Conference Abstract

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Blood Bags Market Post-May 2025

Abdel Ghany Morda

Demophorius Private Limited, Cyprus

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The global blood bags market is poised for significant evolution as it adapts to new regulatory landscapes and advances in blood preservation technology. By May 2025, the EU Medical Device Regulation (EU 2017/745 MDR) will enforce a ban on di(2-ethylhexyl) phthalate (DEHP) content exceeding 0.1% (w/w) in medical devices due to its proven risks. This regulatory shift is set to reshape the global blood bags market, which is projected to grow from USD 234.5 million in 2025 to an impressive USD 637.2 million by 2033, maintaining a compound annual growth rate (CAGR) of 4.23%.

Blood bags, designed for contamination-free blood collection and transfusion, have undergone significant advancements since Carl Walter and W.P. Murphy developed the first plastic bags in the late 1940s. Innovations in blood preservatives have further enhanced blood storage, from citrate-phosphate-dextrose (CPD) enabling 28-day storage to CPDA-1 in 1978 allowing up to 35 days. The current European standard involves using an additive solution called SAGM (Saline, Adenine, Glucose, Mannitol), extending storage up to 42 days at 2-6 °C.

DEHP, a plasticizer that constitutes about 30-40% of standard blood collection bags, has been pivotal in enhancing the preservation of red blood cells. It is known for maintaining RBC morphology, osmotic stability, and storage quality without affecting crucial parameters like 2,3-DPG and ATP levels. However, DEHP's capacity to leach into stored blood and its subsequent accumulation in transfusion recipients has raised significant safety concerns. Adverse outcomes, particularly in patients requiring repeated transfusions, include potential organ toxicity and an increased risk of carcinogenic and endocrine-disrupting effects, as evidenced by animal studies and observations in thalassemia patients.

The classification of DEHP as a category 1B reproductive toxin necessitates regulatory action, thus prompting the forthcoming restrictions in the EU. This has propelled blood service providers and manufacturers to explore alternative plasticizers. Notable DEHP substitutes under examination include 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH), N-butyryl-n-hexyl citrate (BTHC), di(2-ethylhexyl) terephthalate (DEHT), and Tri-(2-ethylhexyl) trimellitate (TOTM/TEHTM). However, current studies indicate that non-DEHP alternatives may increase hemolysis and reduce blood shelf life to less than 35 days, complicating the transition.

As May 2025 approaches, the blood transfusion industry faces a critical need for global collaboration and research to validate safe and effective alternatives. The potential impact on patient care, especially in regions dependent on frequent transfusions, underscores the urgency. While alternatives are being studied, the balance between maintaining red cell viability and ensuring patient safety will shape the future of the blood bags market. Addressing these challenges head-on will require concerted international efforts to align research, regulation, and market readiness.

Disclosure

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