Comment letter: *Public Consultation of Proposal for Generation 2 of Criteria for Nordic Swan Ecolabelling of Disposable Bags, Tubes and Accessories for Health Care - 28 February 2019*

Six reasons why the Nordic Ecolabelling should reconsider its PVC policy

The PVCMed Alliance, a platform representing the PVC medical device value chain, hereby provides comments on the above proposal by listing six reasons why the approach put forward regarding PVC is questionable. This document proposes an alternative way forward reflecting market reality and, in our view, better aligned with the requirements for a high level of environmental and human health protection.

1. PVC remains the only approved and suitable material for blood bags

One of the main changes between the first and the second generation criteria is the extension of the product group definition, so that blood bags now are included and can obtain the Nordic Swan label. The justification for this scope extension appears to be that the Nordic Ecolabelling claims that the EU-funded PVCFreeBloodBag Project "has resulted in a successful result … Hopefully, these blood bags will soon be on the market."[1] For many reasons, this is incorrect and far from reality:

A. Strict requirements for blood bags
The European Blood Alliance, which organises the European blood banks, only accepts blood bags that meet the strict requirements set by ISO 3826 and the European Pharmacopoeia. These include:

- Flexibility
- Compatibility with existing sterilisation techniques
- Thermal stability
- Transparency
- Resistance to leakage
- Oxygen permeability for platelet survival
- Minimum 42 days of storage for red blood cells

There are no reports of which we are aware that the PVC-free blood bag can meet all these requirements. Therefore it is an exaggeration to claim - as the Nordic Ecolabelling does - that the PVCFreeBloodBag Project has been successful. Failing to meet any of these criteria would result in inability to declare Declaration of Conformity and thus the CE could not be applied to the product.

[1] Nordic Ecolabelling (2019). About Nordic Swan Ecolabelled Disposable bags, tubes and accessories for health care, Background to ecolabelling, Draft for consultation, 28 February 2019, Version 2. https://www.ecolabel.dk/~/media/Ecolabel/Files/Hoeringer/Engangsposer-slanger-og-tilbehoer-til-medicinsk-brug-2019/098eo_2_0_BD.ashx, p. 6

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B. Storage period of 21 to 28 days is unacceptable for Europe's medical authorities

Currently, 42 days is the minimum storage period for red blood cells. This is achieved with PVC plasticised with DEHP, which stabilises the red blood cells. In practice, even up to 49 days can be achieved. H. Gulliksson et al. (2017) published the results obtained with the multilayer polyolefin blood bag developed by the PVCFreeBloodBag Project: hemolysis levels exceeded tolerable levels already after 21 days with PAGGS-M solution and 28 days with PAGGG-M solution.[2]

While much blood is used within a few weeks, there are several reasons why a storage period of up to 42/49 days is crucial:

1. The warehousing and distribution of the national blood supplies in Europe are based on up to 42/49 days shelf life. Patients' safety depends on this stability of supply of blood components stored in blood bags, especially of Red Blood Cells (RBCs) that have to meet the criteria of a low hemolysis rate without visible hemolysis in the supernatant.
2. A shorter storage period would have dramatic consequences in the national supply chain for RBCs. A reduced storage time could only be compensated by an increase amount of RBCs including an extension of warehouse capacity and furthermore in increase of donations. To increase the number of donations will be very difficult as the motivation of the population to donate blood is typically low and is thus a challenge in many of the European countries already today. This would increase the risk of blood shortages, an increase in discarding outdated RBCs and pose a threat to patients. Last but not least, an increase in discards of voluntarily donationed blood is also an ethical problem for the public.
3. Rare blood types are often in low stock. Thus, the shelf life of the blood must be as long as possible to have enough supply otherwise, certain patients would be at risk not to receive their life saving blood units.[3]
4. Unforeseen events, big social events, seasonal volatilities such as holiday periods, distribution of blood groups, and compatibility of blood groups are some of the factors that can impact blood supplies. Typically, holiday periods do already today pose a supply risk, this would dramatically increase in case the storage period is reduced to only 28 days. A shorter shelf life would heighten the risk of shortages.

C. Questionable scientific validity of LCAs

In addition to its superficial approach to the technical requirements for blood bags it should also be mentioned that the PVCFreeBloodBag Project has been criticised for not being scientific in the way they have been using life cycle analyses (LCA).

