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Breaking barriers in drug access: The power of bulk importation in albania

Adela Kupe
Profarma, Albania

Albania's pharmaceutical sector has long struggled with fragmented imports, high drug prices, and inconsistent access to essential medicines—particularly for chronic conditions. These barriers limit affordable treatment for large segments of the population. In response, and building on pharmaceutical law innovations introduced in 2023, Profarma has launched a bulk importation strategy aimed at reshaping the national pharmaceutical supply chain. Law No. 95/2022 marked a turning point by allowing bulk importation of medicines for the first time. It also established a more flexible regulatory environment that facilitates large-volume procurement, supports broader sourcing, and strengthens quality assurance in line with EU GMP guidelines. Profarma, as the only Albanian manufacturer with both importation and production capacity, leveraged this shift to pioneer an integrated strategy combining bulk importation with a streamlined regulatory and registration process. This dual innovation—operational and regulatory—has enabled Profarma to efficiently source essential and advanced medications from global suppliers while maintaining alignment with EU quality standards. The model delivers several key benefits: cost efficiency through economies of scale, increased availability of essential medicines, access to advanced drugs not produced locally, and fostering competition in both on-patent and off-patent markets. By acting as the Marketing Authorization Holder (MAH), Profarma also centralizes regulatory responsibilities, reducing the workload and associated costs for suppliers. The model further ensures compliance with higher regulatory and quality standards aligned with EU legislation, opening export opportunities and enabling participation in global health initiatives—particularly those targeting access in low- and middle-income countries through health diplomacy. This alignment strengthens Albania's position in regional and global health systems. Supported by operational data and supply-chain optimization models tailored for emerging health systems, Profarma's strategy shows strong potential. With projections indicating up to a 20% reduction in procurement costs, 30% increase in medicine availability, and 25% improvement in delivery efficiency, the model is both scalable and replicable across similarmarkets.

Biography

Adela kupe is regulatory affairs manager at profarma pharma group, Albania's only domestic manufacturer with both production and importation capacity. She led the design and implementation of Profarma's bulk importation and streamlined registration strategy under Law No. 95/2022, aligning supply chain operations with EU GMP quality standards. Adela provides expertise in dossier preparation, risk management systems, market analysis, and competitive sourcing to support timely approvals and sustained access to essential and advanced medicines. Her work also includes regulatory pathway optimization, business development, and coordination across cross-functional teams to ensure compliance with national and international requirements. She holds a M.Sc. in Pharmacy and is completing a Professional Master's in Health Management. With experience across regulatory operations, pharmacovigilance, and product registration, Adela supports initiatives that strengthen pharmaceutical supply systems and promote access to quality medicines in emerging markets. Her work contributes to the alignment of local practices with evolving European regulatory frameworks.

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