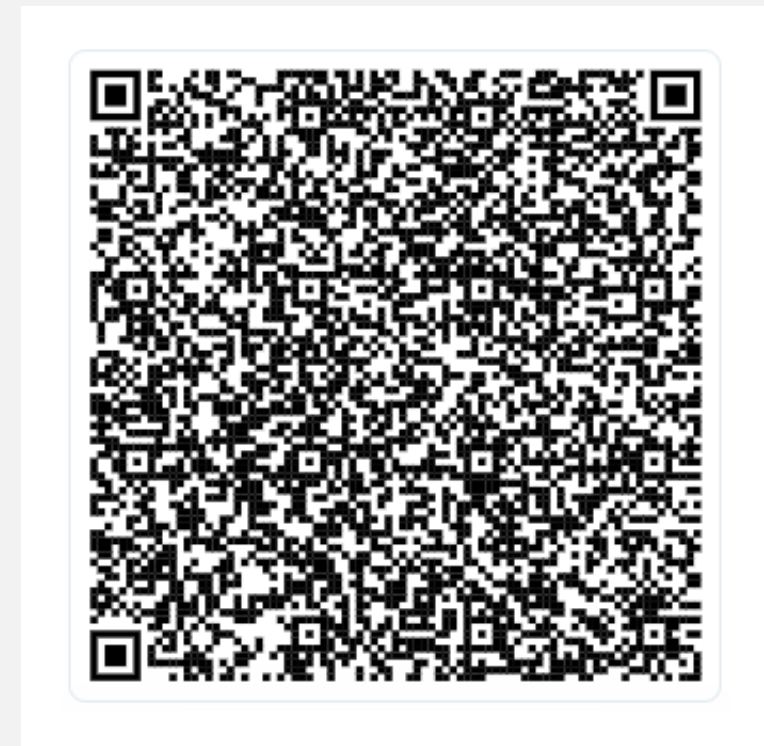


# Resilient Pharmaceutical Supply Chains in Times of Crisis: A Comparative Analysis of Australia, France, Italy, Spain and UK.

HPR175



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## Objectives.

In recent years, the pharmaceutical supply chain across Europe and the JAPAC (Japan and Asia-Pacific) region has come under significant pressure from multiple converging crises: the COVID-19 pandemic, armed conflicts, rising energy costs, and increasingly frequent climate-related disruptions. These challenges have exposed structural weaknesses in the manufacturing and distribution of medicines, leading to a surge in drug shortages, particularly affecting essential medicines and critical therapeutic areas.

The impact extends beyond logistics. For patients, shortages result in delayed treatments, therapy interruptions, and poorer health outcomes, as well as confusion and anxiety due to uncertainty or changes in medication. For healthcare professionals, especially pharmacists, managing shortages represents a heavy operational burden: up to seven hours per week may be spent sourcing alternatives or contacting suppliers, reducing time available for patient care and generating additional costs for health systems.

In this context, the study aims to compare national strategies adopted by five countries, Australia, France, Italy, Spain, and the United Kingdom, to address the growing problem of medicine shortages. The analysis focuses on three main goals: (1) preventing and mitigating shortages; (2) strengthening supply chain resilience; and (3) ensuring equitable and continuous access to essential medicines. Through this lens, the aim is to identify both best practices and scalable, transferable policy interventions that could inform EU-wide or global regulatory and industrial strategies. Special attention is given to how health systems integrate digital infrastructure, regulatory agility, public-private partnerships, and manufacturing autonomy to build systemic resilience.

## Methods.

A qualitative comparative policy analysis was conducted to evaluate national responses and institutional preparedness related to drug shortages and pharmaceutical supply chain resilience. The analysis covered five countries: Australia, France, Italy, Spain, and the United Kingdom.

Data collection involved a review of publicly available documentation, including: regulatory frameworks governing medicine shortages and emergency preparedness, mandatory and voluntary shortage notification systems, publicly accessible shortage databases and monitoring tools, national strategies related to pharmaceutical manufacturing, stockpiling, and critical supply chain components, investment in digital technologies for early warning systems, real-time tracking, and forecasting, policy interventions incentivizing local production or diversifying supply sources.

Primary sources included documents from national medicines agencies (e.g., AIFA, ANSM, MHRA), health ministries, parliamentary reports, and publicly available EMA documentation. The analysis also incorporated recent developments following Regulation (EU) 2022/123, which enhances the EMA’s mandate in crisis preparedness and management of medicine shortages across the EU. Comparative insights were drawn by evaluating each country’s alignment with or divergence from this regulation and associated European initiatives (e.g., EU FAB, HERA, Critical Medicines Alliance). This multi-dimensional approach enabled the identification of common patterns, gaps, and innovative practices across jurisdictions, providing a foundation for cross-country learning and potential policy harmonization.

