An Expert Perspective on the Future of Herbal Medicinal Products in Europe

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Herbal medicinal products (HMPs) in Europe are entering a period of substantial regulatory transformation. The new European Union pharmaceutical legislation, the implementation of the revised variations framework, and the growing integration of real-world data (RWD) and real-world evidence (RWE) into regulatory decision-making present both challenges and opportunities for the herbal medicines sector. These developments require adapting existing regulatory paradigms to enable greater flexibility, regulatory efficiency, and evidence generation throughout the product lifecycle.

In parallel, emerging opportunities for international regulatory collaboration, including increased engagement with global regulatory authorities, have the potential to promote greater convergence of scientific and regulatory standards, foster innovation, and enhance the global competitiveness of HMPs.