EHMA
European Health Management Association

# ASSESSING NATIONAL-LEVEL CAPACITY TO PROVIDE DATA ON HOSPITALS' MEDICATION INVENTORIES

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## EXECUTIVE SUMMARY

This paper discusses the issue of medicine shortages within the European Union (EU), focusing on their impact, root causes, and the urgent need for coordinated solutions. The shortages highlight significant vulnerabilities within the EU pharmaceutical supply chain, especially concerning critical medicines in hospitals. Medicines such as pain relievers, antihypertensives, anti-infectives, and oncology drugs are frequently impacted, leading to delayed treatments, increased healthcare costs, and greater risk of adverse outcomes for patients.

The European Commission (EC), recognising medicine shortages as a public health threat, has initiated a range of actions. This includes the formation of a Critical Medicines Alliance (CMA) to strengthen supply resilience through improved production, diversified supply sources, and a unified approach to medicine stockpiling. The Commission's reform of the EU Pharmaceutical Legislation introduced new shortage prevention plans and mandated proactive, standardised reporting systems, reinforcing obligations for pharmaceutical companies to ensure continuous supply.

Additionally, the European Shortages Monitoring Platform (ESMP) is slated for 2025. This platform, overseen by the European Medicines Agency (EMA), aims to provide real-time tracking and crisis management data on critical medicines. However, the successful implementation of this system depends on hospitals' ability to share timely, accurate stock data, which remains a challenge due to low levels of digitalisation.

Hospitals across the EU struggle with outdated inventory management, often relying on manual data entry prone to errors and inefficiencies. Manual systems hinder real-time monitoring and limit the hospitals' ability to respond swiftly to surges in demand. Key obstacles include inaccuracies in stock levels, delayed response times to shortages, the risk of medication errors and difficulty in tracking expiry dates of medicines. Limited integration of these systems and interoperability with broader healthcare networks exacerbates the issue, preventing cohesive data flow critical for anticipating and managing shortages.

To address these issues, the paper urges prioritising hospital digitalisation across EU Member States. Digital tools, like automated robots and dispensing cabinets and connected IT systems, are essential for enabling the ESMP's real-time monitoring and promoting coordinated responses to shortages. The paper calls for:

- **Legislative support:** Integrate digitalisation into upcoming EU legislation to streamline regulatory processes and better prepare for future crises and pandemics.
- **Focus on digitalisation within the CMA:** Highlight automation in hospital stock management and pharmacy inventory systems by establishing a Critical Medicines Act to strengthen EU supply chain resilience.
- **Allocate EU Funding for the digitalisation of medication management pathways:** Allocate EU funding (such as the EU4Health and Digital Europe programmes) to support hospital digital transformation, automating the capability to manage and report medicine stock data effectively in European hospitals.
- **Development of national interoperable IT systems to enable automated information exchange on supply chains:** Encourage EU Member States to establish national digital platforms compatible with ESMP for standardised, real-time data collection on supply chains.

The paper highlights that resolving medicine shortages demands a collective effort and substantial investment in digital infrastructure to modernise EU healthcare systems. By focusing on digitalisation, the EU can fortify its health security, ensuring hospitals can track and manage supply chains, ultimately safeguarding patient care and public health across the region.

## MEDICINE SHORTAGES IN THE EU

Shortages of medicine within European countries and globally have triggered and attracted public and political concern. The COVID-19 pandemic not only exposed vulnerabilities within global supply chains, but also exacerbated common causes of medicine shortages and heightened awareness of the risk of medicine shortages across all EU Member States[1]. The need for concerted action prompted the European Commission to request a medicine shortages study in 2021 aimed at ascertaining the extent of shortages, their root causes and an assessment of the regulatory framework to devise potential legislative and non-legislative solutions.

The study findings confirmed that medicine shortages occur frequently across the EU with notified shortages having increased over the last 5 to 10 years. According to the European Commission, shortages are however localised, with some countries more severely impacted than others[2]. Furthermore, a survey conducted by the European Association of Hospital Pharmacists (EAHP) in 2023 on medicine shortages in 36 countries showed that 95% of European hospital pharmacists still experience shortages[3].

