **2 million patients receive radiation therapy** every year in Europe
  - ✓**10.000 IVD tests are performed every second** in Europe
- We are pioneers in circular economy and substitution of chemicals of concern
- Our devices contain limited volumes of hazardous substances when no alternatives are available to achieve best performance
- Innovation needs a pragmatic legislative approach adapted to long & complex design cycles of medical devices

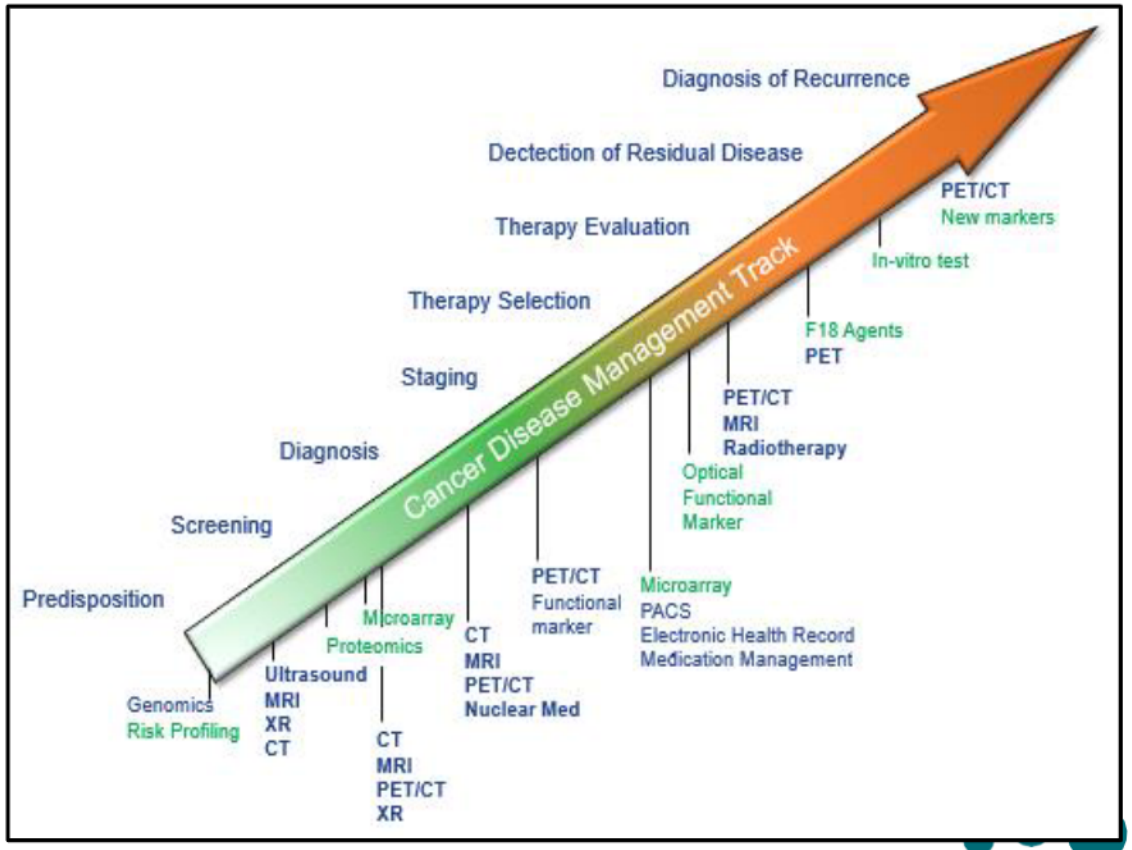
COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

COCIR covers 4 key industry sectors:

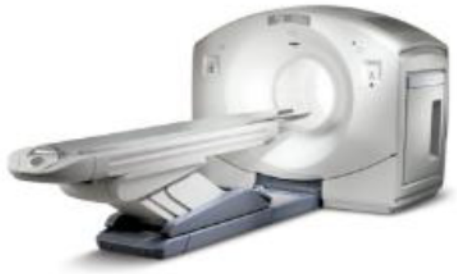
- Medical Imaging
- Radiotherapy
- Health ICT
- Electromedical

- In Europe, around 500,000 workers are employed in the healthcare sector. 95% of medical companies are SMEs employing less than 250 people.
- The global market for medical equipment is worth €100 billion with around €28 billion in Europe, and of this €20 billion for COCIR member companies.

