EHMA
European Health Management Association

POSITION PAPER

The Critical Medicines Act

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Introduction

Europe continues to face recurrent shortages of essential medicines, driven by structural reliance on third-country API manufacturing, limited diversification and concentrated production. Fragmented national monitoring systems and insufficient hospital-level visibility further hinder timely detection and response. Commission assessments confirm that the Union's **pharmaceutical supply chain remains vulnerable to global shocks, price pressures and uneven mitigation** across Member States.

While the European Commission's proposal for the Critical Medicines Act (CMA), published on 11 March 2025, establishes clear obligations for supply-chain mapping, contingency stocks and strategic projects, **it does not establish binding obligations for Member States to operate interoperable IT systems capable of delivering near real-time hospital-level data on stock, expiry, consumption and procurement.** Without such data flows, early-warning mechanisms, solidarity arrangements and strategic stockpiling cannot function effectively.

Hospitals are the first line of care in shortages and crises, yet they remain the least visible in existing reporting structures. **Reliable and timely inventory information is essential to assess burn rates, identify emerging bottlenecks and support evidence-based allocation.** For Union-level solidarity to operate in practice, authorities require an accurate and up-to-date picture of where medicines are available and where needs are most acute.

To close this gap, **targeted amendments are proposed to require each Member State to establish a National Critical Medicines Stock Visibility System (N-CMSVS) interoperable with the European Shortages Monitoring Platform and aligned with the Interoperable Europe Act**. Evidence from the LIUC University on Return on Investment 2025 analysis shows that digitalisation of hospital medication management generates substantial efficiency and safety gains, with an estimated 167% return on investment, €1.96 billion in annual savings and a payback period of approximately 4.5 years.

Digital stock visibility is therefore both a resilience measure and a value-for-money reform, essential to translating the CMA's industrial and procurement provisions into real availability of medicines where patients receive care.

Despite recurring shortages of critical medicines, millions of doses are simultaneously wasted each year, with an estimated annual value of €2.8 billion. This paradox is driven by low adherence, polypharmacy, prescription changes, treatment discontinuation and the persistence of manual medication management processes in hospitals, all of which contribute to premature expiry and unnecessary disposal. Large volumes of unused medicines ultimately enter waste streams and contaminate soil and water.

Automated Dose Dispensing (ADD) systems, which package medicines into individualised doses, have demonstrated clear benefits in improving adherence and reducing leftover medicines and waste. Evidence from Member States that have implemented these systems, including the Nordic countries and The Netherlands, shows measurable gains in safety, efficiency and sustainability. The introduction of ADD requires upfront investments in pharmacy infrastructure, staff capacity and interoperable IT systems, and implementation can be complex and time-consuming. Acknowledging these challenges is important, yet available evidence indicates that the long-term efficiency and safety gains outweigh the initial costs when systems are adequately planned and supported.

Assessment of the European Commission proposal

The European Commission's proposal introduces a coherent framework to strengthen the availability and security of supply for critical medicinal products. Several elements represent substantial progress:

Strengths

- **A structured approach to supply-chain mapping and identification of critical medicines**, allowing vulnerabilities to be assessed consistently across Member States.
- **Establishment of a Union-level resilience toolbox,** integrating diversification, stockpiling and coordinated procurement.
- **Introduction of Strategic Projects** with accelerated permitting and regulatory support to stimulate targeted manufacturing capacity.
- Provisions encouraging **joint procurement and improved coordination** between national authorities and EU bodies.

At the same time, several gaps limit the operational effectiveness of the proposal:

Gaps

- **The absence of a unified EU system for stock visibility.** The proposal relies on national frameworks that vary significantly in maturity and do not systematically capture hospital-level data.
- **The lack of obligations for Member States to digitalise medication management pathways in hospitals**, despite clear evidence that manual systems impair forecasting and shortage mitigation.
- **Patient safety objectives are not consistently embedded across the Act**, even though shortages have direct clinical consequences. No upstream obligation for hospitals and other stakeholders to provide structured, real-time stock and consumption data, which would make ESMP and solidarity mechanisms truly effective.
- **Governance arrangements between EMA, HERA, the European Commission and Member States remain diffuse,** creating risks of duplication or unclear authority in crises.

- **Uncertain budgetary contours for Strategic Projects and diversification measures,** potentially limiting the scope of interventions.
- **The lack of reference to medication waste** arising from low adherence, particularly in polypharmacy, which leads to unused drugs being discarded and contributes to antimicrobial resistance (AMR) when antibiotics enter soil and water systems. In addition, variability in hospital pharmacy roles across Member States leads to inconsistent oversight of polypharmacy and stock management, resulting in uneven medicines-management practices.