Shortages can affect any medication, but pain relievers, antihypertensives, anti-infectives, and oncology drugs are particularly susceptible. Throughout Europe, these shortages frequently pertain to older, off patent, and generic medicines[2]. According to the 2023 shortages study by EAHP, shortages are frequently encountered for antimicrobial agents, painkillers and anaesthetic agents. These shortages significantly impact patient care resulting in delays in the delivery of care and, in some cases, cancellations and suboptimal treatment. Ultimately, patients may be required to use alternatives which may be less efficacious and may increase the risk of adverse reactions thereby resulting in additional healthcare costs[3].

Recognising medicine shortages as a significant public health issue, the European Parliament and Council urged the European Commission, EU Member States, and other relevant stakeholders to take action[4]. Additionally, in June 2023, the European Council emphasised the critical importance of maintaining medicine availability and advocated for a new strategy within the European Health Union (EHU) to address shortages and ensure the adequate production and supply of essential medicines and components[5]. Availability issues, particularly shortages, are identified as a key challenge in the European Medicines Agencies (EMA) Network Strategy to 2025 and the European Commission's roadmap for its Pharmaceutical Strategy, which aims to ensure timely patient access to affordable medicines. In March 2022, the Regulation (EU) 2022/123 reinforcing the EMA's role in crisis preparedness and management of

[1] European Commission. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Addressing Medicine Shortages in the EU.* Available at: eur-lex.europa.eu.

[2] European Commission, Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M. *Future-Proofing Pharmaceutical Legislation: Study on Medicine Shortages: Final Report (Revised).* Luxembourg: Publications Office of the European Union, 2021. Available at: https://data.europa.eu/doi/10.2875/211485.

[3] European Association of Hospital Pharmacists (EAHP). *2023 Shortages Survey Report.* Available at: https://www.acadpharm.org/dos_public/SHORTAGES_SURVEY_REPORT_FINAL.PDF.

[4] European Parliament. *Resolution of 2 March 2017 on EU Options for Improving Access to Medicine* (2016/2057(INI)). Available at: europarl.europa.eu.

[5] European Commission. *European Health Union.* Available at: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en.

medicinal products and medical devices became applicable, making EMA responsible for monitoring medicine shortages[6,7].

A key component of this extended mandate is the establishment of the European Shortages Monitoring Platform (ESMP). The ESMP is designed to gather real-time information on the supply and demand of medicines across the EU and EEA, helping to prevent, detect, and manage shortages of critical medicines. The platform will collect data from national competent authorities and marketing authorization holders, allowing for comprehensive monitoring both during crises and in regular times to prevent potential shortages. The EMA's expanded responsibilities also include the formation of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Emergency Task Force (ETF). These bodies are tasked with overseeing the management of medicine and medical device shortages, providing scientific advice during public health emergencies, and ensuring the continuous supply of critical medicines.

The ESMP will start with basic functionalities and will be progressively enhanced, with the first version expected to be available by February 2025. The platform aims to be interoperable with both national and industry systems, ensuring seamless data exchange and reducing administrative burdens on users.

To diversify supply as well as stimulate and modernise the production of critical medicines with all stakeholders, the European Commission has set up a Critical Medicines Alliance (CMA). The Critical Medicines Alliance will add an industrial policy pillar to the European Health Union. This will allow national authorities, industry, civil society representatives, the Commission and EU agencies to coordinate action at the EU level against the shortages of medicines and to address supply chain vulnerabilities.

Finally, in April 2023 the European Commission, through its proposals for a reformed pharmaceutical legislation, placed a strong emphasis on tackling this ever-growing problem of medicine shortages in the European Union. Legislative amendments to this strategy have targeted medicine shortages through several key measures, which are under discussion and review by the EU Institutions. Some of the proposed amendments to address shortages include strengthening the role of national competent authorities and the EMA in reporting and monitoring medication shortages, joint procurement mechanisms, diversification of the EU's production base and supply contingency plans.

