



CONSUMER
HEALTHCARE
PRODUCTS
ASSOCIATION

Taking healthcare personally.

December 31, 2024

ATTN: Kim Morley
Washington State Department of Ecology
300 Desmond Drive, SE
Lacey, WA 98503-1274

RE: Safer Products for Washington Cycle 2 Draft Identification of Priority Products Report

Ms. Morley,

On behalf of the Consumer Healthcare Products Association (CHPA)¹, thank you for the opportunity to comment on the Washington State Department of Ecology's (DOE) Safer Products for Washington Draft Identification of Priority Products Report. Based on our analysis of the draft report and attendance at DOE webinars, we have significant reservations about the Department's decision to prioritize organochlorine substances in plastic packaging. Our concerns focus specifically on the primary polymers containing organochlorine compounds: polyvinyl chloride (PVC) and polyvinylidene chloride (PVDC). PVC and PVDC are vital components in manufacturing blister packaging for FDA-regulated pharmaceuticals and dietary supplements.

Blister Packaging and Consumer Safety

Blister packaging, also known as unit dose packaging, is widely used in healthcare and pharmaceutical packaging to ensure safe delivery of over-the-counter (OTC) medications and dietary supplements. This type of packaging has been recommended by the FDA to reduce accidental ingestion, misuse, and overuse of medications and other home self-care products.² To enhance product safety, blister packaging can be designed with tamper-evident features, ensuring product integrity and child-resistant blister packs help prevent unintended access and accidental ingestion by children.

Critical use of PVC in Consumer Healthcare Product Packaging

PVC used in blister packaging offers unique durability and flexibility, providing the necessary barrier against moisture, oxygen, and environmental factors that degrade the quality of consumer healthcare products. These characteristics are crucial to maintaining the integrity, efficacy, and shelf life of OTC drugs and healthcare products.

PVC is also cost-effective, contributing to the affordability and accessibility of OTC medications and healthcare products for consumers. PVC blister packs are lightweight, compact, and easy to carry, making them convenient for consumers to use on the go. The

¹ The Consumer Healthcare Products Association is the Washington, D.C. based national trade association representing the makers and marketers of over-the-counter (OTC) medicine, dietary supplements, and OTC medical devices.

² <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-newsteps-help-prevent-new-addiction-curb-abuse-and>

individual compartments in blister packaging allow for easy dosage tracking and help patients adhere to their medication regimens.

Exemptions Should be Made for All FDA-Regulated Products

FDA-regulated pharmaceuticals and dietary supplements should be granted an exemption from any restrictions on PVC and PVDC packaging materials. These polymers are crucial for maintaining product integrity and safety through specialized blister packaging that protects medications from moisture, oxygen, and contamination. The stability and shelf life of many pharmaceutical products depend directly on the unique barrier properties that PVC and PVDC provide. Alternative packaging materials may not offer the same level of protection, potentially compromising drug efficacy and patient safety. Additionally, pharmaceutical packaging undergoes rigorous FDA approval processes, with extensive stability testing to ensure product safety throughout its shelf life. Requiring manufacturers to reformulate packaging could necessitate lengthy and costly revalidation studies, potentially disrupting the supply of essential medicines. Given the critical role these materials play in protecting public health, the extensive regulatory oversight already in place, and the FDA's specific recommendation of this packaging to prevent accidental ingestion, misuse, and overuse of medications and home self-care products, pharmaceutical and dietary supplement packaging represents a unique use case that warrants exemption from broader PVC and PVDC restrictions.³

Conclusion

PVC plays a vital role in the production of blister packaging for OTC medications and dietary supplements. Its durability, versatility, compatibility with multiple formats including tamper-evident and child resistant packaging, cost-effectiveness, and ease of use make it an ideal choice for the healthcare industry. Given the proven benefits of PVC and PVDC in maintaining product integrity and stability, FDA-regulated products require particular consideration to ensure compliance with strict quality and safety standards. As the demand for safe and convenient packaging solutions grows, PVC/PVDC blister packaging will continue to be a key component in ensuring the quality, safety, and accessibility of consumer healthcare products.

Thank you for your consideration and feel free to contact me directly if I can provide additional perspective.

Respectfully submitted,

³ <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-help-prevent-new-addiction-curb-abuse-and>



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