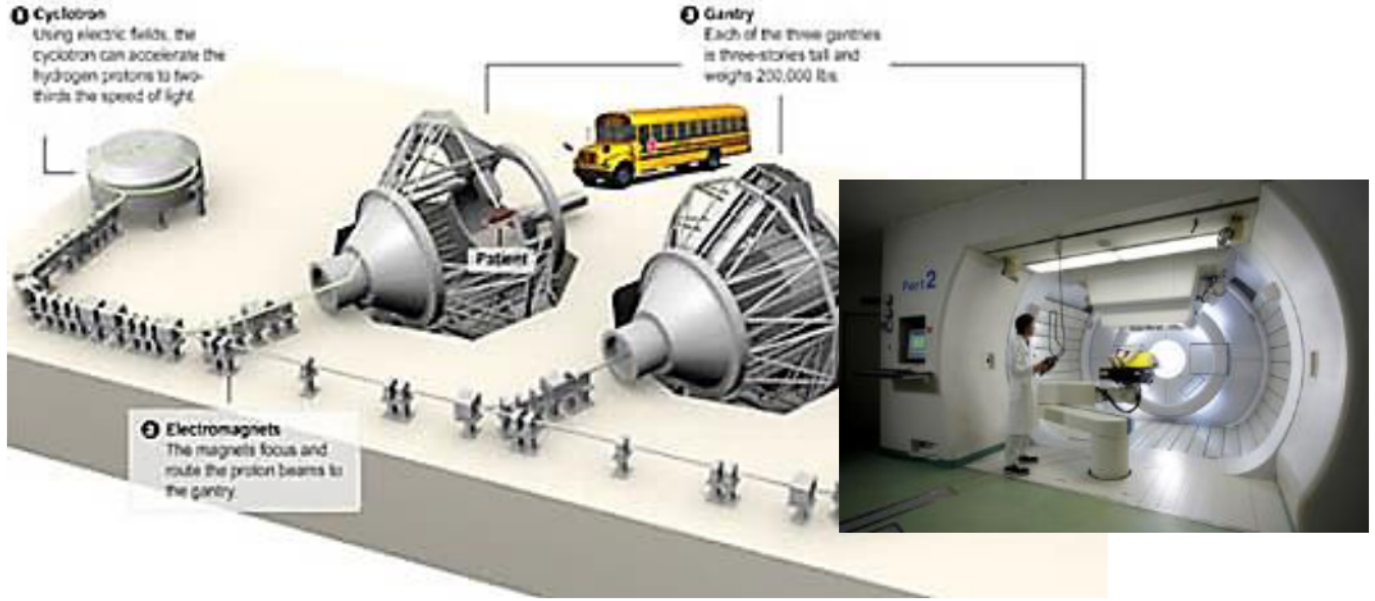


MEDICAL IMAGING and THERAPY DEVICES

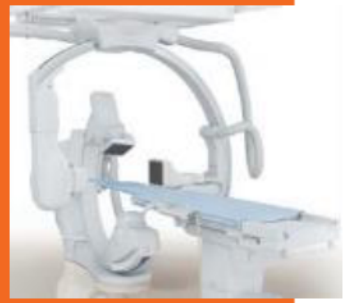
MAGNETIC RESONANCE



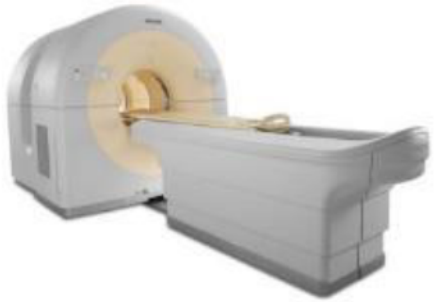
COMPUTED TOMOGRAPHY



PARTICLE THERAPY INSTALLATION



X-RAY



POSITRON EMISSION TOMOGRAPHY

LINEAR ACCELERATOR

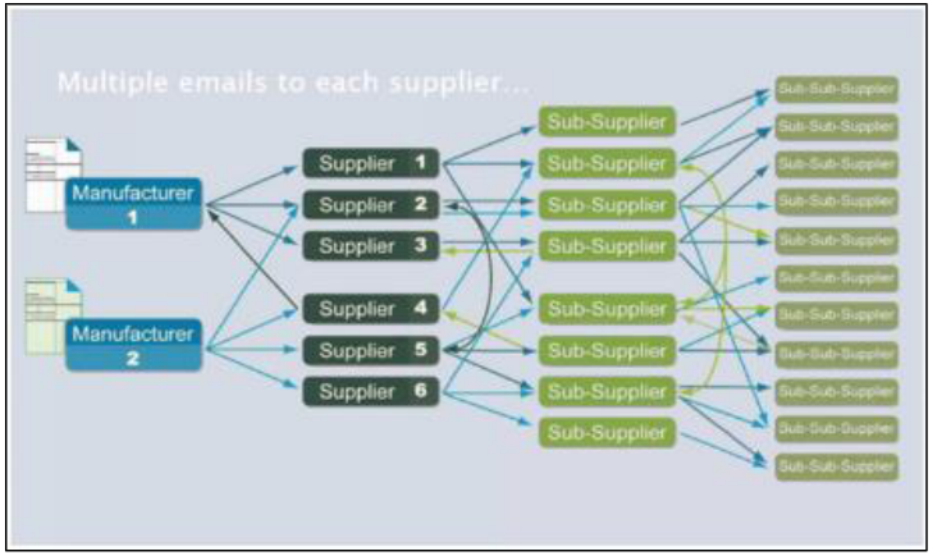
Complex products with long supply chains

Typical MRI unit weighs about 10 tons

- 3,600 assemblies
- 27,000 sub-assemblies
- 120,000 component parts
- More than 1,000,000 “articles”

Typical supply chain has 5 to 7 levels

- About 11,000 suppliers across the world
- 10 different languages



High value devices, low unit sales numbers

