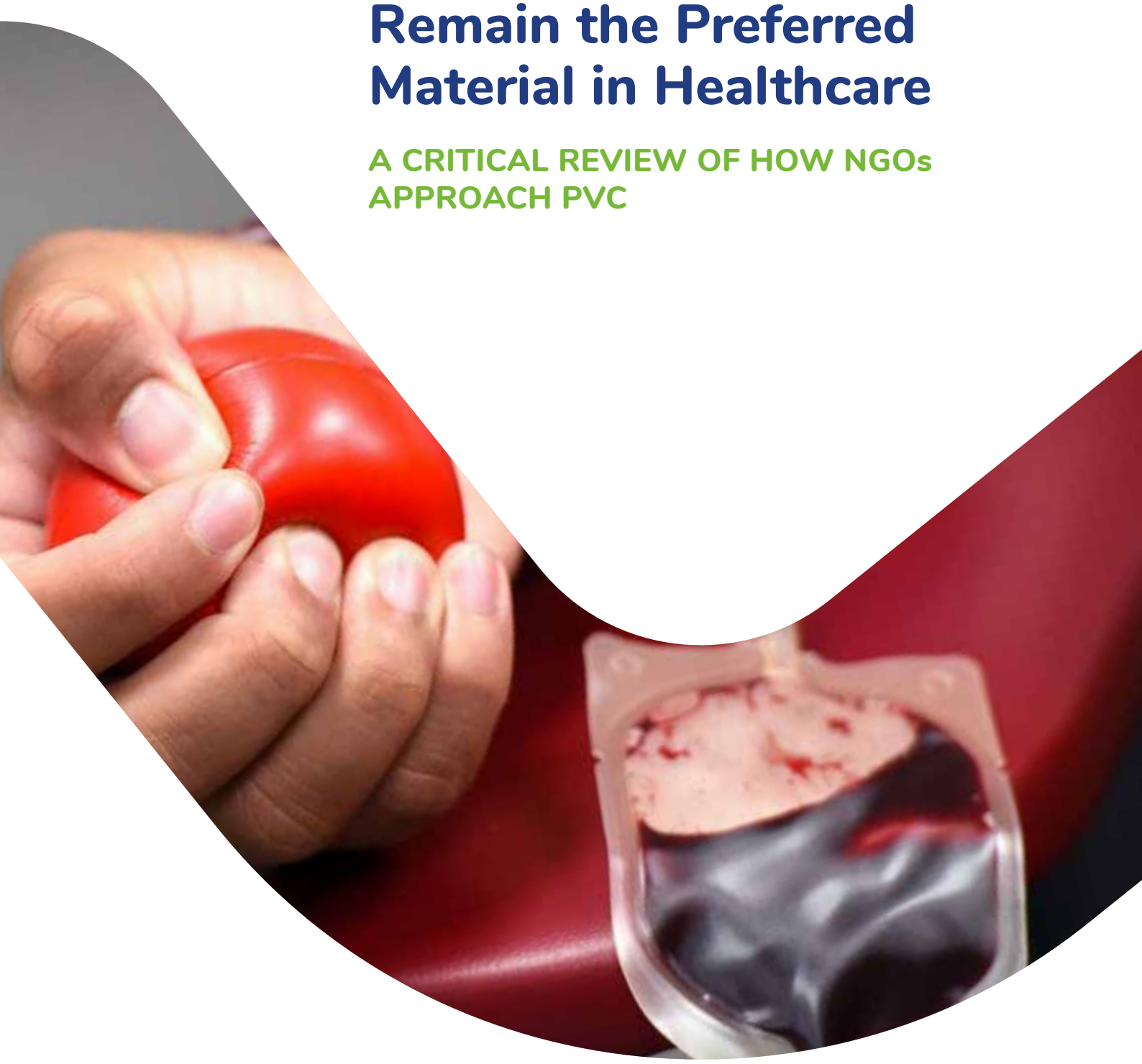
# Why PVC Should Remain the Preferred Material in Healthcare

## A CRITICAL REVIEW OF HOW NGOs APPROACH PVC



PVC Med ALLIANCE

## PVC'S ROLE IN HEALTHCARE – TODAY AND IN THE COMING YEARS

Plastics-based medical devices are vital for safe and efficient patient treatment and care in hospitals around the globe. Many different polymers are used for medical equipment, with polyvinyl chloride – also known as PVC or vinyl – in the leading role.