Policy recommendations

From the perspective of the European Health Management Association (EHMA) and as part of the activities of the EPACT Alliance for the digitalisation of hospitals' medication management pathways, this gap must be closed to ensure that upstream industrial measures translate into real availability of medicines where patients are treated. To make the CMA operational, the EPACT Alliance proposes the following core policy recommendations:

- **Mandate National Critical Medicines Stock Visibility Systems (N-CMSVS) in every Member State**, capturing real-time hospital-level stock, expiry, consumption (burn rate), and expected deliveries, interoperable with the European Shortages Monitoring Platform and other Union-level systems designated under Regulation (EU) 2022/123 aligned with the Interoperable Europe Act.
- **Strengthen crisis coordination and solidarity mechanisms** by ensuring that data from hospitals and large clinical centres feed directly into EMA/HERA-led early warning, allocation and cross-border support decisions.
- **Align CMA implementation with digital transformation goals in healthcare,** enabling hospitals to connect their medication-management and inventory systems securely and automatically through EU4Health, Digital Europe and other funding instruments.
- **Support strategic European manufacturing and procurement reforms** with better demand forecasting and transparent, evidence-based visibility systems that inform contingency stocks and joint procurement.
- **Embed patient safety and clinical continuity as guiding principles of the CMA,** recognising that shortages directly affect treatment pathways, clinical outcomes and operational capacity in hospitals.
- **Promote the deployment of Automated Dose Dispensing (ADD) systems at national and regional levels,** in outpatient, home, long-term care, and institutional healthcare settings, where clinically appropriate, to improve patient adherence and medication safety, reduce leftover medicines and pharmaceutical waste, and mitigate the mismatch between medicine shortages and surplus stocks across the Union. The objective shall be to ensure the implementation and operational use of ADD systems in all Member States by 2030, accompanied by the establishment of national strategies and measurable milestones.

With these additions, the Critical Medicines Act can deliver a complete, coherent and future-proof framework, strengthen Europe's industrial resilience while ensuring that critical medicines reach patients safely, on time, where they are most urgently needed and reducing medication waste and its impact on AMR. EPACT stands ready to support co-legislators, national authorities and EU agencies in implementing these measures and operationalising solidarity across the Union.

Proposed Amendments to the CMA

Hospital-level stock visibility

Proposal for a Regulation, Article 19 – paragraph 3 - NEW

Original	Amendment
	Where Member States impose contingency stocks, they shall ensure that such stocks are monitored through the N-CMSVS established under Article 19a, with transparent expiry tracking and redeployment rules to minimise wastage and enable cross-border solidarity. Each Member State shall establish 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 or automated dispensing cabinet), (d) daily consumption and projected days-of-cover, and (e) open purchase orders and expected delivery dates. 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 pursuant to paragraph 6. Hospitals and other healthcare providers designated by the Member State shall connect their medication-management and inventory systems to the N-CMSVS and provide data in real-time or at least daily; in crisis-preparedness or crisis modes as defined under Union law, data shall be provided at intervals enabling near real-time situational awareness. Data processed under this Article shall respect Union law on data protection and cybersecurity, including the NIS2 Directive. Member States shall ensure role-based access, audit trails and appropriate safeguards for commercially sensitive information.

	The Commission shall, by means of implementing acts, adopt common technical specifications for data fields, semantics, formats and APIs, taking into account the Interoperable Europe Act and relevant international standards, after consultation with the Critical Medicines Coordination Group and the European Medicines Agency. Member States shall ensure the inclusion of specific funding mechanisms and financial incentives in their national health and digitalisation programmes to facilitate the deployment of automation technologies, particularly in public hospitals and smaller healthcare facilities.

Proposal for a Regulation- Article 20 a - NEW

Original	Amended
Text proposed by the Commission	(a) Member States shall develop and implement national strategies to promote, support, and fund the automation and digitalisation of medication management processes within hospitals and other healthcare institutions. These strategies shall aim to enhance patient safety, improve supply efficiency, reduce medicine waste and expiration, and strengthen the overall resilience of hospital medicine supply chains.

