EHMA
European Health Management Association

POSITION PAPER

The European Pharmaceutical Strategy Reform

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Introduction

The European Pharmaceutical Strategy Reform represents a once-in-a-generation opportunity to strengthen patient safety, improve the resilience of medicine supply chains, and make solidarity among Member States operational in practice. Launched by the European Commission in April 2023, the reform package — comprising a Regulation and a Directive — seeks to modernise Europe's pharmaceutical framework, ensuring that medicines remain available, affordable, and safe, while also supporting innovation, sustainability, and competitiveness.

Since then, the Council and the European Parliament have advanced their positions. The Parliament's plenary vote in April 2024 introduced valuable provisions on shortages monitoring, patient safety, and the role of hospital pharmacies, as well as greater alignment of national IT systems with the European Medicines Agency's European Shortages Monitoring Platform (ESMP). However, a critical gap remains. **There is no binding requirement for Member States to ensure real-time visibility of medicine stocks in hospitals** — the frontline of patient care and the setting where shortages first impact treatment.

Closing this gap is essential for making solidarity mechanisms work in practice and for safeguarding patients during crises. Evidence shows that digitalising hospital medication management delivers substantial benefits: reducing medication errors, improving inventory accuracy, and optimising procurement. A recent EU-wide analysis estimated an average return on investment of 167%, or €1.96 billion in annual savings, with a payback time of less than five years. Despite this, most hospitals still rely on manual stock counts and fragmented IT systems, providing only delayed or incomplete visibility to regulators.

Therefore, **the European Health Management Association (EHMA) urges co-legislators to strengthen the Regulation by mandating interoperable National Critical Medicines Stock Visibility Systems (N-CMSVS) in every Member State.** These systems — aligned with the ESMP, the Interoperable Europe Act, and the NIS2 Directive — must capture hospital-level data on stocks, expiry, consumption, and purchase orders for critical and shortage medicines, ensuring near real-time situational awareness.

This reform is both a resilience measure and a value-for-money investment. It will safeguard patients, reduce avoidable harm, improve efficiency in health systems, and provide the data needed to make EU solidarity more than an aspiration. The following section explains why hospitals and digital medication management must be placed at the centre of this agenda.

Why hospitals and digital medication management matter

Hospitals are the frontline of patient care and the first setting where shortages of medicines directly impact treatment. During health crises, hospitals must manage surges in demand for critical medicines such as oncology products, antimicrobials or intensive-care sedatives. Yet, despite their central role, most European hospitals still rely on manual inventory counts and fragmented IT systems, providing only delayed or incomplete visibility of stock levels to regulators.

Without systematic hospital-level reporting, Member States and the European Medicines Agency (EMA) cannot ensure fair allocation of medicines or make the European Shortages Monitoring Platform fully operational. Hospitals, therefore, need interoperable, digitalised medication management systems capable of providing real-time information on available stock, expiry dates, consumption patterns, and open purchase orders.

Evidence shows that such systems deliver not only resilience but also efficiency. A recent EU-wide economic analysis found that automation and digitalisation of hospital medication management generate an average return on investment of 167%, corresponding to approximately €1.96 billion in annual savings EU-wide, with a payback period of only 4.5 years. These benefits arise largely from reduced medication errors, improved inventory accuracy, and optimised procurement practices.

Case studies from across Europe

- **Italy – Lombardy Region:** 40 hospital facilities digitalised their medication pathways, introducing electronic medical records, decision-support tools, and automated drug logistics systems. The regional programme improved collaboration between professionals, strengthened patient safety, and created interoperable data flows for procurement and prescribing.
- **Ireland – National Cancer Information System (NCIS):** This oncology-specific platform integrates prescribing, electronic medication administration, aseptic compounding, and multidisciplinary team management. It has addressed long-standing gaps in information sharing across hospitals and ensures clinicians have access to longitudinal treatment records, enabling safer and more efficient systemic therapy.
- **Germany – Hospital Future Act (KHZG):** With €4.3 billion earmarked for digital health investments, hospitals introduced digital medication management systems to strengthen the resilience of pharmaceutical supply chains. Funding is tied to interoperability and clinical safety goals, creating a strong legal and financial incentive for hospitals to adopt advanced IT systems for prescribing, dispensing, and stock management.