The reason for PVC's dominance is the material's unique properties such as safety, versatility, affordability, and recyclability. Nearly 30% of all plastics-based disposable devices are made of PVC and this share is expected to remain the same in the years to come.

Besides being the most used polymer for life-saving medical equipment such as blood bags, oxygen masks, and tubing, PVC is also the main plastic for blister packaging that safeguards medicines and in building & construction. Around 70% of the PVC is used for durable and recyclable pipes, windows, flooring, roofing membranes, cables, and other building products.

During the last two decades, the production, use, and waste management of PVC in Europe have undergone a significant transformation.

Through VinylPlus®, the European PVC industry's commitment to sustainable development, problematic additives have been substituted, recycling systems have been set up, and emissions from PVC production have further been reduced below the world's most stringent emission limits.

In addition, the European chlor-alkali industry, from which PVC is produced, has also successfully implemented strategic technology choices to reduce its environmental impact.

## KEY POINTS

- **European Chemicals Agency Affirms Safe European PVC Production:** In 2023, the European Chemicals Agency confirmed the safety of PVC production in Europe, stating that the risks to both workers and environment are adequately controlled under current operational conditions.
- **Stringent Regulations and Safety Measures:** Strict EU Occupational Exposure Limits and environmental emission limits ensure safe production of PVC in Europe. The industry has further developed voluntary policies enforced by independent bodies to minimise worker exposure and environmental emissions beyond the legal limits.
- **Chlor-Alkali Vital to Society:** PVC is an integral part of the chlor-alkali industry, serving various critical applications such as water treatment, pharmaceuticals, and clean energy production.
- **Safe and Energy-Efficient Chlorine Production:** Europe has phased out asbestos and mercury technologies in chlorine production, adopting safe and energy-efficient membrane and asbestos-free diaphragm technologies while addressing potential concerns regarding PFAS emissions.
- **Less Primary Energy, Lower Carbon Footprint:** Despite electricity requirements in the chlor-alkali process, PVC's composition, with approximately 60% chlorine, results in significantly lower primary energy consumption compared to other plastics.
- **Non-Toxic PVC With Strict Regulation of Additives:** PVC plastic is recognised as non-toxic and inert, with strict regulation and industry responsibility under REACH to ensure the safety of additives, including plasticisers.
- **DEHP Alternatives Available for Medical Devices:** The European plasticiser industry has invested heavily in developing safe DEHP alternatives, subjected to extensive testing under REACH, and complying with the EU Medical Device Regulation.
- **Environmentally Responsible PVC Recycling and Incineration:** PVC waste incineration is carefully managed in Europe to prevent harmful emissions. Additionally, PVC is increasingly recycled, contributing to a circular economy in healthcare and elsewhere.
- **Complexity of Phasing Out PVC:** Replacing PVC with alternative materials may introduce other additives (e.g. PFAS), potentially causing unforeseen health effects, and regretful substitutions must be considered. Substitution also poses challenges related to technical performance, life cycle impacts, supply disruptions, and increased costs.
- **DEHP-Free PVC Blood Bags:** Efforts to phase out DEHP from blood bags are in progress, with promising results from non-phthalate PVC alternatives. In contrast, the development of a PVC-free blood bag remains a challenge.

# PVC PRODUCTION

**What NGOs typically claim: "The production of PVC generates harmful risks to human and environmental health."**

**Confirmation of PVC Production Safety in Europe by the European Chemicals Agency**
The production of PVC, as many other materials, involve toxic substances such as EDC and VCM as intermediates. However, to prevent worker exposure and emissions to the environment, stringent measures are in place, including strict EU Occupational Exposure Limits and environmental emission limits. Additionally, the PVC industry has developed voluntary policies for PVC intermediates that go beyond the legal requirements and are enforced by independent bodies.[1]

The safe nature of PVC production in Europe has been confirmed by the European Chemicals Agency in 2023, which states "the risks from PVC resin to workers and the environment are considered adequately controlled with the current operational conditions and companies' safety measures."[2]

**The Essential Role of Chlor-Alkali Industry in Modern Society**
PVC is part of the chlor-alkali industry, which is foundational for modern society. In the chlor-alkali process, table salt is split into caustic soda and chlorine. Caustic soda or sodium hydroxide is needed to produce alumina, paper, and plays a critical role in water treatment, drinking water purification, cleaning agents, pharmaceuticals, food processes, and much more.