Governance & coordination mechanisms

Proposal for a Regulation, Article 26 – paragraph 1 - NEW

Original	Amendment
Text proposed by the Commission 1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission, so as to maximise the impact of the measures envisaged and to avoid ~~***and***~~ unintended effects on the internal market**.**	1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission, so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market. To enable effective solidarity and proportional allocation of stockpiles during shortages and health crises, timely and accurate visibility of hospital-level stocks and consumption is essential. Therefore, Member States should establish interoperable national systems providing near real-time information on critical medicines inventories and demand signals, integrated with the European Shortages Monitoring Platform and other Union-level systems designated under Regulation (EU) 2022/123.

Proposal for a Regulation, Article 26 – paragraph 2 (b)

Original	Amended
Text proposed by the Commission (b) facilitate exchanges on the national programmes referred to in Article 19 and ~~enable cooperation on and coordination of Member States public procurement policies with regard to critical medicinal products;~~	(b) facilitate exchanges on the national programmes referred to in Article 19 and the implementation of Article 19a, including the coordination of data standards and the monitoring of hospital-level stock visibility for critical medicinal products.

Proposal for a Regulation, Article 26 – paragraph 3 - NEW

Original	Amended
Text proposed by the Commission 3. The Critical Medicines Group shall enable the exchanges of information between the Member States and the Commission as referred to in Article 17 and shall enable, where necessary, a coordination of respective actions aiming to attain the objectives of this Regulation.	3. The Critical Medicines Group shall enable the exchanges of information between the Member States and the Commission as referred to in Article 17, including data on the level of automation and digitalisation in hospital pharmacies, the impact on medicine waste reduction and estimated economic and environmental benefits and shall enable, where necessary, a coordination of respective actions aiming to attain the objectives of this Regulation.

Proposal for a Regulation, Article 27 –paragraph 1 a - NEW

Original	Amended
Text proposed by the Commission	The Commission shall, in cooperation with Member States, the European Medicines Agency, and relevant stakeholders, develop Union guidance and benchmarks to support consistent and safe implementation.

Proposal for a Regulation, Article 30 – paragraph 2 - NEW

Original	Amended
/	(c) Whereas the Union continues to face recurrent shortages of critical medicines while significant quantities of unused medicinal products are wasted due to low adherence, frequent treatment changes and manual medication-management processes; whereas the use of Automated Dose Dispensing (ADD) have been shown to reduce waste, improve adherence and generate substantial efficiency gains; whereas supporting such innovations can strengthen the resilience and sustainability of the Union's medicines supply chain. (d) Member States shall promote the deployment of Automated Dose Dispensing (ADD) systems at national and regional levels, in outpatient, home, long-term care,

	and institutional healthcare settings, where clinically appropriate, with the aim of improving patient adherence and medication safety, reducing leftover medicines and pharmaceutical waste, and mitigating the mismatch between medicine shortages and surplus stocks across the Union. (e) Member States shall review and, where necessary, adapt their national regulatory frameworks and reimbursement systems to enable and facilitate the implementation of ADD systems, ensuring interoperability with electronic prescribing and medication record infrastructures, and compliance with relevant Union standards on data protection and patient safety. (f) The objective shall be to ensure the implementation and operational use of ADD systems in all Member States by 2030, accompanied by the establishment of national strategies and measurable milestones. (g) Member States shall submit periodic reports to the Commission, within the framework of the monitoring and reporting obligations established under this Regulation, including information on: • the level of deployment of ADD systems and their coverage across care settings, • measurable impacts on medicine adherence, leftover reduction, and waste prevention, • incentives, funding schemes, and policy instruments used to promote adoption, • and any identified barriers or best practices in implementation. (h) The Commission shall, in cooperation with Member States and relevant stakeholders, develop guidance and benchmarks for the safe, effective, and interoperable use of ADD systems, and may facilitate Union-level funding and technical assistance to support their deployment, particularly in under-resourced regions or health systems.

Proposal for a Regulation - Article 31 - NEW

Original	Amended
Text proposed by the Commission This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from [….].	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from the objective shall be to achieve widespread automation and digitalisation of hospital medication

	management processes across all Member States by 2030, ensuring equitable access to the benefits of innovation and efficiency throughout the Union.

Medication waste management - Antibiotic pollution and AMR

Proposal for a Regulation - Article 17 – paragraph 1 (b) - NEW

Original	Amended
Text proposed by the Commission /	1b. Member States shall monitor and reduce the discharge of antibiotic residues into the environment, recognising the contribution of avoidable pharmaceutical waste to antimicrobial resistance, and the role of Automated Dose Dispensing (ADD) systems in improving antibiotic adherence and reducing waste.

