Impact of a Potential Per- and polyfluoroalkyl substances Restriction

Part 1

Analysis of PFAS use and likely impacts of PFAS restriction on the EU medical imaging and radiotherapy sectors

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Authors: Riccardo Corridori (COCIR), Paul Goodman (RINA) and Emily Tyrwhitt Jones (RINA)

This submission has been prepared jointly by COCIR and RINA Tech UK Ltd.

RINA Tech UK Limited | 1 Springfield Drive, Leatherhead, Surrey, KT22 7AJ, United Kingdom | P. +44 0 1372 367350 |
UKinfo@rina.org | www.rina.org
Company No. 07419599 Registered in England and Wales

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ABOUT THIS REPORT : PART 1 OF 2

This document is a **first submission** with detailed information on technical reasons for a long derogation and socio-economic impact assessment of the proposal.

We expect to be able to provide in late Summer 2023 a **second submission** with data on all identified uses and quantities of PFAS. This submission concerns medical imaging and radiotherapy equipment but also other medical devices that are an integral part of modern imaging and radiotherapy suites.

SUMMARY OF ANALYSIS AND RECOMMENDATIONS

COCIR members understand the objectives of the proposal regarding PFAS, but would caution that any replacement, if available at all, should not endanger core functionality of the medical devices in scope, which serve essential tasks in modern medicine.
COCIR members use PFASs in a wide variety of electrical and non-electrical applications in the EU. These materials cannot be easily substituted as they form an integral part of the medical device. Any alternative with inferior performance could degrade the clinical performance of the devices impact directly and significantly the health of millions of EU citizens. The COCIR assessment of uses of PFASs suggests that substitution of PFASs could be possible in 13,5 years for medical imaging and radiotherapy equipment and associated accessories and medical devices required to perform imaging and radiotherapy procedures.
COCIR estimates around **10 tonnes per year** are used in Europe in medical imaging and radiotherapy devices, almost all in fluoropolymers. **0,0012%** of the estimated total usage of PFAS in Eu and **0,02%** of the total usage estimated for the medical devices sector in the restriction proposal.

COCIR's members are still reviewing PFAS uses, and this is not expected to be complete for at least one year. The most common uses of PFAS are as polymers, mainly as flame-resistant polymers used in various types of components and equipment, including:

- Cables and wiring and electrical connectors. Some current uses such as in MRI, X-ray and ultrasound imaging will be very difficult to replace due to the unique properties of fluoropolymers
- Printed circuit boards and, other plastic electrical and electronic components, such as relays, transformers, inductors, sensors, etc.
- Other non-electrical components, such as housings

PFAS are also used in lubricants. So far COCIR has identified an application in automatic injectors used for injecting contrast agents used in imaging procedures such as x-ray and CT. PFAS are used because they provide unique combinations of essential performance, such as flexibility, suitability at high and low temperature, dielectric properties, fire resistance, resistance to sterilising chemicals, biocompatibility, etc.

The following elements, analysed in this report support the request for the derogation duration:

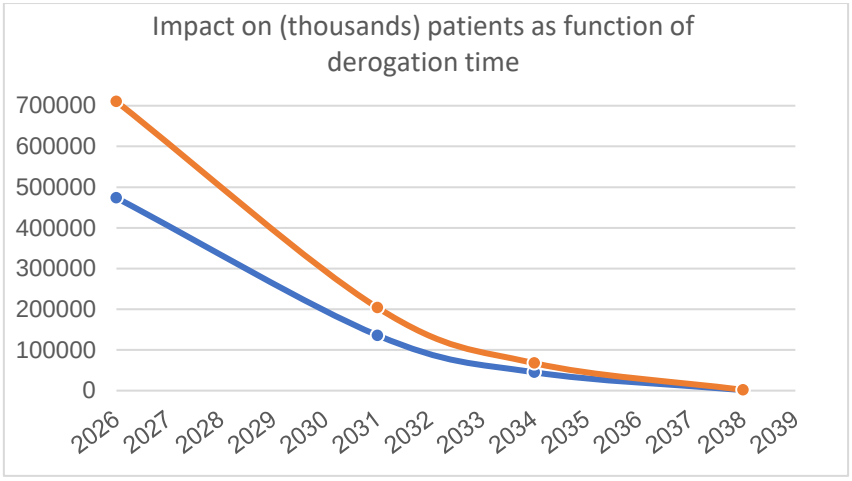
Technical aspects (Chapter 3)

1. Identifying all PFAS applications within a global supply chain of 5.000 to 11.000 suppliers and assess possible alternatives will require years. Many alternatives cannot be tested until the PFAS and possible substitutes identified
2. PFAS-free components can only be tested and integrated into new designs once available. Most of the components will become available just before the expiry of their derogations. If, for instance, a derogation of 5 years is granted to semiconductors, most alternative components probably we will not be able to start testing and equipment redesigning before that expiration date. The design cycle of medical imaging devices is 5 to 7 years while for radiotherapy equipment is 9 to 11.
3. Companies have limited specialized technicians and engineers while having a wide portfolio of applications. As already proven under RoHS, redesign takes time and resources. It is not possible to have too many models being redesigned in parallel.
4. For certain applications there may not be alternatives providing the same clinical performances even in the expected timeframe, and therefore extension of derogations may be required.
5. Despite using some of the best substance tracking tools, there are still likely to be unidentified uses which will not be found by companies until late in the substitution process. Even a 13,5-year derogation cannot shield companies and healthcare providers from the consequences of suppliers' mistakes.
6. Medical imaging and radiotherapy devices are regulated by the Regulation (EU) 2017/745 (MDR). This regulation ensures a high level of certainty, requiring the certification of all devices before their placement on the market. Strict considerations are established in terms of patient safety, demanding extensive testing, clinical evidence and the implementation of risk management systems.

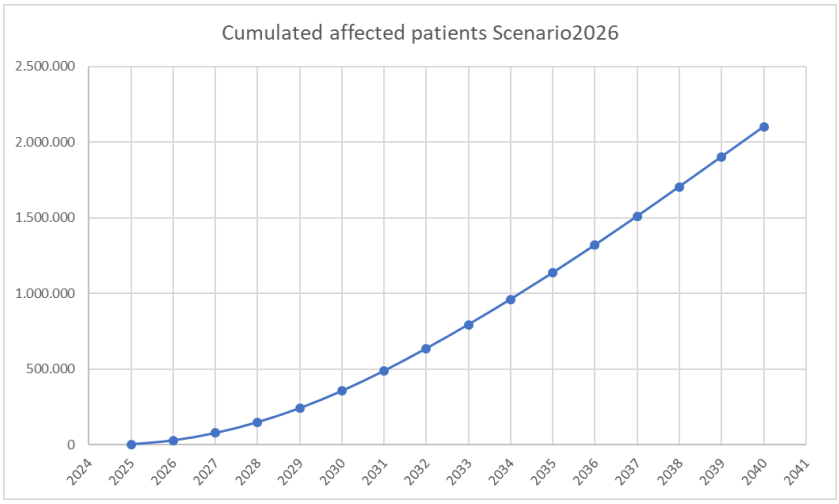
Socio-economic impacts (Chapter 4)

Without a derogation for a sufficient number of years we expect that the technical impossibility to substitute all PFAS applications and to redesign all models will cause serious impacts on the availability of medical devices with the following consequences:

7. Devices being discontinued with a consequential **reduction in access to healthcare for hundreds of millions of patients** for a long period (from EIF to at least 2040). It would take probably far after 2040 before sales would recover but the decrease in the installed base (density) will not. See chapter 4.4.
8. The reduction in density can possibly cause **tens of millions of cancer patients** not to receive proper healthcare and maybe reduce their chances for better outcome (see chapter 4.5) at least until (and beyond) 2040. A 13,5-year derogation could lower such numbers to a few thousands.
9. The impact on cancer patients is compounded by the recent surge in cancer cases, reportedly up by 40%, that will require an even larger increased availability of radiotherapy centres.
10. The already serious problem with waiting times for healthcare getting longer in the EU will be exacerbated and add to the negative impacts so far experienced.



The simulation shows that with a 13,5-year derogation the impact on patients access to healthcare will drop from hundreds of millions to a few millions.



Several million cancer patients at risk of less-than-optimal care (mortality in EU)

For the above-mentioned technical reasons and in order to avoid the social impacts **COCIR recommends derogating medical imaging and radiotherapy devices for 13,5 years.**

At the end of the derogation period it may be possible that some uses could be identified for which alternatives will not be available, or where the alternatives would be regrettable substitutions. In these cases, a mechanism to renew the derogation would be essential. A review clause is included in our proposal, supposing 3 years for the evaluation of derogations are sufficient.

11. The “repair as produced principle” is essential to allow continue servicing and repair of medical imaging and radiotherapy equipment in use at hospitals and clinics in the EU.
12. Refurbishment of medical devices requires spare parts to be available to refurbish used devices. As such, the restriction wording must allow for this practice to continue delivering affordable healthcare and benefits of suitable equipment.

13. It has been already proven under RoHS, for exemption 31a and 47 that the reuse of spare parts is always better from an environmental perspective than generating waste and manufacturing a new one (which may use critical raw materials or other SoCs).

COCIR Recommendations for the wording of a derogation

1. *By way of derogation, paragraphs 1 and 2 shall not apply to PFAS for the use in medical imaging and radiotherapy devices their accessories and other medical devices within the scope of Article 2(1) of Regulation (EU) 2017/745, required in a modern imaging suite or radiotherapy procedures and designed to work in such environments such as contrast injectors, patient monitoring, etc. until EIF+ 13,5 years.*

2. *Paragraph 1 and 2 shall not apply to PFAS for the use in new and recovered spare parts to repair, service, updating of functionalities or upgrading of capacity or refurbishment of medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market before EIF+13,5.*

3. *Paragraph 1 and 2 shall not apply to medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market for the first time before EIF+13,5*

4. *Paragraph 1 ad 2 shall not apply to PFAS in spare parts recovered from and used for the repair, reuse, updating of functionalities or upgrading of capacity or the refurbishment of medical imaging devices, radiotherapy devices and other me, provided that the reuse takes place in auditable closed-loop business-to-business return system and that each reuse of parts is notified to the customer.*

5. *The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector, their accessories and other medical devices required in a modern imaging or radiotherapy suite, by EIF+10 years to assess the need to maintain the derogation for specific applications for which no alternatives are yet available. The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector by [10 years after EIF] to assess the need to maintain the derogation for specific applications for which no alternatives are yet available and to publish proposed amendments to the Regulation.*

This wording proposal ensures, point by point:

1. Enough time for substitution without impacting innovation and availability of medical devices and therefore patients access to healthcare in the EU.
2. Installed medical devices owned by hospitals will be maintained fully functional until the end of their lives instead of being prematurely discarded with a reduction in accessibility to healthcare affecting patients.
3. Medical imaging and radiotherapy equipment (capital investment equipment for healthcare providers) can continue to be sold, transferred, leased, donate between hospitals, taken back and refurbished to increase safety and performances.

4. Circular economy activities such as refurbishment and reuse of recovered spare parts can continue benefitting EU hospitals, ensuring fast and cheaper repairs and shorter downtimes.
5. Certain timelines and obligations would ensure that industry can get the required extension, when needed, without the risk of having to stop orders and sales due to the delays in the evaluation process

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ABBREVIATIONS AND ACRONYMS

3D- CRT	Three dimensional conformal radiotherapy
BOMCheck	A software tool for identifying and managing hazardous substances within product parts
COCIR	European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries
Covid	Coronavirus disease 2019
CT	Computed tomography – multi-directional X-ray for diagnostics
DEHP	Diethyl hexyl phthalate
DP+	Dechlorane Plus
ECHA	European Chemicals Agency
EDI	Electronic data exchange
EEE	Electrical and electronic equipment
EU	European Union
FDA	Food and Drug Administration, USA
G-force	Gravitational force
IGRT	Image guided radiation therapy
IMAT	Intensity modulated arc therapy
IMRT	Intensity modulated radiation therapy
LINAC	Linear particle accelerator, used for different treatment procedures (3-D CRT, IGRT, IMRT, SBRT, IMAT)
MDD	Medical Devices Directive
MDR	Medical Device Regulation
ME / ME device	Medical electrical / Medical electrical device
MR signal	Magnetic resonance signal
MRI	Magnet resonance imaging – detailed imaging of soft tissues
OEM	Original Equipment Manufacturer
PET	Positron emission tomography – A type of nuclear imaging technique used for diagnostics
PVC	Polyvinyl chloride
R&D	Research and development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
RINA	RINA Tech UK Limited
RoHS	Restriction of Hazardous Substances Regulation
RT	Radiotherapy – a photon-based X-ray cancer treatment
SBRT / SABR	Stereotactic body radiotherapy / stereotactic ablative radiotherapy
SPECT	Single photon emission tomography – A type of nuclear imaging technique used for diagnostics
SVHC	Substance of Very High Concern as defined in the REACH regulation, and on the Candidate List for Substitution
TV	Television
US/USA	United States of America
WEEE	Waste electrical and electronic equipment

1 INTRODUCTION

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health information and communications technology (ICT) and electromedical industries. RINA Tech UK Limited (RINA) and COCIR have gathered information from COCIR members and other sources to respond to the call for comment on the restriction of per- and polyfluoroalkyl substances (PFASs). This is the preliminary version of our submission. A more complete version of this report which will include more data on specific uses and quantities of PFAS will be submitted in late Summer 2023.

A restriction of the production, marketing, and use of PFAS is currently under consultation for the forming of the RAC and SEAC Opinions. This report is intended to provide The European Commission, European Chemical Agency (ECHA),the Member States and RAC and SEAC Members insight into the use of PFAS within medical equipment produced by COCIR member companies, and to provide information about the likely impact of restriction on the refurbishment of medical equipment and associated spare parts depending on how much transition time is given to the sector.

1.1 Profile of the COCIR membership

COCIR members manufacture and support medical imaging technology, radiotherapy, and digital equipment for health. Although COCIR is a Europe-wide organisation, it has international presence in China, and its members supply medical devices and equipment internationally.

Medical Imaging Technology

Medical Imaging technology is an essential component of the care pathway, adding value at every stage where it is used. It contributes to better, more accurate diagnoses from the outset and, through ongoing monitoring and measuring, allows for improved care decisions and more effective treatments and outcomes.

Source: COCIR

Figure 1: Example of COCIR member imaging equipment

Source: COCIR

Figure 2: COCIR member imaging and control equipment

Medical imaging using ionising radiation includes anatomical (X-ray, CT) and physiological, or functional, images (Nuclear Medicine – PET and SPECT).

- X-ray radiation can generate three kinds of medical images; conventional X-ray imaging, angiography (using a contrast agent), and fluoroscopy (real-time X-ray to observe movement like beating hearts).
- CT scan, or Computed Tomography, is an imaging technique that combines multiple X-ray images taken from different angles. This produces detailed cross-sectional internal images.
- Positron Emission Tomography (PET) and Single Photon Emission Tomography (SPECT) are types of nuclear imagine techniques that provide physicians with information about how tissues and organs are functioning.

Medical imaging using non-ionising radiation includes Magnetic Resonance Imaging (MRI) and Ultrasound.

- Magnetic Resonance Imaging (MRI) is a technology that uses radio waves and a powerful magnetic field to provide detailed images of organs and tissues. The type of radiation in this kind of imaging technique generates images of the soft tissues, omitting the bones. This characteristic has proven highly effective in diagnosing a number of conditions by showing the difference between normal and diseased tissues.
- Diagnostic ultrasound, also known as medical sonography or ultrasonography, uses high frequency sound waves to create images of the inside of the body and is used to examine soft tissues.

Radiotherapy

Radiotherapy (RT) has evolved to be one of the essential therapies for cancer treatment. It uses X-ray photons to impact tumours and destroy its genetic material to prevent its further growth. Currently, three types of RT are available: external beam radiation, internal radiation (Brachytherapy) and systemic therapy. The type of radiation used depends on several factors including; the size of the tumour, the type of cancer, location in the body, age of the patient, and other possible medical conditions.

Stereotactic radiosurgery is a form of radiation therapy that focuses gamma rays or X-rays on a small area of the body. Other types of radiation therapy are more likely to affect nearby healthy tissue. Stereotactic radiosurgery targets the abnormal area better.

External beam radiation uses a source of X-ray or gamma ray beams directed to the patient, who is positioned in front of the radiation source a few centimetres away. The equipment used for this therapy is called Linear Accelerator (LINAC). The following are examples of External-beam radiation therapy devices:

- Ionizing radiation accelerators using X-rays and gamma rays in combination with a number of different treatment procedures:
  - 3-dimensional radiotherapy (3-D CRT),
  - Image guided radiation therapy (IGRT),
  - Intensity modulated radiation therapy (IMRT),
  - Stereotactic body radiotherapy / stereotactic ablative radiotherapy (SBRT),
  - Intensity modulated arc therapy (IMAT).

Figure 3: External Beam radiation therapy installations

- Ionizing radiation accelerators using charged particles:
  - electron beams,
  - proton beams
  - carbon ion therapy

Figure 4: Proton Therapy installations

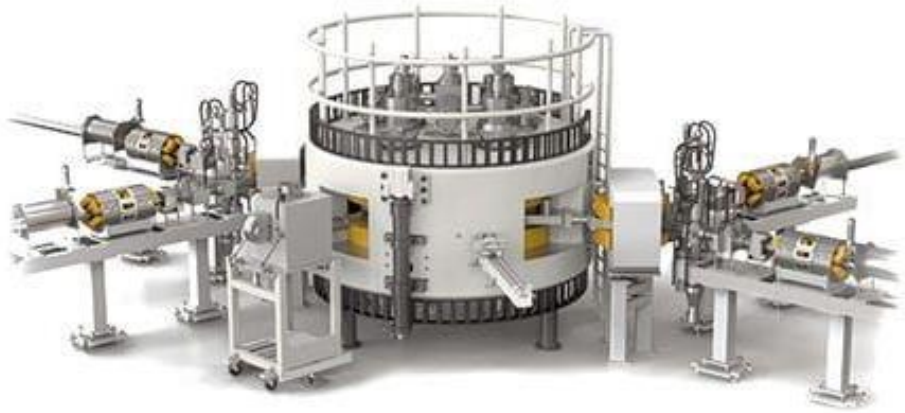


Figure 5: Cyclotron for proton beam generation in a Proton Therapy installation

Figure 6: Schematic of a proton therapy centre

Lower dose Brachytherapy (Internal Beam Radiation therapy) is performed by implanting the radiation source in the body of the patient; the low dose radiation energy source will decay over time, while irradiating the tumour. At the end of the therapy, the source material can be left in the body since the level of radioactivity decays within a matter of hours to days.

High dose Brachytherapy (Internal beam radiation therapy) consists of planting a temporary catheter in order to reach the tumour and provide radiation directly to the tissue, removing the source at the end of the session. The internal beam radiation therapy can be used in combination with an external beam radiation therapy to boost the speed of the therapy.

1.2 Complexity of medical imaging and radiotherapy devices

Medical imaging and radiotherapy devices are very complex technologies. Designing one new model requires between 5 and 12 years that can potentially remain in a company's product portfolio for up to 10-20 years. Companies cannot redesign all of their models simultaneously as there are insufficient design engineers to do this and so it would take much longer to redesign their portfolio of products.

Such devices weigh between 5 and 15 tons on average, with particle therapy installation exceeding several hundred tonnes and consisting of up to tens of thousands of parts (1,000,000 homogenous materials), with thousands of suppliers in several tiers spread all over the world.

Source: COCIR

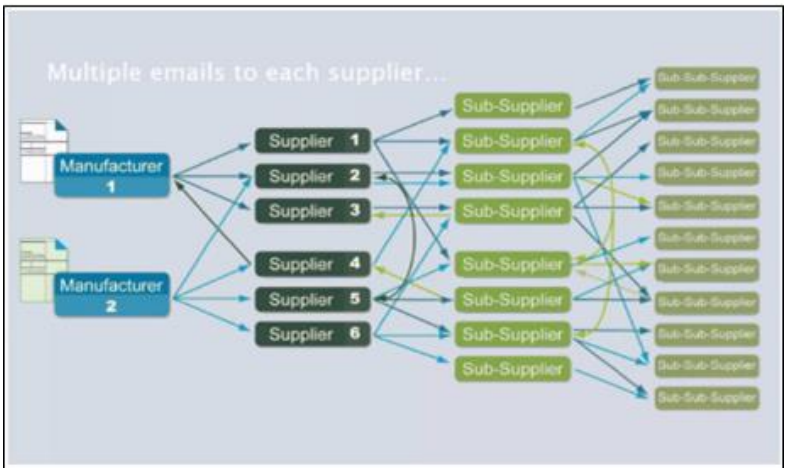
Figure 7: Example medical device: Magnetic Resonance Imaging (MRI) equipment

Typical MRI unit weigh about 10 tonnes and comprise:

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

For COCIR members, the typical supply chain has 5 to 7 levels indicatively comprising:

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



Source: COCIR

Figure 8: Medical Device Supply Chain Illustration

Medical imaging and radiotherapy equipment is very complex and some parts experience hostile and extreme environments, such as exposure to ionising radiation, severe vibration and MRI uses very low temperatures. Most types of MRI scanners made by COCIR member companies use very powerful superconducting magnets. These must be cooled in liquid helium at -270°C for the superconductor to function and this very low temperature limits the types of materials that can be used. Fluorinated polymers are suitable for use at temperatures well below -200°C as it is flexible at this temperature, which is essential because MRI experience severe vibration. Most substitute polymers cannot be used at such low temperature because they are too brittle and the few types of polymers that are specified as suitable are not suitable as flexible wire insulation[1]. For example, PVC is only suitable down to -40°C and silicone to -50°C. Finding a substitute will therefore be challenging and a complete redesign of the system is likely to be needed.

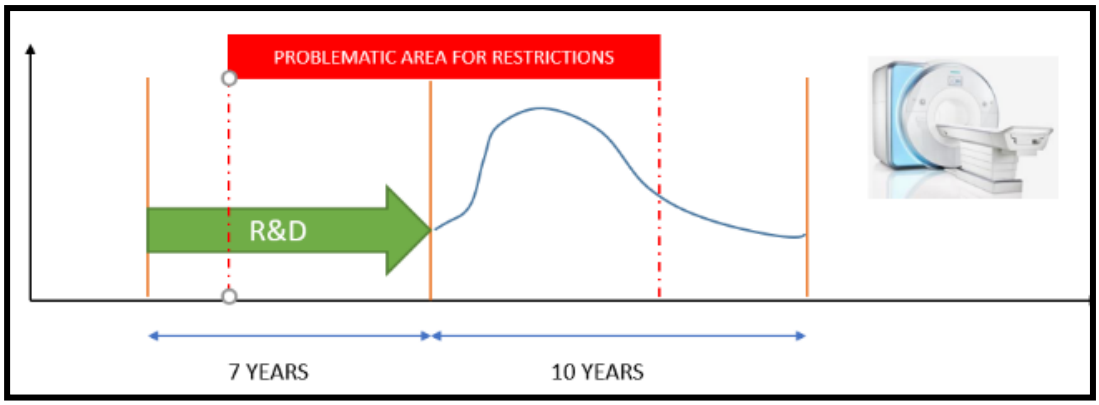
1.3 The importance of innovation in the medical imaging and radiotherapy sector

Innovation in the medical devices sector has historically been purely to develop better medical technologies to diagnose and treat patients in the EU and worldwide. The medical devices sector is one of the most innovative in the EU with companies investing 7 – 8% of annual sales volume on new product development, and the sector is first for the number of patents every year.