About 30% of all chlorine is used to produce PVC, of which around 1% finds its way into life-saving medical devices such as blood bags and tubing. The remaining 70% of the chlorine is used to disinfect drinking water and treat wastewater, in manufacturing of pharmaceuticals – up to 90% of all medicines depend on chlorine chemistry – batteries for electric cars, solar panels, wind turbine blades, polyurethane (PU) insulation, polycarbonate (PC) protective face shields for firefighters, and many other products.

It is important to note that many chemicals, plastics, and medicines use chlorine, although the end product is chlorine-free.

**Advancements in Chlorine Production: Phasing Out Asbestos and Mercury, Embracing Safe Technologies**
In Europe, asbestos and mercury technology to produce chlorine have been legally phased out since 11 December 2017.[3] Only membrane and asbestos-free diaphragm technologies are considered best available techniques (BAT) under the Industrial Emission Directive. No other techniques can be used under a manufacturing permit.

Polymeric PFAS are used in membranes and asbestos-free diaphragms for electrolysis, gaskets and lined pipes or vessels, all of which are critical components in the production process for chlor-alkali and further for PVC. Perfluorinated membranes and membrane technologies used in chlor-alkali production have no known alternatives at the moment and are therefore essential at present.

The chlor-vinyl industry is actively engaged in following regulatory developments around PFAS and continues to re-evaluate all PFAS-containing materials and equipment and investigate available alternatives. This is to reduce the use of these substances where possible while maintaining the safety and reliability of industry operations.

Further, the Montreal Protocol and industry innovation aim to ensure that ozone-depleting substances are not emitted during chlorine production in Europe.

**Energy Efficiency of PVC Production: Comparing With Other Plastics**
Though the chlor-alkali process requires substantial amounts of electricity, the fact that PVC is made from nearly 60% chlorine means it typically consumes less primary energy than other plastics such as high density polyethylene (HDPE), low density polyethylene (LDPE), and polypropylene (PP).[4] Additionally, PVC's carbon footprint is generally lower than that of other plastics.

## PLASTICISERS AND OTHER ADDITIVES

**What NGOs typically claim: "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."**

**Strict Regulation of PVC Additives by REACH: Ensuring Substance Safety**
PVC plastic as such is inert and non-toxic. Additives in PVC are regulated by REACH, the strictest chemical regulatory framework in the world. Under REACH, the onus is on the industry to demonstrate the safety of substances – *no data, no market* is the principle.

**DEHP Alternatives in Medical Devices Are Non-SVHC and Comply With REACH**
For medical devices, DEHP is already regulated, with a sunset date set for 2030 in REACH. The European plasticiser industry has invested over €6 billion in developing safe DEHP alternatives. These alternatives, namely DINCH, DEHT, BTHC, and TOTM, have been subjected to extensive testing under REACH. All toxicological data for these plasticisers are available in the REACH dossiers. Further, the substitutes are not identified as Substances of Very High Concern (SVHC) and not classified in the Classification, Labelling and Packaging Regulation (CLP).

**EU Medical Device Regulation Compliance: Ensuring the Safety of DEHP Substitutes**
In addition, these DEHP substitutes also meet the additional requirements under the EU Medical Device Regulation. This regulation mandates a thorough benefit-risk analysis and safe use demonstration for medical devices, ensuring that any material used meets the highest safety standards.[5] The inclusion of these plasticisers in the European Pharmacopoeia, overseen by the European Directorate for the Quality of Medicines & Healthcare (EDQM) under the Council of Europe, further underscores their safety, as the EDQM adheres to rigorous scientific and impartial evaluation processes.[6]

**Independent Agencies Confirm Safety**
The plasticisers have also been thoroughly evaluated by many independent bodies, such as the European Food Safety Authority (EFSA), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), the Danish Environmental Protection Agency, and the Swedish Chemicals Agency.[7]

**Ongoing Obligation for Plasticiser Producers: Updating Safety Data Under REACH**
The plasticiser producers are adhering to their obligation as registrants under REACH, which is to update their dossiers with new information that may affect the risk management measures or the classification and labeling of the substance. This includes new data on long-term effects, high dose toxicological effects, or other relevant safety information that becomes available.

**Differentiating Plasticisers: Understanding the Safety**
It must be stressed that plasticisers in PVC are tightly bound within the PVC matrix through strong non-covalent forces and their migration is extremely low. Further, the observed adverse effects of DEHP and other low molecular weight (LMW) phthalates are caused by their specific molecular structures. As the molecular structure of the DEHP substitutes are very different, they migrate less and do not show the adverse effects like LMW phthalates.