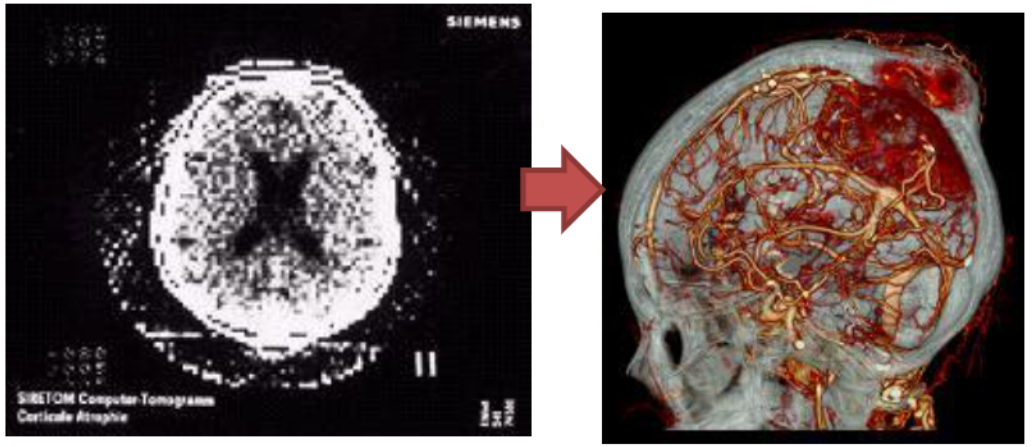
- Limited purchasing leverage even on 1st level suppliers

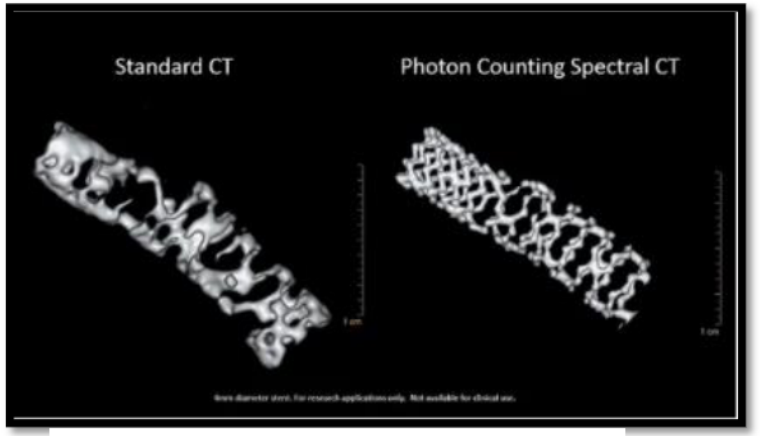
INNOVATION MEANS SAVING LIVES

- With an annual growth rate of 5% and investments in R&D representing up to 8% of sales volume, medical imaging and health ICTs are among the most innovative and dynamic industry sectors in Europe and globally.

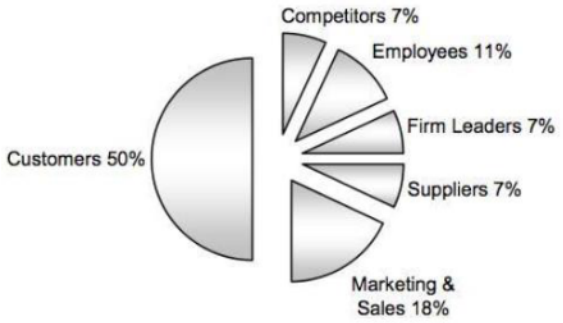
- The medical sector is also the first in EU for new patents

- New technologies contributes to earlier diagnosis and treatment, saving the lives or improving the quality of life for people around the world.



