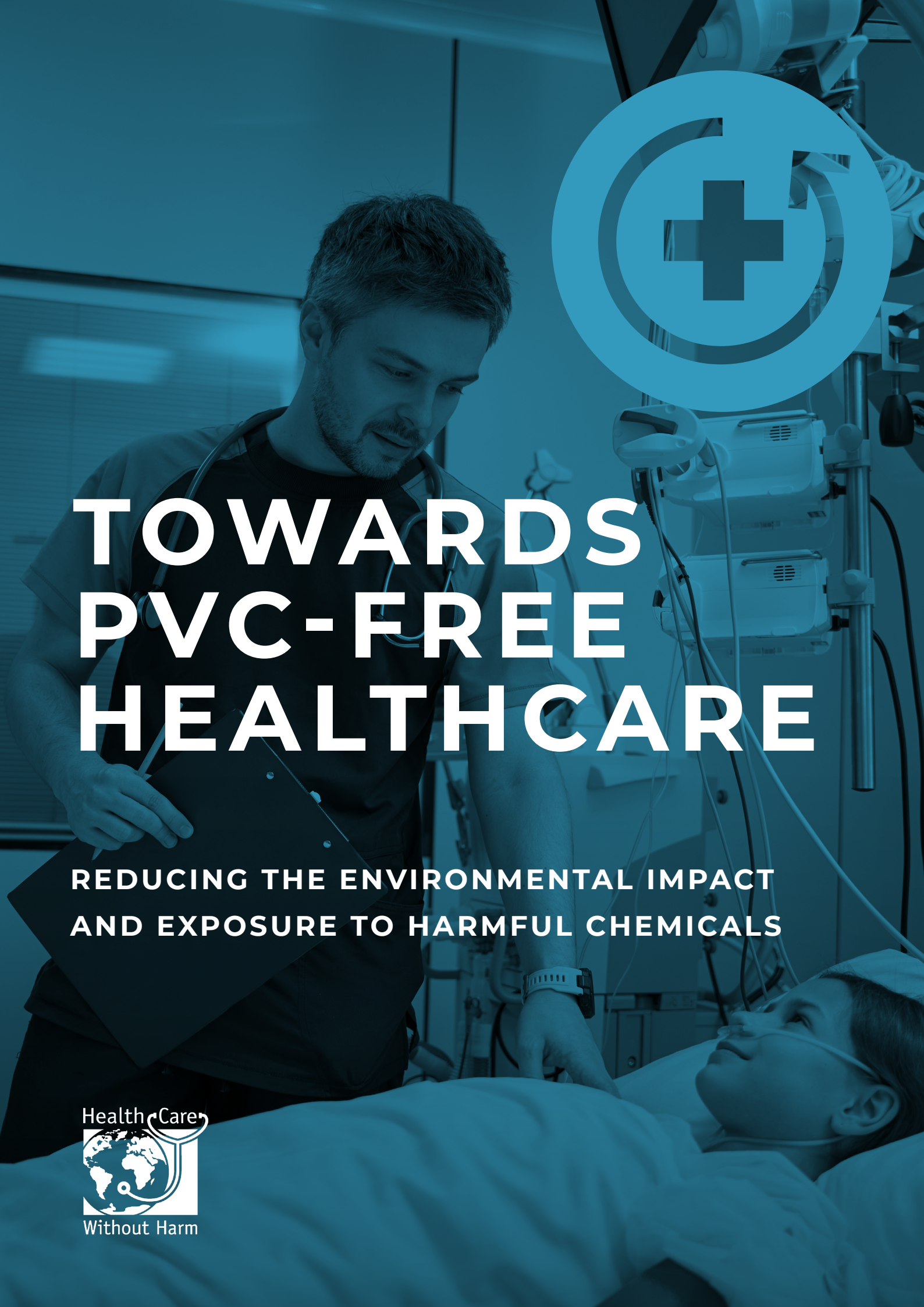


TOWARDS PVC-FREE HEALTHCARE

REDUCING THE ENVIRONMENTAL IMPACT AND EXPOSURE TO HARMFUL CHEMICALS

Health Care Without Harm

ABBREVIATIONS USED IN THIS PUBLICATION

ASE	Alkylsulfonic acid esters
ATBC	Acetyl tributyl citrate
BTHC	Butyryl tri-n-hexyl citrate
CHV	Consorci Hospitalari de Vic
COMGHA	Glycerides, castor-oil-mono-, hydrogenated, acetate
DEHA/DOA	Bis(2-ethylhexyl) adipate
DEHP	Di-2-ethylhexyl phthalate
DEHT	Bis(2-ethylhexyl) terephthalate
DIBT	Diisobutyl phthalate
DIDP	Diisodecyl phthalate
DINA	Diisononyl adipate
DINCH	Cyclohexane 1, 2-dicarboxylic acid diisononyl ester
DINP	Diisononyl phthalate
ECHA	European Chemical Agency
EDC	Ethylene dichloride
E-PRTR	The European Pollutant Release and Transfer Register
GMTS	Global Minimum Transparency Standard
GOSH	Great Ormond Street Hospital
HBN	Healthy Building Network
IV	Intravenous
MDR	Medical Devices Regulation
PCB	Dioxins and polychlorinated biphenyls
PCDD/FS	Polychlorinated dibenzodioxins
PVC	Polyvinyl chloride
PPE	Personal Protective Equipment
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
TOTM	Tris (2-Ethylhexyl) Trimellitate
VCM	Vinyl chloride monomer
WHO	World Health Organization

TERMINOLOGY USED IN THIS PUBLICATION

Plasticisers	Synthetic chemicals added to PVC products to soften and increase the flexibility of the material.
Alternative plasticisers	Substitutes for conventional phthalate plasticisers, with reduced harmful effects.
Infectious waste (as defined by the WHO)	Waste contaminated with blood and other bodily fluids (e.g. from discarded diagnostic samples), cultures and stocks of infectious agents from laboratory work (e.g. waste from autopsies and infected animals from laboratories), or waste from patients with infections (e.g. swabs, bandages and disposable medical devices)

EXECUTIVE SUMMARY

THE HEALTHCARE SECTOR RELIES ON A LARGE VARIETY OF PLASTIC-BASED PRODUCTS MADE FROM POLYVINYL CHLORIDE (PVC), COVERING A WIDE SCOPE OF APPLICATIONS SUCH AS IV BAGS, TUBING, EXAMINATION GLOVES, FLOORING, PIPES, FOOD PACKING, AND OFFICE SUPPLIES.