Numerous local initiatives have been implemented, but due to space constraints, only the most relevant ones have been included. Each activity has been assigned a potential impact on drug shortage resolution/prevention, rated on a scale from 1 to 3 (with 1 indicating low impact and 3 indicating high impact).

## Results.

All countries analyzed have established national working groups dedicated to addressing medicine shortages, promoting a shared governance model that includes health authorities, regional entities, and healthcare professionals. They all maintain regularly updated public lists of temporarily unavailable or critical medicines, serving as essential tools for transparency and early warning. Legal frameworks enabling pharmacists to substitute medicines during shortages have been implemented in Australia, the UK, France and Spain to ensure continuity of care. France, Italy, and Spain are actively investing in reshoring pharmaceutical production, particularly for active pharmaceutical ingredients and essential drugs. France and Spain have also adopted seasonal and contingency plans to manage demand peaks during winter or health crises, along with inspection and sanction mechanisms to enforce compliance among pharmaceutical companies. Additionally, both Italy and Spain require marketing authorization holders to submit continuity plans for critical medicines as part of their preventive strategies.

TOPIC	AUSTRALIA	ITALY	FRANCE	SPAIN	The UK
Dedicated national working tables	✓	✓	✓	✓	✓
Periodically updated lists of shortages	✓	✓	✓	✓	✓
Automatic replacement mechanisms to ensure continuity	✓		✓	✓*	✓
Investing in local manufacturing capacity		✓	✓	✓	
Seasonal preparedness measures			✓	✓	
Sanctions/inspections on companies to ensure product supply			✓	✓	
Submission of a supply plan to the local HTA agency		✓		✓	
Emergency importation	✓	✓		✓	

\*only if the substitute has the same active substance, pharmaceutical form, route of administration, and dosage

### AUSTRALIA

In Australia, the Therapeutic Goods Administration (TGA) defines a medicine shortage as a situation where the supply of a medicine is unlikely to meet the usual or anticipated consumer demand at any time within the next six months.

ACTION	BRIEF DESCRIPTION	POTENTIAL IMPACT
Mandatory Shortage Reporting & Medicine Shortage Database	Legal requirement for sponsors to promptly report medicine shortages or discontinuations; includes updates on duration and resolution of shortages. There is a publicly accessible database listing all reportable medicine shortages.	3
Medicines Watch List	A legislative list of critical medicines; shortages of these medicines are automatically classified as having a critical patient impact.	3
Section 19A Approvals Database	Lists non-ARTG medicines temporarily approved for import and supply to address shortages of registered, essential medicines.	2
Medicine Shortages Hub	A centralized TGA webpage providing tailored information for consumers, healthcare professionals, and sponsors regarding medicine shortages.	1
Serious Scarcity Substitution Instruments (SSSI)	Legal instruments allowing pharmacists to substitute certain medicines without prior prescriber approval under defined conditions.	3

### ITALY

The Italian Medicines Agency (AIFA) is committed to proactively preventing and managing medicine shortages. To this end, it supports the strengthening of domestic production of active ingredients and excipients, and promotes the integration of data on dispensing, consumption, and pharmaceutical stocks as a strategic tool to enhance the system’s responsiveness.

ACTION	BRIEF DESCRIPTION	POTENTIAL IMPACT
Temporary Shortage List	A list of temporarily unavailable medicines, updated at least twice weekly, based on information from marketing authorization holders and verified reports.	3
Production Capacity Self-Declaration	Requirement for companies to submit during the HTA process a self-declaration confirming their commitment to maintain a constant supply adequate to meet the needs of the National Health Service.	2
Permanent Technical Committee	A multi-stakeholder committee including regions, local health authorities, pharmacies, and general practitioners to monitor shortages, plan interventions, and communicate.	2

### FRANCE

France has put in place several measures to mitigate drug shortages, enhance pharmaceutical supply chain resilience, and ensure long-term sustainability of medicine access considering the geopolitical and environmental stress. Local production of drugs is also being encouraged in France.