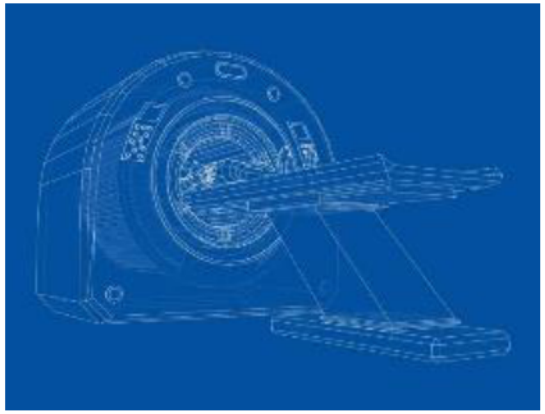


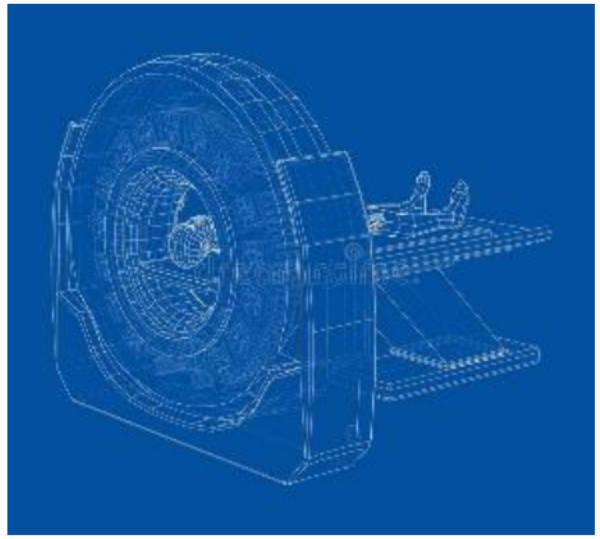
"What are the most important sources for innovative ideas?"



INNOVATION IS A COMPLEX AND LONG PROCESS

Since the ‘70s, 5 generations of PET scanners





7 years design cycle for imaging

20 years for IVDs

11 years for radiation therapy

10 years of market availability

THE EU CHEMICAL POLICY AND INNOVATION IN THE MEDICAL DEVICES SECTOR

THE EU CHEMICAL POLICY

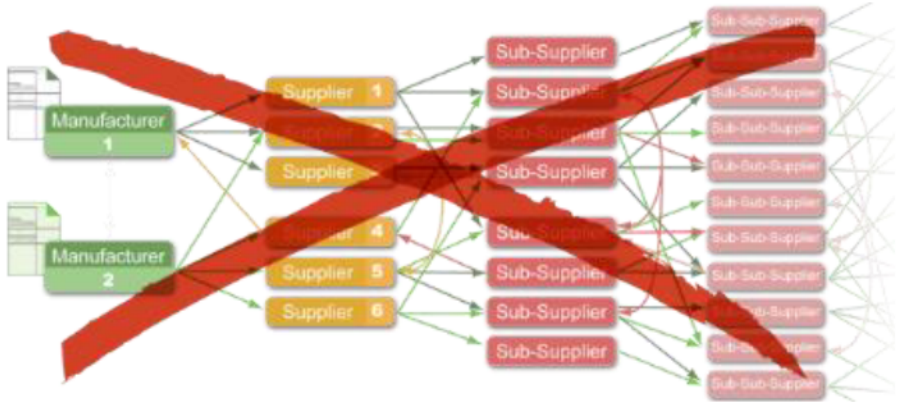
- Medical devices uses some substances of concerns as they provide benefits to patients (e.g. lead in shielding, cadmium in detectors)
- Legislation that applies to MDs
  RoHS, REACH, POPs, Batteries, MDR, etc
- To manage compliance, COCIR created in 2008 BOMcheck
- Today BOMcheck is the most advanced, blockchain based, commercial tool for managing the use of regulated substances along the supply chain