To document the negative health and environment impacts of DEHP-PVC, two LCAs have been conducted as part of the Project. Both concluded that the polyolefin bag had less negative impact on health and environment than DEHP-PVC. However, independent LCA experts from Manchester University, commissioned by the European Council of Vinyl Manufacturers, have seriously questioned the scientific validity of both LCAs. In Manchester University's review of the 2012 LCA, it is for instance stated that "the methods used to carry out the LCA are not consistent with the LCA

[2] Gulliksson, H., Meinke, S., Ravizza, A., Larsson, L., & Höglund, P. (2016). Storage of red blood cells in a novel polyolefin blood container: A pilot in vitro study. *Vox Sanguinis, 112*(1), 33-39. doi:10.1111/vox.12472, p. 1

[3] Raat, N., Berends, F., Verhoeven, A., de Korte, D. and Ince C. (2005). The age of stored red blood cell concentrates at the time of transfusion. *Transfusion Medicine* 15, 419–423. doi: 10.1111/j.1365-3148.2005.00606.x

ISO standards 14040/44" and "the assumptions on the leakage and uptake of DEHP appear to be arbitrary as they are not supported by evidence or published references."[4]

D. The blood supply value chain cannot just change polymer

PVC replaced glass containers for blood in the 1950s and has since remained the only accepted material for blood bags. During that time, significant resources have been invested in technological innovation throughout the value chain in equipment, production processes, sterilisation etc. so as to continually improve the performance of the PVC blood bag. Further, it should be noted that blood banks' equipment is also set up for PVC blood bags. Thus, changing from PVC to another polymer is a massive task that would take years of research and development throughout the value chain. Especially radio frequency (RF) sealing technique are based on the material properties of PVC. RF sealing is not only used during blood bag production of practically all manufacturers, but also during all process steps of the blood component production in blood centers. It remains a crucial technology to seal bags and tube and thus ensure the close and sterile blood bag systems.

H. Gulliksson et al. seem aware of this issue. On page 6, they write that the non-PVC alternative's "sealing conditions are somewhat different, implicating that the present sterile connecting devices probably can be used, but new sealing equipment for closing blood bag tubing will be needed."[5] These technical issues, which will require substantial investments in research and development, must be solved before a new bag can be considered. In addition, PVCFreeBloodBag Project member and Professor at Karolinska University Hospital Petter Höglund has stated that "the bag is more fragile than the traditional bag and must be packed in a protective foam and placed with caution in the centrifuge to avoid breakage. The tubing is less flexible and more difficult to work with … The bag will be more expensive."[6] These statements from the Karolinska professors clearly demonstrate that PVC remains a unique polymer for manufacturing safe and affordable blood bags, tubing and other medical devices. To claim, as the Nordic Ecolabelling does, that the PVCFreeBloodbag Project has been a success when the alternative is lacking essential technical properties and will increase healthcare costs is a distortion of reality.

2. Substituting PVC is no guarantee for better protection of health and environment

The underlying assumption in the criteria document is that replacement of PVC by alternative materials is preferable. Documentation, however, is lacking to justify that, and it is highly doubtful if non-PVC medical devices are better for health and environment.

When discussing replacement of PVC, it is most often the classified phthalates that are in focus. Yet with the substitution of classified phthalates that is ongoing, the issue of substituting PVC is becoming more and more irrelevant. According to a newly published report by the Danish EPA, "it cannot be concluded from using LCAs that another type of plastic is generally better than PVC ... The

[4] A. Azapagic (2012). Critical review of the study "Life Cycle Assessment, LCA, study of PVC blood bag. Manchester University. https://pvcmed.org/wp-content/uploads/2019/03/Critical_review-of-the-study-Life-Cycle-Assessment-of-PVC-blood-bags-2012.pdf p. 2

[5] Gulliksson, H., Meinke, S., Ravizza, A., Larsson, L., & Höglund, P. (2016). Storage of red blood cells in a novel polyolefin blood container: A pilot in vitro study. *Vox Sanguinis, 112*(1), 33-39. doi:10.1111/vox.12472, p. 6