Moreover, comprehensive biomonitoring data for key plasticisers like DINCH and DOTP demonstrate that exposure levels across all sources remain safely within conservative and tolerable limits. These safety thresholds incorporate a substantial safety margin, often 100 times greater than the doses proven to have no effects in extensive animal studies, ensuring a high level of protection for human health.

**The Risk of Regretful Substitution: Concerns With Replacing PVC**
To avoid plasticisers, some are calling to phase out PVC with other materials that do not require plasticisers to be softened. However, just because a plastic material does not need plasticisers, it does not mean it is free from additives that may migrate into the body with possible adverse effects.

Today, around 16,000 substances are used to provide different properties to different plastics. According to a recent study, at least 4,200 of these chemicals have been identified as substances of potential concern.[8] Thus, regretful substitution cannot be excluded if PVC as such is replaced by just other plastics.

## END-OF-LIFE & CIRCULARITY

**What NGOs typically claim: "The disposal of PVC generates harmful risks to human and environmental health. PVC incineration can release dioxins and generates large amounts of neutralisation residues. PVC is the least recyclable plastic and cannot contribute to a non-toxic circular economy."**

### PVC Waste Incineration is Safely Managed

For safety reasons, non-recyclable medical waste is generally incinerated with energy recovery. In Europe, strict regulation ensure technologies are in place to avoid emissions of harmful substances such as dioxins and hydrochloric acid from incineration of chlorine-containing waste.[9]

PVC is often cited in discussions about dioxin production during waste incineration. Yet according to the European Chemicals Agency (ECHA), dioxin formation is not directly proportional to the amount of chlorine present in the waste. Instead, it depends significantly on how the incineration process is managed. Further, ECHA states that other sources of chlorine, e.g. salty foods, are always present in the waste.[10]

ECHA acknowledges that waste incineration plants can safely accept waste with PVC content up to 2%, a threshold that helps manage the release of hydrochloric acid during combustion and mitigate potential boiler corrosion. Europe's incineration facilities possess adequate capacity to handle this level of PVC waste.[11]

### PVC is Already Part of the Circular Economy

PVC can, depending on application, be recycled mechanically 8 to 10 times without loss of functional properties.[12] PVC has the longest history of plastic recycling. It is estimated 35% of the PVC waste generated each year is recycled – above the average for plastics.[13] Since 2000, 8,100,000+ tonnes of PVC have been safely recycled and used in new products through VinylPlus®. Legacy additives in recyclates are being handled safely in accordance with the REACH regulation.[14]

### Pioneering Medical Plastic Recycling

PVC is also leading the way in the healthcare sector: VinylPlus® Med helps hospitals turn their DEHP-free PVC medical device waste into useful products for the healthcare sector, such as vinyl wall covering. The partnership brings together hospitals, waste management companies, adult daycare centers, recyclers, and the PVC industry. Today, 25+ Belgian hospitals are part of the scheme and 30+ are on the waiting list to join. Plans are underway to roll out VinylPlus Med in other European countries, starting with France.

### Recycling Instead of Incineration Yields Significant $CO_2$ Savings

To investigate how much $CO_2$ is saved from recycling instead of incineration, the PVCMed Alliance commissioned third-party consultancy Ecovamed to conduct a comprehensive Life Cycle Assessment (LCA) on typical PVC medical tubing used in Europe. Ecovamed explored two disposal methods: Incineration with energy recovery and acid flue gas treatment, and recycling through the VinylPlus® Med initiative, achieving an 80% yield. The findings revealed that recycling the tubing can reduce greenhouse gas emissions by 25% across its life cycle compared to incineration, translating to a saving of 2,0 kg$CO_2$eq per kilogramme of tubing.[15]

### Exploring the Recyclability of Flexible PVC

The PVCMed Alliance is at the forefront of exploring recyclability of flexible PVC. Renowned Spanish plastics technology centre, AIMPLAS, has been commissioned to explore how many thermal cycles PVC medical tubing can withstand without losing its functional properties. The preliminary results are promising: So far, the tubing has undergone 5 thermal histories without significant degradation.