Investments in research and development (R&D) have a very long-term horizon ranging from 7 to 12 years. This contrasts with the fast pace of EU chemical policy as it regularly introduces new requirements which can impact on R&D programmes and increase the risk for long term investment, therefore reducing the capability of companies to develop and bring to the market new medical technologies that offer benefits for patients.

Any restriction entering into force during the R&D phase can force companies to stop the project and lose several years in redesigning their new technologies (the closer to the end of the R&D, the worse this impact is). In a similar way, any restriction entering into force during the sales of a model, can halt the sales as redesigning existing models is usually not an option.

[1] *https://www.findoutaboutplastics.com/2020/01/high-performance-polymers-suitable-for.html#:~:text=Besides%20fluoropolymers%2C%20other%20high%20performance,PI%20can%20also%20be%20used.*



Source: COCIR

Figure 9: Illustration of impact of introducing a substance restriction on a large medical device

2 USES OF PFAS WITHIN COCIR MEMBER COMPANY PRODUCTS

Some uses of PFAS are already known to COCIR's members which are outlined within this report, however additional uses are expected to be identified in the updated report that will be submitted closer to the Summer Break 2023. It is very likely though, due to the complexities of the products, number of PFAS and lack of CAS numbers that many PFAS uses will remain unknown by the deadline of the submission..

Electrical components and cables

Some types of electrical and electronic components contain fluoropolymer insulated wires. This is required because these components are surface mount soldered onto circuit boards by heating them inside ovens at over 240°C and most alternative polymers cannot withstand this temperature. COCIR will need to rely on component manufacturers to substitute PFAS in components such as surface mount relays, transformers, inductors, etc. and the electronics industry has stated that this will take five years. It is likely that some components will become obsolete, and this is especially likely for those parts made in only small numbers or if substitution proves to be technically impossible. This would mean that there will not be drop-in replacements for some types of components available to COCIR members and so their only option will be to redesign circuit boards and equipment. This is regarded as a significant change requiring Medical Devices Regulation approval which will take many years after the component supplier announces the obsolescence. Under these circumstances, it is more likely that the product will become obsolete.

Fluoropolymer insulated cables are used in many types of imaging equipment due to its unique combination of properties which include:

- They are inherently flame resistant, so flame retardants do not need to be added to the polymer.
- Excellent flexibility which is important when making connection to moving parts such as patient tables in MRI and connections to X-ray sources and detectors.

- They maintain flexibility and stability over a very wide temperature range, for example, fluorinated ethylene propylene (FEP) can be used in temperatures well below -200°C to over +200°C. Some areas close to the superconducting magnet inside MRI scanners can reach very low temperatures, with some instances below -200°C.
- Cables with fluoropolymer insulation are suitable for very high frequency signals, which is essential for transmitting huge amounts of data generated by MRI, PET, and CT scans.
- Fluoropolymers are biocompatible according to ISO 10993, which means that they can be placed in physical contact with patients' skin. Most alternatives have not been certified as biocompatible.
- Other essential performance properties include suitability for heat, chemical and UV sterilisation and low friction resistance.

Further illustrative example uses of fluoropolymer cables in medical devices include:

- Cables used to connect to MRI coils which are devices that are placed onto the parts of patients being scanned. These cables must have a negligible impact on the image quality. MRI detect hydrogen atoms in materials in patients' bodies and so hydrogen atoms in the materials of cable connections must be minimised by careful selection of materials. Fluoropolymers have a very low hydrogen atom content being based on -CF2- groups in polymer chains whereas all non-PFAS polymers are based on -CH2- groups. Substitution for PFAS will therefore be very difficult.
- Insulation made with PFAS polymers can be very thin and very flexible; this is essential for making electrical connections to some types of ultrasound probes which require 40 – 50 thin individual wires to connect to the ultrasound probe array. The wires must be very thin and flexible to allow the medical technical to move the probe precisely to where it is needed. Also, the PFAS insulation used is biocompatible according to ISO 10993. Very few other polymers are biocompatible and most other polymers used for wire insulation are thicker and less flexible.

Integrated circuits (IC) are widely used by all of the electronics industry. PFAS is used to manufacture these components and so where this occurs in the EU, it is likely that many types of IC will become obsolete. Medical device manufacturers will therefore need to redesign circuit boards when this happens. One COCIR member company has reported that one MRI contains 600 separate printed circuit boards all of which contain ICs. It typically takes one design engineer one year to redesign one circuit board. If many ICs become obsolete and many circuits need to be redesigned, this can take many years due to the limited number of design engineers who are capable of doing this work. In addition, after redesign, the MRI must be tested and re-approved by an EU Notified Body before it can be sold in the EU which takes many years. Another COCIR member reports that when one important IC was made obsolete, it took nearly 5 years before a redesigned product could be sold in the EU and at a cost of €5million.

Lubricants

PFAS is used in lubricants. A critical use that have been identified so far, is the use in automatic injectors that are used to inject minute quantities of contrast agents into patients for most imaging procedures, such as CT or fluoroscopy examinations.

2.1 Quantities used in medical imaging and radiotherapy products

In this chapter we provide an initial estimation of the quantities of PFAS fluoropolymers used in the medical imaging and radiotherapy devices sector.

Considering we are still collecting data we considered all possible applications of PFAS as actual application unless proven differently. This is probably producing an overestimate.

In general, we estimate 300g of PFAS fluoropolymers for big scanners such as CT, MRI, PET etc and similar quantities for LINACS. Far lower amount in smaller devices such as Ultrasound and X-ray devices.

This first exercise results in a total of **10.6 tons** of PFAS used in the sector in Europe every year, almost 100% fluoropolymers.

Considering the quantitates reported in the restriction proposal, COCIR accounts for a **0,0012% of the total manufacture and uses** of PFAS in Europe and **0,02% of the use in the medical devices sector**

Total COCIR usage of PFAS

Quantity (t/y)	% of total use	% of use in the medical devices sector
10,6	**0,0012%**	**0,02%**

3 TECHNICAL ASSESSMENT OF TRANSITION TIME TO PFAS-FREE ALTERNATIVES

PFASs are reported by COCIR members to be widely used in medical devices and therefore many materials and components will need to be changed. In many cases, substitution will be initially carried out by the component manufacturer. Once these alternatives are available, medical device manufacturers will then need to assess the alternative to ensure it meets the necessary technical and safety requirements. Only when all of the substitutes have been identified, replaced, evaluated, and proven to be suitable, and proven to be no less reliable, accurate or effective and safe can they be used in a medical device, and it can be approved for sale in the EU.

Additionally, changes in electronic components, such as different IC die attach formulations, will need extensive life testing to ensure the medical equipment is safe and reliable. Many components are used in harsh environments that produce excessive mechanical and thermal stresses, such as high G-forces in CT gantries, extreme temperatures in MRI magnets, and extremely high magnetic fields.

As an example of this, when the Restriction of Hazardous Substances Regulation (RoHS) Directive took effect in 2006, it was found that many older types of IC became obsolete with

no compliant versions being made to replace them. If this occurs due to restriction of PFASs, users of these components will need to redesign circuitry, rewrite software and for medical devices, obtain approval under the Medical Device Regulation (MDR). In the past, exemptions under the RoHS Directive have never been granted for obsolete components as circuit redesign is regarded as an alternative, however this takes a considerable length of time.

There may be some parts which will be relatively easy to find suitable substitutes; for example, simple mains power cords are used in most mains powered electrical equipment and suitable replacements should be available once all relevant testing has been undertaken on the change. This is likely to be an uncommon situation though, as fluoropolymers are relatively expensive so are used only when cheaper alternatives are unsuitable or give inferior performance. It is also worthwhile noting that medical devices also use special cable assemblies of complex designs that need to function in unusual conditions. For example, there are cables in CT that need to operate at very high frequency and high power.

Source: COCIR

Figure 10: Representation of the complex internal structure of a CT cable

There are cables used in Magnetic Resonance (MR) devices that will experience extremely low temperatures and severe stresses while they need to be safe in high magnetic fields and to be extensively tested in MR environment to ensure image quality is not affected:

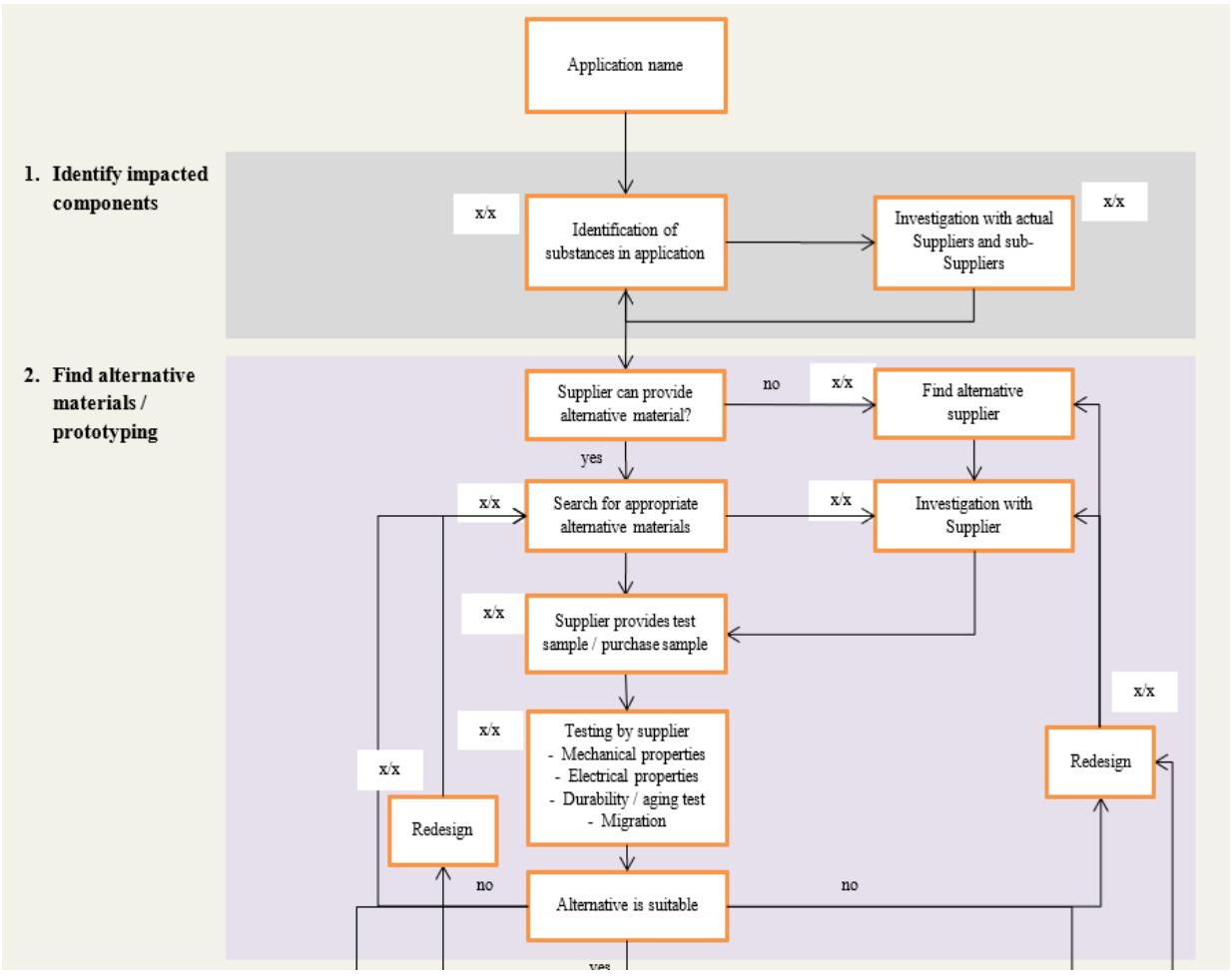
- MR signal: All materials used in or near the imaging volume of MRI scanners are required to not exceed a certain level of electromagnetic response in the frequency range of interest for MR imaging during and after exposure to electromagnetic excitation by MR transmit signals.
- Spikes: Any material used within the MRI exam room has to be evaluated for potential build-up of electrostatic energy that could discharge during imaging to an extent hampering MR imaging (spikes).

Although there may sometimes be alternatives, these will only rarely be a suitable drop-in replacement and so material reformulation will usually be needed. In many cases, no suitable alternative material is identified, then substitution may be achieved only via redesign, and this will take much more time and will require re-approval by an EU Notified Body. In these instances, a derogation from the restriction would be essential for the continued supply to EU hospitals and clinics of these products, or alternatively exclusion

from the restriction altogether by derogation, so that the sector has the necessary time to develop an alternative for these applications.

3.1 How alternatives are tested and validated

The flowchart produced by COCIR[2] shown over the next few figures illustrate all the steps that companies in the medical imaging and RT devices sector have to take to find suitable alternatives. How the overall workflow fits together is illustrated in Appendix A.

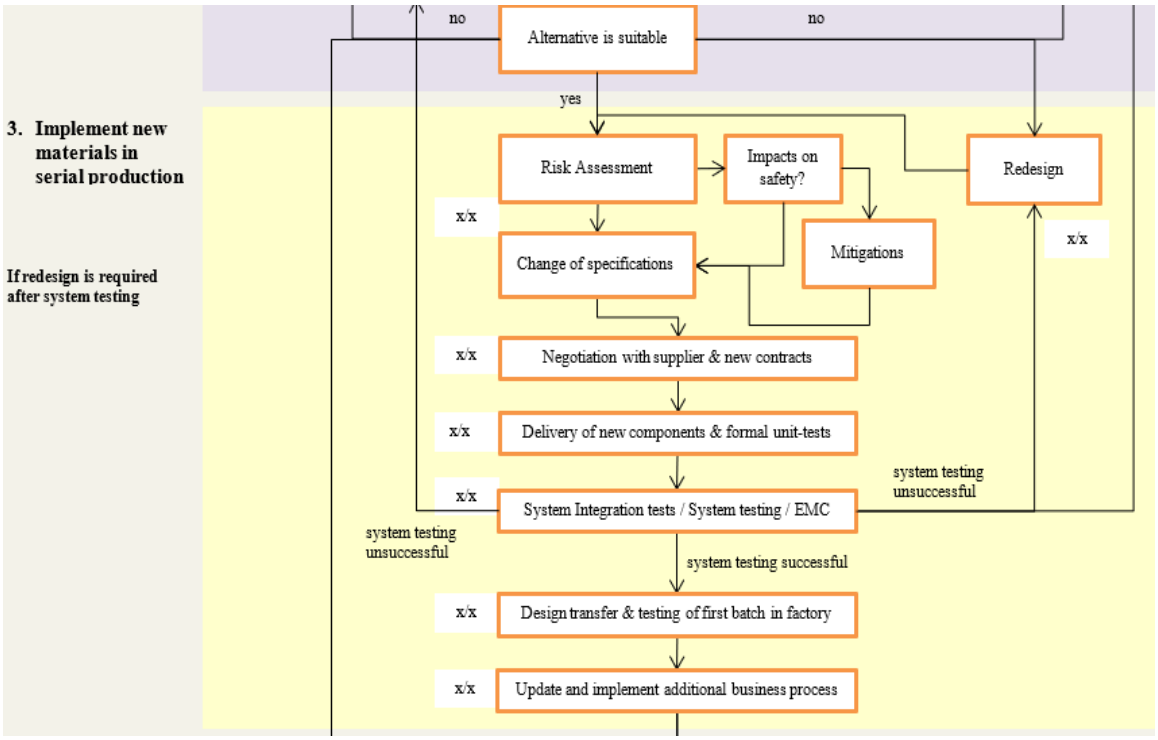


Source: COCIR

Figure 11: Flowchart steps 1 & 2: Identifying alternatives working with suppliers prototyping and testing of new components

This flowchart is continued in Figure 12 below.

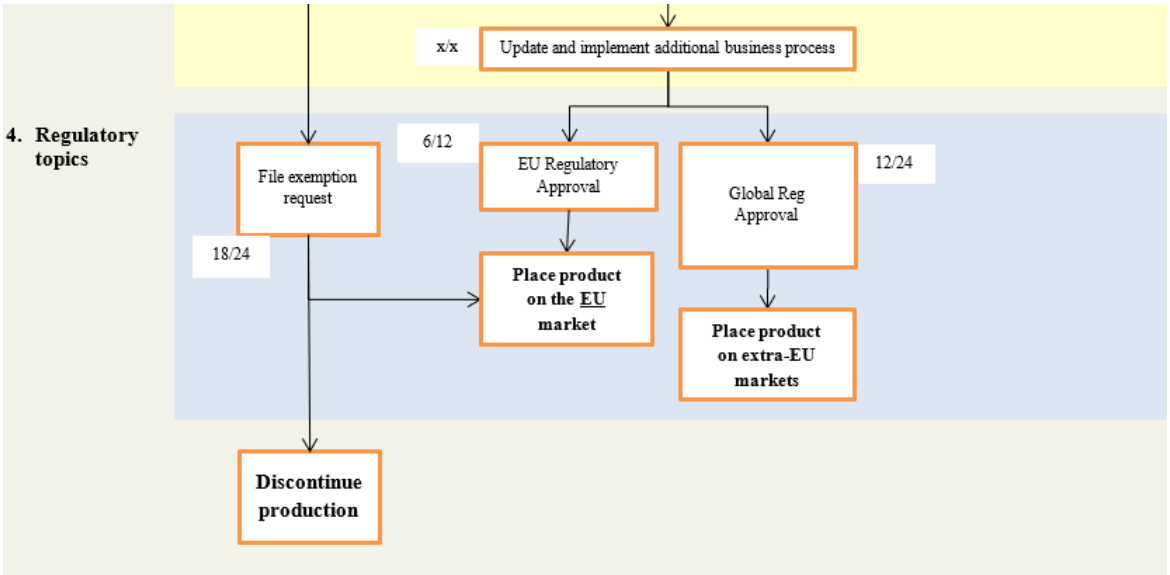
[2] *These were generated by COCIR for the purposes of RoHS exemptions, but the steps are the same for REACH restrictions. X/X is the time taken for that step and would be added by the relevant subject matter expert planning the work.*



Source: COCIR

Figure 12: Flowchart step 3: Implementation in serial production.

If system integration tests of system testing fail, it is required to redesign the equipment to fit the new component or to go back to test a new alternative.



Source: COCIR

Figure 13: Flowchart step 4: Regulatory approval of alternatives/alternative designs or exemption requests / discontinuing production

3.1.1 Detailed explanation about the flowchart

1: Identification of applications

The manufacturer must collect evidence from the supply chain on the use of the banned substance. It is important to consider that while certain applications may be known from the beginning through simple evaluations, others may take longer to be identified. This is often an issue with medical devices made in relatively small numbers because components are not sourced directly from the original manufacturer who has this information, but from distributors who may be many steps in the supply chain from the manufacturer. Therefore, requests for information and answers pass through many companies (distributors, importers / exporters, etc.) and this can take several months. Often the questions need to be repeated when no answers are received. The research for an alternative cannot start until the presence of the restricted substance is identified and confirmed.

Therefore, when estimating the time needed for substitution for an entire sector, the time required to collect information on all the possible applications (known and unknown) have to be taken into account. Experience from previous EU substance restrictions is that this can take more than 1 year.

2: Finding an available alternative

A substance subject to a ban commonly does not have one alternative which is “available”, and which works for all applications. Each single application needs to be analyzed and a specific suitable alternative substance or formulation needs to be identified.

For the manufacturing industry, substitution will be carried out mostly by the component manufacturer or the plastic material manufacturer. Once this has been completed, manufacturers will then need to assess the alternative. Although there may be many alternatives, all have different properties so drop-in replacements will not usually exist. Only when all of the substitutes have been identified, the PFAS has been replaced, the alternative evaluated and proven to be suitable (for at least one use) and be shown to be no less reliable, accurate, effective and safe can they be used in the EU. Additionally, when substitution results in changes in electronic components, the medical sector will need extensive life testing to ensure safety and reliability in particular for components used in harsh environments or subject to excessive mechanical and thermal stresses.

The process of testing/failing/testing each alternative must be included in the development process. This can be represented as iterative “loops” in the flowchart (see Figure 11 above). If the first substitute is found to be unsuitable, then the second choice is tested, etc. until a suitable alternative is found. There are two kinds of loops in this second phase:

- Alternative Loop: An alternative substance does not pass the testing and therefore a new one has to be identified and tested.
- Component redesign loop: An alternative substance does not pass testing but a redesign of the component or of the product or sub-assembly[3] can allow the new substance to work properly. Product/sub-assembly redesign usually takes much longer than component redesign.

[3] *Such as a circuit board or internal power supply unit*

Before finding a suitable alternative, many alternatives may have to be tested. Therefore, multiple iteration around loops may have to be considered, there is therefore always uncertainty over the time needed for this step.

3: Implementation in the serial production

This section encompasses all the steps required for a company to introduce a new component/substance into serial production of the final product and to ensure a stable supply chain.

Another very important aspect is “system testing”. While the new component will have been tested individually (mostly by the supplier) in Step 2, in Step 3 the component is tested as part of the equipment by the medical device manufacturer.

Even in this phase there are loops that need to be represented in the flowchart:

- New substance loop: The alternative component fails system testing and therefore it is necessary to go back to Step 2, looking for a different alternative material or for a design change in the component.
- System redesign loop: The component fails system testing but it is possible (and convenient) to redesign the product to make the component work properly.

As an example, COCIR reports a case where flexible polymers were used instead of PVC containing DEHP in a specific cable. Due to the new stiffness, the tension on connectors was excessive and therefore system testing failed. The manufacturer had two alternatives:

- New substance loop: A new alternative to PVC with DEHP could be tested (back to Step 2).
- System redesign loop: The connectors could be redesigned to withstand the increased stress.

There may be similar effects with replacement of PFAS, where some alternatives will have an impact on flexibility, and others may have unwanted effects relating to magnetism, nuclear interactions, or effect of X-ray exposure.

4: Regulatory approval

Regulatory approval is an additional aspect which should be considered for sectors where the assessment of conformity involves additional burden such as the involvement of EU Notified Bodies as is required for compliance with MDR. This is essential because without approval a product cannot be placed on the market. For medical devices, the approval process of new devices/components with alternative substances can take up to 1 year.

At the same time, it may be important to consider the time to achieve regulatory compliance with non-EU regulations or certifications as this may impact negatively the competition on non-EU markets. Usually, only one design of medical device is made for the global market and so production lines cannot be changed until approvals have been obtained for all important markets. This is an aspect which should be considered by the European Commission when assessing the business impact of a legislative proposal. Global approval typically takes up to two years.