Investing in hospital digitalisation is both a public health imperative and a value-for-money reform. It safeguards patient safety, strengthens crisis preparedness, and reduces unnecessary costs, while providing the reliable data streams needed for solidarity-based allocation of medicines across the EU.

REMAINING Gaps & EPACT's PROPOSALS

Patient Safety and Risk Management

Call to action 1

The European Parliament strengthened the Pharmaceutical Reform with provisions on patient safety, including broader definitions of medication errors and new obligations for hospital pharmacies. However, important gaps remain. While errors and risk management are acknowledged, there is no binding requirement for hospitals to adopt digital systems that systematically reduce such risks. **We propose targeted amendments to embed digital medication management as a core patient safety measure.**

Proposal for a Regulation, Chapter 1 Subject Matter, Scope & Definitions, Article 2 Definitions 16 – NEW

Original	Amended
/	Adverse reaction means a response to a medicinal product that is noxious and unintended and includes medication errors and uses outside of the terms of the marketing authorisation, including the misuse and abuse of the medication product

Proposal for a Regulation, Chapter 1, Article 4 (59) – NEW

Original	Amended
Adverse reaction means a response to a medicinal product that is noxious and unintended	Adverse reaction means a response to a medicinal product that is noxious and unintended and includes medication errors and uses outside of the terms of the marketing authorisation, including the misuse and abuse of the medication product.

Proposal for a Regulation, Chapter VII Pharmacovigilance, Amendment 223, Article 101, paragraph 1, subparagraph 3 – NEW

Original	Amended
The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.	The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, *including errors in relation to medication,* and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.

Proposal for a Regulation, Cooperation with Member States, Article 111, paragraph 1 - MAINTAIN

Original	Amended
The Agency and the Member States shall cooperate to continuously develop pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.	The Agency and the Member States shall cooperate to continuously develop pharmacovigilance systems*, including those that record adverse events including medication errors, processes and standards for medication safety,* capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.

Proposal for a Directive, Chapter I Subject matter, scope and definitions, Amendment 82, Article 1, paragraph 5, point ca - MAINTAIN

Original	Amended
Text proposed by the Commission	(ca) medicinal product prepared in advance, in duly justified cases, by the pharmaceutical department of a hospital ('hospital formula'), supplied on medical prescription to one or several patients by the hospital's pharmaceutical department.

Proposal for a Directive, Amendment 186, Article 66, paragraph 2a – MAINTAIN

Original	Amended
Text proposed by the Commission	2a. Each single dose of the blister pack shall include the following labelling particulars: (a) the name of the medicinal product followed by its strength and pharmaceutical form. (b) a data matrix code in which the following information is encoded: (i) the Global Trading Index Number (GTIN) (ii) the expiry date (iii) the batch number.

Proposal for a Directive, Recording and reporting of suspected adverse reaction by Member States, Amendment 223, Article 97, paragraph 1, point ea - MAINTAIN

Original	Amended
5. Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004].	5. Member States shall ensure that reports of suspected adverse reactions arising from an error, *including those* associated with the use, *administration, and dispensation* of a medicinal product, *by professionals,* that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004].

Proposal for a Directive, Amendment 232, Article 106, paragraph 5a - MAINTAIN

Original	Amended
Text proposed by the Commission	5a. Reports of adverse reactions arising from incorrect administration or dispensation of a medicinal product shall be available in the Eudravigilance database and shall be included in periodic safety update reports. Where relevant, Member States shall take corrective action to achieve high standards

	of medication safety in healthcare settings after consultation of healthcare professionals and other relevant stakeholders.