[6] Danske Bioanalytikere (2017). Nu er den endelig på vej – blodposen uden farlig kemi. http://www.dbio.dk/fag-og-viden/fagbladet-Danske-Bioanalytikere/tidligerenumrepdf/Documents/2017/149678_dbio_8_17_WEB.pdf

alternatives will typically be slightly more expensive than PVC and/or have technical properties minor to PVC."[7]

The Nordic Ecolabelling seems to agree that PVC-free products are not better for health and environment *per se*. On page 3 it is mentioned that "there are alternatives to the use of PVC in many types of disposable products in the health care sector"[8]. Yet on page 5 it is stated that "plastic materials other than PVC can also contain additives with a possible negative impact on the environment and health."[9]

Another point of critique used against PVC is issues related to waste incineration. In the criteria document it is mentioned that "due to the waste problems with PVC, Denmark has specific national legislation on this matter."[10] It is true that Denmark for almost 20 years has had a different PVC waste policy than the other Nordic countries. For many years, incineration of PVC waste has been regarded as a serious environmental problem by Danish authorities and has subsequently been subject to regulation. However, a new report from 2018 by the Nordic Council of Ministers shows that the other Nordic countries have chosen not to follow in the Danish footsteps in this matter. Sweden, Norway and Finland find it environmentally sound, through incineration, to recover the energy of the PVC waste that is not recycled.[11]

The reason why incineration of PVC waste is seen as an issue is explicitly mentioned in the criteria document: "The neutralisation process generates a large amount of problematic residues in the incineration plant, and this residue must be deposited under special conditions."[12] In a 2018 report by the Danish Environmental Agency it has been calculated that PVC waste is responsible for under 5% of the neutralisation residues that must be disposed of as hazardous waste. Taking into account that PVC used for medical devices only account for 1% of the overall PVC consumption, the share of neutralisation residues originating from PVC medical devices must be regarded as a minor issue compared to all the obvious benefits PVC medical devices give to society. Furthermore, projects show that recycling of uncontaminated PVC medical devices is indeed possible and has a huge potential. This is due to PVC's recyclability, which in most cases is superior to other polymers. With increasing recycling rates, the share of PVC medical devices sent to incineration will most likely decline.

3. PVC-based medical devices enable recycling

In the criteria document it is mentioned that "medical disposable products are mainly sent for incineration, as recycling is difficult as such products very often have been in contact with medical products or body fluids."[13]

It is true that the healthcare sector has often been kept out of the discussion about circular economy due to fear of contamination from used medical devices. However, the Nordic Ecolabelling does not seem to be aware that successful projects in Australia, New Zealand and the UK show a great

[7] Lassen, C. et al. (2018). Kortlægning af PVC i Danmark 2018. Miljøprojekt nr. 2049. Miljøstyrelsen, p. 90, 120
[8] Nordic Ecolabelling (2019), p. 3
[9] Nordic Ecolabelling (2019), p. 5
[10] Nordic Ecolabelling (2019), p. 3
[11] Fråne, A., Miliute-Plepiene, J., Alexandra Almasi, M. & Westöö, A.K. (2019). PVC waste treatment in the Nordic countries. Nordic Council of Ministers. http://norden.diva-portal.org/smash/get/diva2:1287469/FULLTEXT01.pdf
[12] Nordic Ecolabelling (2019), p. 7-8
[13] Nordic Ecolabelling (2019), p. 7

potential to collect medical devices and recycle them into useful products. Hospitals save money by diverting waste from expensive treatment processes for clinical waste and at the same time contribute to circular economy, reduce carbon emissions and help save energy. The collection and recycling are done without risk to hospital staff, patients or recyclers as the collection is limited to PVC medical devices which have only been used on pre-screened patients and have not been in contact with bodily fluids or medicines. This practice can be likened to collection schemes for deposit bottles. PVCMed Alliance is willing to work with Nordic authorities to test similar recycling projects.

A prerequisite for successful plastics recycling is mono-streams. As most PVC-based medical devices are made from only one polymer, they are ideal for recycling. Non-PVC medical devices are often made from a combination of different polymers with multiple additives, which makes recycling impossible with current technologies.

