Til: Dorte Bjerregaard Lerche ([redacted]@mim.dk), Rikke Donchil Holmberg ([redacted]@mim.dk)
Fra: Henrik Søren Larsen ([redacted]@mim.dk)
Titel: VS: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients
Sendt: 02-06-2023 16:04
Bilag: 2023-06-02_COCIR.draft.Letter.on.PFAS.RAC&SEAC.Opinion - Denmark.pdf; COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients.eml; 2023-06-02_COCIR.draft.Letter.on.PFAS.RAC&SEAC.Opinion - Denmark.pdf; SV: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients.eml;

Kære Dorte
Vil du være venlig vedhæftde mail i at lægge i F2?
På forhånd tak
Henrik

Fra: Riccardo Corridori <[redacted]@cocir.org>
Sendt: 2. juni 2023 14:50
Til: Henrik Søren Larsen <[redacted]@mim.dk>
Emne: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients

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Today COCIR submitted its first report to the public consultation on the Annex XV report. Our assessment shows that, without a proper derogation, critical medical devices will not be available anymore for EU hospitals and clinics with the entry into force of the restriction, significantly impacting healthcare in EU.

Please do not hesitate to contact us for any additional information.

Best regards,

Riccardo Corridori
Senior Manager
Environmental, Health and Safety Affairs
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BluePoint - 80 Bd A. Reyers - 1030 BRUSSELS (B)
Tel.: +32 (0) 2 706 89 66 - Fax: +32 (0) 2 706 89 69
http://www.cocir.org

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Mr. **Henrik Søren Larsen**
Ministry of Environment and Food
Head of Department, Chemicals

Brussels, 2 June 2023

PFAS Restriction Proposal

Dear Mr. Larsen

Following my previous letter in March this year, I am re-contacting you about the published PFAS restriction proposal. As anticipated, the restriction does not include any exemption for medical imaging and radiotherapy devices, including medical devices that are an integral part of a modern imaging or radiotherapy suite.

Please be informed that COCIR has submitted today its first contribution to the public consultation for the RAC and SEAC opinions with our estimation for the socio-economic impacts of the proposed restriction and a technical assessment of the time required for substituting the many applications of PFAS, mostly fluoropolymers. A second submission will include all our collected knowledge about applications, alternatives, and plans for substitution.

Our key concern is that the current proposed restriction will result in a complete halt to sales of critical medical devices in Europe in just a few years. This would have a direct impact on not just the sector, but mostly on hospitals and patients in the EU. Medical imaging and radiotherapy equipment fall under Regulation (EU) 2017/745 (MDR). Substitution under MDR is a lengthy process due to the complexity of devices and the extensive testing and certification requirements.

Our simulations show that with a proper derogation for at least 13,5 years and the possibility to extend it for specific applications in the future where alternatives may not be available, the number of patients affected may be reduced. Please see the summary of our analysis and recommendations below.

Given the urgency of the matter, and the upcoming RAC and SEAC meetings in the beginning of June 2023 we kindly ask for your support in ensuring the concerns above are recognised so that medical imaging and radiotherapy technologies remain available to the health care sector in the EU/EEA countries.

Please do not hesitate to contact us for any question you might have.

Yours sincerely,

Annabel Seebohm
COCIR Secretary General

ANNEX:
SUMMARY OF ANALYSIS AND RECOMMENDATIONS

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 and may directly and significantly impact the health of millions of patients in the EU.
The COCIR assessment of PFAS uses suggests that substitution of PFASs could be possible in 13,5 years for medical imaging and radiotherapy equipment and associated accessories and medical devices that are an integral part of 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.

The following elements support the request for the derogation duration for 13,5 years:

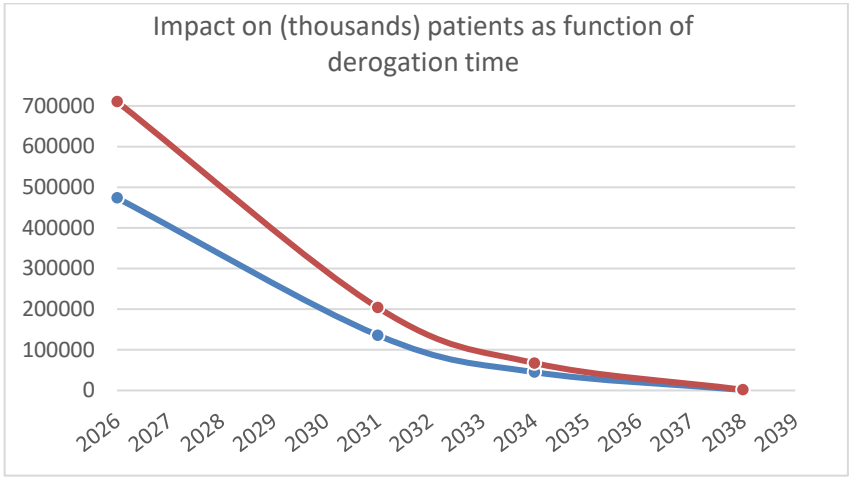
Technical aspects (Chapter 3 of COCIR 1st submission)

1. Identifying all PFAS applications within a global supply chain of 5.000 to 11.000 suppliers per company and assessing possible alternatives will require years.
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 expire of their derogations. The design time 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.
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.