Proposal for a Directive, Amendment 233, Article 107, paragraph 3a – MAINTAIN

Original	Amended
Text proposed by the Commission	3a. The Agency or the national competent authorities, as appropriate, shall make publicly available the reports referred to in paragraph 1, points (a) and (b). * (a)monitor the outcome of risk minimisation measures contained in risk management plans and of conditions referred to in Article 12, paragraph 4, points (d) to (g), or in Article 20, paragraph 1, points (a) and (b), and in Articles 18(1) and 19; (b)assess updates to the risk management system;

Medication Shortages

Proposal for a Regulation, Recital 137 - MAINTAIN

Original	Amended
To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe.	To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe. *To combat certain shortages, medicinal products prepared for individual patients in a pharmacy according to a medical prescription, known as a 'magistral formula', or according to the pharmacopoeia and intended to be supplied directly to patients served by the pharmacy, known as an 'officinal formula', may be used.*

Call to action 2

The European Parliament acknowledged shortages as a systemic risk and strengthened monitoring obligations. However, the current text does not fully capture the role of hospitals and digital stock management in securing supply. **We propose amendments to ensure hospitals and ambulatory care settings are recognised as key actors in shortage reporting and mitigation.**

Proposal for a Regulation, Amendment 262, Article 121, paragraph 1, point ba - MAINTAIN

Original	Amended
Text proposed by the Commission	(ba) create a system allowing patients to report shortages of medicinal products and request pharmacies supplying hospitals and hospital pharmacies to electronically communicate data on available stock of the medicinal product concerned, in order to avert or mitigate an imminent or existing supply shortage relevant to the supply of a medicinal product.

Proposal for a Regulation, Amendment 262, Article 121, paragraph 1, point ba – MAINTAIN, but add further specification

Original	Amended
Text proposed by the Commission	(ba) create and operate a National Critical Medicines Stock Visibility System (N-CMSVS) to collect, process and transmit near real-time information on the availability and consumption of critical medicinal products at hospital and other relevant healthcare provider levels within its territory. The N-CMSVS shall, at a minimum, record for each critical medicinal product: (a) on-hand quantities by presentation and lot, (b) expiry dates, (c) location granularity (hospital, pharmacy, ward). Member States shall ensure that the N-CMSVS is interoperable with the European Shortages Monitoring Platform (ESMP) and other Union-level systems designated under Regulation (EU) 2022/123, using common technical specifications adopted in order to avert or mitigate an imminent or existing supply shortage relevant to the supply of a medicinal product.

Proposal for a Regulation, Amendment 266, Article 121, paragraph 2a – MAINTAIN

Original	Amended
Text proposed by the Commission	2a. After the expansion of the ESMP referred to in Article 122(6) and for the purpose of Article 118(1) and Article 121(2), point (a), competent authorities of the Member States shall set up national IT systems which are interoperable with the ESMP and allow for the automated exchange of information with the ESMP while avoiding duplication of reporting.

Proposal for a Regulation, Amendment 266, Article 121, paragraph 2a – MAINTAIN, but add further specification

Original	Amended
Text proposed by the Commission	2a. The competent authorities of the Member States shall create and operate a National Critical Medicines Stock Visibility System (N-

	CMSVS) to collect, process and transmit near real-time information on the availability and consumption of critical medicinal products at hospital and other relevant healthcare provider levels within their territory. The N-CMSVS shall, at a minimum, record for each critical medicinal product: (a) on-hand quantities by presentation and lot, (b) expiry dates, (c) location granularity (hospital, pharmacy, ward). Member States shall ensure that the N-CMSVS is interoperable with the European Shortages Monitoring Platform (ESMP) and other Union-level systems designated under Regulation (EU) 2022/123, using common technical specifications adopted.

Proposal for a Regulation, Amendment 272, Article 122, paragraph 1a – MAINTAIN

Original	Amended
Text proposed by the Commission	1a. For the purpose of Article 118(1a) and based on the information provided pursuant to Article 121(1), point (cb), and Article 121(2), the Agency shall assess the actions planned or taken by a Member State to mitigate a shortage at national level with regard to any potential or actual negative impacts of those actions on the availability and security of supply in another Member State and at Union level. The Agency shall inform the Member State concerned and the MSSG, as well as the Member States potentially or actually impacted, of its assessment in a timely manner through the single point of contact working party referred to in Article 3(6) of Regulation (EU) 2022/123. The Agency shall also inform the Commission of its assessment.