BOMcheck.net

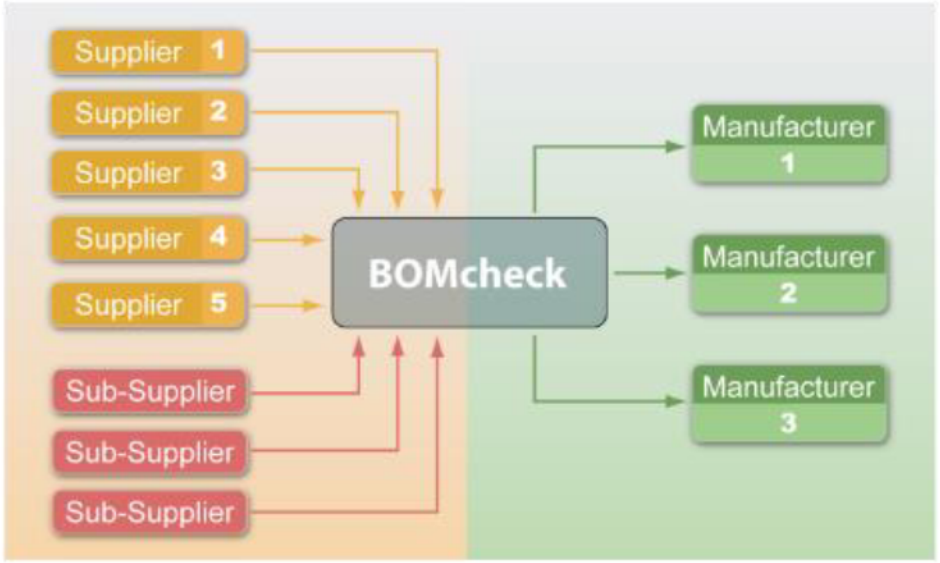
Bomcheck: The most effective way to comply with the SCIP database

Used by thousands of manufacturers and suppliers to track regulated substances in million of parts

Multiple emails to each supplier



Centralised system



21 March 2021

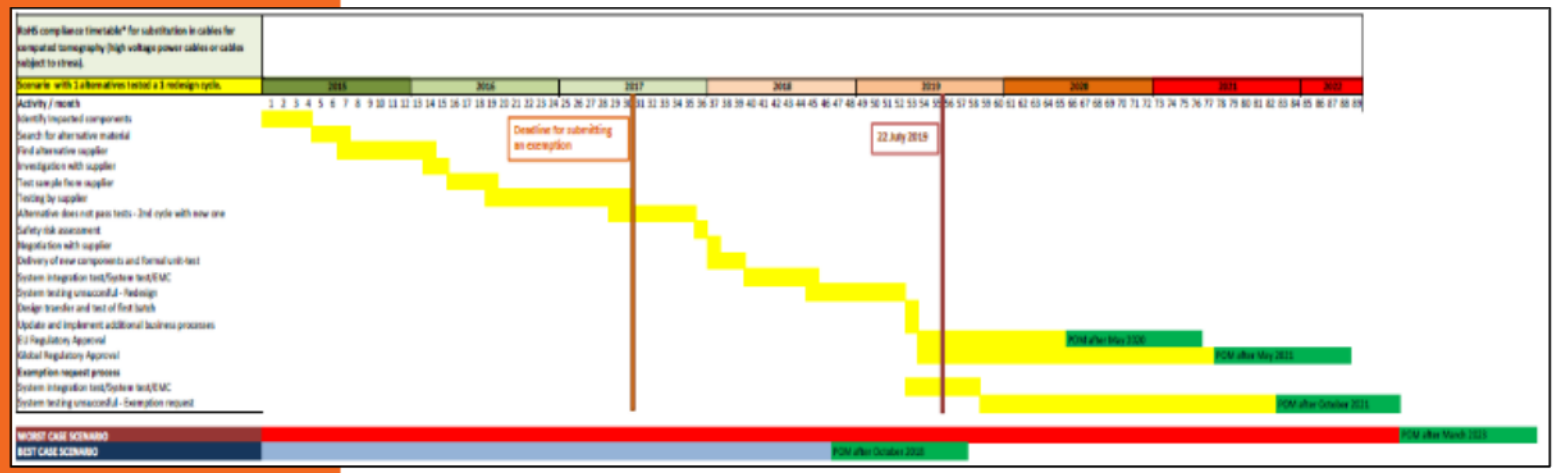
80% of the 6 million submissions to the SCIP database have been sent through BOMcheck