## THE DOWNSTREAM: HOSPITALS

Hospitals are key stakeholders in preventing and mitigating medicine shortages. Hospitals must maintain inventories of a high number of essential drugs at any given time to treat patients, making the continuous availability of these medicines crucial. While media attention focuses on the impact of shortages on community pharmacists, shortages of critical and generic medicines equally impact hospital pharmacists, and healthcare staff, particularly doctors and nurses. As the COVID-19 pandemic has demonstrated, hospitals play a pivotal role during healthcare crises

[6] European Parliament and Council of the European Union. *Regulation (EU) 2022/123 of 25 January 2022 on a Reinforced Role for the European Medicines Agency in Crisis Preparedness and Management for Medicinal Products and Medical Devices.* Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0123.

[7] European Medicines Agency. *Medicine Shortages and Availability Issues.* Available at: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/medicine-shortages.

and medicine shortages will continue to pose a serious threat to the functionality of hospitals during future crises, if not adequately addressed.

The visibility of medicine stocks in hospitals is critical to prevent and mitigate medicine shortages:

**Efficient supply chain operations**

- Monitoring the stock levels in hospitals allows suppliers to adjust production schedules and supply routes to meet demand effectively. This reduces the likelihood of overstocking or understocking, both of which can lead to shortages or waste.

**Inventory management**

- Hospitals can manage their inventories more efficiently by having a clear understanding of their stock levels and expected demand. This helps in maintaining optimal stock levels and avoiding last-minute shortages. This includes alternative medicines in case of shortages.
- Member States can use regulatory exemptions to allow medicines to reach patients in a timely manner, including extending shelf-life or the quick authorisation of alternatives. There will be a dedicated Joint Action in 2024 to promote the effective use of these flexibilities.

**Public and stakeholder awareness**

- Regular updates and transparent communication about stock levels and potential shortages keep all stakeholders informed. This includes healthcare providers, patients, and policymakers, enabling them to make informed decisions and plan accordingly.

**Stakeholder collaboration**

- Enhanced visibility fosters collaboration between hospitals, suppliers, and regulatory bodies. This collective effort is crucial in addressing systemic issues that lead to medicine shortages.

European hospitals must have the right protocols and technology systems in place to ensure the visibility of stocks to anticipate and manage medicine shortages. However, the current hospital medication inventory management, mainly based on manual counting by pharmacists, is time-consuming and inefficient. This can significantly contribute to a general lack of real-time supply chain visibility and may potentially impede the EMA's ability to maintain an effective monitoring platform. While hospital pharmacies have the best view of medication inventory, as medication is stored in the pharmacy, stock visibility decreases significantly when medicines are transferred to dispensing locations.

Some of the main potential implications of low visibility of inventory in the hospital supply chain are:

**Before shortages**

- Inability to predict potential shortages due to manufacturers / wholesaler supply chain issues.
- Low reliability of medication ordering, driving potential medicinal product stockouts.
- In case of a product recall, time-consuming tasks to investigate and find impacted drugs batches on hospital wards.

**During shortages**

- Inability to allocate production among hospitals in a region, a country, or within the EU during shortages crises.
- Incremental time and resources for the best management of alternatives medicines.

The main implications of manual inventory management in hospitals are:

1. **Inaccurate inventory records**
    - **Human error:** Manual entry and record-keeping are prone to human errors, such as incorrect data entry, misplaced records, and omission of crucial information. These errors can lead to discrepancies between actual stock levels and recorded data.
    - **Time-consuming:** Updating inventory records manually is a time-consuming process, which can delay the availability of real-time data. This lag can result in delayed decision-making and potential stockouts of critical medicines.

2. **Limited real-time monitoring**
    - **Lack of real-time updates:** Manual inventory systems do not provide real-time updates on stock levels. This makes it challenging to monitor the availability of medicines and to promptly respond to emerging shortages.
    - **Delayed response to shortages:** Without real-time data, it is difficult to anticipate and manage shortages effectively. Hospitals may not realise they are running low on certain medications, leading to emergency procurement which is often more costly and less efficient.