# SUBSTITUTION OF PVC IN HEALTHCARE

**What NGOs typically claim: "The use of PVC-free materials represents a more precautionary approach."**

### EU Agencies Identify Challenges With PVC Substitution

Healthcare providers are often urged to procure so-called PVC-free medical devices. Yet according to recent reports from the European Union's Chemicals Agency (ECHA) and DG Environment (DG ENV), substitution of PVC can be very challenging and may have negative consequences for health, environment, and economy:

1. **POSSIBLE DRAWBACKS IN TECHNICAL PERFORMANCE MAY COMPROMISE PATIENT SAFETY**
   According to DG ENV, "in procuring PVC-free products, hospitals and patients may initially experience some drawbacks in technical performance of new products. These would need careful testing to ensure patient safety is not compromised."[16] Some alternatives, such as polyethylene (PE), polypropylene (PP), polyurethane (PU), ethylene-vinyl acetate (EVA), and thermoplastic elastomers (TPE), are used in certain applications but cannot replace PVC in all medical uses.[17]

2. **LIFE CYCLE IMPACTS OF ALTERNATIVES ARE LARGELY UNKNOWN**
   Due to the lack of comparable studies, it is impossible to draw robust conclusions about PVC's performance compared to alternative materials from a life cycle perspective. This uncertainty adds another layer of complexity to the decision-making process.[18]

3. **ALTERNATIVES MAY IMPLY HEALTH RISKS**
   According to DG ENV, "use of alternative plastics in direct physical contact with patients poses similar issues to PVC with regard to transfer of toxic additives to the body."[19] For instance, alternative materials like rubber latex is known to cause allergic reactions in some individuals. This presents a significant health risk that must be accounted for when considering alternatives to PVC.[20]

4. **POSSIBLE DISRUPTIONS IN SUPPLY OF CRITICAL EQUIPMENT**
   Material changes in medical equipment trigger re-evaluation of safety, efficacy, and reliability. This process demands additional time for testing, revalidation, and re-registration of individual products, thus extending the transition period significantly. Further, there may be availability constraints of alternative materials.[21]

5. **POSSIBLE STRAINS ON HEALTHCARE BUDGETS**
   PVC alternatives are generally more expensive.[22] Phasing out PVC may lead to higher material costs, investments, and expenses related to technological redesign of products, new production equipment, testing, validation, and approval of new materials for medical applications. This will translate into higher costs for healthcare providers.[23] Data from Norway shows the cost of replacing PVC with alternative materials would equate a 30% price increase for medical devices.[24]

**A PVC-Free Blood Bag Is Not on the Horizon**
It is often claimed that a PVC-free blood bag is close to market, yet that is not the case. The PVC-Free Blood Bag Project (2011-2018), a part of the EU's Life+ Environmental Programme, aimed to produce a PVC-free blood bag that met the required specifications, including CE labeling.[25] This aim was not achieved: Gulliksson et al. (2016) found that the novel polyolefin blood storage bag failed to maintain acceptable hemolysis levels within the conventional 42-day storage period.[26]