3.2 Determining the time required for substitution of PFAS

Medical devices have significant differences compared to other types of products in scope of the proposed restriction:

- Products are often safety critical, with improvements to medical products helping to save lives or improve the quality of life of EU citizens.
- The number of items produced is relatively small when compared with consumer products.
- Medical devices can have a long product lifecycle with long lifetimes and development timeframes. Consequently, many products require long-term reliability of supply of parts to support long product lifetimes.
- Availability of skilled engineering and leadership within the market is limited owing to the complexity of the products. This limits the ability of manufacturers to develop new innovative products if their engineers have instead to work on substitution of substances.
- Components used in medical devices often require bespoke parts to be developed and qualified; therefore, the redesign and testing requirements for each company can be very significant.
- Patient safety and performance of medical devices are both extremely important and cannot be compromised. This is not permitted by the Medical devices Regulation. COCIR's members are looking for substitutes but in many cases have not been able to find a substitute material which does not compromise on safety or performance. A substitute that has inferior performance that would be acceptable in consumer products would not be "good enough" to be used in medical devices

Potential alternatives must be evaluated on a case-by-case basis, taking into account technical, medical, regulatory as well as economic aspects. As such, qualifying alternative materials could require changes in the design of the devices, as well as changes in the manufacturing process to accommodate the properties of alternate materials – thus triggering the need for rigorous testing to ensure it does not have a detrimental impact on the function and performance of the medical device. Without taking into account such considerations for testing, the proposed restriction will have a significant and negative impact on the availability of medical devices in the EU.

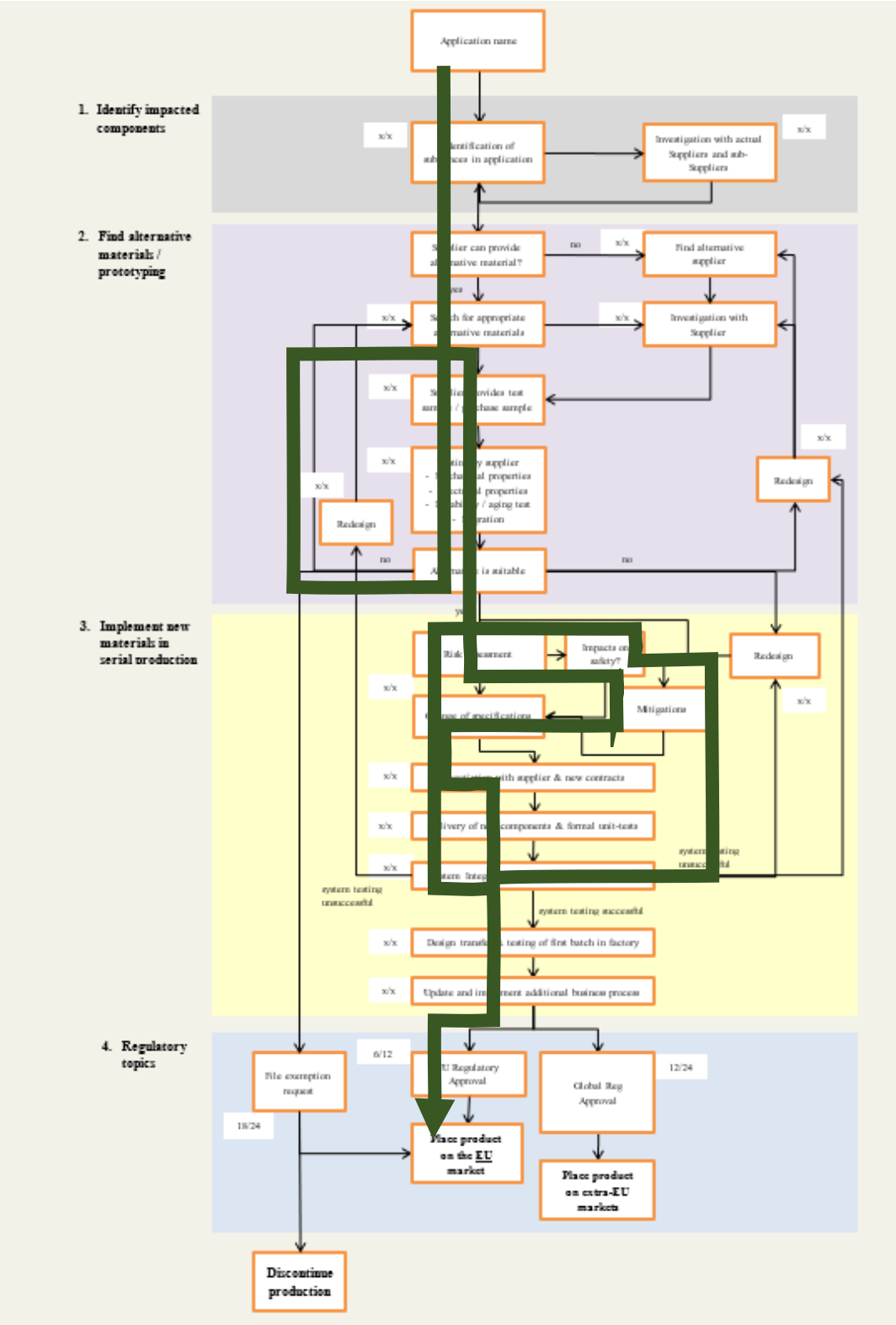
The time required to accomplish each step of the process (shown as X/X in Figure 14) can be estimated by each company's relevant experts within a reasonable range. Factors such as the following must be taken into consideration:

- Difficulties in communication with the suppliers (these typically increase with the length of the supply chain).
- Difficulties in identifying a new supplier.
- Difficulty in identification of suitable alternative materials or components.
- Supplier overload due to number of requests from clients.

- Lack of availability of personnel/resources due to the workload for the substitution of many substances at the same time.
- Un-availability of testing labs as they are booked for testing other applications/alternatives.
- Delays in receiving test material from supplier.
- Delays in obtaining prototypes for testing.
- Multiple attempts for redesign loops.

Due to the presence of loops in the process, the time required for substitution of a substance does not simply mean following the flowchart from beginning to the end (without repeating steps via loops). The actual elapsed time will depend on how many different times alternatives failed and new ones had to be tested. For the same reason, redesign cycles can be repeated more than once.

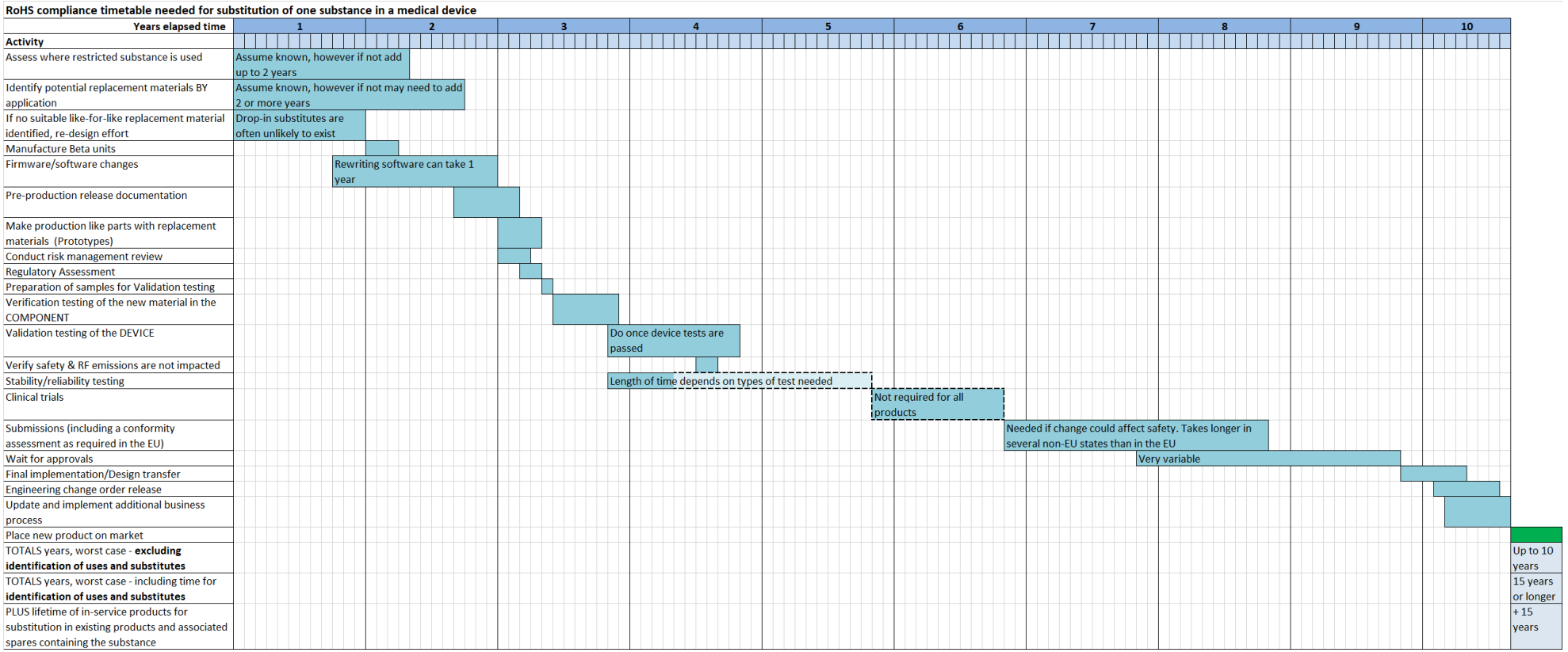
A “reasonable” path through this flowchart is best defined and documented according to experts’ judgment. This path in the flowchart determines how many times loops are repeated, and this path may differ for each application. An example of such a path can be represented graphically as shown below by the green arrow.



Source: COCIR

Figure 14: 'Reasonable path' through the substitution flowchart

The figure below illustrates the timeline for substituting PFAS in an example new product based on the steps indicated in the flowchart (left column). Some testing and developments can be performed in parallel but mostly tasks have to be performed in series. This chart shows the timeline where just one important component requires substitution, but a similar chart can be drafted for each component that requires an alternative.



Source: COCIR

Figure 15: Illustration of the timeline for substituting PFASs in new products

Note that where several substitution projects are proceeding in parallel, this can lead to certain tasks overlapping in time leading to bottlenecks such as availability of testing labs. This would further increase the time required for full substitution (system testing can only be performed on installed devices). Installation is frequently a complex procedure that requires moving several tonnes equipment in testing labs equipped with radiation shielding, EM shielding, safety features and the installation of all the electrical systems and safety testing. Also, due to the limited number of skilled engineers, some steps shown above cannot be carried out simultaneously and so the overall time scale to redesign several products will be significantly longer than is needed for one product redesign.

3.3 Timescale Required to Substitute in New Equipment Design

The steps indicated above require at least 5 - 7 years, for a single application (change of material or simple component), when an alternative can be identified in a reasonable scenario (2 alternatives tested and one redesign cycle). However, for very complex products, this can take much longer as shown in Figure 15.

To replace all applications using PFAS and considering some would probably require significant efforts, COCIR members estimate this the process will require at least 13,5 years (further discussed below) to undertake for many applications, but there will be some circumstances where a much longer time period is needed. This is based on the knowledge COCIR members have on substitution of other substances, such as those regulated under the RoHS Directive. Until all current uses of PFAS are identified, it is not possible to state with certainty how long this process will take.

As detailed earlier, a complex design of cable assembly, which is just one component of a complex medical device, can be replaced **if no problems** are encountered, in 5 - 7 years, with 7 years being more likely. Note that if a potential alternative is found to be unsuitable at any point in the substitution project, then the process must start again – quite possibly from the beginning which will therefore require more time.

The nature of the substitute assessment process means that any problems with the potential alternative for one single application may be enough to make it impossible for the company to place medical devices on the market (unless enough time is granted before the restriction takes effect for medical devices). Considering many applications have been identified for PFAS, the medical device industry is going to have to assess multiple applications at the same time, which would greatly increase the time to reach full substitution of PFAS.

On the basis of the experience gathered with the RoHS Directive, the medical device sector's concerns are that:

- Many substitute parts will not be available from suppliers to be tested and evaluated until a short time before the expected entry into force date of the restriction (i.e. 2026). This has been the experience each time EU substance restrictions have previously been adopted. For many applications the whole process cannot even start before alternative full-scale production components (which may be different to prototypes) are actually available to be tested by medical equipment manufacturers.
- As drop-in substitutes will usually not be available, for many applications, additional efforts such redesign will be required. 13,5 years could be a reasonable estimation to complete the transition without forcing companies to discontinue products causing

scarcity of critical medical devices in the EU. Redesign always involves regulatory approval and possibly clinical trials. A 13,5 year period included in the draft PFAS Restriction proposal would allow for a smooth transition and reduce the negative impacts for companies. As such this would have the benefit of ensuring access to healthcare for patients, although a longer period may be needed for a few specific uses of PFAS where substitution proves unexpectedly to be much more difficult. It is important to note that 13,5 years may not be a sufficiently long time period if medical equipment manufacturers are forced to wait 5 years before new PFAS-free components become available or if critical ICs become obsolete, as described below.

- The electronics industry is claiming that a minimum of 5-year transition period is required, whereas the semiconductor industry will be requesting 13.5 years for complete transition to PFAS free alternatives. This means that the medical imaging and RT sector will not be able to even start the testing of all alternatives earlier than 5 years into the restriction timescale. It is possible, however, that some components including ICs will become obsolete instead of being modified but this may not be known for more than 5 years (this is a common occurrence in the electronics industry where component manufacturers do not want to prevent future sales by announcing in advance that products will become obsolete). COCIR's members cannot start their substitution and redesign efforts until the status of all of the components they use is known.
- It is possible that the only viable alternatives are themselves are regrettable substitutions, and as such will not provide the environmental and health benefits from the restriction that are intended. In this case, a further derogation may be the best option until a safer alternative exists.
- As there is uncertainty over how long complete substitution will take for the reasons explained above, one option is to grant a time-limited derogation of 13,5 years for all medical devices of the types made by COCIR members, but carry out a review after, say 10 years to determine if research has shown that more time is needed for certain types of product or specific uses. The restriction would then need to be amended to allow more time for these products and uses, otherwise, these products will no longer be available in the EU after the derogation ends.

3.4 Gathering information through the supply chain

The process of screening all components for all possible applications of PFAS at a materials level and gathering information for thousands of suppliers was launched in BOMcheck[4] in 2022 with the addition of an initial limited list of some PFAS (the US EPA list). In March 2023, the proposed restriction encompassed more than 10,000 substances, requiring a further change in BOMcheck that, at the time of writing this report, is expected to take at least till the end of 2023 and as such is too late to provide this information during this consultation. Nonetheless it is estimated by COCIR Members that it would take several more years before it is possible to identify all applications where PFAS occurs and problems may be encountered, because not all suppliers realise that they have PFASs in their product (especially distributors and importers), and when they become aware, it is late in the process. Furthermore, many suppliers will not make significant investments in new designs until the proposed restrictions are at an advanced stage of definition, and the requirements are clear.

[4] *https://sphera.bomcheck.com/*

3.5 Conclusion on technical time required for substitution

COCIR members believe, based on the methodology and analysis in this section and on the considerations reported above, that a derogation for medical imaging and radiotherapy devices is required and the minimum technical period is:

- *By way of derogation, paragraphs 1 and 2 shall not apply to PFAS for the use in medical imaging and radiotherapy devices,* their accessories and other medical devices required in a modern imaging suite or radiotherapy procedures and designed to work in such environments such as contrast injectors, patient monitoring, etc. *until EIF+13,5 years.*

However, in addition, this would be acceptable only if there is a mechanism put in place in the derogation text for a mandatory review by the European Commission of the derogations with the possibility of extensions for some applications where evidence is provided to justify delay in the expiry date. COCIR members know that substitution is currently not possible for many of their current uses and so are not able to start working on PFAS replacement. It seems certain that after 13.5 years COCIR will be aware of certain applications for PFAS that further longer derogation will be needed to allow the continues sale of medical devices. This mechanism, such as a review followed by amending the REACH Regulation must result in new derogations in force before the 13.5 year after EIF period expires.

3.6 Spare parts timescale

A derogation for PFAS in spare parts that are used to repair and maintain devices placed on the market before this restriction takes effect (repair as produced principle) will need to be significantly longer than a derogation for PFAS in new equipment. This is because:

With an equipment derogation, medical devices could continue to be sold until substitution is complete and PFAS-free products are available in the EU. Based on the timescales in section 3.5, this will take up to an estimated 13,5 years. These types of products will be in use in EU hospitals for up to 20 years and sometimes even longer and may require spare parts at any time, but especially later in their lifetimes. Therefore, a derogation for spare parts as defined below will be needed for at least 34 to 36 years.

Therefore, COCIR would like to highlight the need for a derogation along the lines of the following:

PFAS in spare parts used to repair or refurbish medical devices that were placed on the market before the PFAS restriction took effect including the time allowed for any applicable derogation.

Spare parts may be used for an additional 20 years so in total 33,5 years after EIF.

3.7 Used equipment timescale

The EU Circular Economy Policy encourages reuse of equipment. This is common practice in the medical sector where manufacturers take back and refurbish equipment for second users and hospitals also sell medical devices to other hospitals. Some medical equipment is leased to multiple users. Reuse will not increase emissions of PFAS because all production emissions have already occurred, there are none in the use phase and any at end of life will occur irrespective of when this happens. Resale, refurbishment and leasing of medical

devices should be permitted without a derogation that should be valid for at least 15 years after the end of any derogations granted for new medical devices.

4 SOCIO ECONOMIC IMPACT ASSESSMENT - IMPACT ON AVAILABILITY OF MEDICAL DEVICES AND HEALTHCARE IN EU

4.1 New approach to the socio-economic impact assessment for medical technologies

The impact of any legislative initiative on the medical device sector and the provision of healthcare in the impacted region is difficult to quantify. While it is possible to estimate manufacturer costs associated with redesign and material substitution as well as those associated with healthcare system technology acquisition. There is no current methodology to quantify how such initiatives would impact access to medical technologies and the patients they serve.

However, it is reasonable to assume that a correlation can be drawn between healthcare outcomes and access to critical medical technologies by EU citizens. Should the density of such technologies decrease, suddenly or over time due to some types of medical devices no longer being available in the EU, it is likely that negative effects on the general health of the population would be observed. The recent experience with the Medical Devices Directive (MDD) being replaced by the Medical Devices Regulation (MDR) where the new regulation required that all medical devices be re-approved by specific deadlines is a clear example of how a reduction in the number of devices can impact vulnerable communities. See section 4.2 for more details.

In this report, COCIR has therefore attempted to develop a novel methodology to calculate future medical device densities modelled on the current PFAS REACH restriction proposal and to estimate the number of patients likely to be negatively affected. While it is not possible to predict patient health outcomes based solely on device density, COCIR contend that lack or difficulty of access to state-of -the-art medical technologies will result in less-than-optimal healthcare.

In a second step COCIR has attempted to utilise publicly available health data to assess how a lack of devices can impact specific diseases or populations, such as cancer, where imaging and radiotherapy devices are used throughout the course of treatment. This second step is similar to a methodology employed by the Global Task Force on Radiotherapy (GTFRCC). See section 4.4.1. for more details

4.1.1 Correlating the PFAS restriction with expected density of imaging medical devices

COCIR considers that while such correlation can be described in general, defining it in a deterministic way is not possible due to the high number of concurring factors. Therefore, the objective of section 4 is to illuminate the potential impact of an artificial scarcity of medical technologies on the EU population.

COCIR makes no assumptions about mortality but rather limits its contentions to negative impacts as a consequence of lack or difficulty of access to critical technologies (which could cause delays or having to use less than optimal diagnosis or treatment methods). When a

substance restriction enters into force it applies to all medical devices, both those in development and those already being marketed. COCIR call the latter "legacy devices" that should not be confused with the same term used under EU MDR[5].

Post-entry into force of the restriction, if insufficient time has been granted for transition new products and legacy devices (which are almost all of the medical devices being sold at that time) would be non-compliant and could not be sold anymore in the EU as redesign would not be possible in the short timeframe available. In general, experience shows that even simple redesigns of a legacy device is often not possible for economic reasons due to the cost of testing and re-approvals.

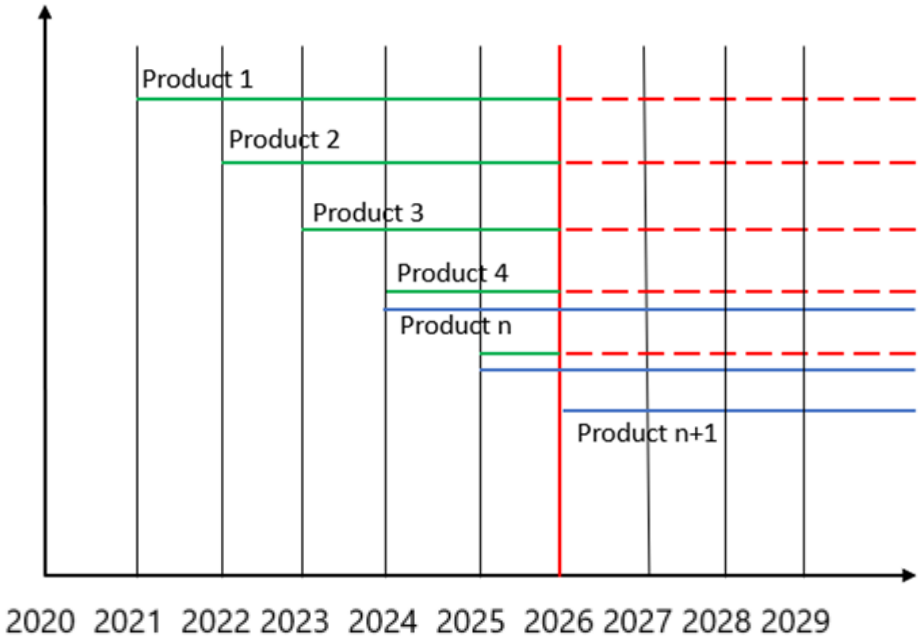
R&D teams are necessarily focused on innovation, designing the next generation of products to be safer and better performing for both patients and the environment. However, R&D resources are finite and redirecting innovation to the continual redesign of existing products significantly stymies progress.

The cost of redesign is often sufficiently high to discourage continued market placement. Substitution of substances in existing designs is particularly undesirable when the high compliance cost may not be recouped by future sales, but also because substitution does not give any direct health benefits to patients and design engineers are prevented from working on new products. In many cases, legacy medical devices containing newly restricted substances are simply discontinued. The more ubiquitous a substance in the design and manufacture of medical devices, the higher the potential impact on device availability. As PFAS is widely used in almost all medical imaging and radiotherapy devices, the impact on devices is expected to be very significant. Companies will have to divert significant resources for R&D to find alternatives to PFAS and make difficult decisions about which product to continue placing on the market in the EU and which must be withdrawn. This would have the following very strong negative impacts:

- Hospitals could not be able to buy the medical devices they may need anymore. The remaining models left in the portfolio of the manufacturers may not meet the needs of the healthcare provider.
- The higher price of new technologies compared to old models could deter hospitals from buying the devices they need to improve the healthcare services to EU patients.
- Loss of revenue from legacy devices (currently available models) would impact the capacity of R&D to innovate new more sustainable medical technologies.

In addition, many EU hospitals buy refurbished medical devices because these provide the diagnostic and treatment capability that they need but at a lower cost. This would no longer be an option if PFAS is restricted without a derogation for products and spare parts made before the restriction entered force.