ACTION	BRIEF DESCRIPTION	POTENTIAL IMPACT
Mandatory Safety Stock for MITMs	Since 2021, manufacturers must maintain 2-4 months of safety stock for medicines of major therapeutic interest (MITMs). The measure is enforced by ANSM through inspections and significant financial penalties for non-compliance.	3
National Roadmap 2024-2027	A multi-ministerial strategy covering real-time monitoring, therapeutic substitution, rapid diagnostic testing, reshoring of key medicines, price-volume agreements, and shared digital platforms to improve supply chain resilience and transparency.	3
Industrial Policy and Reshoring	Over 100 pharmaceutical manufacturing and supply projects supported under France Relance and France 2030 to boost domestic production of APIs and essential medicines.	2
Seasonal and Emergency Measures	Contingency plans for winter and crisis periods, including local reservation of antibiotics and emergency authorizations for hospital pharmacies to compound medicines during prolonged shortages.	2
Governance and Regulatory Measures	Establishment of a high-level interministerial committee, ban on exporting MITMs during shortages, mandatory risk reporting by manufacturers, and deployment of real-time digital traceability systems.	2

### SPAIN

Spain has adopted a multi-pronged strategy to tackle medicine shortages through regulatory, industrial, and digital interventions. AEMPS contacts alternative holders to verify their ability to meet demand during shortages, while new legislation is being developed to enhance prevention and response mechanisms. Measures also include temporary approval of medicines packaged or labeled for other markets, export bans during shortages, and exceptional imports to maintain national supply. Additionally, AEMPS collaborates with pharmacy and medical organizations to share data and coordinate local and national actions.

ACTION	BRIEF DESCRIPTION	POTENTIAL IMPACT
Public Shortage List & Digital Tools for Monitoring	Frequently updated public list of medicines in shortage, based on MAH reports and verified data. Enhances transparency and early detection. SEGUIMED (mandatory reporting), CisMED (real-time pharmacy stock), and FarmaHelp (medicine locator app for patients and pharmacies).	3
Critical Medicine Forecasting	Periodic stock and sales data collection to anticipate and mitigate shortages of high-priority medicines.	3
Manufacturer Inspections & Sanction Procedures	Inspections to detect manufacturing issues that may lead to shortages. Enforcement actions against companies that unjustifiably interrupt supply.	3
Prevention Plans from MAHs	Marketing authorization holders must submit continuity plans for critical medicines.	2
Regional & Local Coordination	Collaboration with regional health services and pharmacies to monitor and manage local shortages.	2
Proactive Seasonal Coordination	Seasonal plans with companies to increase stock of critical medicines like antibiotics and antivirals.	2
Official Informative Notes	AEMPS regularly publishes guidance and updates on shortages, alternatives, and prioritization.	2

### The UK

The UK addresses medicine shortages through mandatory early reporting by MAHs, digital reporting platforms, and national coordination by the Department of Health and Social Care (DHSC). Key tools include the DaSH portal, Serious Shortage Protocols (SSPs), and real-time alert systems to support rapid response and continuity of care.

ACTION	BRIEF DESCRIPTION	POTENTIAL IMPACT
Mandatory Shortage Reporting	Since 2019, MAHs are legally required to notify DHSC of expected shortages or discontinuations at least six months in advance, or as soon as reasonably practicable.	3
Discontinuations and Shortages (DaSH) Portal	A secure portal launched in 2020 for MAHs to report supply issues, discontinuations, and provide updates directly to the DHSC Medicines Supply Team.	3
Medicines Supply Tool	A password-protected tool providing healthcare professionals with real-time updates on current supply issues, searchable by drug class and severity.	2
Serious Shortage Protocols (SSP)	Allows pharmacists to substitute medicines without prescriber approval, under predefined protocols, ensuring treatment continuity during shortages.	3
Supply Disruption Alerts (CAS)	Urgent alerts issued via the Central Alerting System to NHS and care providers in case of critical medicine shortages, ensuring rapid mitigation actions.	2
DHSC Medicine Supply Team	A dedicated team of pharmacists and technicians managing national responses to shortages, coordinating with MAHs to enable early intervention.	2
MIMS UK Drug Shortages Page	Subscription-based platform offering updates, trackers, and resources to support healthcare professionals in managing shortages.	1

## Conclusion.

Despite differences in implementation, countries converge on core principles: mandatory reporting, real-time monitoring systems, substitution protocols, and coordinated governance.

To strengthen preparedness for increasing medicine shortages, several best practices stand out. Mandatory early reporting by marketing authorization holders and the creation of real-time, public shortage databases significantly improve transparency and early response. Legal frameworks allowing pharmacists to substitute medicines without prior prescriber approval help ensure treatment continuity. Investing in local manufacturing capacity, particularly for essential drugs and APIs, reduces dependency on external supply chains. Finally, requiring continuity plans for critical medicines and enabling seasonal preparedness measures, including stockpiling and emergency compounding, can greatly enhance system resilience in the face of geopolitical and market disruptions.

However, as pharmaceutical shortages are increasingly global, stronger international coordination will be essential to mitigate systemic supply change vulnerabilities across national borders.

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