Numerous studies reveal that the production, use, and disposal of PVC pose serious health and environmental risks, underlining the need to eliminate PVC. This is particularly important in the healthcare sector, where plasticised PVC is a source of exposure.

Patients often come into contact with harmful substances, such as the plasticisers used in PVC medical devices. This presents a significant risk for vulnerable patients undergoing multiple medical interventions or being exposed chronically over extended periods, including infants in neonatal care or dialysis patients.

PVC-free alternatives are already in use, and many countries have initiated a phase-out for some product categories by adapting their procurement criteria for healthcare products. Healthcare providers can play a pivotal role in championing the phase-out by supporting substitution and inspiring healthcare communities to replace PVC wherever feasible.

In light of its long track record of advocacy on PVC, HCWH Europe has produced this report with the help of its members and experts in the field to support PVC restriction in the EU and the elimination of PVC in the healthcare sector. This publication builds upon HCWH Europe's previous paper and provides insights in three chapters addressing concerns about plasticisers and patient exposure, providing a comprehensive overview of environmental concerns related to the PVC lifecycle, and highlighting how healthcare providers are taking steps towards PVC-free healthcare.

KEY POINTS

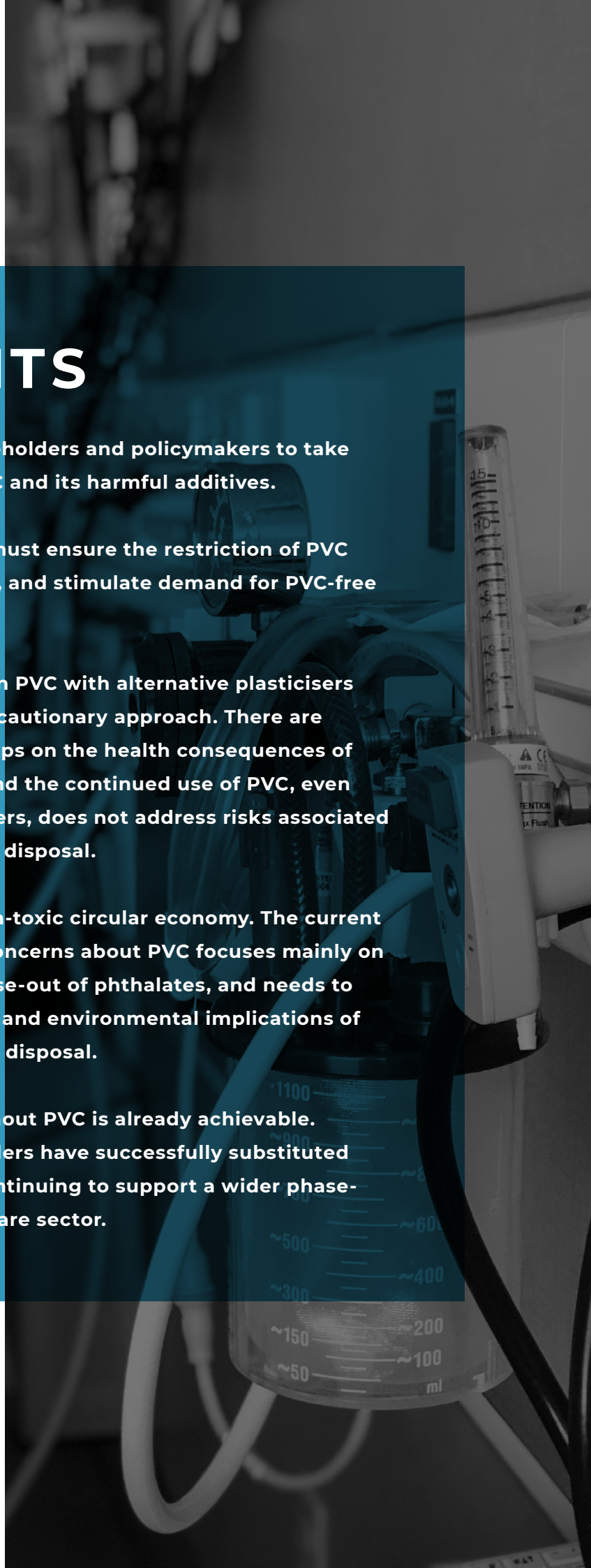
It is crucial for European stakeholders and policymakers to take action towards restricting PVC and its harmful additives.

- **European policymakers must ensure the restriction of PVC and its harmful additives, and stimulate demand for PVC-free alternatives.**

- **Substituting phthalates in PVC with alternative plasticisers does not align with a precautionary approach. There are significant knowledge gaps on the health consequences of alternative plasticisers and the continued use of PVC, even with alternative plasticisers, does not address risks associated with PVC production and disposal.**

- **PVC has no place in a non-toxic circular economy. The current regulatory response to concerns about PVC focuses mainly on the substitution and phase-out of phthalates, and needs to address the wider health and environmental implications of PVC production, use, and disposal.**

- **A healthcare system without PVC is already achievable. Several healthcare providers have successfully substituted PVC products and are continuing to support a wider phase-out of PVC in the healthcare sector.**



INTRODUCTION

Due to its low production cost and diverse range of applications, PVC is widely used in different sectors. In healthcare, the application of PVC includes healthcare products and medical devices, many of which are used in direct contact with patients. Other uses include building materials, office supplies, and consumer products.[1] [2]

Within healthcare PVC is primarily used in catheters, drip chambers, transfusion sets, diagnostic equipment and other medical equipment. Other lower volume uses include medical bags, masks, tubing, gloves and other Personal Protective Equipment (PPE), such as kits of aprons, gowns or head and shoe covers.[2] [3]