[5] *https://health.ec.europa.eu/system/files/2021-02/legacy_dvc_management_en_0.pdf*



Source: COCIR

Figure 16: Indicative timeline showing how a restriction would prevent the sale of existing designs, resulting in reducing availability for healthcare providers

In Figure 16 illustrative example products 1 to 4 contain the restricted PFAS substances. and such products will not be allowed to be placed on the market after 2026 (marked by the red line) without a derogation. After 2026, only PFAS-free products (blue lines) can be placed on the market. It is easy to see that the **availability and variety of products is going to be much lower even if substitution has happened before the deadline for a few new models**. While some of the old models probably could be redesigned to remove PFAS (although this is far from certain and will not be known until R&D is carried out), this is not very likely to occur in most cases. A reduction in the offering of medical devices would therefore have a serious negative impact on hospitals' operations. As hospitals will not be able to buy new equipment, their existing medical devices will become older, more likely to fail and need spare parts for repair that cannot be supplied due to this proposed restriction.

ESR, the European Society of Radiologists wrote to the European Commission in October 2020 regarding the discussions on RoHS exemptions 27 that could have hampered the availability of MRI coils. Impacts on the healthcare sector were underlined:

> • *A large proportion of the installed base of imaging equipment in EU is represented by old machines, at least 5 years old. Such machines are in use in hospitals and provide critical and essential healthcare to patients. The impossibility to source replacement coils for such machines may hamper access to healthcare services.*
> • *A reduced availability of substitution coils or new coils would affect all hospitals in Europe. To ensure the functionality of radiology departments and their ability to provide diagnostic services to patients, it is of utmost importance that all coil models are available whenever clinically needed and in the shortest time possible. The ESR believes that the availability and quality of care to patients duly justifies the abovementioned exemption requests.*

ESR also reminded the EC about the need to consider impacts on innovation that could follow restrictions:

> *Given the fast development of new coil technology (and medical imaging technology in general), we suggest the European Commission to take into due consideration the impact on innovation and on patients' health of any legislative measure involving medical devices.*

As an example, almost all companies in the imaging sector are working to develop the next generation of x-ray detectors, the so-called photon counting detectors. Such new technology will bring immense benefits to patients allowing for better image resolution, lower doses, spectral imaging etc. Diverting resources to substitute PFASs in old models will unnecessarily delay the development of new detector technologies.

4.2 MDR caused a scarcity of medical devices in 2022/2023

The recent experience with the EU MDR[6] serves to illustrate the potential impact of legislative measures on the provision of medical technologies. The inadequate deadlines provided in the MDR regulation resulted in a critical paucity of medical devices, leading doctors, and hospitals to request urgent action by the European Commission to save the lives of patients and, in particular, children with congenital heart disease.

Below are some priority examples[7] of public requests from the healthcare sector (links below):

- ESCARDIO - European cardiologists call for urgent action to prevent medical device shortages. 49% of their members have experienced issues with the availability of medical devices and in 42% of cases, the use of an alternative medical device was not as effective.
- AEPC - Association for European Paediatric and congenital cardiology: The implications of EU-MDR for the treatment of congenital heart disease.
- CPME - European doctors are concerned about the availability of many medical devices on the European market. An internal survey showed that doctors are already struggling with shortages that could become much more serious in the near future.
- Biomed Alliance - Clinicians concerned about limited availability of medical devices.
- Report on orphan devices (for rare diseases) - There is a possibility that the MDR may result in products becoming unavailable, with the consequent risk of a loss of some interventions that rely upon those devices. Devices that are used for orphan or paediatric indications are in a particularly vulnerable situation.

European institutions struggled **to fix the problem by extending the transition period of MDR to 8 years since the initial deadline.** Unfortunately, this late action would only

[6] *The original directive was replaced by the new MDR which included deadlines that manufactures needed to comply including having to have all medical devices re-approved by specified deadlines.*

[7] *Links to articles and press releases referenced above on MDR: https://www.escardio.org/The-ESC/Press-Office/Press-releases/european-cardiologists-call-for-urgent-action-to-prevent-medical-device-shortage; https://www.aepc.org/news/the-implications-of-eu-mdr-for-the-treatment-of-congenital-heart-disease; https://www.cpme.eu/api/documents/adopted/2022/11/cpme.2022-159.Letter.EC.Medical.Devices.Regulation.18112022-1669286574.pdf; https://www.biomedeurope.org/images/news/2023/Report_survey_results_v3.pdf https://europepmc.org/article/MED/36258097*

partially solve the problem as many devices have already been discontinued and their production will not resume.

This will happen again, potentially with a worse impact, with most devices having to be withdrawn from the EU market due to the PFAS restriction, unless an adequate transition time is granted for medical imaging and radiotherapy equipment. This has the potential to yield similar or even more deleterious impacts than the MDR Regulation. Once medical imaging and radiotherapy devices become scarce, it would be too late to fix the problem. Companies are already struggling with scarcity in the supply of critical raw materials and semiconductors, so if a PFAS derogation were not to be agreed this would make a difficult situation even more challenging.

It would be appropriate to note that Europe is currently facing a cancer epidemic that is already producing a higher mortality rate. Medical imaging and radiotherapy devices are essential in cancer diagnosis and treatment and the role of radiation therapy is bound to grow due to the high cost-effectiveness of the technology. Unnecessarily curbing innovation and increasing scarcity is going to have irreversible impacts on the health of millions of cancer patients.

Some examples of media outlets addressing the cancer public health crisis:

- Politico: Europe's coming cancer wave.[8]
- The Guardian: Europe faces 'cancer epidemic' after estimated 1 million cases missed during COVID-19.[9]
- CNN: A global epidemic of cancer among people younger than 50 could be emerging.[10]

4.3 Impact on access to healthcare: from scarcity of medical devices to patients not able to receive healthcare (2021-2040 simulation)

COCIR reports biannually[11] about the installed base of several imaging modalities. Since 2008, the number of installed medical imaging devices has been steadily growing in EU (see Figure 17).

[8] *https://www.politico.eu/article/europes-coming-cancer-wave/*
[9] *https://www.theguardian.com/society/2022/nov/15/europe-faces-cancer-epidemic-after-estimated-1m-cases-missed-during-covid*
[10] *https://edition.cnn.com/2022/10/14/health/early-onset-cancer-increase/index.html*
[11] *https://www.cocir.org/fileadmin/Publications_2021/COCIR_Medical_Imaging_Equipment_Age_Profile_Density_-_2021_Edition.pdf*

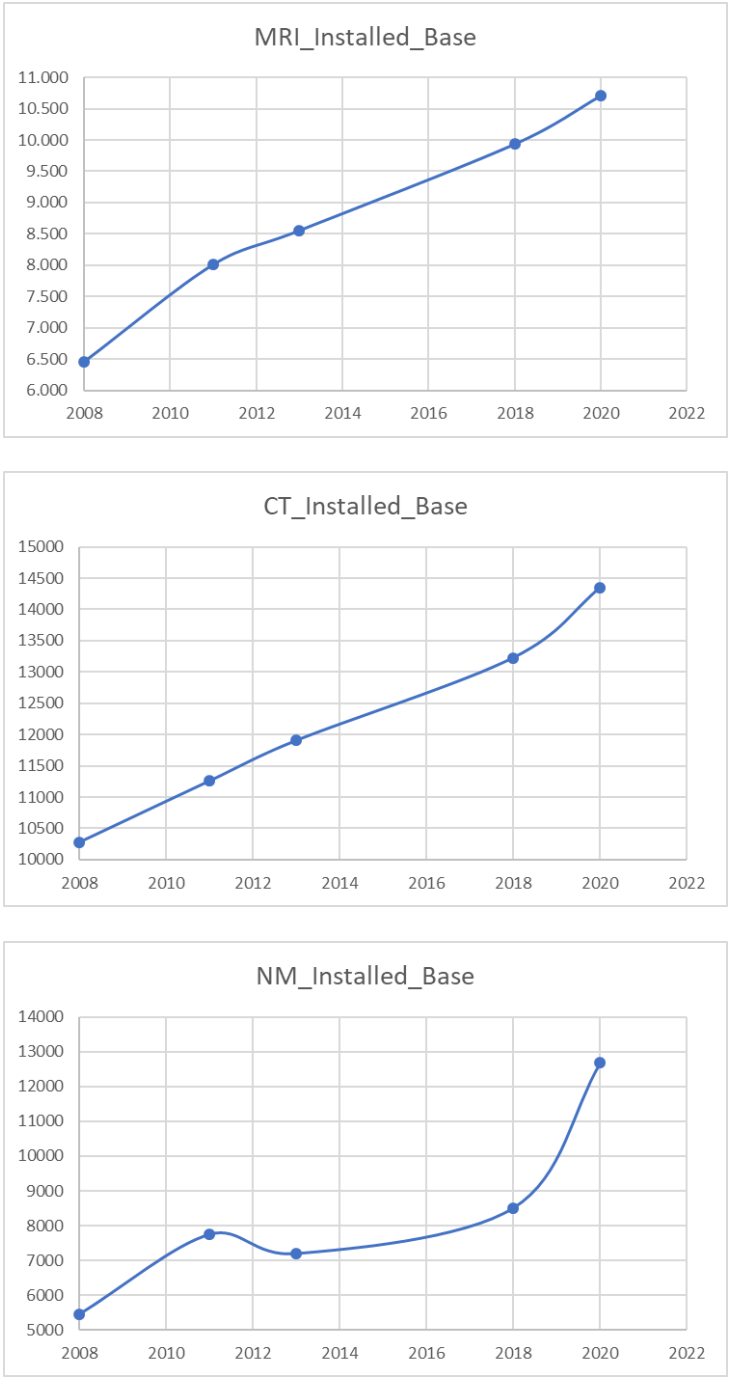


Figure 17 COCIR Age profile and Density report 2021

The increase of the number of imaging devices has facilitated greater access to this technology, with the number of examinations now in the order of 80 million for MRI, 90 million for CT and 16 million for nuclear imaging (PET and SPECT).

In general, a single MRI can scan between 4 000 to 6 000 patients per year, while a CT can definitely examine more than 6 000 patients per year and reportedly up to 17 000 patients per year. PET and SPECT can scan between 2 000 and 2 500 patients per year. It has been suggested that a radiotherapy treatment unit can treat 400-500 patients per year.

The PFAS restriction is going to considerably affect the future sales of medical imaging devices in the EU depending on the date of EIF. However, the impact will be lessened by a sufficiently long derogation.

Assuming the EIF for the medical imaging and RT sector is not changed (2026) we estimated the scenario (Scenario 2026) described in the following information.

We expect that our companies will not be able to produce PFAS free medical imaging or radiotherapy devices for a long time after the proposed EIF of the restriction in 2026. The following graph has been designed based on expectation of COCIR members about time needed for technical substitution in terms of which percentage of MRI devices will be able to be PFAS free over time.

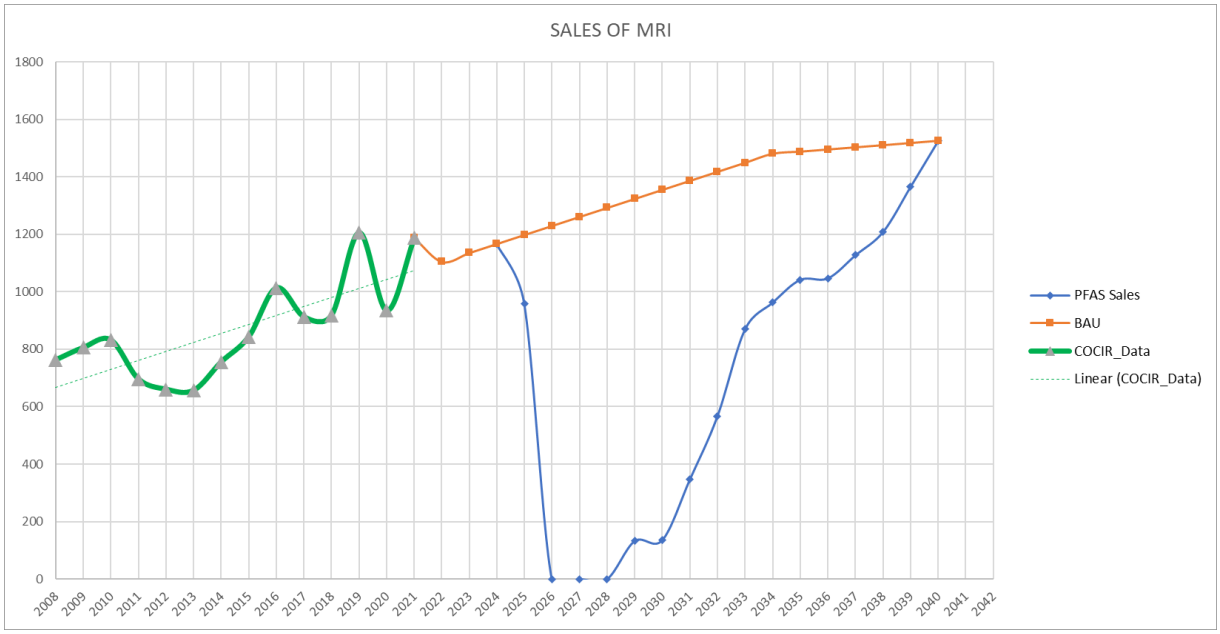


Figure 18. Likely availability of medical devices in the EU with no derogation (blue line) and with a derogation (red line)

The blue line (expected sales of products previously reliant on PFAS) shows a rapid decrease in sales in 2026, when they become almost zero and a slower increase after 2028 with a return to normal only by 2040. This is based on the opinions of companies' experts and experience with restrictions that affected the sector for the past 20 years. We are aware that the sales are not the same as the percentage of PFAS free devices, as some of the missed sales can be compensated by other models, but it is also true that medical imaging devices are designed for specific function (pediatric, cardiology, brain, etc.) and therefore this would still support a healthcare system delivering lower benefits to patients.

The drop in sales will affect the installed product base, as for many years, older devices (7 to 10 years old or older) will continue being discarded.

NOTE: In this analysis we do not consider the case of increasing faults due to unavailability of spare parts that contain PFAS for repair in case a derogation for these is not granted. In such a case the density of the installed base would be reduced even more.

Due to the technical time for testing and validating alternatives, it is expected that no medical imaging or radiotherapy devices will be available until at least 2028. We expect radiotherapy equipment, due to their extremely long design time will not be available (PFAS free) at least until 2033 and for all products not before 2040, while some simple ultrasound and x-ray device may be able to be available earlier after the EIF, but more complex devices will take longer. However, replacement of all models is not expected until 2040 at the earliest. Note that hospitals require the full range of imaging equipment models as each performs unique diagnostic and treatment functions. Some medical procedures can be carried out only by one specific type of MRI, ultrasound, or CT, etc.

In Figure 19, below, the orange line represents the known development of the installed base, between 2008 and 2021. The grey line is the forecast (simple extrapolation) of the installed base in a no-PFAS-restriction (business as usual) scenario. Using the effect of the restriction on future sales as estimated in a PFAS-restriction scenario shown above (blue line in Fig 18), COCIR has calculated the projected installed base development for MRI. While the uncertainty in such projection is very high, we regard this as an interesting example on how a wide-ranging restriction can impact the availability and access of critical medical devices.

4.3.1 Impact on patient access to MRI diagnostic

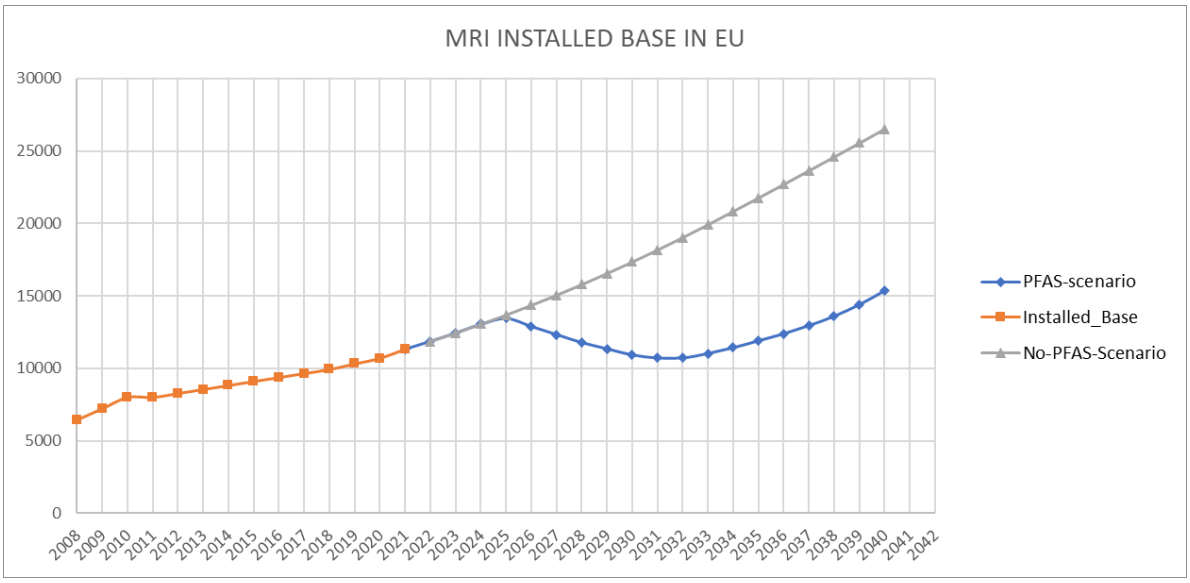


Figure 19. COCIR projections of the development of the MRI installed base in EU27 in different scenarios (no PFAS restriction vs restriction)

The PFAS-restriction scenario shows an installed base reaching 15 800 units (blue line) in 2040 against a possible 26 500 units in a no-PFAS-restriction scenario (grey line), which is a difference of 11 000 MRIs. The difference between the two scenarios represents the number of MRI equipment that will not be available for European patients. Considering the productivity of an MRI, as indicated above, we can estimate the number of patients that will not be able to receive a proper healthcare treatment due to the PFAS restriction outlined in Figure 20.

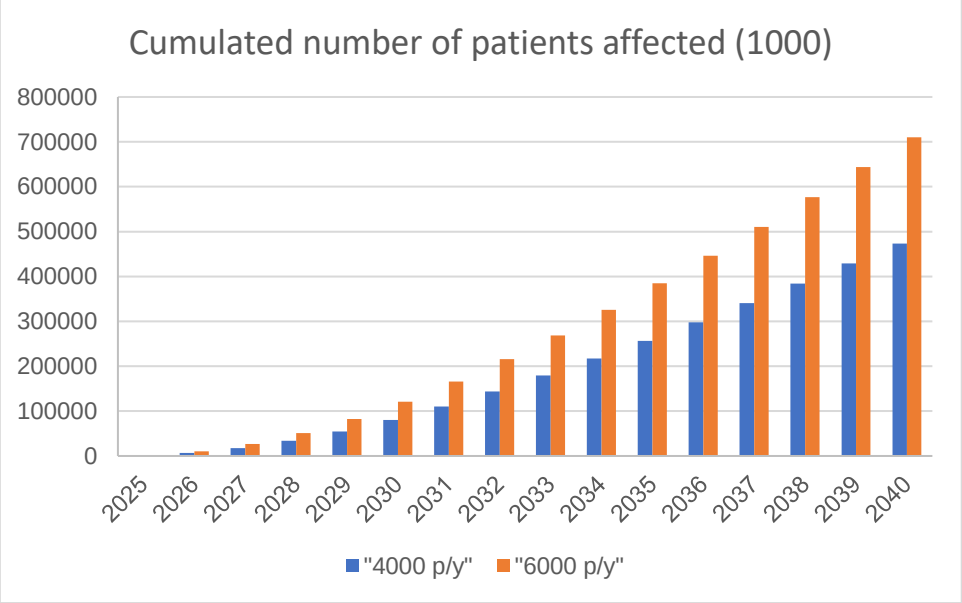


Figure 20. Cumulated number of patients that could receive less-than optimal healthcare due to the PFAS restriction

In the end, the PFAS-restriction Scenario 2026 will cause several hundred millions of patients, between 2026 and 2040 to not be able to receive the best healthcare and they will experience more problems in accessing MRI diagnosis than in a scenario with a longer derogation period for medical imaging devices. A recent study has shown that this could result in many additional but unnecessary deaths because every month of delay in receiving cancer treatment increases the risk of premature death by 10%[12].

While we are conscious of the extreme limits of this estimation and the possible corrective effect of non-considered parameters and assumptions, such as possible increased productivity, the difference between number of patients and examinations, the possibility to use different technologies, etc., we consider it provides a picture of the possible consequences of reducing availability of critical medical technologies regardless. Even if our estimation is wrong by several orders of magnitude it can be expected that **hundreds of thousands, if not millions of patients** will have trouble accessing MRI. There could also be a similar situation with radiotherapy treatment with resultant harm to patients' health. Some patients will die as a result, although COCIR is unable to calculate how many.

4.3.2 Impact on MRI access with different transition times/derogations

The impact on access to medical technology can be mitigated by appropriate transition periods or temporary derogations, to allow companies to transition to PFAS-free devices without having to discontinue products or to stop sales altogether.

As examined in section 3, which showed that medical imaging and radiotherapy devices manufacturers need a consistent period of time to identify all applications, test alternatives with suppliers, prototyping and then testing at component and system level, before the

[12] https://www.bmj.com/company/newsroom/every-month-delayed-in-cancer-treatment-can-raise-risk-of-death-by-around-10/#:~:text=Every%20month%20delayed%20in%20cancer,death%20by%20around%2010%25%20%7C%20BMJ

long regulatory approval process in the EU. Additional time is needed to phase out legacy devices, which can happen only when new devices, designed for the same clinical indications are developed and are available in the EU.

In the past, the EU has granted time under several pieces of EU legislations to the medical device sector to allow time for substitution:

- 8 years for substitution of six the original RoHS substances (RoHS Directive).
- 5 years for substitution of four phthalates (RoHS Directive).
- 7 years validity period for derogations (RoHS Directive exemptions).
- 8 years for medical imaging for substitution of dechlorane plus (REACH Restriction).
- 10 years for radiotherapy devices for substitution of dechlorane plus (REACH Restriction).
- Additional 10 years to 2041 for DP+ in spare parts used in medical devices (recently granted by the Stockholm Convention).

Considering the huge number of PFAS and applications we have estimated the impact on healthcare using the same methodology with example derogation periods of 5 years, 8 years and 12 years. It is important to note that the simulation is based on the following assumptions, although neither of which is likely to be 100% correct:

- All the components we purchase will be PFAS free starting from 2026 as substitution is successfully achieved by their manufacturers.
- No critical applications will be discovered where alternatives are not available or provide reduced clinical value for patients.

In such cases more time would be needed or a mechanism in the restriction wording that allows for requesting or extending derogations based on years of testing evidence.

4.3.3 Different Scenarios – derogations for 5, 8 and 12 years after the entry into force

COCIR estimates the impact of the PFAS restriction based on three different transition time scenarios (5, 8, and 12 years).