Medication waste management - Polypharmacy & adherence

Proposal for a Regulation - Article 18 – paragraph 4 - NEW

Original	Amended
Text proposed by the Commission *4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights.*	*4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights.* The Commission shall develop EU guidance on medication optimisation, including polypharmacy management, structured medication reviews, deprescribing and patient adherence interventions, with the objective of improving clinical outcomes, reducing avoidable medication waste and lowering system costs.

Justification

Introducing a binding Article 19a is both a proportionate and essential measure to operationalise the objectives of the Critical Medicines Act. Without a harmonised digital backbone at the point of care, namely within hospitals (Articles 19, 26) of the CMA cannot function as intended. The absence of interoperable, hospital-level data on medicine stocks, expiries, consumption, and expected deliveries creates systemic blind spots. These gaps in visibility delay risk detection, undermine joint procurement efficiency, and hinder proportional cross-border allocation during crises. National fragmentation in digital capabilities continues to limit the Union's capacity to act cohesively in times of shortage or disruption.

A dedicated legal provision mandating National Critical Medicines Stock Visibility Systems (N-CMSVS), aligned with the European Shortages Monitoring Platform (ESMP) and Interoperable Europe Act, is the only way to deliver the real-time insights required for Union solidarity to become actionable and for emergency response mechanisms to function at scale.

Expected impact

- **Turing solidarity into practice:** Real-time hospital-level visibility enables the EMA, HERA, and Member States to make data-driven, proportional decisions on stock allocation during shortages, transforming solidarity from aspiration into actionable coordination.
- **Faster detection and mitigation of shortages:** Daily data on on-hand quantities, expiry, consumption and expected deliveries allows authorities to identify bottlenecks significantly earlier than current national reporting systems, enabling faster interventions and reducing service disruption.
- **Smarter contingency stock management:** Monitoring contingency stocks through the N-CMSVS ensures expiry tracking, reduces wastage, and allows safe redeployment to areas of higher clinical need, strengthening preparedness while improving public spending efficiency.
- **Stronger coherence between national systems and EU-level tools:** Integrating contingency stocks into the N-CMSVS allows transparent expiry tracking, facilitates timely redeployment to high-need areas, and enhances the efficiency and cost-effectiveness of preparedness measures.
- **A unified data architecture:** Enforcing interoperability with ESMP and applying common technical specifications closes structural gaps between national systems and EU-level tools, ensuring cohesion in implementation and comparability in performance.
- **Improved crisis governance and coordination:** By integrating hospital visibility into Article 26 coordination processes, the amendments improve the Critical Medicines Group's capacity to assess risks, guide Member States, and support a coordinated Union response.
- **Informed industrial and procurement policy:** More accurate demand and consumption data improve forecasting, inform diversification measures and reinforce joint procurement planning, thereby supporting the Union's long-term supply-security objectives.
- **Stronger patient safety and clinical continuity:** Reliable, timely visibility of medicine availability supports uninterrupted treatment, particularly for high-risk therapies and critical care, reducing preventable harm and preserving trust in healthcare systems.
- **Reduced medication waste, AMR and environmental burden:** Digitalised systems, including ADD systems for polypharmacy, facilitate more efficient use of stock, reduce surplus and expired medicines, improve medication adherence and reduce medicines leftovers and support greener pharmaceutical practices, advancing the Union's goals under the European Green Deal, the Zero Pollution Action Plan.

Conclusions and legislative ask

To make solidarity operational, authorities must be able to see the stocks where patients are actually treated. Manufacturing incentives and procurement reforms are necessary components of the Critical Medicines Act, but they are not sufficient on their own. Without national, interoperable systems that provide near real-time hospital-level visibility of on-hand quantities, expiry, consumption patterns and expected deliveries, the Union cannot anticipate shortages, coordinate allocation fairly or manage crises effectively. **Introducing a dedicated Article 19a to mandate National Critical Medicines Stock Visibility Systems (N-CMSVS), aligned with the**

European Shortages Monitoring Platform and the Interoperable Europe framework, would close this structural gap.

When hospitals' digital medication management systems feed accurate, timely data, decision-makers gain the insight required to safeguard continuity of care. Evidence from recent EU-wide analyses confirms that these reforms not only strengthen resilience, but also reduce medication errors, minimise waste and generate substantial efficiency gains. Embedding these measures in the CMA will ensure that Europe's solidarity mechanisms are grounded in actionable information and capable of protecting patients in real time. **Co-legislators now have an opportunity to close a long-recognised structural gap by establishing binding visibility requirements at the point where shortages manifest: hospitals.**

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