

Resilient Pharmaceutical Supply Chains in Times of Crisis: A Comparative Analysis of Australia, France, Italy, Spain, and UK

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OBJECTIVES: To compare national strategies adopted by Australia, France, Italy, Spain and the UK to prevent and mitigate drug shortages, strengthen pharmaceutical supply chain resilience, and ensure equitable access to essential medicines during periods of geopolitical instability, climate-related disruptions, and public health emergencies with the aim of identifying best practices and scalable solutions.

METHODS: A qualitative comparative analysis was conducted through review of regulatory frameworks, shortage notification systems, shortage lists, digital infrastructure, and industrial policy interventions. Sources included national agencies, government reports, and European Medicines Agency (EMA) documentation, with particular focus on Regulation (EU) 2022/123 and associated initiatives.

RESULTS: All countries have implemented mandatory reporting of shortages and maintain publicly accessible databases. Australia, the UK, and Spain support real-time monitoring through dedicated platforms (e.g., TGA portal, DaSH, SEGUIMED/CisMED). France mandates reserve stock for critical medicines and promotes domestic manufacturing under national investment plans (France 2030). Italy and Spain emphasize predictive analytics and proactive data collection (e.g., DruGhost, FarmaHelp). Substitution protocols such as SSSIs (Australia) and SSPs (UK) ensure treatment continuity without prescriber intervention. Spain and France impose export restrictions during crises, while Italy and the UK employ multi-stakeholder governance structures to coordinate responses. Across all countries, digital and legislative mechanisms have been integrated to enhance transparency and rapid response

CONCLUSIONS: Despite differences in implementation, countries converge on core

principles: mandatory reporting, real-time data infrastructure, substitution protocols, and coordinated governance. France's industrial strategy, Spain's legislative depth, and Australia's import frameworks offer scalable models. Lessons from this analysis can inform European-level harmonization efforts under EMA-led frameworks and contribute to more resilient pharmaceutical systems.

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