Socio-economic impacts (Chapter 4 of COCIR 1st submission)

Without a derogation for enough years the restriction will cause serious impacts on the availability of medical devices with the following consequences:

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



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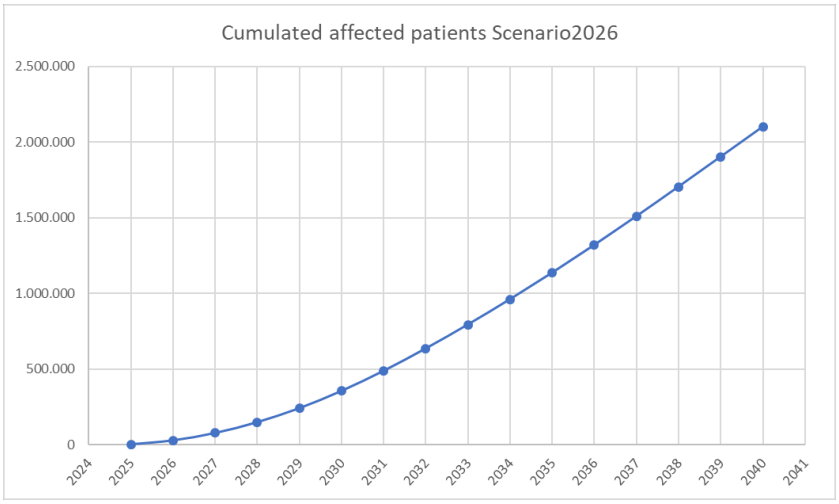

Several million cancer patients at risk of less-than-optimal care (mortality in EU)

A derogation is therefore required for at least 13,5 years. In addition, the wording must allow for the reuse of spare parts for refurbishment and repair of devices placed on the market before the entry into force of the restriction for the sector:

10. The “repair as produced principle” is essential to allow continued servicing and repair of medical imaging and radiotherapy equipment in use at hospitals and clinics in EU.
11. 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 to suitability.
12. 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 with clear deadlines and obbligations would be essential.

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.

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*

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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
2. Installed medical devices owned by hospitals will be maintained functional until the end of their lives instead of being prematurely discarded with a reduction in accessibility to healthcare affecting patients.
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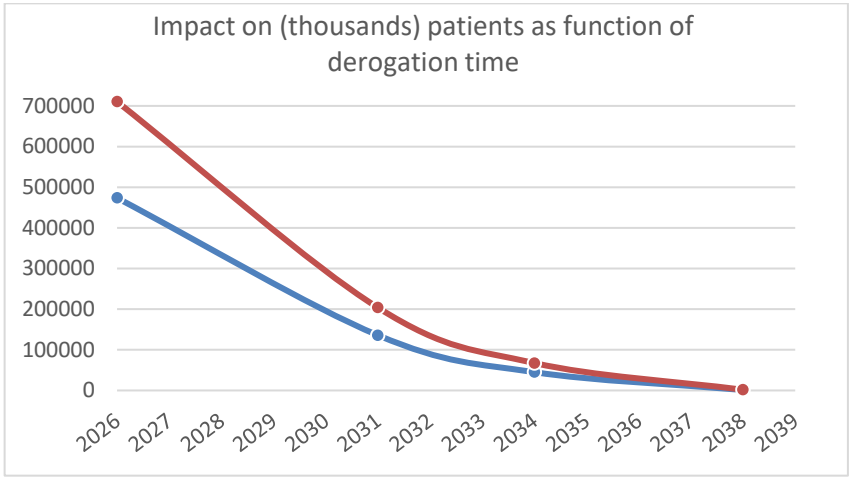

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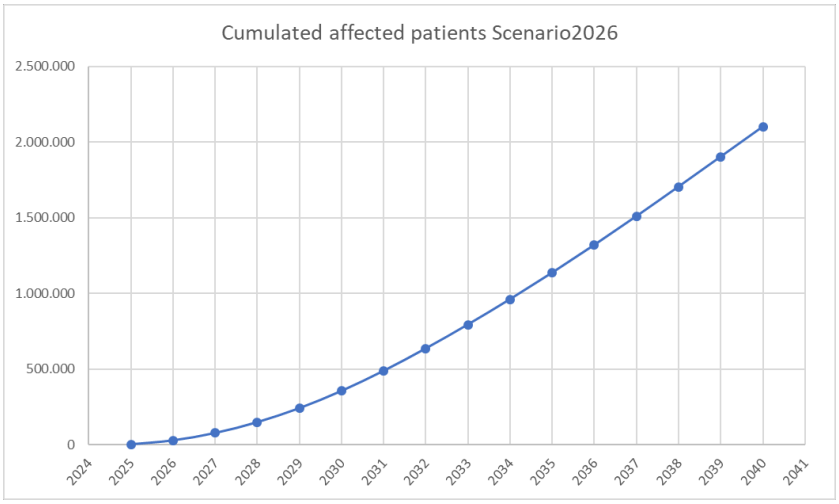

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Best regards,
Henrik Søren Larsen

Kind regards,

Henrik Søren Larsen
Head of Department | Drinking Water & Chemicals
+45 23 31 40 37 | [redacted]@mim.dk

Ministry of Environment
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Facebook | Twitter | Instagram I LinkedIn

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