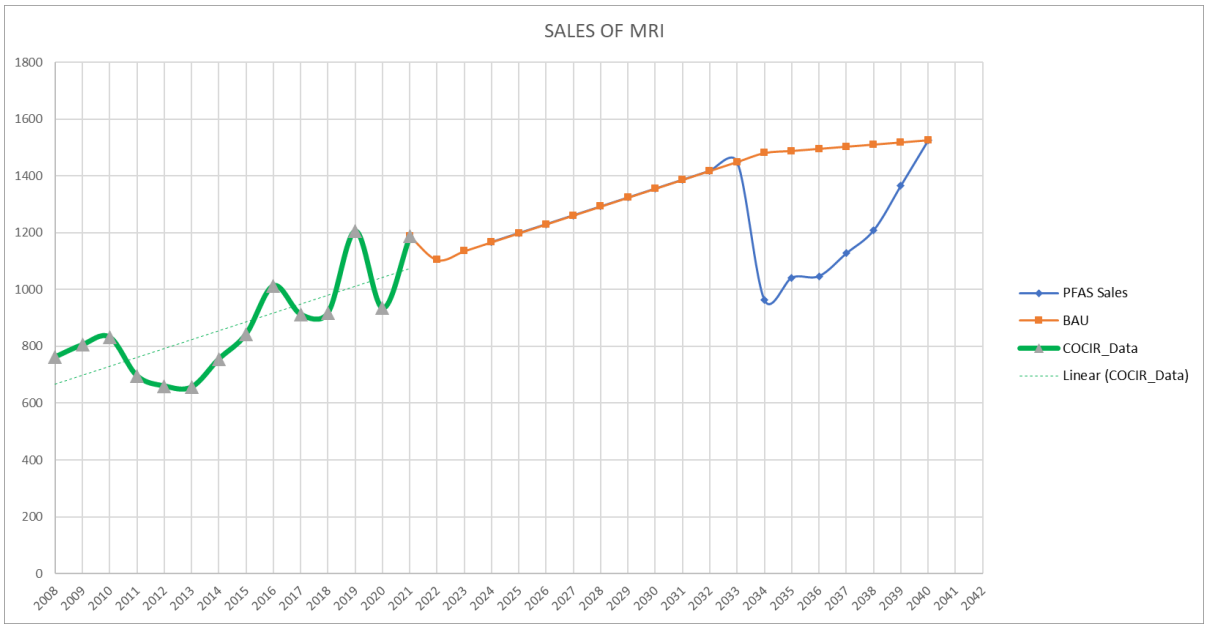


Figure 21. 8-year derogation scenario (similar to derogation granted for the Dechlorane Plus (DP+) restriction) for medical imaging equipment.

As shown by the graph in Figure 21, sales will continue as usual until 2033 and then will drop due to entry into force of the restriction, with most existing types of medical devices being discontinued. New PFAS-free devices will slowly recover to the previous number of sales by 2040.

The increase in installed base will decrease only slightly as shown in Figure 22.

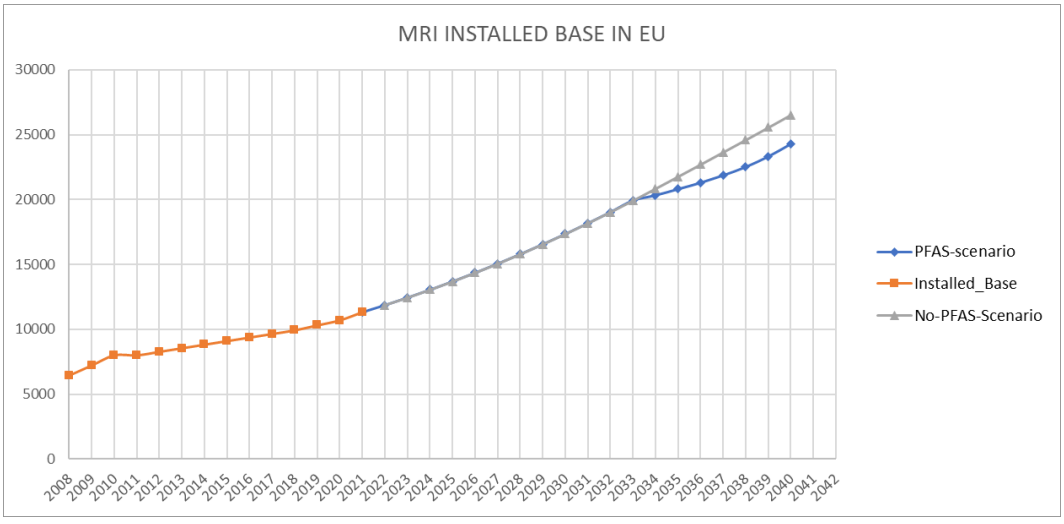


Figure 22. Installed base of MRI in the EU comparing a PFAS restriction from 2026 with a derogation for 8 years

Considering again the range 4 000 to 6 000 patients are treated per year per MRI it is possible to estimate the number of patients that will be affected by the restriction.

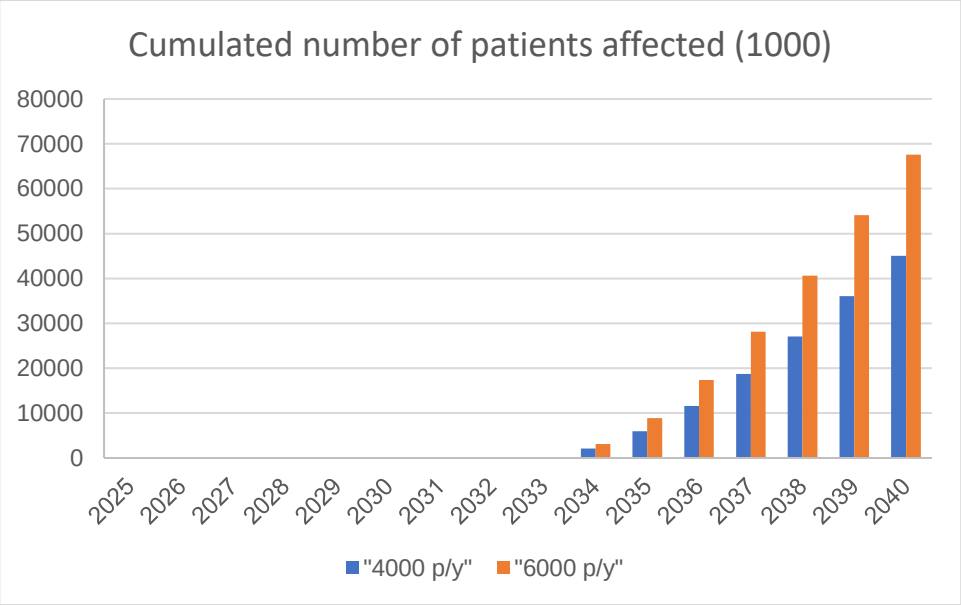


Figure 23 Cumulated affected patients in an 8-year derogation scenario

Despite all the possible uncertainty and extreme assumptions, the methodology shows that with an 8-year derogation, 10 times less patients, 70 million instead on 700 million will be negatively affected between 2026 and 2040 (although there is also an impact after 2040).

If a 12 year derogation is used, the same methodology provides the following result outlined in Figure 24.

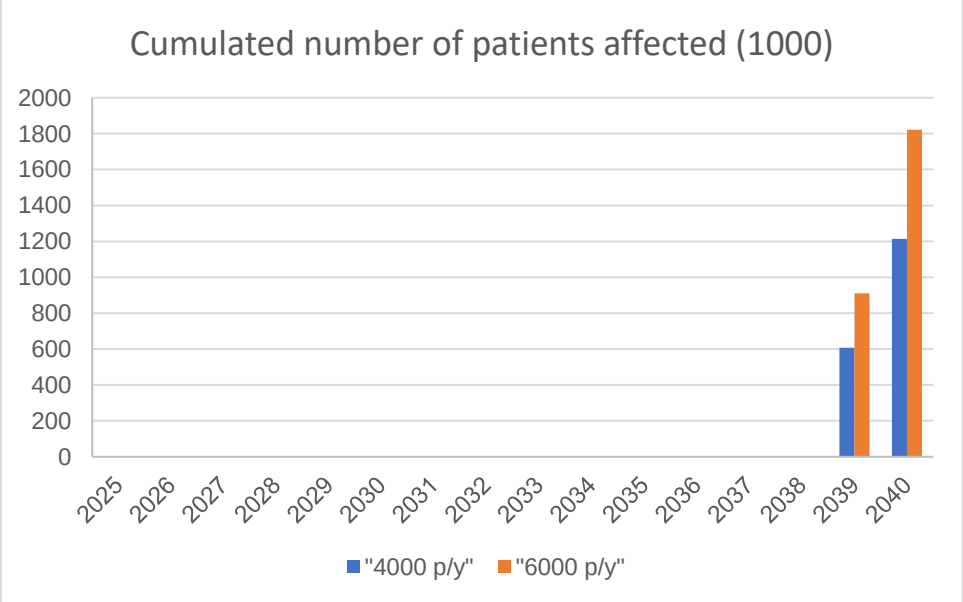


Figure 24. Cumulated affect patients in a 12-year derogation scenario

Between 1.2 million and 1.8 million patients will be negatively affected by a much smaller decrease of the installed base. A number 30 times lower than the 8-year scenario and 350 times lower than a scenario with no derogation for medical imaging or RT devices.

At this point it is possible to generate a graph of the impact of the PFAS restriction by plotting the number of patients (in 1000s) being negatively affected, versus the time granted for derogations (18 months (no derogation), 5, 8 and 12 years) in Figure 25 and interpolating the resulting curves. The red line is for the upper estimates of the number of patients that can be treated by one MRI and the blue line is the lower estimate.

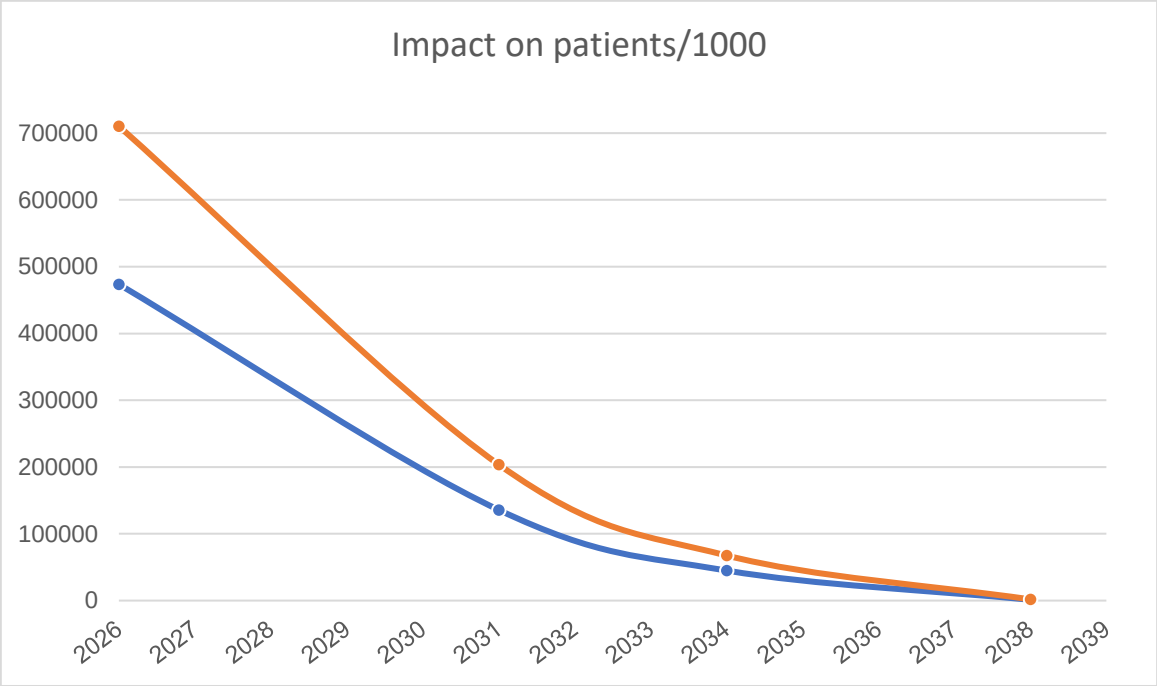


Figure 25 Number of patients (in thousands) affected by the restriction as a function of the time granted for derogation (maximum (red line) and minimum (blue line)

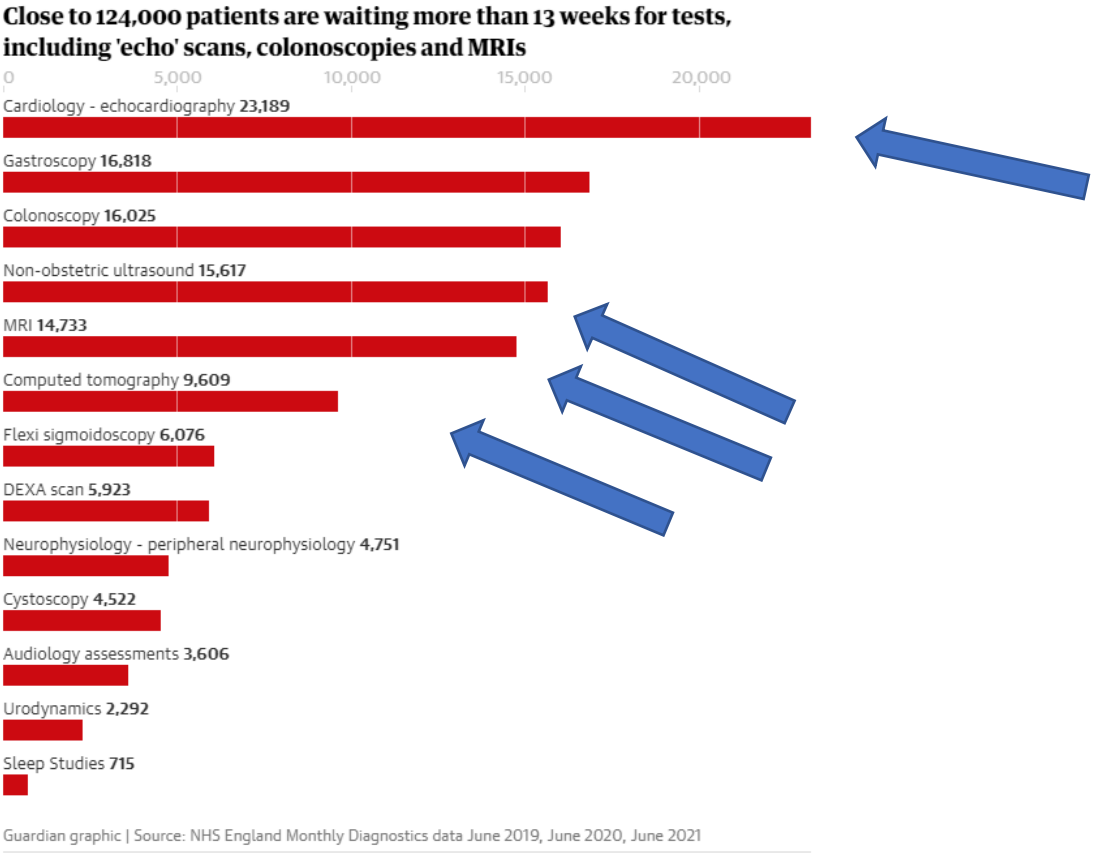
The graph in Figure 25 shows how the impact on the number of patients that would be negatively affected by the restriction would rapidly decrease from several hundred millions with no derogation to just a few millions with a 12 years derogation. A derogation until 2038 will prevent most EU patients from not having access to MRI and other medical imaging devices due to this restriction and even fewer patients would be negatively affected with a 13,5 year derogation after EIF.

4.3.4 Extension of the calculation to other imaging modalities

The calculations for MRI can be performed for Computer Tomography (CT) and X-ray Angiography as COCIR has been collecting sales of such modalities in units (not just market value) and data about density of the installed base. For other modalities such as PET and SPECT, ultrasound, general radiology, mammography, or fluoroscopy we are not able to perform similar simulations, but we do not expect results to be dissimilar.

Considering that CT and X-ray devices are even more numerous in Europe than MRI, with far more examinations per year, it is hard to estimate if the impact of reduced availability of equipment can be partially supplemented by higher use of the existing installed base. Unfortunately, recent data on waiting times for diagnostic examinations in Europe are pointing to a fairly different picture, where existing equipment is already being used at maximum capacity and so any decrease in availability with have a negative effect on EU patients' health.

Some data from the UK[13] shows that after the COVID-19 emergency, the number of patients waiting longer than 13 weeks for simple exams is growing considerably.



[13] *Although the UK is no longer in the EU the status of healthcare provision in EU Member States will overall be similar. The UK publishes detailed health data unlike most EU Member States.*

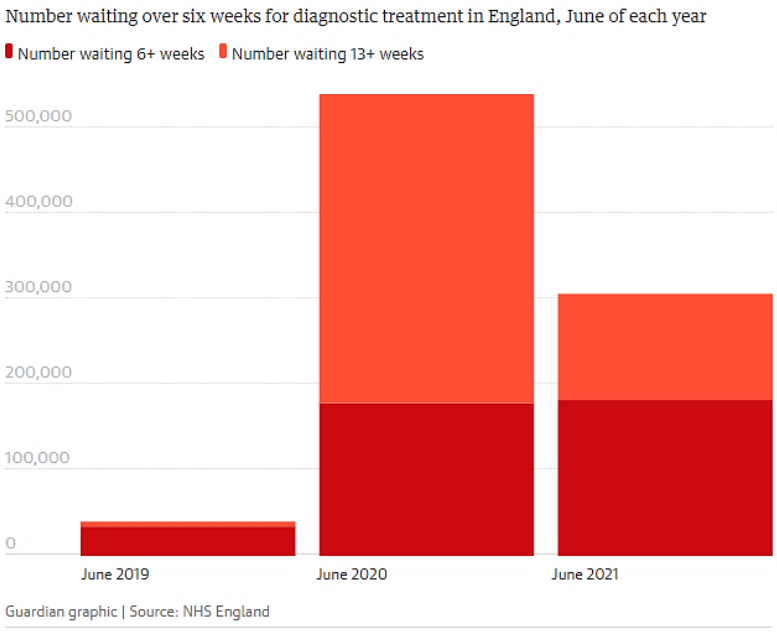


Figure 26. UK data on waiting times before and after the COVID-19 pandemic

A similar trend is expected in the whole of the EU and as such it is highly unlikely that the situation will be back to normal in the coming years as there is no spare capacity in most EU Member States.

It is therefore reasonable to assume that the induced scarcity and the consequent reduction or lack of growth of the installed base for other imaging modalities (CT, X-ray, ultrasound, nuclear imaging) is only going to follow a pattern similar to MRI, thus exasperating the number of patients that will be negatively affected.

Cutting the availability of medical imaging devices right now, with an impact from restriction of PFAS from 2026, could only add to the problem of long waiting times for healthcare in all of the EU, and exacerbate the negative consequence for millions of patients.

4.3.5 Limitations of the methodology

The forecast of MRI sales and the expected development of the installed base are based on expert opinions and simple linear extrapolations. It is possible that sales and in particular the installed base will stabilize at a certain point due to the finite number of hospitals and clinics in the EU (around 24K). This has been reflected by changing the curve at 20K installed MRI. Of course, older MRI will become obsolete /malfunction and need to be replaced by new or refurbished MRI scanners and this would not be possible if MRI sales are prevented by a PFAS restriction that is adopted too early.

Publicly available data about usage of imaging modality reports the number of examinations in EU and not the number of patients. We assumed that “1 examination” = “1 patient” which is probably an overestimation with some patients needing more than one examination.

We also assumed equipment will be used at full capacity despite the increase in the installed base, in particular in the business-as-usual scenario. The assumption seems to be

justified at least for the coming years, but it is hard to estimate how the situation of healthcare could be the closer we get to 2040.

The correlation between cancer mortality and equipment density is very weak, due to the many influencing factors that affect survival and the limited variability in density in the EU. However, qualitatively, it is known that cancer outcomes are improved by early diagnosis and treatment and so any effect that delays diagnosis, will inevitably negatively affect mortality[12].

One other important assumption is that most types of medical imaging equipment will be PFAS-free and approved for sale in the EU within 13.5 years after EIF. This may be over-optimistic as COCIR's members do not currently know of suitable substitutes for most current applications. If this work takes longer then more patients will be affected by a shortage of equipment, there will be longer delays and so logically, more cancer deaths could occur.

4.3.6 Conclusions

As already explained, COCIR notes that these estimations are based on broad and rough assumptions and that the real impact could be one or more orders of magnitude lower. Nonetheless it is undoubted that:

- An impact is going to stem from the restriction affecting access to healthcare in particular imaging diagnostics and radiotherapy.
- Several million, probably hundreds of millions of patients will be negatively affected depending on the time granted for a derogation considering all imaging modalities together.
- The longer the time for companies to transition to PFAS free solutions, the lower will be the impact on patients in the EU.
- The artificially induced scarcity of medical imaging and RT devices will exacerbate the already serious problems healthcare systems are facing in the EU with excessively long waiting times that translate in worse healthcare and a higher excess death rate.

Considering the MDR experience, described above, and the current difficulties being experienced by national healthcare Systems, COCIR believes that a 13,5 year derogation period plus a review that considers additional specific derogations could be the best solution as it will ensure the phase out of PFAS where technically possible with the most limited impact on access to healthcare and on the health of patients.

4.4 Impact on cancer mortality

Medical imaging and radiotherapy devices, as already said, are used in the complete care pathway for cancer, from screening to treatment.

It is undisputable that there must be a correlation between the access to medical imaging and radiotherapy technologies and the cancer mortality. On the other hand, establishing the correlation is not simple as many factors are involved in the outcome of cure. However, the recently published study by UK and Canadian researchers[12] that shows a 10% increase in risk of death for a one month delay in treatment suggests that there could be serious consequences of too early adoption of a restriction.

A further complicating factor is the apparent increase in cancers that has been observed. It is reported that almost 9 million patients died of cancer globally in 2016, which was an 18% increase from the previous ten years. A further significant increase is also expected in the future[14]. Therefore, any slowdown in supply of cancer treatment equipment will inevitably result in a higher death rate than if supply were unrestricted.

4.4.1 The GTFRCC and "expanding the access on radiotherapy" report

In 2013, the Board of the Union for International Cancer Control convened the Global Task Force on Radiotherapy for Cancer Control (GTFRCC) to address the global inequity in access to radiotherapy. The GTFRCC brought together over 100 experts, including radiotherapy professionals, industry partners, cancer control organisations, and economists. to clarify the challenge and quantify the investment needed to ensure global access to radiation therapy. The GTFRCC was able to estimate the global burden of cancer amenable to radiation therapy as well as the associated infrastructure and professional development costs. These data were not only critical to closing the equity gap but also demonstrated the potential for economic gains as a result of an investment in radiation therapy and resultant healthier populations.

Invited by the Lancet Oncology to be a commission of the Lancet, the GTFRCC published their results in a standalone edition of the journal in September 2015. The release of the findings helped dispel misconceptions about radiotherapy being too costly to deliver. It brought global attention to the severity of the radiotherapy inequity problem, demonstrated a positive return on investment for radiotherapy, and articulated the need to act immediately to remedy the crisis.[15]

To estimate the needed increase in RT density and access the GTFRCC used an epidemiological evidence-based approach where the appropriate level of radiotherapy use is estimated by using decision models underpinned by evidence-based guidelines, cancer type and disease stage to allocate patients to radiotherapy or no treatment.

To assess the benefits of the expanded access, a Cancer-site-specific Markov model was developed for the top 10 cancers to simulate remaining lifetime after diagnosis. The probability of survival with radiotherapy was estimated against the counterfactual of survival without radiotherapy.

The methodology developed by the GTFRCC proves that it is possible to correlate access to critical devices and health outcomes.