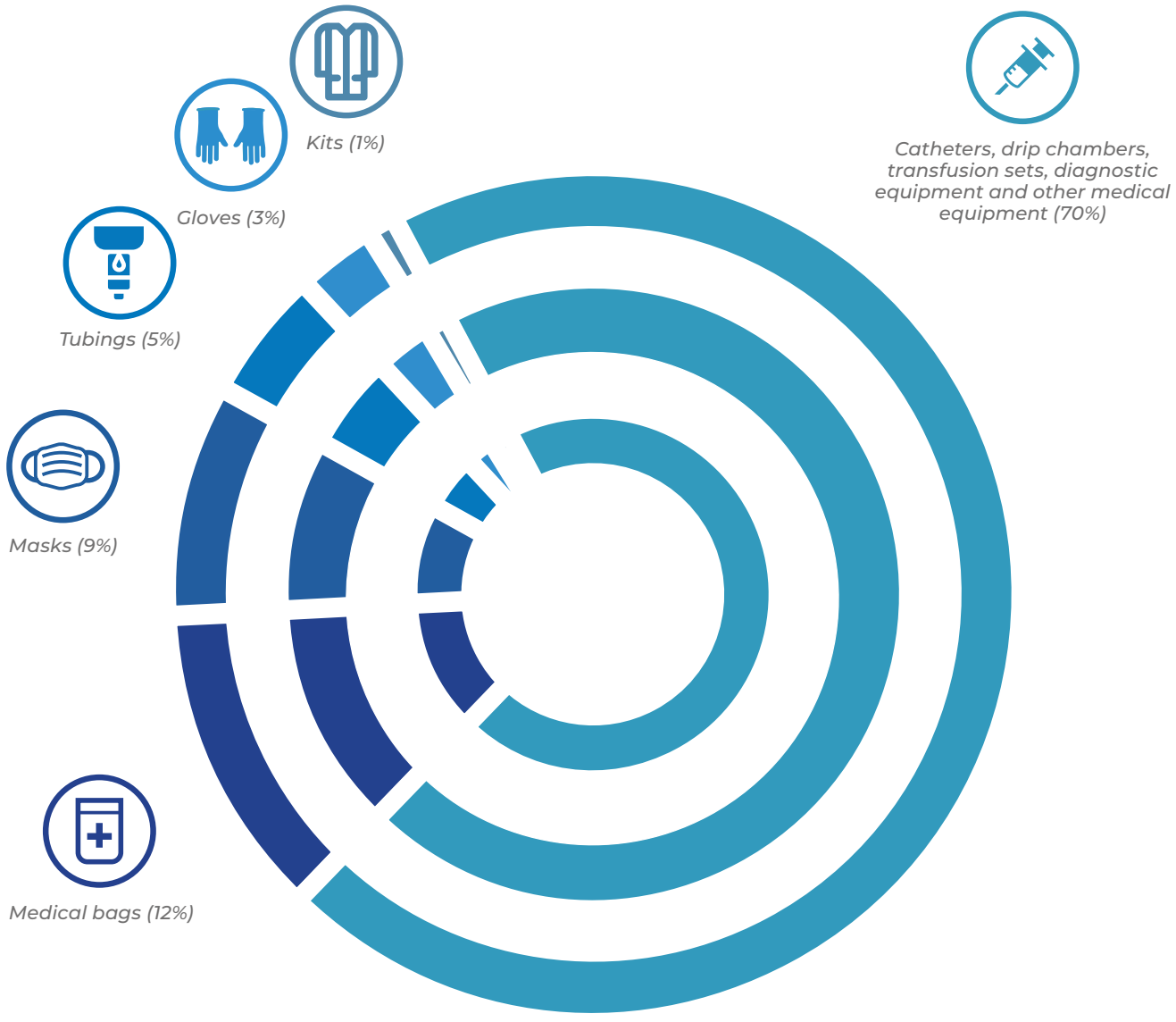


Fig. 1 A breakdown of the PVC medical market. (PVC Med Alliance, 2021)

PVC is the most commonly used polymer for medical devices. In 2021, the Europe Medical Polymer Market Report recorded that PVC represented 26% of medical devices globally and 27% in Europe.[3]

Medical devices play a critical role in healthcare but can be harmful to patients, the environment and public health. During the use of PVC medical devices, patients are directly exposed to harmful chemicals due to the plasticisers contained in PVC, with a consequent risk of leaching into the body and compromising patient safety.[4]

PVC is an unsustainable and problematic material; its production requires the use of toxic substances and causes pollution throughout its lifecycle. At the end of life, PVC is typically landfilled or incinerated, releasing harmful dioxins. Though the reduction and reuse of products is the main priority of a sustainable, circular economy model, recycling plastic is still preferable to single-use, disposal products. PVC recycling is, however, challenging and can pose occupational, public, and environmental health risks.[5 6]

In 2022, the European Commission introduced PVC and its additives into the Restriction Roadmap[7] - a prioritised list aimed at banning the most harmful chemicals and materials. The Roadmap is a significant milestone for the Chemical Strategy for Sustainability, but the phase-out of PVC is unlikely to happen in the short term due to the lengthy decision-making process. After the European Commission's request to analyse PVC in the context of a non-toxic environment in Europe, the European Chemicals Agency (ECHA) will investigate the use of PVC and its additives by May 2023.[8 9]

Despite efforts by healthcare providers to move away from PVC, there is still limited demand for PVC-free medical devices and healthcare products. Considering the political momentum to advance progressive zero-pollution measures, this report aims to support and strengthen the regulatory framework to ensure the restriction of PVC, provide an updated overview of the associated impact, and outline the steps that healthcare providers have taken in moving towards a phase-out.

1 PATIENTS ARE EXPOSED TO HARMFUL PLASTICISERS

PVC is a thermoplastic polymer consisting of 60% chlorine by weight. It can be soft or rigid (depending on which additives are used). In its pure form, PVC cannot be made into products or used on its own. It is rigid and brittle at ambient temperatures and if subjected to heat, accelerating dehydrochlorination reactions will degrade its structure. Inorganic and organic salts have been used as stabilisers to avoid heat and UV-light degradation or to prevent air oxidation.[10]

Due to its rigidity, PVC is mixed with additives to improve its mechanical properties. Plasticisers, heat stabilisers, fillers, pigments, lubricants, and other agents are used to achieve the desired functionality of the products, e.g. durability, stability, colour, and flexibility.[9]

Additives pose a risk for human health. Studies show that these harmful substances can leach out of PVC, mostly in plasticised form.[8] Plasticised PVC contains concentrations of additives above 10%. Higher concentrations (over 70%) of additives in plasticised PVC are frequently found on the plastics market.[9 11]

Phthalate plasticisers

Phthalate plasticisers are a group of commercial synthetic chemicals added to PVC to provide flexibility in medical devices, and are used in applications such as in infusion or transfusion sets and feeding tubes.[4] Phthalates are not bound to the PVC matrix and may leach from medical devices into the human body and the environment.[12]

Exposure to phthalates and harmful chemicals at vulnerable moments of human development is a serious concern. Such exposures can alter development with lifelong consequences.