3. **Difficulty in tracking expiry dates**
    - **Expired medicines:** Manual tracking of expiry dates is challenging and often results in expired medicines remaining on shelves. This poses a safety risk and also leads to financial losses as expired drugs need to be discarded.
    - **Waste management:** Managing the rotation of stock to ensure older medicines are used first (first-in-first-out) is more difficult with manual systems, increasing the likelihood of waste.

4. **Lack of integration with other systems**
    - **Standalone systems:** Manual inventory systems are typically not integrated with other hospital management systems, such as electronic health records (EHRs) or automated dispensing systems. This lack of integration hampers the seamless flow of information and coordination across departments.
    - **Data silos:** The absence of integrated and interoperable data leads to silos, where different departments may not have visibility into each other's inventory levels, hindering efficient resource sharing and redistribution.

When real-time inventory medicine levels are not visible the procurement process of medicines may not be efficient. The main implications are:

1. **Static ordering patterns**
    - **Unresponsive to changes:** Ordering the same amount every month does not account for fluctuations in demand, leading to overstocking or stockouts.
    - **Lack of flexibility:** This rigid approach cannot adapt to sudden changes, such as seasonal illnesses or unexpected emergencies.

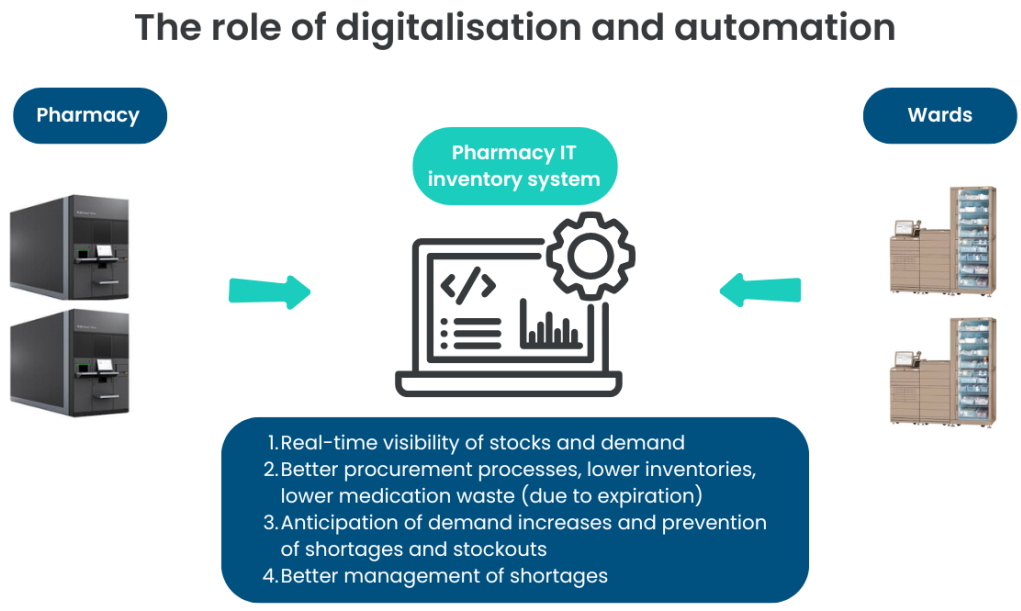
2. **Inability to anticipate spikes**
    - **No demand forecasting**: Without analysing usage patterns and trends, hospitals miss opportunities to forecast and prepare for increased demand.
    - **Missed signals**: Potential indicators of rising demand, such as increased patient admissions or emerging health crises, are not acted upon in time.

3. **Resource misallocation**
    - **Overstocking and waste:** Consistent ordering can lead to overstocking of items that may expire or become obsolete, wasting resources.
    - **Stockouts:** Essential supplies may run out during periods of high demand, compromising patient care.