4.4.2 Density of medical imaging correlation with mortality

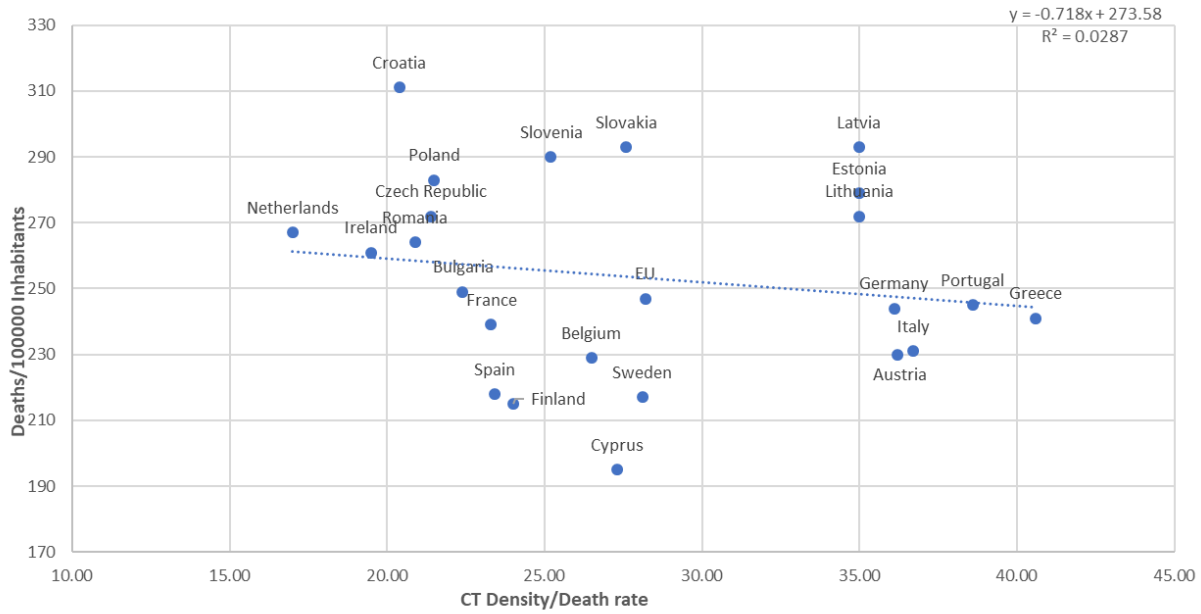
The OECD recently published the "EU Country Cancer Profiles 2023"[16] with a lot of interesting data. COCIR used such data and the IARC data to explore the relationship between density of medical imaging and RT devices, and mortality. This was not with the objective to define a precise relationship but just to explore if in a quasi-qualitative way aa reduction in the density of such devices could affect the outcome of cure.

While we are aware that such an approach would not stand any scientific peer-review, our

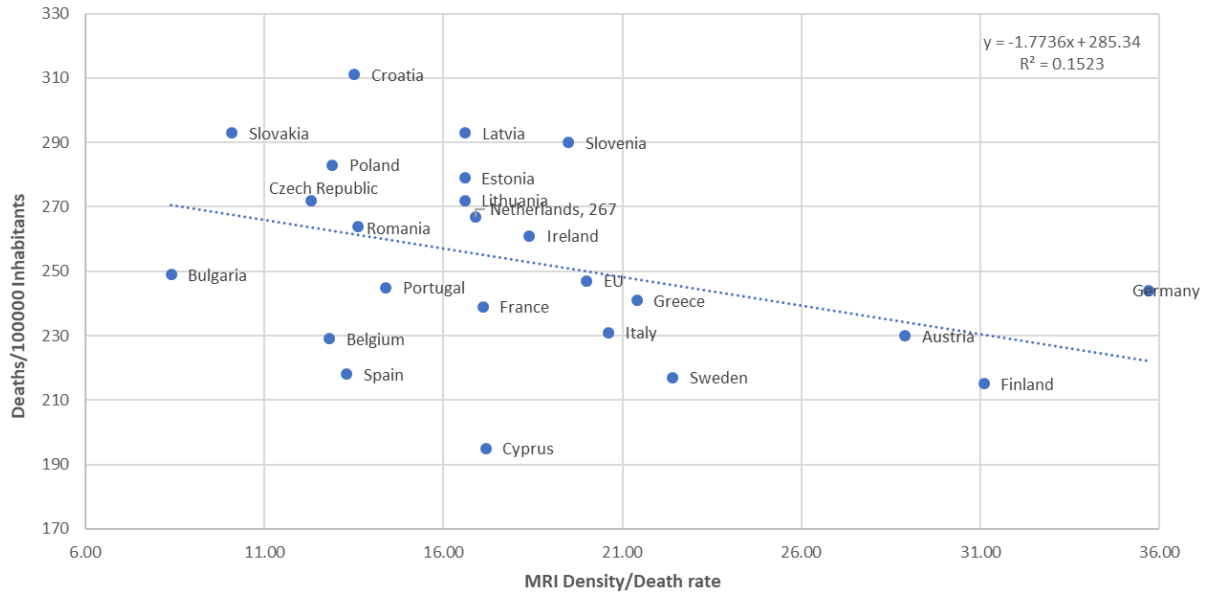
[14] *https://www.thegreenjournal.com/article/S0167-8140(17)32678-6/fulltext*
[15] *Abstract by Atun et al. 2015 available from https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)00222-3/fulltext*
[16] *https://www.oecd.org/health/eu-cancer-profiles.htm*

objective is simply to share some considerations on how a restriction on PFAS that impacts the installed base can ultimately also affect life expectancy for cancer patients. It can also be used to show how such impact can be mitigated in a such a way that both the environmental protection goals and the patients' legitimate expectations to survive can equally met.

Plotting the cancer mortality (OECD) against the actual density of CT (COCIR) we can see a limited correlation, in line with expectations.



The correlation with MRI shows a slightly higher R^2 value.



As we have estimated the number of MRIs and CTs according to different scenarios and we

know the evolution of the EU population[17] it is possible to calculate the density of MRI and CT with the use of some linear interpolation for the population.

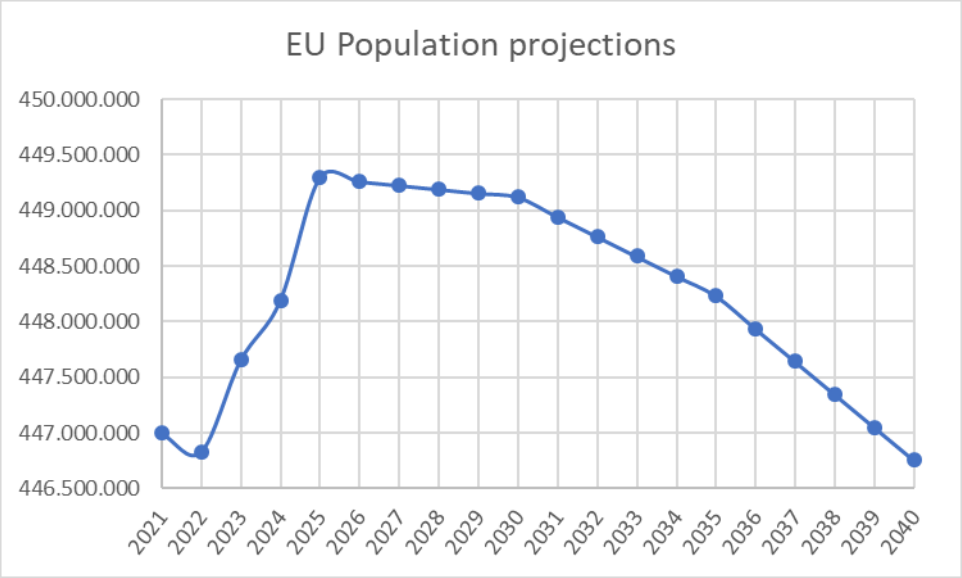


Figure 27. Projection of EU population until 2040, Eurostat data[18].

Charting the evolution of density according to the Scenario2026 (restriction with no derogation) and the business-as-usual (no-PFAS restriction) we see that the density will still be growing overall by 2040, but there will be significantly fewer with no PFAS restriction (Figure 28).

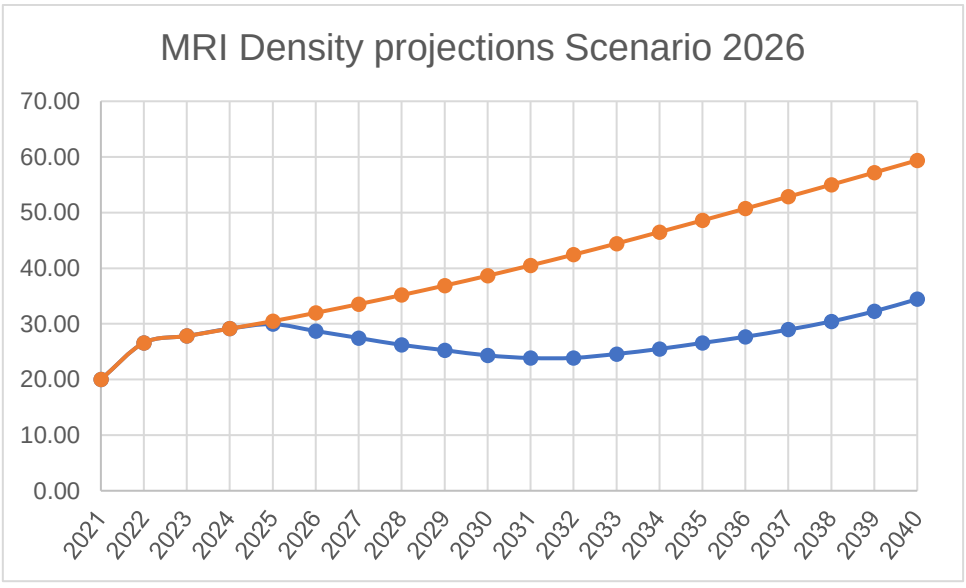


Figure 28 Projections of MRI density for the Scenario2026 (PFAS restriction in force from 2026), red line no PFAS restriction, blue line with PFAS restriction from 2025

The OECD data shows that for most EU Member States, deaths from cancer per 100 000 of

[17] *https://ec.europa.eu/eurostat/statistics-explained/index.php?oldid=497115#Population_projections*
[18] *As Eurostat data are 5 years apart some interpolations were required.*

population has decreased between 2011 and 2019. The next step is to use the correlation between density and average mortality for cancer to estimate the impact of a reduced density of equipment as shown in Figure 28. Due to the several assumptions and simplifications the objective is not to assess how many patients could potentially lose their lives due to the effects of the PFAS restriction, but COCIR considers the exercise offers a valuable resource to understand how the restriction may affect the optimal outcome for patients suffering from cancer.

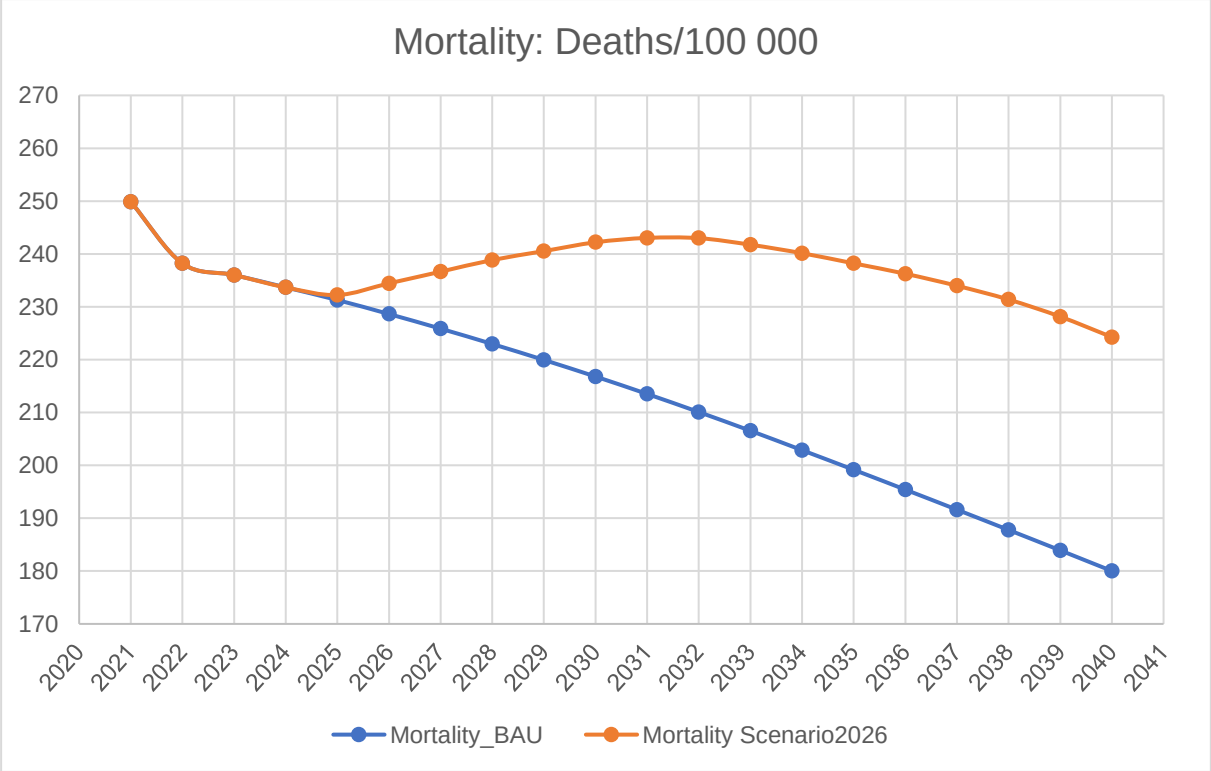


Figure 29 Estimation of cancer mortality (hundred thousands of people) based on MRI density for the Scenario2026 (PFAS restriction in force from 2026) compared to a business-as-usual (BAU) scenario where no PFAS restriction is in place.

It is interesting to note that the introduction of the PFAS restriction and its negative effect on the installed base could cause a reduced improvement in cancer mortality (a temporary increase in deaths is indicated) due to the lack of critical medical devices. While this cannot be quantified with any degree of accuracy, it is an expected impact as the importance of early diagnosis and proper staging and contouring are critical for any following treatment is well established.

Using the EU population projections and the difference between mortality rates in the two scenarios we can estimate how many patients may not have the best outcome due to the consequences of a PFAS restriction entering into force in the sector in 2026. Over the span of 12 years a few million people (more than 2 million) may have their access to optimal healthcare jeopardized by the PFAS restriction.

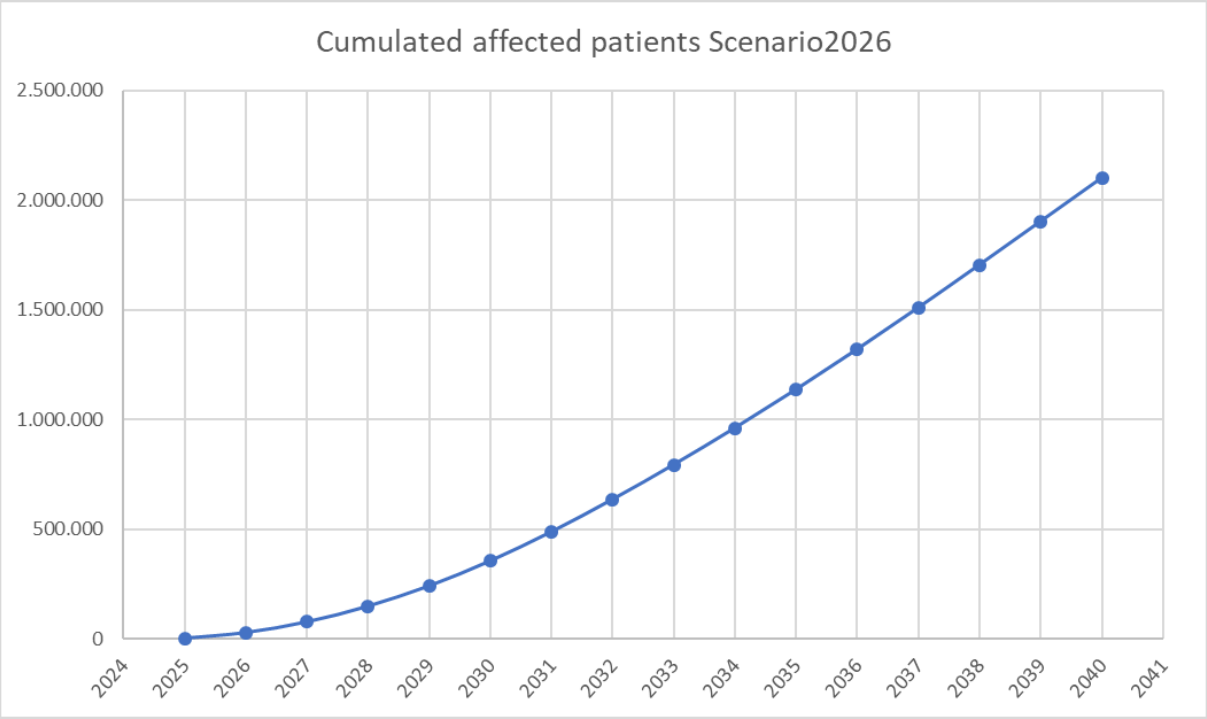


Figure 30 Cumulated number of cancer patients that may have a less than optimal treatment outcome in the Scenario2026 (no derogation)

Following the same methodology as before, COCIR has calculated the same value for the Scenario 2038 (12-year derogation for PFAS) and plotted it with the BAU scenario (no PFAS restriction). The next graph in Figure 31 shows only a very small difference in mortality rate between the 2 scenarios.

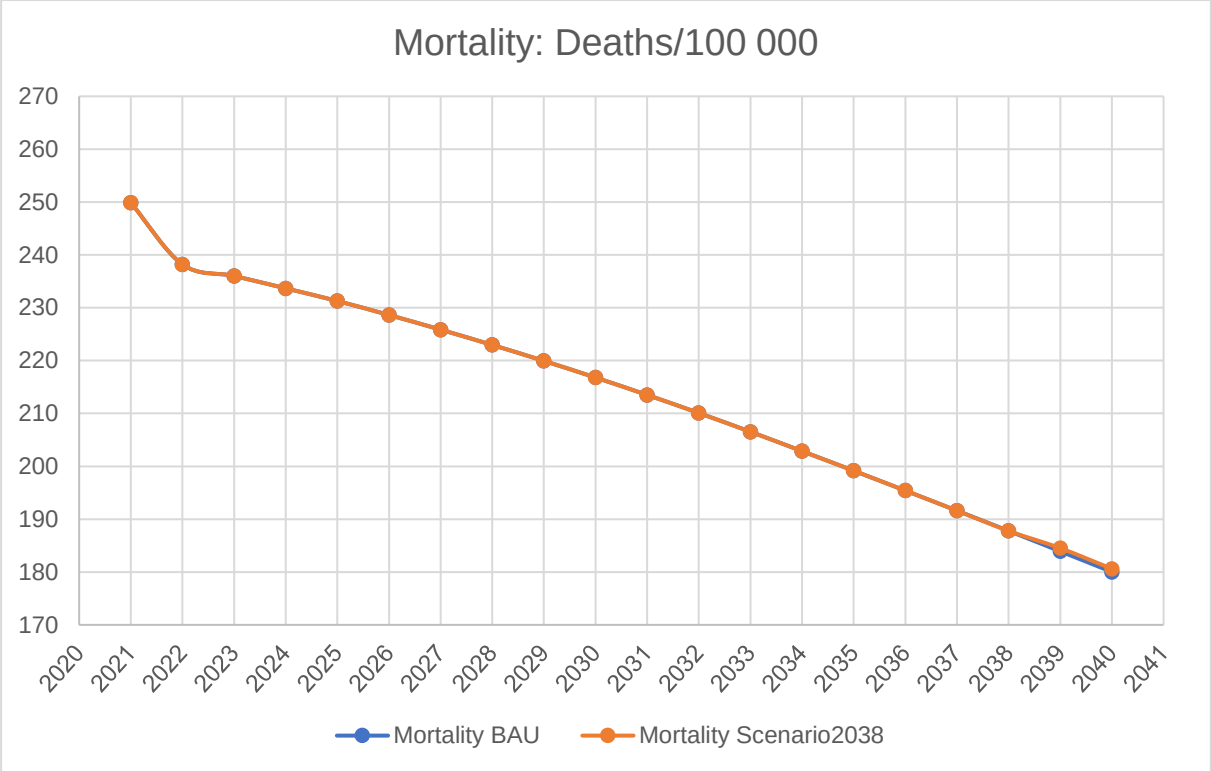


Figure 31 Evolution of density of MRI in EU in the Scenario2038 (12-year derogation) compared to BAU

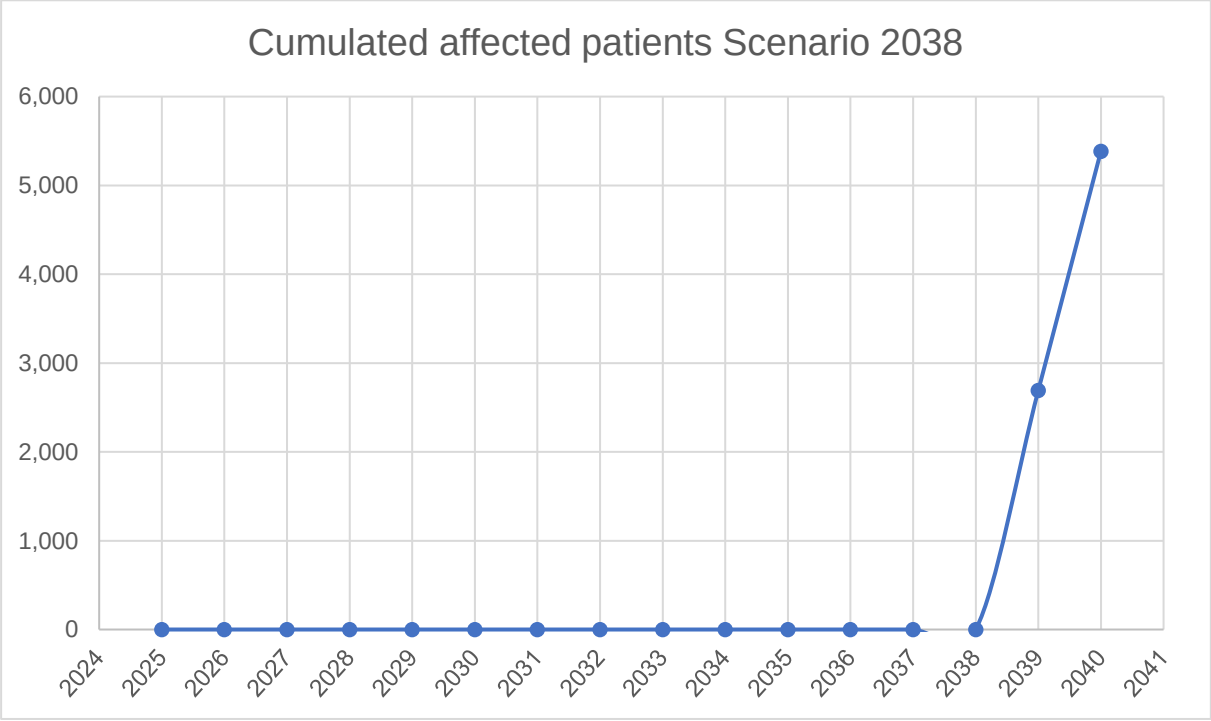


Figure 32 Cumulated number of cancer patients that may have a less than optimal treatment outcome in the Scenario2038 (12-year derogation)

The second graph (Figure 32) shows that the number of affected patients would be very small compared to the previous Scenario at 5 500 people compared to a few million.