Infants and unborn children are at a much higher risk of adverse effects because of their lower body weight and reduced ability to metabolise chemical substances, as well as the ongoing development of their organs and systems, and their limited diet.[13] [14]

Members of vulnerable groups can be exposed to unsafe levels of diethylhexyl phthalate (DEHP), a plasticizer often used in medical devices, during medical treatments.[17] DEHP is the most researched and understood phthalate to date and is still present in the medical market despite the provisions (Annex 1, Chapter II, Section 10.4.1) under the EU Medical Devices Regulation (2017/745) in respect of its proven toxicity and hormone disruption.

The Medical Devices Regulation does not, however, prevent manufacturers from using substances of very high concern in medical devices “where justified”. In addition, because it is not yet completely banned (sunset date in 2025), DEHP is still used in plastic medical devices in the Neonatal Intensive Care Unit (NICU) and exposures remain elevated above the tolerable daily intake.[15] [16]

Alternative plasticisers may result in regrettable substitutions

Substituting plasticisers does not support a phase out of PVC nor address the many issues surrounding PVC. However, with growing concerns about DEHP, several manufacturers are substituting DEHP with alternative plasticisers in healthcare products. Alternative plasticisers are either phthalates other than DEHP or non-phthalates substitutes.[5]

Alternative PVC plasticisers include:

- **ASE - alkylsulfonic acid esters**
- **ATBC - tributyl O-acetylcitrate**
- **BTHC - butyryl trihexyl citrate**
- **COMGHA - glycerides, castor-oil-mono-, hydrogenated, acetates**
- **DEHT - bis(2-ethylhexyl) terephthalate**
- **DINA - diisononyl adipate**
- **DINCH - diisononyl cyclohexanedicarboxylate**
- **DOA/DEHA - Bis(2-Ethylhexyl) Adipate**
- **ESBO - epoxidized soybean oil**
- **OTM/TEHTM - trioctyl trimellitate/tri-(2-ethylhexyl)-trimellitate)**

Alternatives to DEHP plasticisers might provide opportunities to reduce toxicity, but data regarding human health effects remain limited and the potential toxicity at high exposure still needs to be fully assessed. Academic studies and EU biomonitoring data indicate the knowledge gaps and the potential risk for use, as these alternatives have not been as extensively studied as DEHP. [17] [18] [19]

The European Human Biomonitoring Initiative (HBM4EU) suggests regulating the use of DINCH (in use and on the market since 2002) since further toxicological research is needed. This substitute is thought not to be an endocrine disruptor, however, effects on the kidneys have been observed in rat studies at high doses.[20]

Research published in 2022 indicated that premature neonates requiring parenteral nutrition (stored in plastic PVC bags and administered intravenously through plastic infusion circuits) are exposed to DEHP and alternative plasticisers, including TOTM, ATBC, DEHT and DEHA.[21]

A computer modelling study on the endocrine-disrupting activity of three non-phthalate alternatives - DINCH, ATBC, and DEHA - suggested potential thyroid hormone disruption.[22]

The PVC industry promotes the safety of plasticisers such as DINCH, DEHT, TOTM, and butyryltrihexylcitrate (BTHC), even though comprehensive toxicological data are not available for all of them. Opting for non-PVC polymers in healthcare products eliminates the need for plasticisers and therefore the risk of using problematic substitute plasticisers.[5]

2 PVC CAUSES HARM ACROSS ITS LIFECYCLE

PVC AND ASSOCIATED SUBSTANCES CAUSE HARM THROUGHOUT THEIR LIFECYCLE. During the use phase patients are exposed to the harmful effects of plasticisers, but the production and disposal of PVC also generate harmful risks to human and environmental health. The wider restriction of PVC is therefore needed to address all the health and environmental concerns associated with its lifecycle.

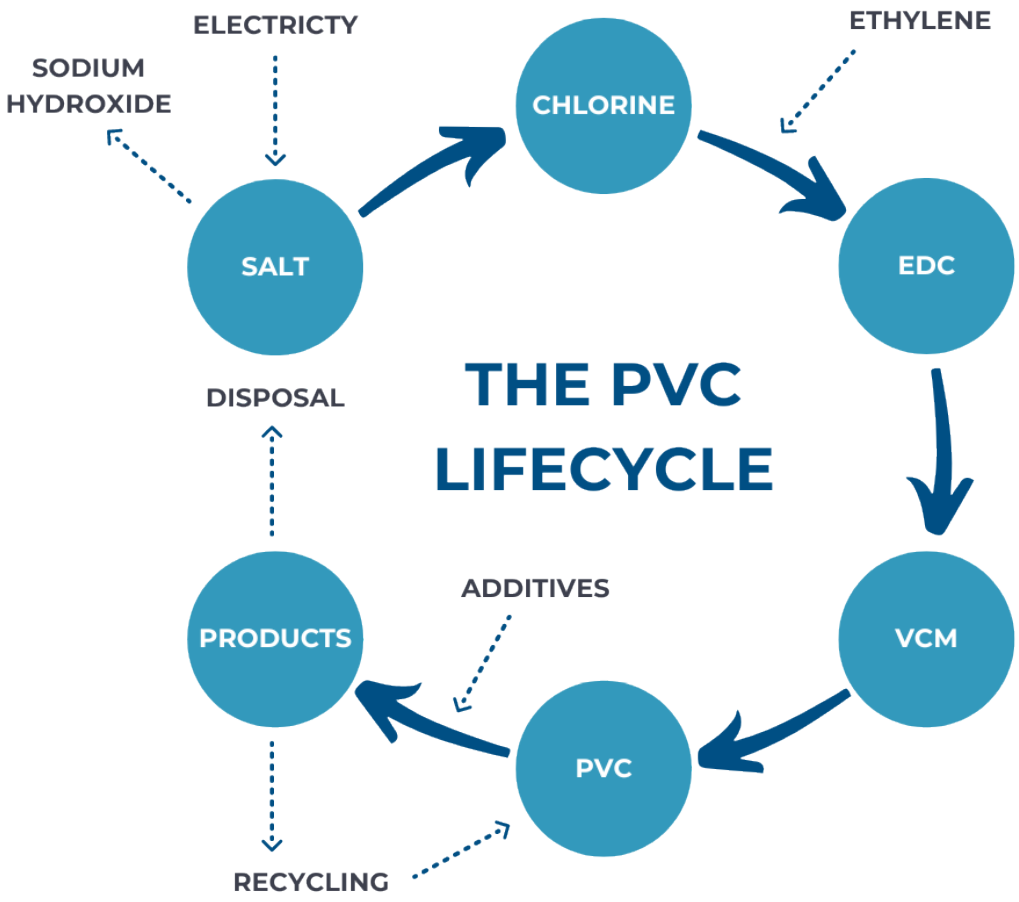


Fig. 2 The production cycle of PVC (HCWH Southeast Asia, 2019)