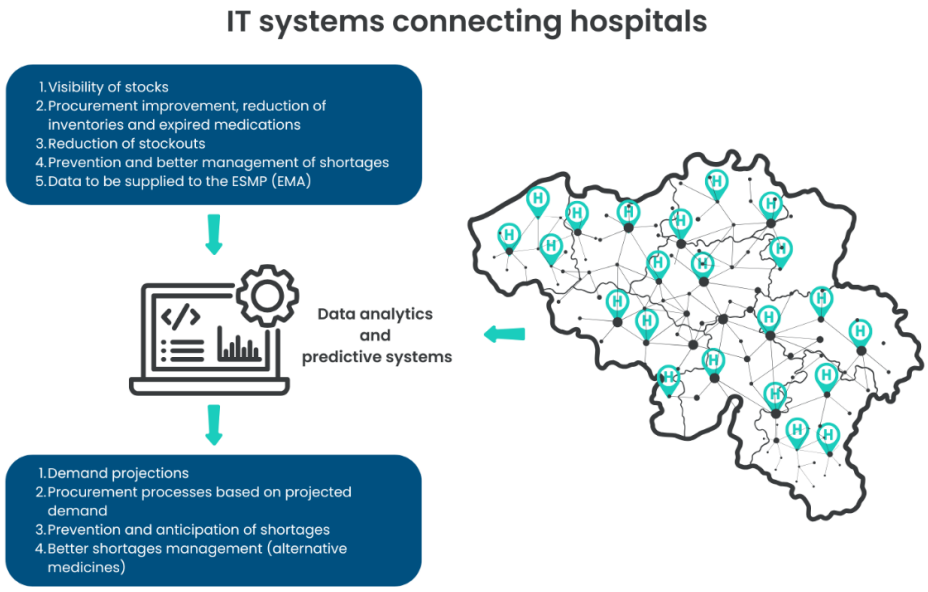
When demand starts to increase for predictable (seasonal) or unpredictable (crisis) factors, the lack of real-time visibility of stocks may preclude hospitals from anticipating the spike in demand. When hospital wards communicate stockouts at the last minute, urgent and substantial orders may need to be placed with distributors, wholesalers, and manufacturers. The multiplier effect of hundreds of hospitals in the EU simultaneously ordering the same medicines may contribute to medicine shortages in the supply chain and increased hospital expenditures.

**The solution**

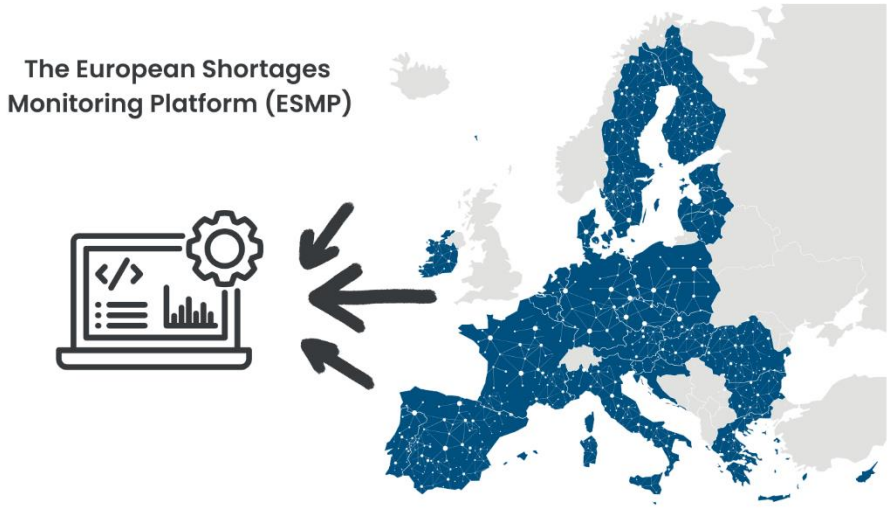
Digital and automated tools, such as inventory robots, automated dispensing cabinets and connected IT systems, can provide full visibility of medicine stocks, demand projections, and ordering processes for hospitals. Inventory robots in hospital pharmacies provide real-time and electronic inventory data of medicines stored in the pharmacy warehouse; while automated dispensing cabinets located in the wards provide real-time and electronic inventory data from the wards. Inventory IT systems connect all these electronic real-time inventory data to provide full visibility of stocks in the hospital.