A similar calculation can be performed for CT or for the combined CT+MRI density yet COCIR can deduce the results would be similar due to the introduced simplifications.

For other modalities such as ultrasound, mammography, PET, and SPECT it is not possible to run simulations due to the lack of data, but similar operations can in principle be conducted for specific diseases, such as breast cancer for mammography. We would expect that each exercise will end by showing a negative impact on the proper healthcare of patients.

4.4.3 Density of radiation therapy devices and mortality: benefits of radiation therapy

As COCIR has started only recently (2019) to collect data on the density and sales in units of radiation therapy devices, it is not possible to perform the same simulations to estimate the impact on mortality rate. However, based on the records available COCIR is confident this would have resulted in even more significant data as the benefits of radiotherapy on cancer mortality are an object of continuous research.

The GTFRCC estimated that scaling up radiotherapy to optimal levels could bring the following benefits from 2015 to 2035:

- 6,3 million discounted life-years low-income countries
- 9,9 million discounted life-years low-middle income countries
- 10,7 million discounted life-years upper-middle income countries

What the PFAS restriction is going to achieve, unless enough time for the transition is granted for the RT sector, is to scale-down radiotherapy services with the result that some patients' lives may be shorter than if roll-out of new radiotherapy equipment is not delayed.

4.4.4 Limits of the methodology

The correlation between cancer mortality and density is very weak, due to the many influencing factors and the limited variability in density in EU. On the other hand, it is obvious that there must be a correlation between access to healthcare, imaging and best available treatment options, and cancer outcomes, and that density is a very important factor in access, even if it is not the only one.

4.5 Impact on enforced obsolescence: spares /repairs / maintenance and refurbishment

Medical imaging and radiotherapy devices are capital investment equipment, designed to be easily repairable to ensure limited downtimes for hospitals and their patients. Manufacturers ensure spare, new, or refurbished parts are easily available so that repairs can be performed in the shortest time possible and also at low cost to the hospital or clinic.

A medical device can only be repaired with spare parts that have been validated for that

specific model during the regulatory approval process[19]. Using different parts is not permissible as it could cause safety risks that have not been assessed. Redesigning spare parts for old equipment is impossible (it would require revalidating and verifying the design across all jurisdictions where the product is sold). Examples of spare parts include discrete electronic components, wire assemblies with connectors, circuit boards, modules such as power supply units, etc. Not all parts will contain PFAS, but it is expected that many will.

If spare parts are not allowed to contain PFASs to repair medical devices that were originally placed on the market before the EIF of the PFASs restriction, potentially all installed medical devices will be unable, in the short term, to be repaired and hospitals in the EU. As a result of this hospitals will not be able to provide healthcare anymore to EU patients and citizens. Malfunctioning medical equipment cannot be repaired because suppliers will not be permitted to supply parts that contain PFAS, even if these parts were manufactured before the restriction EIF[20].

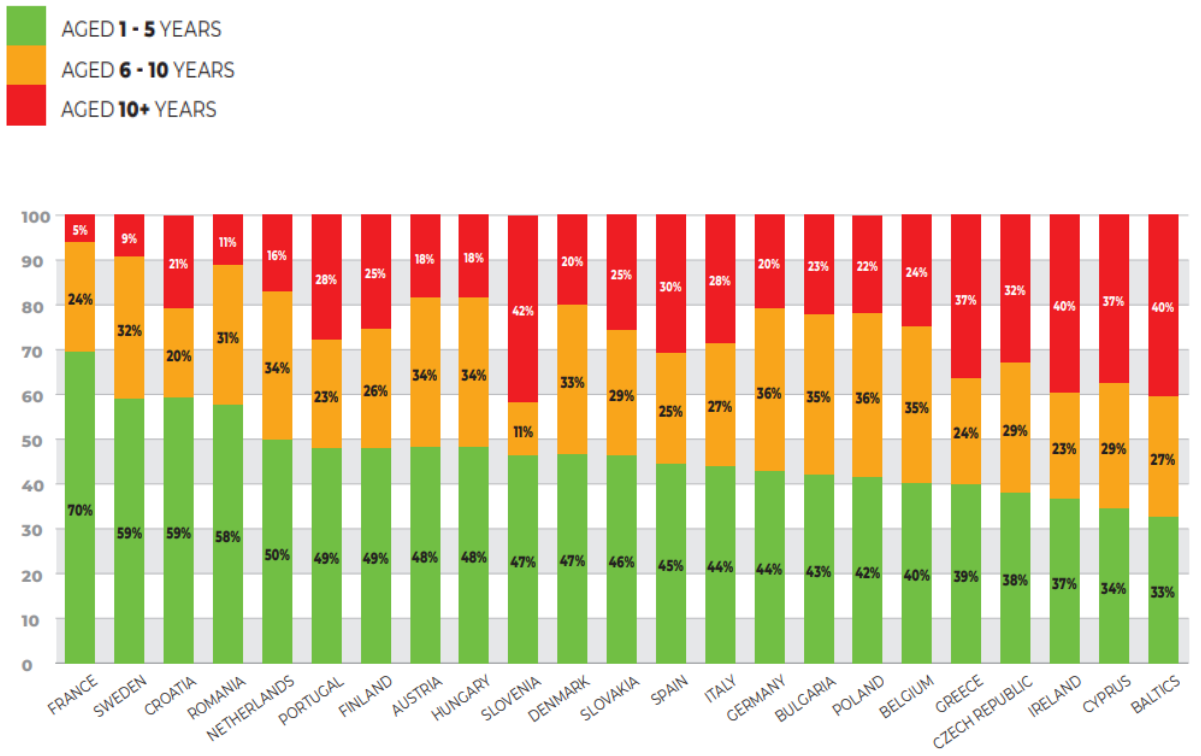
To understand the magnitude of the impact it is useful to refer to the COCIR "Age Profile Report". Every two years COCIR publishes a report[21] about the age profile of the installed base both for imaging and radiotherapy devices. This gives an indication by age of the prevalence of older and therefore refurbished equipment. As can be seen from Figure 33, Figure 34, and Figure 35 taken from the COCIR report, on average 20 to 30% of the installed units are older than 10 years and almost 60% are older than 6 years.

The several thousand installed equipment in the EU need to be maintained, serviced, and repaired until the end of their life. **This often exceeds 15 years** (up to 20 years in certain cases).

[19] *Medical devices require verification and validation of the design and manufacturing processes in EU according to the MDR (EU) 2017/745. In the US,FDA's rule 21 CFR 820.75, and similarly design validation and verification requirements are outlined in the FDA's rule 21 CFR 820.30.*

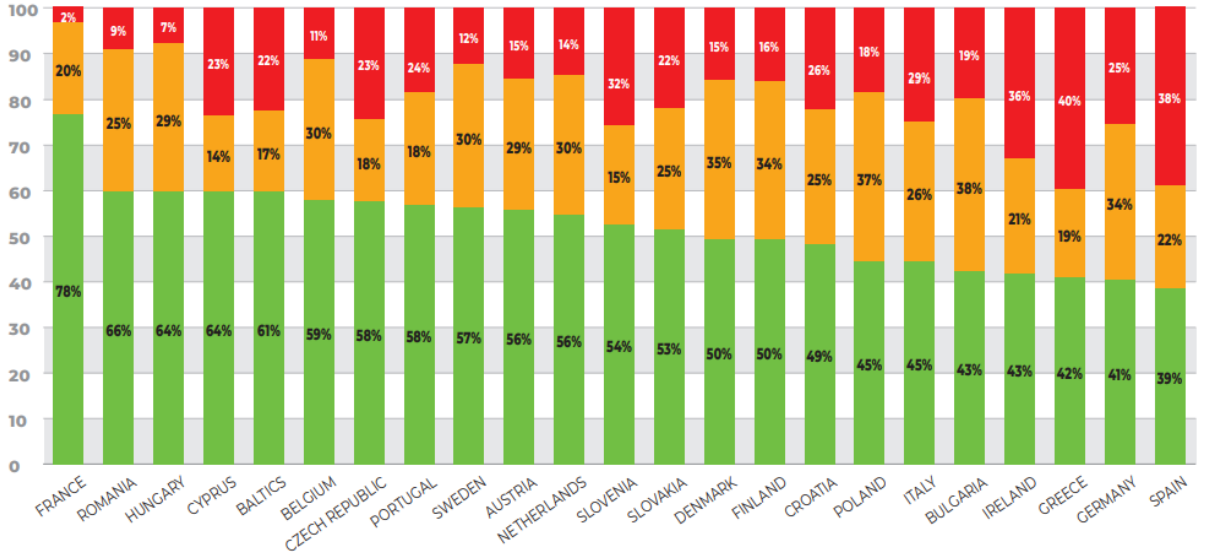
[20] *This is COCIR's interpretation of the proposal.*

[21] *Medical Imaging Equipment Age Profile & Density, 2021 Edition, COCIR, https://www.cocir.org/fileadmin/Publications_2021/COCIR_Medical_Imaging_Equipment_Age_Profile_Density_-_2021_Edition.pdf*



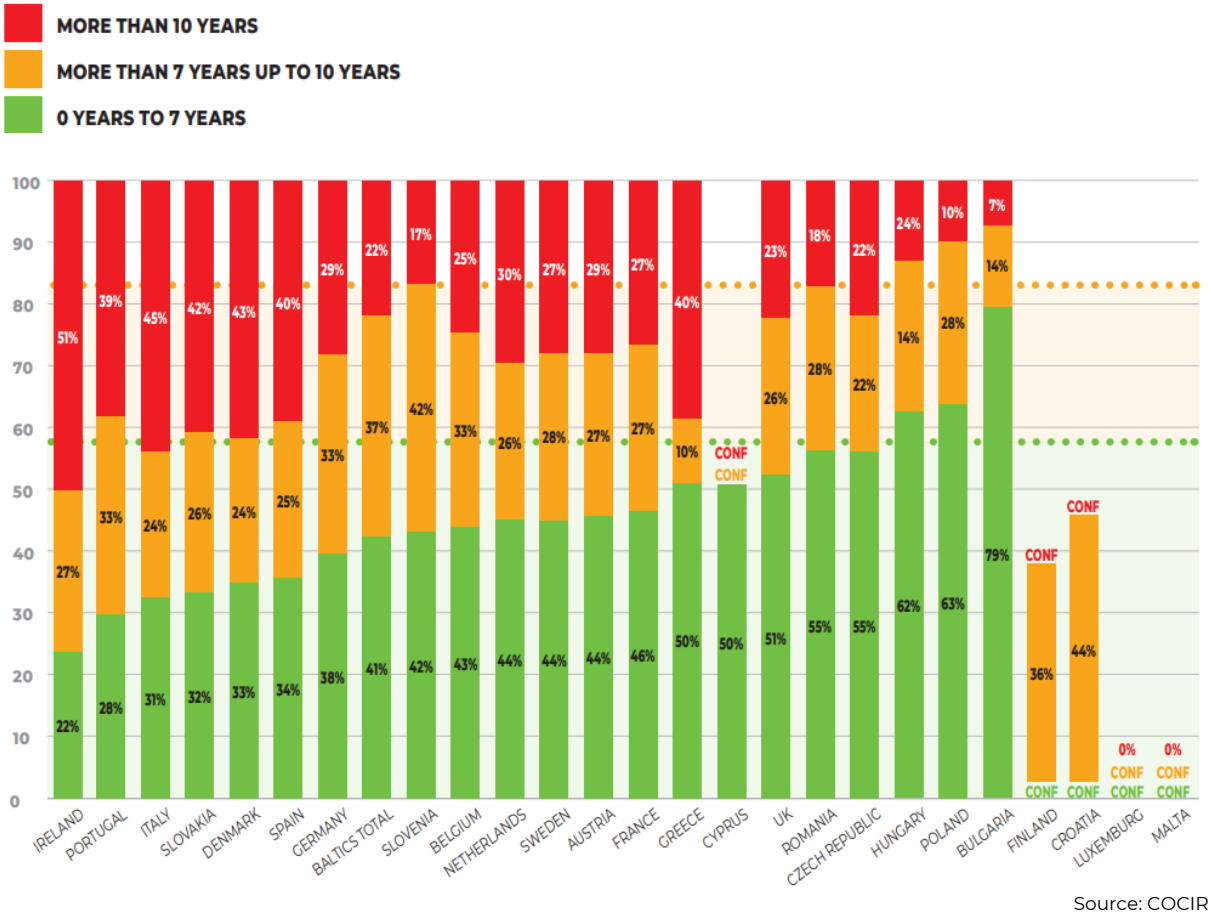
Source: COCIR

Figure 33: CT Age distribution



Source: COCIR

Figure 34: MRI Age distribution



Source: COCIR

Figure 35: External Beam Radiotherapy Age distribution

If spare parts and refurbished products containing PFASs are not available to service existing medical devices, then most of them will quickly become obsolete if they cannot be maintained or repaired. The older is the equipment, the sooner it may need to be repaired and, as a consequence of the lack of spare parts, it would become inoperable and then waste.

Including the "repaired as produced" principle in the PFASs restriction is critically important for medical devices and their owners (EU healthcare providers) to avoid serious consequences for EU patients:

- EU Healthcare providers own equipment worth billions of euros that could not be repaired and would need to be unnecessarily disposed of.
- The depreciation to zero of capital investment equipment. This will impact hospitals budgets, with the potential of bankrupting in some cases.
- The reduced availability of medical imaging and radiotherapy devices will impact the healthcare of patients in the EU. Even if budgets, allow, many hospitals could not replace defective equipment due to the availability issues described elsewhere in this submission.
- Considering the already strained budget of national healthcare system, it is likely that defective, waste devices could not be replaced with new ones for many years because

many could not be repaired with spare parts contain PFAS, unless there is a suitable derogation.

It is important to note that spare parts are only newly manufactured for a limited time and that for older products, the required spare parts are not manufactured but are recovered from other used equipment, during maintenance, repair and disposal for recycling. Such parts are refurbished and reused. Even if the "repair as produced" principle is adopted, availability of spare parts that contain PFAS will decrease until none remain. However, allowing a derogation for already existing parts to be reused will have no environmental impact as explained in section 5.

Recommendation: include the "repair as produced principle" in the PFAS restriction. This principle is already included in the RoHS Directive. A proposal for the derogation wording proposals is provided in section Error! Reference source not found.**.**

4.6 Economic impact on hospitals and healthcare

It has not been possible to calculate the overall costs to hospitals if PFAS containing spares are no longer available, however some illustrative information has been gleaned which may help inform the socioeconomic analysis.

Given the age profile for MRI scanners in Figure 34, it is reasonable to assume that 30% of the existing scanners in operation in the EU (10 703 scanners[22]) would require repair in the first year after the PFASs restriction. As the supply and use of any spares containing PFASs would be illegal, and alternative spares are not made (not feasible or not permitted under the MDR without too costly redesign and re-approvals), these scanners will be impossible to repair, and will become unavailable for treating patients.

The impact on patients could be estimated by adding to the scarcity of new replacement equipment caused by the PFAS restriction in section 4.2 and 4.3. Not only the availability of medical devices will be reduced due to stopping of their sales, but also to many existing products in use not being able to be repaired. However, the following costs and risks are expected to arise, for the example of MRI scanners:

- In terms of financial costs to hospitals, there will be the cost of the new MRI system, training, installation labour and potential changes to the building to accommodate each new scanner. COCIR members indicates costs of at least €1.5 million and up to €3 million for the most common models.
- If a hospital or clinic has 10 MRI technicians to retrain at 40 hours each, 400 hours of labour will be utilised in training with an estimated cost to the hospital or clinic of more than € 35 000 for training assuming labour cost with overhead of € 89/hour.
- Spares companies are contracted to provide spare parts including refurbished spare parts, but they will not be able to provide these, as much of their stock will contain PFAS, and no substitute PFAS-free parts will be available. These companies will be unable to fulfil their contracts. There is a high likelihood of significant financial strain for these types of businesses and the possibility of business collapse.

Although these costs can only be estimated at this stage it can be clearly seen that the severity of impact is expected to be high for EU healthcare providers and ultimately for

[22] *Based on information collected by COCIR.*

patients, considering there are around 24 000 hospitals in Europe.

If, for example, the average lifetime of MRI scanners was reduced by just two years because repairs were not possible, there are estimated to be 10 703 MRI scanners in the EU[23]. If the current average lifetime is about 10 years but this is shortened by two years because faults cannot be repaired, then 20% will need to be replaced early. If each has a replacement cost of €2 million, this cost would be €0,2 million per year over a 10-year lifetime. If the lifetime is reduced by two years, the additional cost to hospitals for 10703 MRI scanners will be 10703 x €200 000 x 2 = €4,3billion, There, will also be hypothetical replacement costs for other types of equipment such as CT, PET, ultrasound, etc. In reality however, most hospitals will not be able to afford these very high costs with the result on healthcare as explained above.

It might be assumed that if an MRI, CT, PET etc. is no longer functional at one hospital, then patients can be sent to another. However, patients often cannot be treated elsewhere as all equipment in most EU hospitals is usually fully utilized. At best, very ill patients will experience delays and have to travel long distances, potentially to other countries as occurred during the COVID-19 pandemic[24].

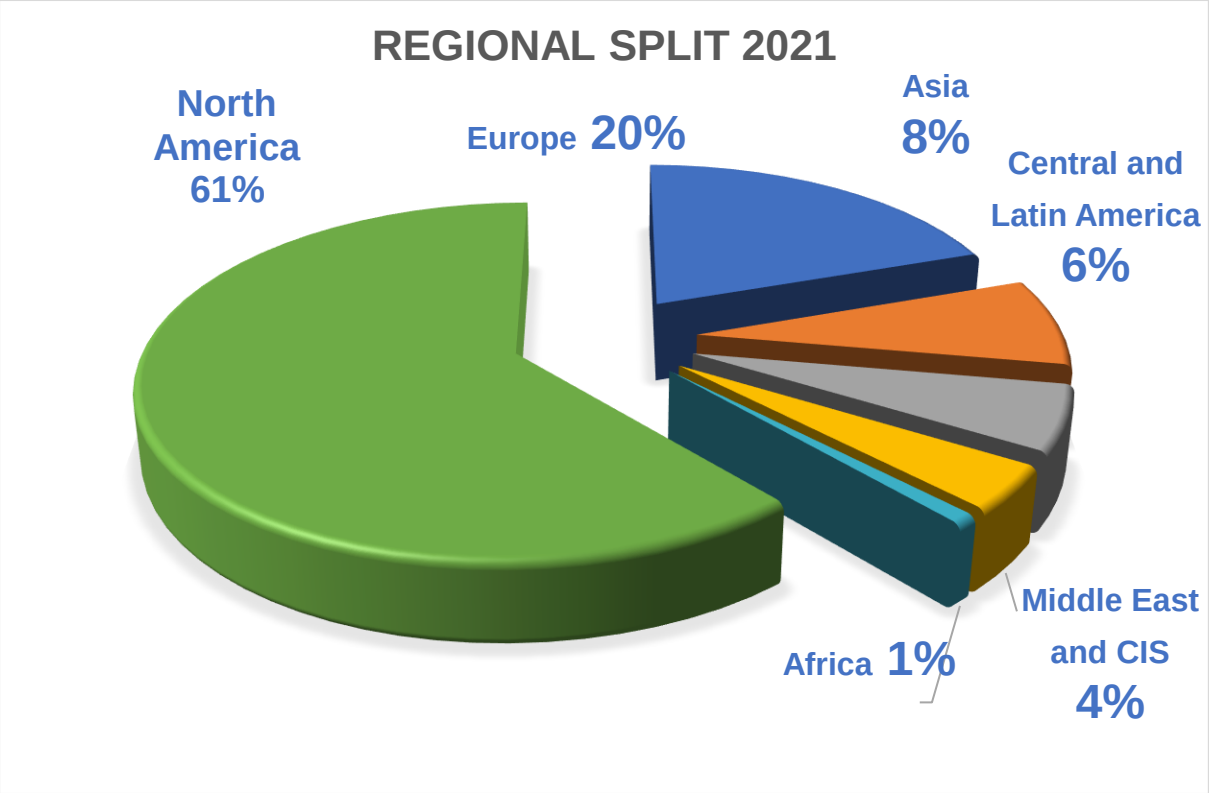
Another significant impact will be caused by the lack of a derogation for products placed on the market before the entry into force of a restriction for medical imaging and radiotherapy products. Such devices have a service life between 10 and 20 years and they are moved, donated, sold between hospitals several times. They can also be repurchased by OEMs of 3rd party providers for refurbishment and then sold again to other hospitals and clinics.

Medical imaging and radiotherapy devices are capital investment equipment with a significant residual value even when used, from hundreds of thousands to millions of euro. The impossibility to sell or trade such equipment will impact hospitals budget that will see the value of their assets dropped to zero. Not only is this going to decrease access to healthcare, but it is also going to put a financial stress of many hospitals in Europe that are already living in difficult times.

4.7 Impact on circular economy and refurbishment

Medical devices are frequently refurbished by the original manufacturer for reuse. Many refurbished medical devices are sold in the EU as EU hospitals have limited budgets and refurbished equipment provides the capability that they need.

[23] *Based on information collected by COCIR.*
[24] *https://www.reuters.com/article/us-health-coronavirus-germany-italy-idUSKBN21B2GL*



Refurbishment market split – Source COCIR SHARE data

The global refurbished medical devices market was valued at approximately $10 130 million in 2020[25], of which the EU is about 20% of the total according to market research undertaken by Data Bridge.[26] This trend is anticipated to grow over the coming years in the EU.

Refurbishment Includes actions such as repair, rework, update, and replacement of worn parts with original/new parts from stocks or refurbished parts. Many types of part are removed from used medical devices during refurbishment, repair, servicing, or maintenance and then these parts are re-used for the repair, refurbishment, servicing, and maintenance of different medical devices.

The refurbishing of medical devices is a circular economy business practice that was already introduced before the beginning of this century, and it is now defined by the IEC 63077 standard. Refurbishment of medical equipment contributes to important societal challenges and is encouraged by the EU's Circular Economy Policy. Refurbishment contributes to the conservation of resources by saving energy in the production of new equipment, reducing material consumption and related mining requirements. The reduction of waste, with reports such as the one released by DITTA[27], estimate that around 30 MWh can be saved for each tonne of refurbished medical devices.

Refurbishment uses recovered spare parts (which have also been refurbished themselves) as using new parts is not an option because they are no longer produced, or it would be

[25] *https://www.mordorintelligence.com/industry-reports/global-refurbished-medical-devices-market-industry*
[26] *https://www.databridgemarketresearch.com/reports/global-refurbished-medical-device-market*
[27] *http://globalditta.org/*

uneconomic (less than 10% of parts used for refurbishment are new ones). Recovered and refurbished parts are also reused as spare parts for repair and maintenance of the installed base in the EU.

4.7.1 PFAS restriction could stop refurbishment

COCIR expects that the first PFAS-free medical devices will come back for refurbishment around 10 – 15 years after the EIF of the restriction for medical devices (i.e. sold about 5 years after EIF plus about 7 years with the first user), if 13,5 years are granted as requested by COCIR. When the first medical devices are available for refurbishment, there will not yet be PFAS-free recovered spare parts as parts are recovered from devices that have reached their end of life. Stock of PFAS-free recovered parts is slowly built over time with more and more devices coming back for refurbishment.