Production

PVC is produced from vinyl chloride monomer (VCM), which is comprised of 57% chlorine (obtained by electrolysis from a solution of brine), and 43% ethylene (derived from crude oil refining and further cracking steps). PVC production involves the reaction of chlorine with ethylene to form dichloroethane (EDC), which is then processed into VCM through thermal cracking of 1,2-dichloroethane or the hydrochlorination of acetylene.[10]

The initial monomer VCM, added in the REACH Candidate List, is a halogenated hydrocarbon with acute toxic and chronic carcinogenic effects.[23]

VCM itself requires the production of chlorine, an energy-intensive process that involves splitting sodium chloride (NaCl) from seawater or brackish underground water into chlorine gas and caustic soda (sodium hydroxide, NaOH).[24] Chlorine production is accomplished through several technologies using further harmful substances, such as mercury cells, asbestos diaphragms, or PFAS-coated diaphragms or membranes.[5]

PVC cannot be produced, used and disposed without using (and releasing) some of the most harmful, persistent, bioaccumulative, or toxic chemicals substances into the environment.[25] PVC is therefore considered to be one of the most hazardous polymers, according to several reviews, not only due to its toxic nature but because of the hazardous feedstocks, monomers, and intermediates used in its production.[26] This has led to PVC being ranked among the most hazardous polymers by Clean Production Action.[27]

Substituting PVC with alternative materials will help to reduce the production of these hazardous chemicals (and related exposure). In early 2023, a train derailment in the US involving VCM highlighted the hazards of the production, transportation, use, and disposal of harmful chemicals in PVC.[28]

The Healthy Building Network (HBN)'s project, Chlorine and Building Materials: A Global Inventory of Production Technologies and Markets, highlights the world's largest chlorine and PVC factories by indicating the chlorine sources for 113 PVC production plants. The project reflected on the pollution caused by this production, concluding that all PVC resins are produced with one form of toxic technology or another, be it asbestos, mercury, or PFAS. Under the HBN project, information about chlorine and PVC resin factories in the EU and worldwide is available in an open-access global inventory.[29]

Under the Industrial Emissions Directive, industrial plants that produce PVC and its feedstock chemicals must monitor and report emissions of highly toxic chemicals. However, public data provided through the E-PRTR is believed to underreport environmental emissions, as shown by a recent global inventory of chlorine, VCM, and PVC production plants.[31] The study by HBN examined data from national pollutant-registries in Canada, the US, and Europe for chlor-alkali plants and associated plants. The study found that releases of chlorine and chlorinated compounds vary significantly among facilities, but most chlorinated pollution is associated with the production of EDC, VCM, and PVC resins, not chlorine alone. In the European Union, toxic release data reporting is incomplete, but data for chlorinated pollutants is most robust for EDC and VCM, and their releases correlate with their respective production.[31]

[i] Candidate List of substances of very high concern for Authorisation
echa.europa.eu/fr/substance-information/-/substanceinfo/100.000.756

Factory workers and people living in proximity to production sites can be exposed to chemicals used to manufacture PVC, including VCM.[30] A study investigated occupational exposures to VCM and related diseases in Italy, finding that most exposures occurred in the manufacture of chemicals and plastic products, and concurrent exposures were frequently detected. Male exposed workers had a higher proportion of deaths from liver cancer, indicating that VCM exposure remains a concern in chemical and plastic industries, despite low doses.[31]

Health issues such as pulmonary diseases, determined by chest radiographic abnormalities, have also been associated with exposure to PVC particles due to inhalation of airborne PVC dust during manufacturing.[32] [33]

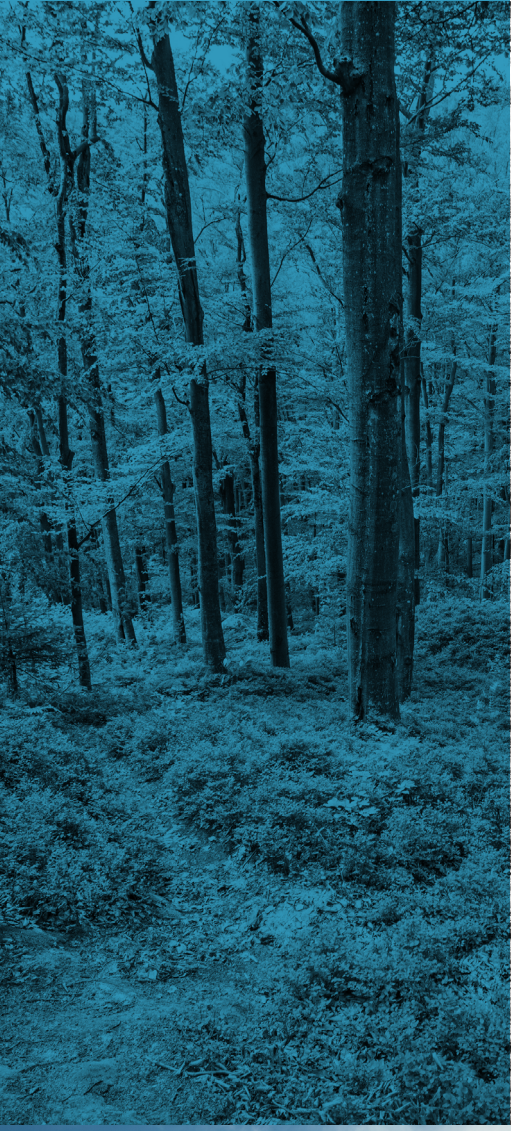
Most of the PVC sold in the EU market is produced in China, the world's biggest producer of PVC. The Helena Kennedy Centre's report on PVC production provided evidence of chemical pollution in China's Uyghur Region, where 20% of the China's PVC production is situated, using a combination of coal, chlorine, and mercury. The report documents harmful exposures to coal dust and chemicals of concern used during PVC production and also highlights violations of human rights with forced labour, and that shipments to Europe from Chinese suppliers conflict with EU regulations.[34]

Disposal/end of life

When PVC products in the healthcare sector reach their end of life the primary disposal method is incineration, which can release chlorinated dioxins (PCDD/Fs) - considered among the world's most toxic substances. Incineration also releases other persistent environmental pollutants that have a detrimental impact on both human health and the environment.[5 35 36 37]