BOMCHECK and NEW SUBSTANCES

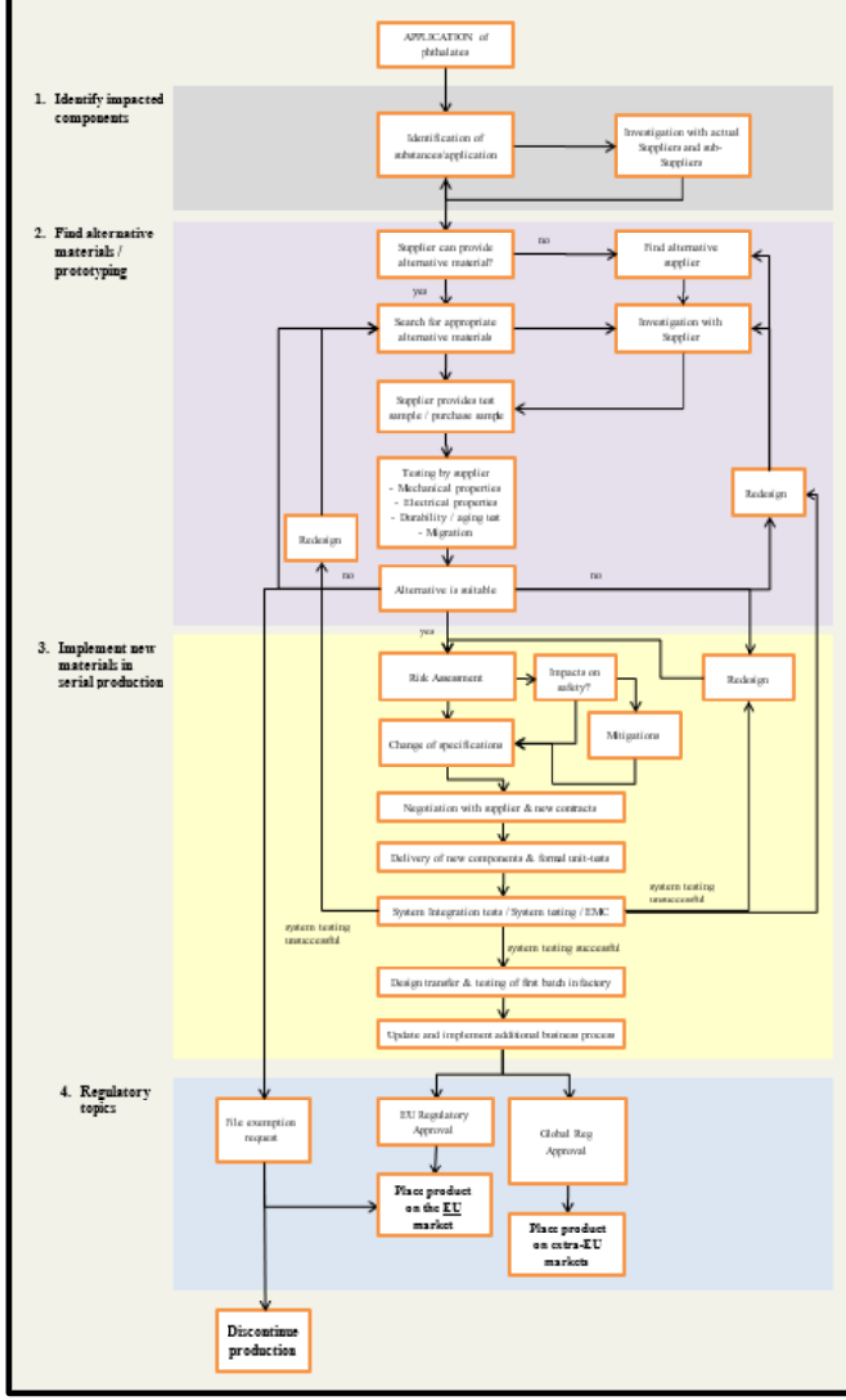
- When a new substance is added to the list of regulated ones anywhere in the world BOMCheck Team assess the uses.
- The substance is added to the next release of BOMcheck (3 months).
- All suppliers are notified to update their declarations in BOMcheck. The request is then propagated to the supply chain that still do not use BOMcheck. (in total 5k-10k)
- It takes 6 months to start getting information on uses.
- Some critical uses may be identified too late to request exemptions.
- Despite using the most advanced tool, it is impossible to collect complete information on uses/applications in the short time normally given for consultations (3-6 months).