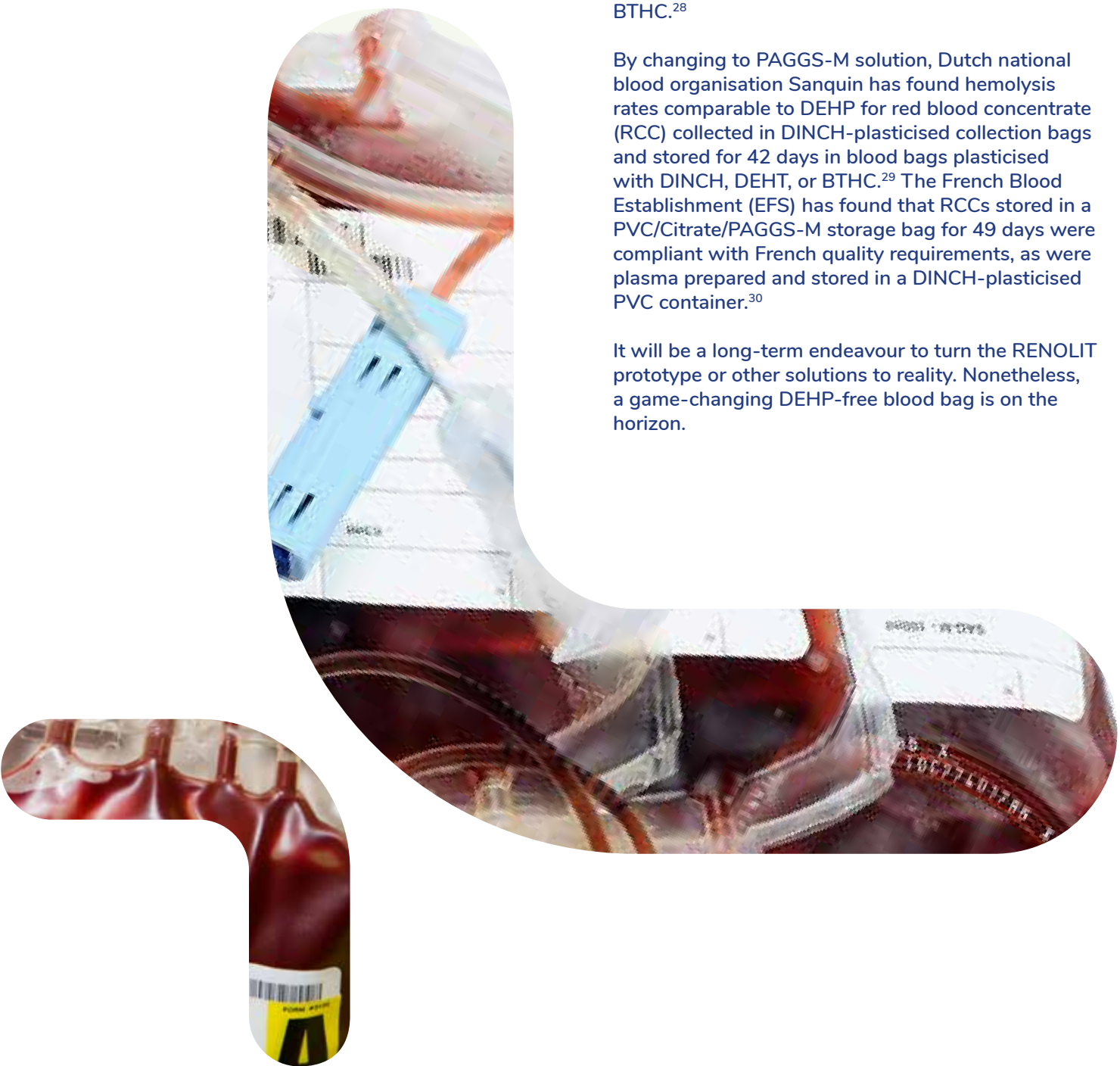
Since the conclusion of the project in 2018, there has been a notable lack of progression towards a market-ready PVC-free blood bag. This stagnation can be attributed to the absence of continued interest or involvement from commercial partners, blood banks, and other stakeholders in further developing or commercialising the technology.

**A DEHP-Free PVC Blood Bag Is on the Horizon**
Historically, the use of DEHP as a plasticiser in PVC blood collection systems, including bags and tubing, has been integral for maintaining the stability and integrity of red blood cells (RBCs), which is crucial for effective blood transfusions. The updated EU Medical Device Regulation and the REACH regulation now mandate the phase-out of DEHP from blood bags before 1 July 2030.[27]

RENOLIT Healthcare, a PVCMed Alliance partner and leading film producer for blood bags and other medical applications, is at the forefront of this transition. Early test results of blood bags using a prototype non-phthalate PVC film, called RENOLIT Bloodprotect 42Plus, show RBC haemolysis level (0.17 ± 0.1%) with no significant difference to DEHP (0.16 ± 0.2%) after 42 days of storage, when using conventional SAG-M storage solution, thereby exceeding the performance of the current DEHP replacements DINCH, DEHT, and BTHC.[28]

By changing to PAGGS-M solution, Dutch national blood organisation Sanquin has found hemolysis rates comparable to DEHP for red blood concentrate (RCC) collected in DINCH-plasticised collection bags and stored for 42 days in blood bags plasticised with DINCH, DEHT, or BTHC.[29] The French Blood Establishment (EFS) has found that RCCs stored in a PVC/Citrate/PAGGS-M storage bag for 49 days were compliant with French quality requirements, as were plasma prepared and stored in a DINCH-plasticised PVC container.[30]

It will be a long-term endeavour to turn the RENOLIT prototype or other solutions to reality. Nonetheless, a game-changing DEHP-free blood bag is on the horizon.



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PVCMed Alliance Project Leader Ole Grøndahl Hansen (left) and Communications Manager Tobias Johnsen (right).

**About the PVCMed Alliance**

The PVCMed Alliance is the European Council of Vinyl Manufacturers' (ECVM) value chain platform, focusing on raising awareness and promoting informed decisions about the use of PVC in healthcare. Established in 2012, it represents leading companies in the medical PVC value chain. The vision that informs the PVCMed Alliance's work is of a healthcare environment that best benefits patients and healthcare professionals. Such an environment offers the finest PVC-based products and applications with the required properties and excellence needed to provide top quality healthcare while being increasingly sustainable.

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