Digital solutions can prevent and improve medicine shortages management and provide accurate and real-time data for the future European Shortages Monitoring Platform (ESMP). This process can be further strengthened by nation-wide IT systems able to connect hospitals directly with the ESMP and provide real-time data.




Digital solutions can also support the reallocation of medicines stock across Member States, while still allowing healthcare professionals and patients to access dispensation information in their language.




However, based on a survey by the European Collaborative Action on Medication Errors and Traceability (ECAMET), the adoption of digitalisation and automation in the EU is very low[8]. Approximately 74% of hospitals in Europe work with manual shelves and counts of medicine stocks in the pharmacy department and in the wards and only 66% have IT systems in the pharmacy. 82% of hospitals do not have robots for inventory management and in the wards, only 25% of Intensive Care Units have Automated Dispensing Cabinets (ADCs)[9].

[8] European Alliance for Access to Safe Medicines (EAASM). *Medication Errors: A Study of Medication Errors in the EU.* Available at: https://ecamet.eu/wp-content/uploads/2022/03/21016698-IN0104-EAASM-Medication-errors_Consolidated.pdf.

[9] European Alliance for Access to Safe Medicines (EAASM). *Medication Errors: A Study of Medication Errors in the EU.* Available at: https://ecamet.eu/wp-content/uploads/2022/03/21016698-IN0104-EAASM-Medication-errors_Consolidated.pdf.

To raise awareness about this crucial topic among policy makers, the European Health Management Association (EHMA) launched a project consisting of:

1. **Surveys and interviews with EMA offices in EU Member States** to gather insights regarding the role of hospitals in managing medication shortages, particularly during the COVID-19 pandemic, and their preparedness to provide real-time and accurate data on critical medicine stocks.
2. **One survey targeting hospital pharmacists in EU Member States**, with the support of the European Association of Hospital Pharmacists, to better understand if hospital managers and pharmacists to identify how hospitals collect and share data on medication stock and demand, identify barriers to collecting relevant and necessary information and explore any workload burden and need to digitalise hospital pharmacy workflows associated with collecting and sharing medication inventory data with national and regional competent authorities as indicated by the new EMA mandate.
3. **A call to action** for the EU to prioritise digitalisation in the EU health policy agenda and mobilise EU funding mechanisms to support the digital transformation of our healthcare systems in Europe

## EU INITIATIVES AND THE KEY ROLE OF VISIBILITY OF THE SUPPLY CHAIN IN THE DOWNSTREAM: HOSPITALS

1. **The EU4Health Programme**

   The EU4Health Programme is the European Commission's landmark €5.3 billion response for investment in EU member state health systems following COVID-19. The objective of the programme is to strengthen Europe's health system and promote innovation. Three of the four programme focus areas are crisis preparedness, health systems and healthcare workforce, and digitalisation with a cross-cutting focus on cancer. The Programme builds synergies between other Union programmes, policies, instruments and actions including the Union Civil Protection Mechanism/rescEUSearch, the Digital Europe Programme and the Connecting Europe Facility and the Emergency Support Instrument.

   EU health systems depend on the availability of high-quality digital health services and the availability of a high-quality workforce. Staff must be employed in environments that reduce the risk of adverse reactions and medication errors. This in turn will reduce risks to their psychosocial, and emotional, wellbeing. A resilient healthcare workforce and modern hospital infrastructure are crucial to ensure that health systems can monitor and collect information on medicines and be prepared for the next crisis or health emergency.