Substituting substances in the medical device sector

- Complexity of the technology
- Need to carefully test alternatives to ensure safety, reliability and clinical performances
- Substitution requires a lot of time and resources, in term of engineers, researchers and technicians



Time required to substitute phthalates in high voltage CT cables

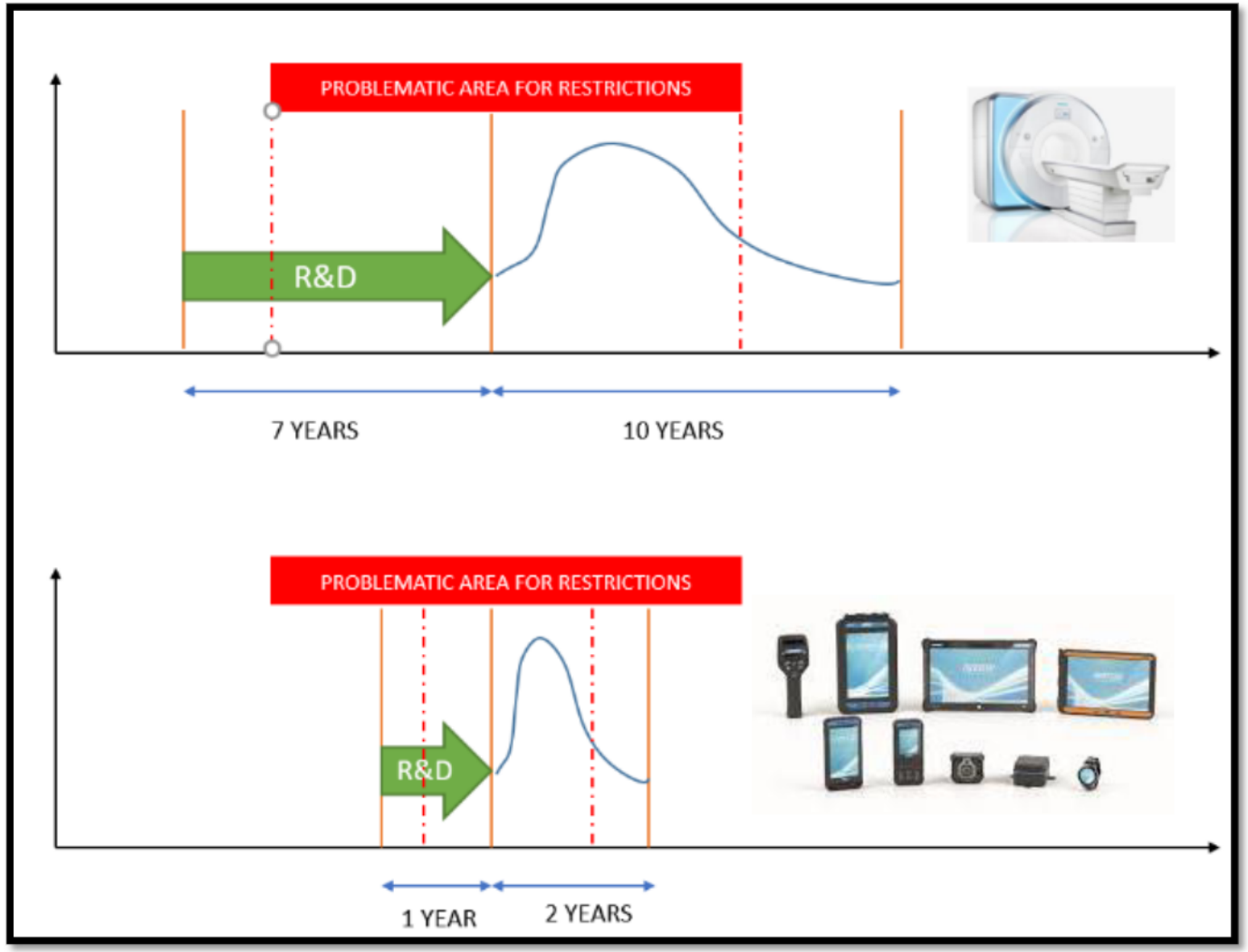


WHAT INNOVATION NEEDS

To continue innovate Companies require low investment risk:

Stable and predictable regulatory environment

- Enough time between restrictions not to interrupt R&D programmes
- Enough time to finish marketing old designs



CASE STUDY – ROHS EXEMPTIONS

	Medical Devices Years	Categories 1-7,10 Years
Innovation cycle	7	1
Market availability	10+	1-3
Total Life Cycle	**17+**	**<4**
Exemption validity	**7**	**5**

Innovation /Duration

7:7

1:5

A better balance must be found for medical devices

THE CURRENT CHEMICAL POLICY ENDS UP IN HIGH IMPACTS

- COCIR has taken active role in the evaluation of the RoHS 2 Directive.
- Study on impacts and benefits submitted to the consultant ECORYS
- RoHS benefits limited to 2,4% reduction
- 40+ exemptions out of 80 are for Medical Devices
- RoHS impacts were not envisaged during RoHS 2 Impact Assessment