The restriction for PFAS must be worded in such a way to allow the use of PFAS containing parts to refurbish medical devices made before the PFAS restriction EIF taking into account any current and future equipment derogations, when needed. A similar wording has been already adopted for the RoHS Directive (exemption 31a) and has been successfully used since 2014. Recently the wording has been renewed and extended to the 4 substances recently added to the list of restricted substances under RoHS (exemption 47). If this is not allowed, the market of refurbished devices in the EU will shrink depriving healthcare providers of the possibility of purchasing cheaper and high-quality devices. As new devices are more expensive (assuming that they are available), non-availability of refurbished equipment in the EU will reduce the total quantity of new equipment that each hospital (with limited budgets) will be able to buy each year with a knock-on effect on healthcare provision.

4.8 Impact of restriction on innovation

All manufacturers have a hierarchy for expenditure:

1. Factory worker safety
2. Product compliance
3. Maintenance of factories and infrastructure
4. New product development / Innovation

The first 3 points are critical obligations and therefore no reduction in expenditure can be accepted. The more companies have to spend on compliance, the less is available for new product development and innovation. COCIR has determined that companies in the medical imaging sector invest 7 – 8% of annual sales volume on new product development which corresponds roughly to €1,2 billion per year.

Innovation in the medical device sector is entirely driven by improving the outcomes for patients, in terms of diagnostics which detect health issues earlier, through more precise treatments, and reduction of side effects from treatment. COCIR members recognize that this will no longer be able to be the sole driver for research and development, as substances of very high concern such as PFASs will require very significant investment and skilled workforce dedicated to their substitution.

Healthcare providers in EU Member States (i.e. hospitals and clinics) all have limited budgets which would not be increased due to legislative requirements imposed on equipment such as a PFASs restriction. Consequently, if prices were to increase, less new

equipment would be able to be purchased and the health benefits from new technology would be delayed. This in turn would result in less effective detection and diagnosis of disease and inferior treatment of patients leading to reduced quality of life and inferior outcomes including possibly deaths occurring earlier than if these obligations were either not imposed or were imposed over a significantly longer period of time to allow manufacturers to continue research on new innovative products as well as PFAS substitution.

COCIR members understand that, in order to keep price rises to an acceptable minimum, it will be necessary to divert resources towards activities to replace substances in medical devices, both in terms of funding and allocation of limited-availability and suitably qualified personnel to work on such devices. This means advancements in unique technical functionality of medical devices might be delayed or postponed.

It is therefore arguable that the pace of clinical diagnostic and treatment improvement will continue to slow as more resource is diverted from innovation to removal of hazardous substances from new and existing products, with either no innovative healthcare benefit or potentially a loss of performance depending on the impact of the substitute substance or technology on the product.

5 ENVIRONMENTAL IMPACT, END-OF-LIFE AND WASTE CONSIDERATIONS

The medical devices produced by COCIR members are generally long-life items, with a good market for refurbishment and reuse of products. COCIR member companies, as far as we know, do not use PFAS process chemicals, but use parts and components that contain mainly polymeric PFAS to manufacture their products.

5.1 Environmental fate and risk from manufacturing releases

COCIR members do not make chemical forms of PFAS and are users only of parts that contain PFAS. COCIR member companies intend to substitute for PFAS as soon as possible as described earlier in this submission. The issue of spare parts is, however, important. As explained above, spare parts are essential for repair of existing medical devices to enable EU hospitals and clinics to treat patients. It is essential that spare parts are readily available to ensure that the equipment can quickly be repaired and used because while it is not functioning, patients cannot be treated, and delays can cause serious harm to EU patients.

Spare parts include replacement circuit boards, sub-assemblies, and components and these are required by the EU MDR to be identical to the original parts that were used in the new product. If the restriction as proposed is adopted, those parts that contain PFAS could not be supplied or used without a derogation. As explained above, equipment made by COCIR's members is often repaired using spare parts recovered from used equipment and these parts are also used to refurbish used equipment. Assuming that a derogation for medical imaging and radiotherapy equipment is granted, all of these parts and the equipment that will be refurbished will have already been manufactured before this restriction takes effect and so there will be no additional PFAS production required and so no further impact on the environment or health from production of PFAS. Already produced parts will reach end of life either after they are reused to repair or refurbish equipment and this reaches end of life or without a derogation, they will become waste earlier when PFAS is restricted. Any emissions from these spare parts will be the same

irrespective of when they become waste, the only difference is the date when these parts reach end of life.

If new spare parts are needed that contain PFAS, this will only be because PFAS-free alternatives cannot be made or are not available. These will be needed only to repair existing equipment without which patients cannot be treated and some may die.

5.2 PFAS Emissions

Most PFAS emissions are understood by COCIR to occur during the manufacture of these substances and their use to make polymers and other chemicals. Based on the data that has been gathered by COCIR members as of this report most of their uses are of polymeric forms in components, cables, and assemblies, yet further research is needed to identify all uses. The use of PFAS polymers to make components, the use of equipment containing non-volatile PFAS and end of life of COCIR's members' equipment is likely to cause relatively small or negligible quantities of emissions compared to the initial PFAS production phases, but COCIR cannot provide evidence for this. If any emissions occur from continued use of existing equipment, repair using already manufactured spare parts and disposal at end of life by recycling in the EU, this will happen with or without a PFAS restriction. In any event, PFAS emissions during these phases would be negligible in comparison with PFAS production emissions.

COCIR has no quantitative data on emissions, but PFAS polymers and other substances are thermally very stable and are not normally heated during equipment production[28] or use. Recycling is usually carried out only by licensed EU recyclers.

5.3 Environmental fate of end-of-life product and associated spares

Equipment manufactured by COCIR members is regulated by the Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU). COCIR's members' equipment is valuable metal-rich and so is always recycled to recover the metal content. It is very unlikely that any is sent to landfill. Due to the heavy nature and high value of most of COCIR members' equipment, it is possible to consider that all equipment is recycled within the EU and the recycling processes used are regulated by EU waste legislation including the Industrial Emissions Directive (2010/75/EU). According to several US studies on incineration of PFAS, at the high smelting process temperatures used for metal recovery all PFAS should be completely destroyed so there would be negligible emissions at end of life, although EU recyclers are not obliged to monitor PFAS emissions[29]. Recently studies have been published that show that no harmful PFAS emissions occur with well-run incinerators.[30] COCIR's members' equipment does not contain volatile PFAS such as hydrofluorocarbons and so these substances should not cause emissions. Electrical equipment recycling is carried out in the EU and most medical devices are recycled within the EU when they reach

[28] *This is with the exception of soldering, however PFAS polymers are used because they are unaffected by soldering temperatures.*
[29] *Two seconds at 1000°C should be enough to destroy PFAS, according to https://www.epa.gov/sites/default/files/2019-09/documents/technical_brief_pfas_incineration_ioaa_approved_final_july_2019.pdf . Most steel and non-ferrous smelters operate at much higher temperature.*
[30] *Aleksando, K., Gehrmann, H-J., Hauser, M., Matzing, H., Pigeon, D., Stapf, D., Wexler, M. (2019). Waste Incineration of Polytetraluoroethylene (PTFE) to Evaluate Potential Formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in Flue Gas and Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, A. Krasimir et.al. Chemosphere 226 (2019) 898 - 906*

end-of-life. EU metal smelters who recover metals from e-waste are already obliged to ensure that there are no emissions of polychlorinated biphenyls, furans and other toxic by-products and the conditions required to achieve this should also completely destroy PFAS.

5.4 Fate of end-of-life of waste cable and wire

Fluoropolymer insulated copper wire will be recycled in the EU by smelting to recover the copper metal. First the insulation layer is removed to separate quite clean copper. Copper has a melting temperature of 1085°C and so at least 1100°C is needed to melt the wire and at this temperature, any fluoropolymer insulation residues should be destroyed. The removed fluoropolymer is incinerated to destroy the PFAS. Publications indicate that it is likely that some CF4 may be produced, which is not a PFAS as defined by the proposed regulation. Other emissions will be of CO_2, water vapor and simple hydrocarbons[31].

5.5 Minimization of release of PFAS from waste and end-of-life product

COCIR's members take back used equipment from their customers either for refurbishment and re-use or for disposal. Collection of a high proportion of many types of equipment is achieved and so COCIR's members can ensure that disposal is carried out in the EU according to the requirements of EU legislation and therefore minimize emissions of harmful substances. Hospitals sometimes dispose of their own equipment and due to its high value as scrap, this is recycled by licensed EU waste recyclers.

[31] *https://www.ghd.com/en/about-us/examining-thermal-destruction-for-pfas-waste.aspx*

6 DISCUSSION AND CONCLUSIONS

COCIR members intend to phase out the use of per- and polyfluoroalkyl substances (PFASs) in all applications where it is identified. COCIR members use PFASs in a wide variety of electrical and non-electrical applications in the EU. These materials cannot be easily substituted as they form an integral part of the medical device. Any alternative with inferior performance could degrade the clinical performance of the devices impact directly and significantly the health of millions of EU citizens.

COCIR estimates around **10 tonnes per year** are used in Europe in medical imaging and radiotherapy devices, almost all in fluoropolymers. **0,0012%** of the estimated total usage of PFAS in Eu and **0,02%** of the total usage estimated for the medical devices sector in the restriction proposal.

The COCIR assessment of uses of PFASs suggests that substitution of PFASs could be possible in 13,5 years for medical imaging and radiotherapy equipment and associated accessories and medical devices required to perform imaging and radiotherapy procedures.

COCIR's members are still reviewing PFAS uses, and this is not expected to be complete for at least one year. The most common uses of PFAS are as polymers, mainly as flame-resistant polymers used in various types of components and equipment, including:

- Cables and wiring and electrical connectors. Some current uses such as in MRI, X-ray and ultrasound imaging will be very difficult to replace due to the unique properties of fluoropolymers
- Printed circuit boards and, other plastic electrical and electronic components, such as relays, transformers, inductors, sensors, etc.
- Other non-electrical components, such as housings

PFAS are also used in lubricants. So far COCIR has identified an application in automatic injectors used for injecting contrast agents used in imaging procedures such as x-ray and CT.

PFAS are used because they provide unique combinations of essential performance, such as flexibility, suitability at high and low temperature, dielectric properties, fire resistance, resistance to sterilising chemicals, biocompatibility, etc. COCIR members already know that, most likely, for a long time, there will be no drop-in replacements or even materials that are "good enough" for use in medical devices.

The following elements, analysed in this report support the request for the derogation duration:

Technical aspects (Chapter 3)

1. Identifying all PFAS applications within a global supply chain of 5.000 to 11.000 suppliers and assess possible alternatives will require years. Many alternatives cannot be tested until the PFAS and possible substitutes identified
2. PFAS-free components can only be tested and integrated into new designs once available. Most of the components will become available just before the expiry of their derogations. If, for instance, a derogation of 5 years is granted to semiconductors, most alternative components probably we will not be able to start testing and equipment redesigning before that expiration date. The design cycle of

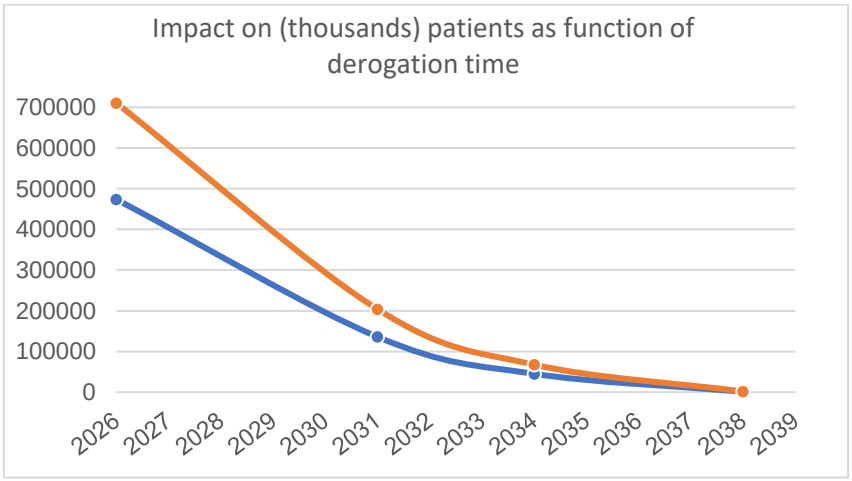
medical imaging devices is 5 to 7 years while for radiotherapy equipment is 9 to 11.

3. Companies have limited specialized technicians and engineers while having a wide portfolio of applications. As already proven under RoHS, redesign takes time and resources. It is not possible to have too many models being redesigned in parallel.
4. For certain applications there may not be alternatives providing the same clinical performances even in the expected timeframe, and therefore extension of derogations may be required.
5. Despite using some of the best substance tracking tools, there are still likely to be unidentified uses which will not be found by companies until late in the substitution process. Even a 13,5-year derogation cannot shield companies and healthcare providers from the consequences of suppliers' mistakes.
6. Medical imaging and radiotherapy devices are regulated by the Regulation (EU) 2017/745 (MDR). This regulation ensures a high level of certainty, requiring the certification of all devices before their placement on the market. Strict considerations are established in terms of patient safety, demanding extensive testing, clinical evidence and the implementation of risk management systems.

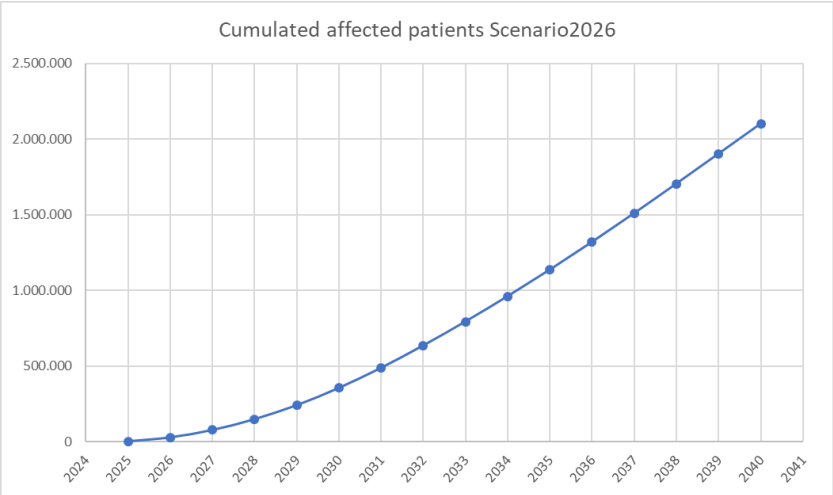
Socio-economic impacts (Chapter 4)

Without a derogation for a sufficient number of years we expect that the technical impossibility to substitute all PFAS applications and to redesign all models will cause serious impacts on the availability of medical devices with the following consequences:

7. Devices being discontinued with a consequential **reduction in access to healthcare for hundreds of millions of patients** for a long period (from EIF to at least 2040). It would take probably far after 2040 before sales would recover but the decrease in the installed base (density) will not. See chapter 4.4.
8. The reduction in density can possibly cause **tens of millions of cancer patients** not to receive proper healthcare and maybe reduce their chances for better outcome (see chapter 4.5) at least until (and beyond) 2040. A 13,5 years derogation could lower such numbers to a few thousands.
9. The impact on cancer patients is compounded by the recent surge in cancer cases, reportedly up by 40%, that will require an even larger increased availability of radiotherapy centres.
10. The already serious problem with waiting times for healthcare getting longer in the EU will be exacerbated and add to the negative impacts so far experienced.



The simulation shows that with a 13,5-year derogation the impact on patients access to healthcare will drop from hundreds of millions to a few millions.



Several million cancer patients at risk of less-than-optimal care (mortality in EU)

For the above-mentioned technical reasons and in order to avoid the social impacts **COCIR recommends derogating medical imaging and radiotherapy devices for 13,5 years.** A review clause is included in our proposal, supposing 3 years for the evaluation of derogations are sufficient.

11. The "repair as produced principle" is essential to allow continue servicing and repair of medical imaging and radiotherapy equipment in use at hospitals and clinics in the EU.
12. Refurbishment of medical devices requires spare parts to be available to refurbish used devices. As such, the restriction wording must allow for this practice to continue delivering affordable healthcare and benefits of suitable equipment.
13. It has been already proven under RoHS, for exemption 31a and 47 that the reuse of spare parts is always better from an environmental perspective than generating waste and manufacturing a new one (which may use critical raw materials or other SoCs).

At the end of the derogation period it may be possible that some uses could be identified for which alternatives will not be available, or where the alternatives would be regrettable substitutions. In these cases, a mechanism to renew the derogation would be essential.

For the above-mentioned technical reasons and in order to avoid the social impacts COCIR recommends derogating medical imaging and radiotherapy devices: for 13,5 years. A review clause is included, supposing that two years for the evaluation of essential derogations are sufficient.

COCIR Recommendations for the wording of a derogation

1.	*By way of derogation, paragraphs 1 and 2 shall not apply to PFAS for the use in medical imaging and radiotherapy devices their accessories and other medical devices within the scope of Article 2(1) of Regulation (EU) 2017/745, required in a modern imaging suite or radiotherapy procedures and designed to work in such*

environments such as contrast injectors, patient monitoring, etc. until EIF+ 13,5 years.

2. *Paragraph 1 and 2 shall not apply to PFAS for the use in new and recovered spare parts to repair, service, updating of functionalities or upgrading of capacity or refurbishment of medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market before EIF+13,5.*

3. *Paragraph 1 and 2 shall not apply to medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market for the first time before EIF+13,5*

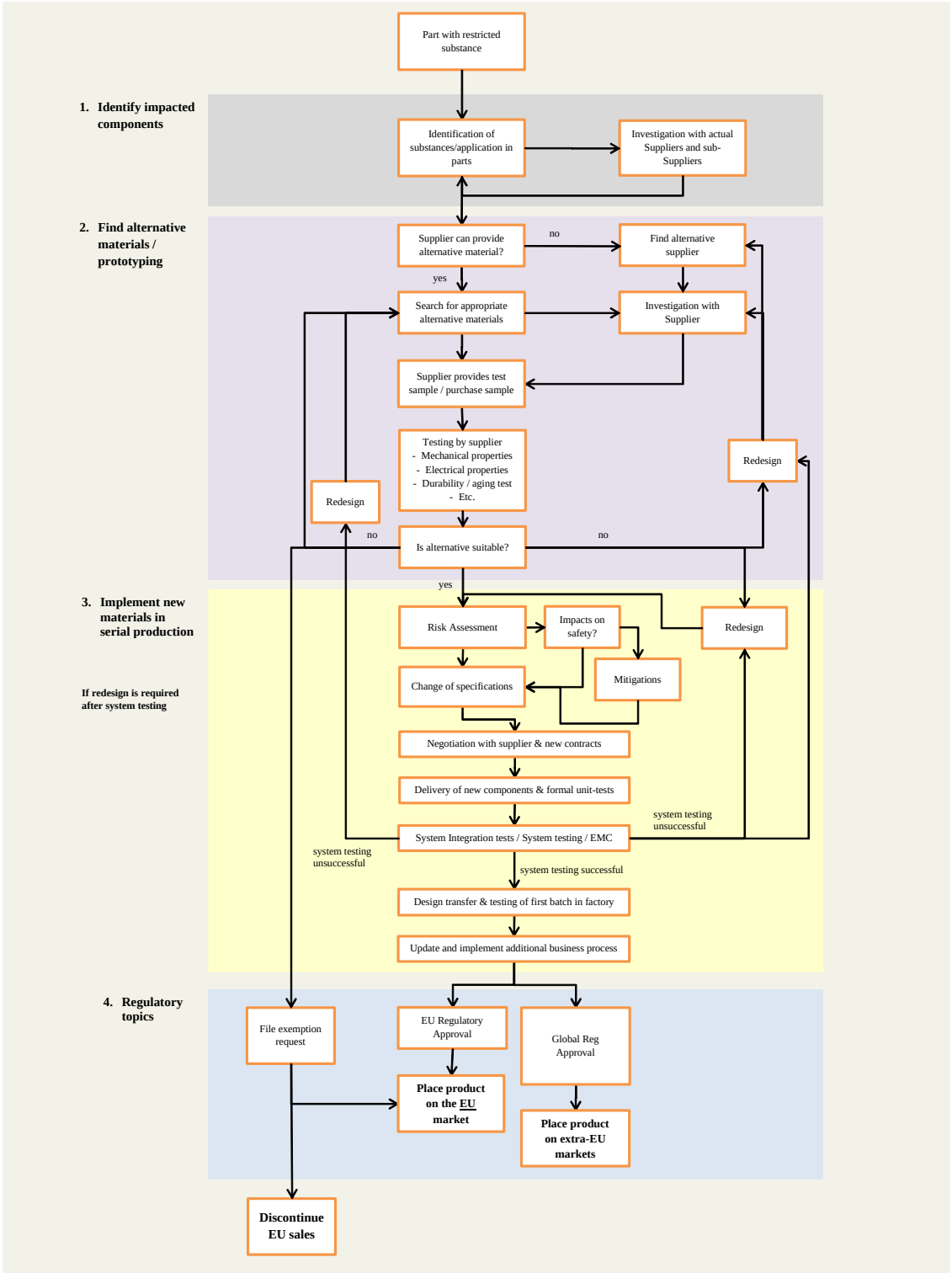
4. *Paragraph 1 ad 2 shall not apply to PFAS in spare parts recovered from and used for the repair, reuse, updating of functionalities or upgrading of capacity or the refurbishment of medical imaging devices, radiotherapy devices and other me, provided that the reuse takes place in auditable closed-loop business-to-business return system and that each reuse of parts is notified to the customer.*

5. *The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector, their accessories and other medical devices required in a modern imaging or radiotherapy suite, by EIF+10 years to assess the need to maintain the derogation for specific applications for which no alternatives are yet available. The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector by [10 years after EIF] to assess the need to maintain the derogation for specific applications for which no alternatives are yet available and to publish proposed amendments to the Regulation.*

This wording proposal ensures, point by point:

1. Enough time for substitution without impacting innovation and availability of medical devices and therefore patients access to healthcare in the EU.
2. Installed medical devices owned by hospitals will be maintained fully functional until the end of their lives instead of being prematurely discarded with a reduction in accessibility to healthcare affecting patients.
3. Medical imaging and radiotherapy equipment (capital investment equipment for healthcare providers) can continue to be sold, transferred, leased, donate between hospitals, taken back and refurbished to increase safety and performances.
4. Circular economy activities such as refurbishment and reuse of recovered spare parts can continue benefitting EU hospitals, ensuring fast and cheaper repairs and shorter downtimes.
5. Certain timelines and obligations would ensure that industry can get the required extension, when needed, without the risk of having to stop orders and sales due to the delays in the evaluation process

Appendix A: Flowchart of the restricted substance substitution process



Source: COCIR

Note that this chart shows the overall workflow, which is then replicated on the subsequent figures to make it more readable in this report (See section **Error! Reference source not**

found.).

RINA Tech UK Limited | 1 Springfield Drive, Leatherhead, Surrey, KT22 7AJ, United Kingdom | P. +44 0 1372 367350 | Company No. 07419599
UKinfo@rina.org | www.rina.org