Proposal for a Regulation, Chapter X Availability and security of supply of medicinal products, Section 2 Security of Supply, Article 129 Obligations on other actors – NEW

Original	Amended
For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.	For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public, including hospitals and ambulatory care

	settings, shall provide any information requested in a timely manner.

Proposal for a Directive, Chapter I Subject matter, scope and definitions Article 1 (6) - NEW

Original	Amended
Medicinal products referred to paragraph 5, point (a), may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven days.	Medicinal products referred to paragraph 5, point (a), may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital.

Proposal for a Directive, Amendment 65, Recital 123 a - MAINTAIN

Original	Amended
Text proposed by the Commission	(123a) Pharmacists and other health care professionals have an important role in primary care, particularly to compound, dispense and sell medicinal products that patients need, to provide advice on their proper use and possible adverse effects and to support patients suffering of acute and chronic illnesses. In a hospital environment, hospital pharmacists set up pharmaceutical consultations and designate personalised pharmaceutical plans, in cooperation with other health professionals, patients and carers. Hospital pharmacists and community pharmacists could play a significant role in the use of electronic package leaflets, as well as for understanding the information contained in paper leaflets.

Digitalisation and interoperability

Proposal for a directive, Amendment 223, Article 97, paragraph 1, point ea - NEW

Original	Amended
Text proposed by the Commission	(f) Hospital and retail pharmacies and dispensers shall progressively adopt digital dispensing and medication management systems (e.g. barcode scanning, inventory automation, computerised decision support, stock-level monitoring) with the objective of reducing overstocking, preventing expiry-based waste, optimising returns, and enhancing the quality and safety of dispensing operations.

Call to action 3

The European Parliament recognised the role of data in shortage monitoring and pharmacovigilance but did not go far enough on interoperability and systematic reporting. **Our proposals ensure adverse reactions, errors, and stock levels are digitally captured and exchanged among systems.**

Expected impact

The proposed amendments do not only address technical gaps in the Pharmaceutical Reform; they deliver tangible benefits for patients, healthcare professionals, and health systems across the Union. Their impact is threefold:

strengthening resilience, generating efficiency, and aligning with the wider EU digital and regulatory environment.

Public health resilience

By embedding digital medication management and systematic shortage monitoring as part of patient safety and supply continuity, the amendments strengthen the Union's ability to anticipate, prevent, and respond to crises. Hospitals and ambulatory care settings will gain tools to reduce medication errors, detect risks earlier, and maintain access to critical medicines even in emergency conditions. This directly supports the EU objective of creating more resilient health systems capable of withstanding geopolitical, demographic, and public health shocks.

Efficiency and economic savings

Medication errors and supply shortages currently generate avoidable costs for hospitals and public health authorities, from prolonged hospital stays to waste in procurement. Interoperable digital reporting and automated data exchange reduce duplication, administrative burden, and manual record-keeping. By integrating digital safety and supply monitoring into the pharmaceutical framework, Member States can achieve measurable economic savings that can be reinvested into patient care, workforce capacity, and innovation.

Coherence with other EU legislation

The amendments also ensure the Pharmaceutical Reform does not operate in isolation but is aligned with wider EU digital and regulatory strategies:

- **European Health Data Space (EHDS):** Real-time pharmacovigilance and shortages data generated at hospital level will complement the secondary use of health data, strengthen evidence for EU-wide research and policymaking, and improve patient safety monitoring across borders.
- **Critical Medicines Act (CMA):** The CMA sets the Union list of critical medicines and strengthens manufacturing and procurement tools. By aligning the Pharmaceutical Reform with N-CMSVS obligations, policymakers ensure that the upstream CMA measures are matched with downstream hospital-level visibility, making solidarity mechanisms effective in practice.
- **Interoperable Europe Act:** By mandating interoperable National Critical Medicines Stock Visibility Systems, the Reform contributes directly to the EU's goal of seamless cross-border data exchange, using common standards and specifications. This avoids fragmentation of reporting systems and ensures that hospital data feeds into Union-wide platforms like ESMP in a consistent way.
- **NIS2 Directive:** Hospitals and national authorities are already designated as essential entities under NIS2. Requiring digital medication safety systems and interoperable stock visibility platforms ensures that critical medicine data is managed with cybersecurity by design, protecting sensitive patient and inventory information from disruption or misuse.