RoHS substance	Amount used pre-RoHS (kg)	Removed by RoHS I (or REACH) (kg)	Quantity removed due to inclusion of category 8 in scope of RoHS 2 (kg)	Percentage removed due to inclusion of category 8 in scope of RoHS 2
Lead	1,119,546	2,955	26,591	2.4%
Cadmium	6,986	56	0	0%
Mercury	11	1	0	0%
CrVI	0.04	0.03	0	0%
PBDE*2	10,000	10.000	0	0%
PBB	Not used	n.a.	n.a.	n.a.
TOTAL	**1,136,543**	**13,012**	**26,591**	**2.4%**

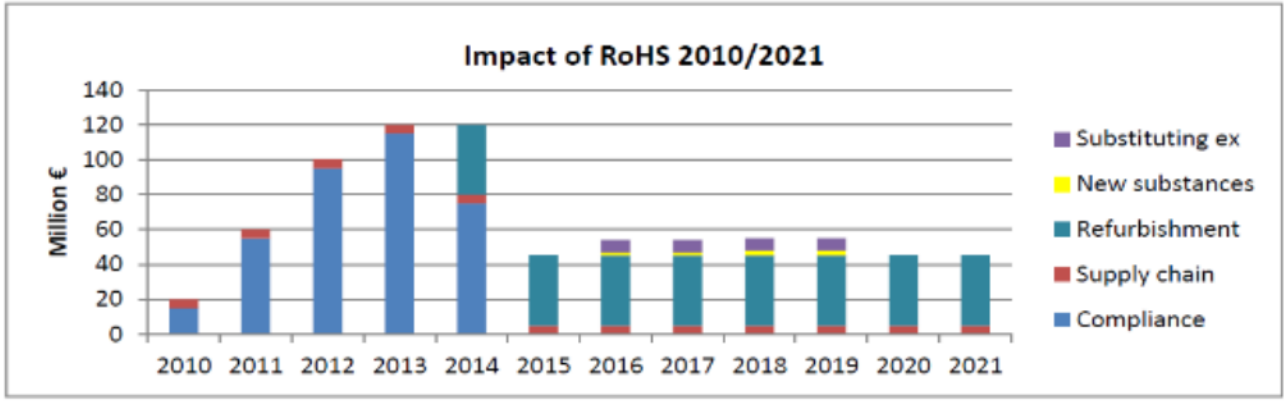


Fig. 8: Annual costs from the RoHS directive

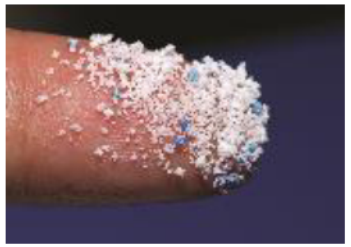
PROPORTIONALITY IS CRITICAL

Substitution with less harmful alternatives, while always welcome, may however not have significant benefits to human health or the environment

Lead in bearings of x-ray tubes

- 50g of lead per year, as much lead **as the content of a single reel of soldering wire. Cost 5€.**
- Would require costs for research programs, testing of alternatives, developing new ones, prototyping and testing, redesigning and regulatory approval.

80g of lead (100g of tin-lead alloy)



Microplastic in IVDs

- 200 Kg used in all Europe per year.
- Substitution would take 20 years of R&D program just to achieve the same performances of IVD tests
- Hospitals to invest Mils € on collecting wastewater instead of improving healthcare
- Huge environmental cost for incinerating millions of cubic meters of wastewater

Chemical strategy for sustainability

1. The current Chemical Policy changes too fast for complex medical devices.
2. Impact assessment of measures is performed for industry as a whole
3. The CSS will accelerate the EU Chemical Policy (more substances restricted in a shorter time)

CONTINUING INNOVATION IN MEDICAL TECHNOLOGIES

Innovation in the medical devices sector cannot be secured even by:

1. **Longer transition times** for new restrictions
2. **Longer duration** of exemptions/exclusions
3. **Dedicated cost/benefit and impact assessment** on innovation and healthcare to determine proportionality and mitigate undesired impacts

However, what is really needed is:

An alternative solution to restrictions that can achieve the same environmental protection goals limited to:

- Essential uses
- Small quantities
- Controlled conditions
- Monitored exposure and uses

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danke
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спасибо
dank je
thank you
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