Although recycling plastics is preferable to disposal, PVC recycling should not be encouraged as a solution. When PVC is mixed with other polymers in mechanical recycling it contaminates these polymers, degrading their structural properties and hindering production processes, e.g. extrusion.[38] PVC recycling therefore cannot contribute to a non-toxic circular economy, as the diverse additives in PVC products hinder recycling efforts and enter other products.[31]

Concerns have also been raised from the industry itself: The Healthcare Plastics Recycling Council identifies PVC as the "less desirable design practice for healthcare plastics", underlining the need to limit its use when possible. PVC recycling perpetuates the use and presence of harmful additives.[39]



The environmental consequences can be even more problematic when it comes to single-use medical devices that are treated as infectious waste, where the main disposal route remains incineration.[37] [40] Adverse impacts on health and human rights are associated with poor waste management practices in the healthcare sector.[38]

It is estimated that very little post-consumer PVC plastic is actually recycled. According to VinylPlus (European PVC industry), they have achieved their target of recycling 800,000 tonnes of waste per year by 2020. Within the VinylPlus schemes, however, 810,775 tonnes of PVC waste were recycled in 2021, with 63.6% being pre-consumer waste and 36.4% post-consumer waste. The 800,000-tonne figure for recycled PVC still represents a small percentage (10%) of the 8.1 million tonnes of PVC products manufactured annually in the EU.[41] [37]

To implement the recycling in a toxic-free circular economy in healthcare products, specific technical standards certifying the proportion of recycled material in each individual product are required. This could initially be on a voluntary basis, similar to the Ecolabel in the EU, and then later reinforced through regulation.[42]

The Global Minimum Transparency Standard (GMTS) has been developed to enable companies to disclose the identity of chemicals in their materials and products throughout their lifecycle. All stakeholders need publicly available information about toxic ingredients in plastic materials and products throughout the lifecycle.[43]

Read more about the PVC lifecycle
in HCWH Europe's 2021 position paper:
Why PVC remains a problematic material.[ii]

[ii] HCWH Europe (2021) *The polyvinyl chloride debate: Why PVC remains a problematic material*, noharm-europe.org/documents/polyvinyl-chloride-debate-why-pvc-remains-problematic-material

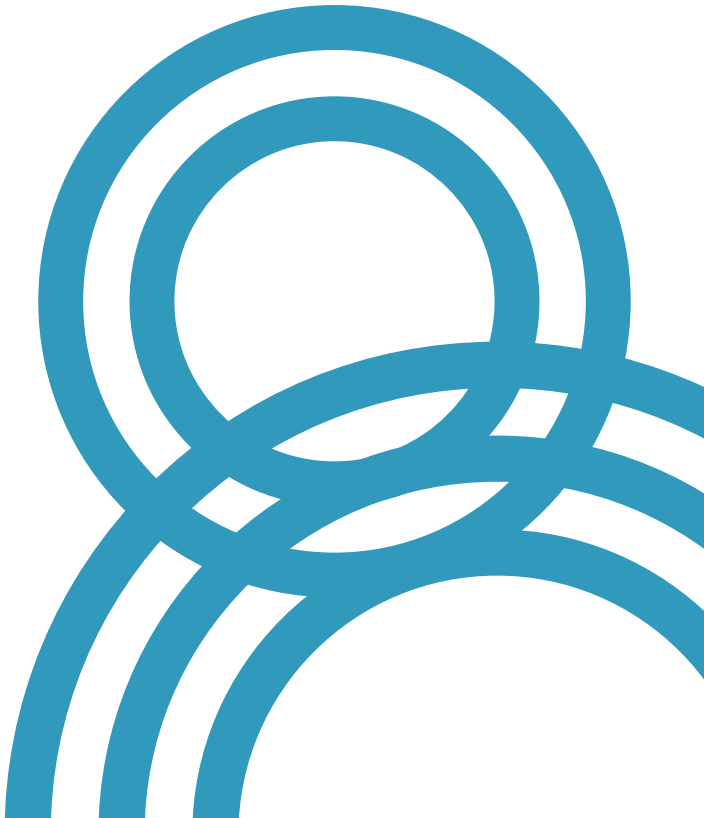
3 LESSONS FROM HEALTHCARE PROVIDERS

The use of PVC-free materials such as silicone, polyolefins, polyethylene, polypropylene, polyethylene, or polyurethane represent a more precautionary approach. Using these substances where possible and appropriate reduces the use of potentially harmful plasticisers or additives and reduces the hazards associated with producing, using, and disposing of PVC medical devices.[5]

Used alongside the waste hierarchy[iii], PVC-free alternatives can contribute to a sustainable, non-toxic, and circular approach. For example, Hospitals in Latin America (e.g. Hospital Universitario Fundación Valle de Lili) have successfully replaced disposable PVC face masks with 100% silicone-based alternatives, which are reusable up to 100 times. Silicon masks can be safely steam disinfected and reused for a lifespan of five to six months.[44] [45]

PVC-free alternatives for IV bags are also already in use such as polyethylene or polypropylene. European hospitals may also switch to glass IV containers in maternity and neonatal areas.[15] [46] [47]

There are alternatives to PVC flooring in healthcare, such as rubber or linoleum, which are already used in many hospitals across Europe and beyond.[48] There are also alternatives to the use of PVC in furnishings, wall coverings, hospital beds, packaging, shower curtains, office supplies, and many other uses.[49]



[iii] The waste hierarchy ranks sustainable waste management methods. Reducing the creation of waste is the first priority with recycling, landfill, and incineration the last resort. See more: noharm-europe.org/articles/news/europe/reducing-plastic-healthcare-best-practice