By adopting these amendments, the Pharmaceutical Reform will achieve its core objectives of protecting patients and ensuring access to medicines, while also maximising synergies with digital transformation and resilience policies. The result will be safer, more efficient, and future-proof health systems across Europe.

Conclusions

The Pharmaceutical Reform can only deliver on its promise of availability, safety, and solidarity if hospital-level data are visible, interoperable, and timely. Co-legislators have already improved provisions on patient safety and shortages; the final step is to make digital stock visibility in hospitals a legal requirement and to ensure it is interoperable with EU platforms and secure by design.

Core legislative ask (Trilogue priority)

Insert a new provision (e.g. Article 19a in the Regulation) to mandate National Critical Medicines Stock Visibility Systems in every Member State, interoperable with the ESMP, the Interoperable Europe Act framework, and NIS2. These systems should capture, in near real time, hospital-level data on on-hand stocks, expiry, consumption/dispensing, and purchase orders for medicines on Union or national critical/shortage lists.

Why this matters now

Hospitals are the frontline for crisis response and continuity of care. Without structured, near real-time visibility of hospital inventories, authorities cannot allocate fairly, prevent wastage, or protect patients across borders. Evidence shows that digital medication management yields high returns on investment (ROI 167%, €1.96 billion in annual savings) while reducing errors and administrative burden, making this reform both a resilience measure and a value-for-money reform.

Implementation that works in practice

- **Scope and phasing:** Begin with critical/shortage lists and hospital pharmacies, then expand to additional therapeutic classes and ambulatory settings on a defined timeline.
- **Minimum data set and standards:** Adopt a common dataset and interoperability specifications aligned with ESMP, building on Interoperable Europe common solutions.
- **Governance and safeguards:** Clarify roles for EMA/MSSG, national competent authorities, and hospitals; ensure cybersecurity (NIS2) and data protection by design; include clear incident and continuity procedures.
- **Funding and support:** Mobilise EU and national funding (structural funds, RRF, EU4Health, Digital Europe), complemented by technical assistance for hospitals.
- **Monitoring and accountability:** Define KPIs (reporting timeliness, data completeness, error rates, stock-out duration) and require annual public reporting at EU and national levels.

Red lines for trilogue

- Hospital-level visibility cannot be optional or left to voluntary pilots.
- Interoperability with ESMP and security requirements must be explicit (not aspirational).
- The role of hospital pharmacies in patient safety and shortages management must be retained and operationalised (including digital medication safety systems).

What success looks like

Within 24–36 months of entry into force, Member States operate N-CMSVS connected to ESMP; hospitals submit automated feeds; authorities have situational awareness to anticipate and mitigate shortages; medication errors fall; and the EU's solidarity mechanisms function in real time, protecting patients and budgets alike.

Call to co-legislators

The European Parliament, Council, and Commission should conclude trilogues with a balanced compromise that:

- **embeds Article 19a (N-CMSVS):** Mandate National Critical Medicines Stock Visibility Systems in every Member State, interoperable with ESMP, Interoperable Europe Act, and NIS2.
- **cements digital patient-safety provisions:** Ensure the reform retains and operationalises medication-error reporting and the role of hospital pharmacies, including the uptake of digital medication safety systems.
- **locks in interoperability and cybersecurity across the medicine's life cycle:** Make interoperability with ESMP explicit and mandatory, with cybersecurity and data protection built in by design.

By doing so, the Reform will be future-proof, operational, and fiscally responsible - and solidarity will be made real where it matters most: at the bedside.

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