4. Alternatives to DEHP

Since 2007, when the first criteria were published, four alternatives to DEHP have been additionally included in the European Pharmacopoeia.[14]

Further, the new Medical Device Regulation (MDR, Regulation (EU) 2017/745) requires starting from 2020 medical device manufacturers to justify the continued use of CMR substances, including DEHP. Preliminary guidelines as indicated in the MDR were published in March 2019 and will become mandatory following publication of the final guidelines. As alternatives to DEHP are available and CE marked medical devices are already on the market, it will most likely be very difficult to justify the continued use.

5. The PVC industry is on a journey towards sustainable development

In the period between the first (2007) and second criteria (2019) the European PVC industry value chain has achieved substantial results through VinylPlus, its Voluntary Commitment to sustainable development. Achievements include recycling of more than 4.2 million tonnes PVC since 2000, replacement of unwanted additives, emission controls etc. As a result, VinylPlus is now regarded as a frontrunner for the circular economy by the European Commission and a role model for other industry sectors by the UN.

VinylPlus is financing different environmental projects related to PVC, for instance the UK take back scheme for PVC medical devices, RecoMed.

The VinylPlus programme, its large investments and sustainability achievements are completely ignored by the Nordic Ecolabelling, which must be considered as a fundamental lack in the criteria document.

6. Chlorine chemistry is key to our society

The Nordic Ecolabelling expresses concerns about chlorine and chlorine production. Yet chlorine chemistry is key to our society. Besides being a raw material for polyvinyl chloride, chlorine is used to disinfect drinking water and treat waste water, in manufacturing of life-saving pharmaceuticals,

[14] EDQM (2018). The Ph. Eur. revised its general chapters on plasticised PVC materials. https://www.edqm.eu/en/news/ph-eur-revised-its-general-chapters-plasticised-pvc-materials

computers, circuit boards, batteries for hybrid car, car tyres, smartphones and a wide range of other products.

During the last decades, the chlor-alkali industry has made a targeted effort to phase out mercury cell technology for chlorine production. In the EU chlorine production is now mercury-free as all plants have shifted to membrane technology. This technology is safe and contributes to significant energy savings. The same shift to mercury-free chlorine production is happening in the rest of the world through the Minamata Convention.

A better path forward

Polyvinyl chloride is the largest type segment for medical plastics. PVC is the third most widely produced synthetic plastic polymer after polyethylene and polypropylene. The demand for PVC is high, as PVC is compatible with different kinds of additives that make it a versatile polymer and thus, suitable for use in the manufacturing of medical plastics. Moreover, the polymer is affordable, which is crucial with rising healthcare costs. The demand for medical PVC is expected to see significant growth rates globally in the years to come.

The term "PVC-free" is decades old, and though many attempts have been made to substitute PVC in healthcare it remains the material of choice for many applications, namely flexible containers and tubing. Instead of calling for a PVC-free healthcare sector, which so far has been unsuccessful, a better path forward should be to combine the unique cost and performance of PVC with replacing unwanted substances and increasing recycling. This development is already ongoing. Indeed, the medical industry is fully aware of it and works at it while investigating all related aspects, including alternative plasticisers and/or processing technologies, with the objective to offer safe, affordable and reliable health solutions.

Recommendations

If the Nordic Ecolabelling wants to play an active role in the sustainable development of medical devices there is another more realistic way to follow than the antiquated PVC-free claim:

First of all, the Nordic Ecolabelling should promote DEHP-free devices, which indeed are available.

Second, the Nordic Ecolabelling should promote recycling of PVC-based medical devices, and as stated above PVCMed Alliance is willing to cooperate with Nordic authorities in this matter. Recycling is already happening in other parts of the world: In Australia and New Zealand, where around 200 hospitals collect PVC medical devices for recycling, and recycling is becoming the norm in procurement of medical devices. For instance, the Victorian Health and Human Services Building Authority is introducing PVC recycling collections to all metropolitan public hospitals and health services. The initiative is being delivered as part of its environmental sustainability strategy 2018-19 to 2022-23.

Third, the Nordic Ecolabelling should promote PVC medical devices that are manufactured from raw materials that comply with the legal requirements and follow the European Pharmacopoeia. Members of VinylPlus supply such materials and strive for the above scenario to become reality, also in partnership and with the support from the PVCMed Alliance.

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