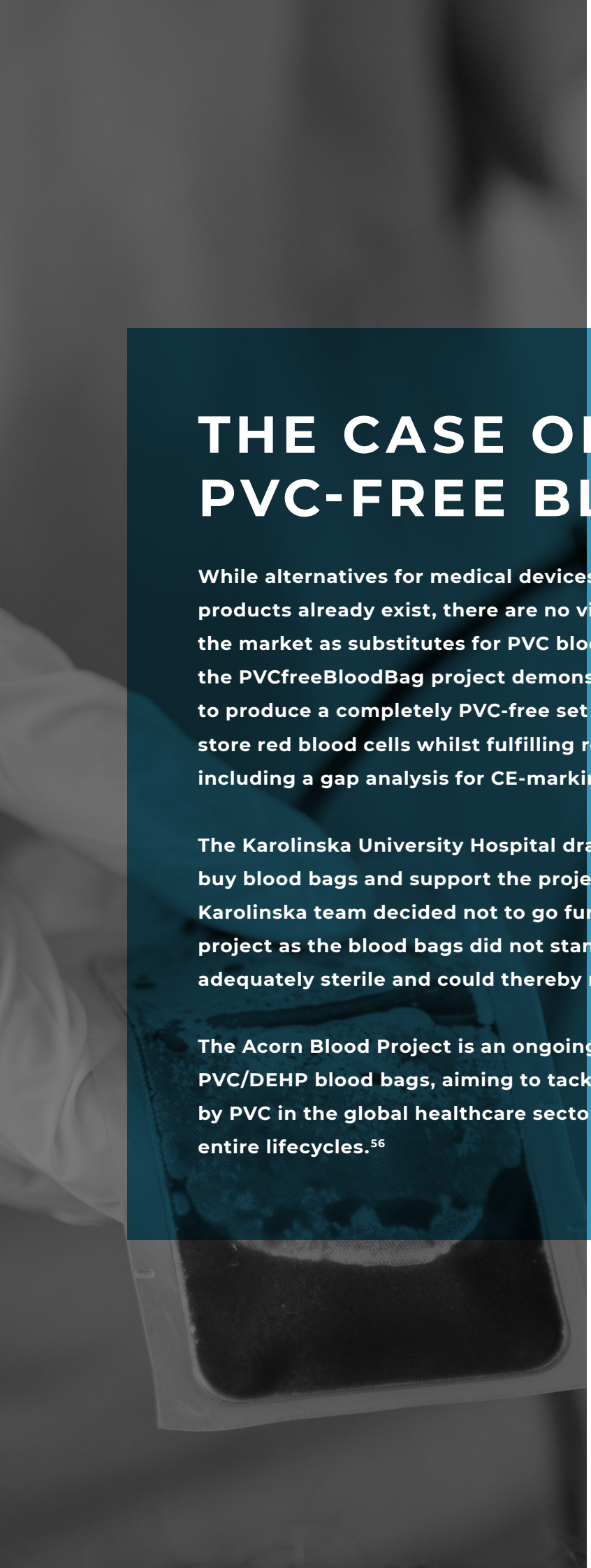
Reducing PVC through procurement

Several healthcare procurement teams in Europe have already established voluntary procurement criteria to drive the healthcare sector towards sustainable and toxic-free solutions. In 2011, ÖkoKauf Vienna (Green Public Procurement in the City of Vienna) introduced “Ecological Criteria” to eliminate PVC in disposable medical products in neonatology, prioritising PVC-free materials. The Children's Hospital "Kinderklinik Glanzing” is the first hospital in Europe to initiate a PVC-free NICU, beginning the PVC phase-out in 2001.[50]

The Landspitali hospital in Iceland set PVC-free criteria in 2014 for products such as central venous catheters and installation trays and specified standard requirements to request PVC-free products since 2015. The neonatal ward is almost completely PVC-free and the hospital has stopped using PVC gloves since 2017. Landspitali has also conducted market analyses to prepare tenders and PVC is excluded in both products and packaging.[51]

Certifications and criteria are also used for building and sustainable materials. The new Karolinska Hospital in Sweden opted for PVC-free floorings as part of the contractual requirement to achieve “Environmental Building Gold” (Miljöbyggnad Guld). This Swedish certification assesses a total of sixteen different criteria such as energy use and hazardous substances.[52] [53] Whilst demand is still low, the high cost of certain alternatives can impede purchasing decisions to phase out PVC. However, internal strategies and campaigns have helped healthcare providers to continue their PVC-free actions.

The Consorci Hospitalari de Vic (CHV) in Catalonia has replaced PVC gloves. The hospital is aware that substituting PVC gloves might be more expensive, and so it is conducting a campaign amongst staff to reduce unnecessary use of gloves and reduce overall glove consumption, helping to neutralise higher costs. This follows the example of the successful “Gloves are off” campaign at the Great Ormond Street Hospital (GOSH).[54]



THE CASE OF PVC-FREE BLOOD BAG

While alternatives for medical devices and other healthcare products already exist, there are no viable options available on the market as substitutes for PVC blood bags. Concluded in 2017, the PVCfreeBloodBag project demonstrated that it is possible to produce a completely PVC-free set of four bags able to safely store red blood cells whilst fulfilling requirement specifications - including a gap analysis for CE-marking.

The Karolinska University Hospital drafted a letter of intent to buy blood bags and support the project findings.[55] However, the Karolinska team decided not to go further after the end of the project as the blood bags did not stand centrifugation and were not adequately sterile and could thereby not be used in production.

The Acorn Blood Project is an ongoing project to substitute PVC/DEHP blood bags, aiming to tackle the challenges caused by PVC in the global healthcare sector by considering products' entire lifecycles.[56]

The phase-out list in healthcare to initiate substitution (Norway)

The European Healthcare phase-out list[57] is a powerful tool that harmonises and aligns progressive market demands to minimise harmful chemicals in the supply chain. Taking action now will reduce the health burden of these harmful chemicals whilst regulation is continually delayed and slow to be implemented.

In 2021, the Norwegian Hospital Procurement Trust (Sykehusinnkjøp HF) led the work on the new European healthcare phase-out list, which listed chemicals of concern already under regulation as well as those that will be regulated in the future. Taking a step beyond what is required by regulations, the list forms the basis of their tenders on medical products, and phasing out PVC is part of it.

The Norwegian Healthcare regions have set a goal to eliminate the use of harmful substances in 75% of hospital products by 2030. The Hospital Procurement Trust has a crucial role in achieving this objective, as they are responsible for procuring all the necessary items for hospitals.

In September 2021, the Hospital Procurement Trust surveyed major suppliers of medical commodities and surgical equipment based on the European Healthcare phase-out list. This provided an insight to the number of products containing substances on the phase-out list. Suppliers reported that nearly 25% of the products surveyed contained PVC; however, for over 10% of products, they were unable to confirm if they contained PVC.

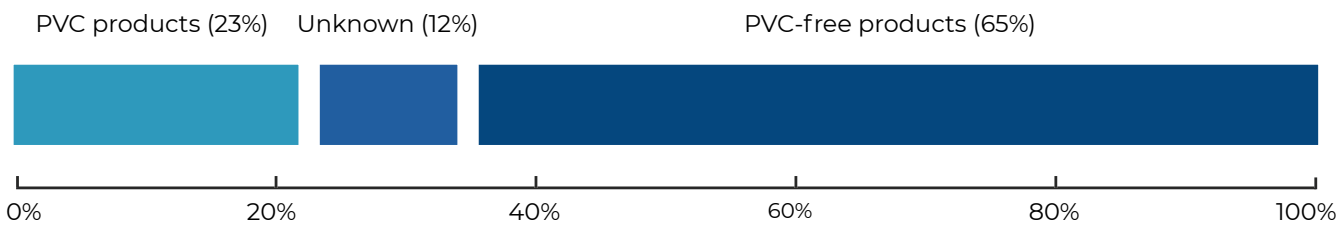


Fig. 3 Proportion of healthcare products containing PVC (The Norwegian hospital procurement Trust, 2021)

Many healthcare tenders in Norway have since contained demands for PVC-free products when possible, especially for medical products. The dialogue with the biggest suppliers is mainly open and several are now offering PVC-free products. It can be difficult to meet the demand for PVC-free products and in some cases where it is not feasible to obtain such products, exceptions may be made from the phase-out list through market dialogue.

It is too early to say how the development has been as a whole, but there are some concrete tenders where it has been possible to secure PVC-free products, including airway and respiratory devices, infusion and transfusion sets, invasive pressure sets etc.

In some cases, PVC-free products have been more expensive or have not met quality demands, which is to be expected in a transition phase. Generally, however, when healthcare personnel involved in the tenders have tested PVC-free products, the majority have met expectations and been evaluated as high quality.

Some products have been recently awarded the Nordic Swan label, indicating they do not contain any harmful substances. This includes absence of chemicals listed on the REACH candidate list, or any other chemicals that have been classified as environmentally damaging, toxic, allergenic, or endocrine disrupting i.e. CMRs, PVC, phthalates, bisphenols.

The Norwegian Hospital Procurement Trust confirms the absence of harmful chemicals from the phase-out list in unlabelled products by providing written statements from suppliers, unless the use of such substances is deemed clinically necessary, such as antimicrobial substances in wound dressings to prevent infection.

KEY ACTIONS AND RECOMMENDATIONS

This report, alongside many others, provides clear evidence of the risks that PVC production, use, and disposal poses in healthcare.[32 57 58] It demonstrates the need to restrict and ultimately phase out PVC and its additives from healthcare, a sector that should not be exempted from further derogations.

Switching to alternative plasticisers while maintaining a wide use of PVC is not sufficient; many of the alternatives have not been studied adequately, and, more importantly, this does not address many other serious issues surrounding PVC, which is problematic throughout its entire lifecycle. Simply put: there is no place for PVC in a toxic-free, circular economy.

Many healthcare providers across Europe have made considerable progress by adopting phase-out policies and committing to using products that are less harmful for patients and demonstrating that the majority of uses have PVC-free alternatives. Policy and economic measures to increase the demand and promote the development of new alternatives are required to accelerate the transition towards the phase-out and PVC-free products.

RECOMMENDATIONS FOR POLICY-MAKERS

Do not exempt the healthcare sector from a PVC restriction, including medical products and devices.

Instead, adopt the phase-out of PVC in the healthcare sector and give priority to medical devices that can result in patient exposure to hazardous chemicals that leach from them resulting in a higher risk of harm to patients.

PVC products should be substituted whenever other safer alternatives exist and the use is non-essential.

Encourage and boost opportunities for PVC-free products.

Many alternatives are currently expensive, leading to low demand and limiting their availability on the market.

Close the innovation gap.

Provide support and incentives for innovation and technologies to create and further develop products that currently lack alternatives and rely on harmful plasticisers.

RECOMMENDATIONS FOR MANUFACTURERS

Substitute harmful substances.

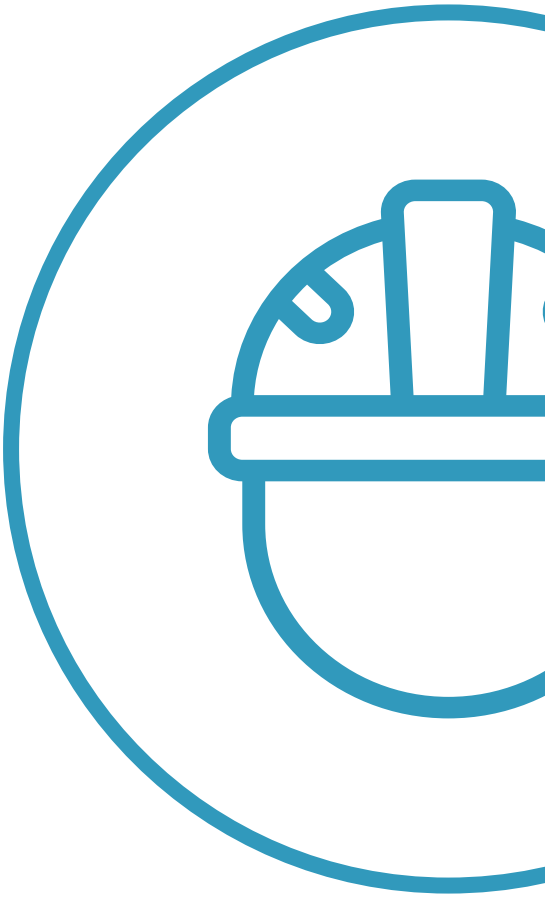
Go beyond current minimum requirements, and anticipate pending regulation. Position yourself as a progressive supplier and a market leader. Initiate a market dialogue with your customers to integrate chemicals criteria and identify opportunities to innovate for PVC-free alternatives.

Increase transparency.

Share and allow the exchange of information across the entire value chain so that stakeholders can understand all the chemicals used in production.

Focus on PVC-free.

Innovation, research, and sustainability efforts should focus on replacing PVC instead of continuing its use whilst endeavouring to reduce harm, e.g. alternative plasticisers or ineffective recycling schemes.



RECOMMENDATIONS FOR HEALTHCARE PROVIDERS

Influence market supply.

Adopt procurement criteria for the phase-out of harmful chemicals to influence purchasing decisions and open an active dialogue to engage with stakeholders to transition towards PVC-free alternatives.

Set a clear demand for manufacturers.

Manufacturers should publicly disclose information on alternatives.

Educate staff.

Raise awareness on the environmental impact of PVC products and encourage sustainability efforts.

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