2. **The Digital Europe Programme**

   The Digital Europe Programme will provide strategic funding to answer digitalisation innovations and challenges, supporting projects in five key capacity areas: supercomputing, artificial intelligence (AI), cybersecurity, advanced digital skills, and ensuring a wide use of digital technologies across the economy and society, including through the Digital Innovation Hubs. The Programme, however, will not address these challenges in isolation, but rather complement the funding available through other EU programmes, such as the Horizon Europe Programme, the Connecting Europe Facility, the Recovery and Resilience Facility, and the Structural Funds, to name a few. The programme forms part of the current long-term EU budget, the Multiannual Financial Framework 2021-2027.

The European Commission, in the document 'Assessing the impact of digital transformation of health services Report of the Expert Panel on effective ways of investing in Health (EXPH)[10], includes, among other digital opportunities, European automated dispensing of medication and robots for manipulation. The success case of Ireland's National Cancer Information System for Oncology demonstrates the importance of digitalisation of medication management in generating harmonised data for treatment evaluation, research, and AI. Such digitalisation will play a key role in providing harmonised and interoperable data for research on treatments, medicines, implementation of AI and improving the efficiency of healthcare services and patient care. The existing low levels of digitalisation in European hospitals are a critical barrier impeding the digital transition of health services.

3. **The Role of the Health Emergency Preparedness and Response Authority (HERA) in establishing a Union List of Critical Medicines under the Critical Medicines Alliance (CMA) for the development of the Critical Medicines Act**

The COVID-19 pandemic management in intensive care units has dramatically increased the prescriptions of sedatives (propofol, midazolam) and neuromuscular blockers (NMB) at the international level, creating shortages in all countries. Hospitals were not prepared to provide visibility of stocks in real-time and electronically to crisis management bodies at the Member State level. In many countries, pharmacists performed manual counts of sedative stocks in the intensive care units and provided back the information in the form of text messages, excel files, etc.

The European Voluntary Solidarity Mechanism for medicines flags a Member State's needs for a given medicine to other Member States, which can respond by redistributing medicines from their available stock. The procurement and stockpiling of medical countermeasures (MCMs) is one of the core areas of work within HERA's mandate. By acquiring stocks of critical medical items such as medicines, vaccines, and personal protective equipment through different procurement mechanisms, including by acting as a central purchasing body for Member States, the Commission works to ensure that the EU maintains a high level of preparedness for future cross-border health threats.

In October 2023, several actions were adopted by the European Commission to mitigate medicine shortages: among them, a Union list of critical medicines[11]. A significant number of medicines included in the list of critical medicines are administrated in hospitals, reinforcing the important role that hospitals play in anticipating and managing medicine shortages, especially during health crises, and the important role that digital systems play in ensuring the visibility of stocks.

Additionally, in January 2024, the European Commission established a Critical Medicines Alliance[12], a consultative body that unites stakeholders from EU Member States, key industries, civil society, and the scientific community. The Critical Medicines Alliance aims to pinpoint crucial areas and priorities, proposing solutions

[10] European Commission. *Digital Transformation of Health and Care in the Digital Single Market: Public Consultation Report.* Available at: https://health.ec.europa.eu/system/files/2019-11/022_digitaltransformation_en_0.pdf.

[11] European Medicines Agency. *First Version of the Union List of Critical Medicines Agreed to Help Avoid Potential Shortages in the EU.* Available at: https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu.

[12] Critical Medicines Alliance. *Overview of the Critical Medicines Alliance.* Available at: https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance_en.

to bolster the supply of critical medicines in the EU and improving efforts to prevent and address shortages effectively. These include:

- Coordinating public procurement practices at the EU level.
- Exploring how to diversify global supply chains through strategic partnerships.
- Boosting Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients in a coordinated way.
- Developing a common strategic approach to medicines stockpiling in the EU.
- Leveraging and aligning EU and national funding.

The Critical Medicines Alliance is grounded in the EMA's list of critical medicines and the European Commission's supply chain vulnerability assessment. The Alliance focuses on the most vulnerable medicines, providing recommendations for mitigating risks through supply diversification boosting manufacturing capabilities and complementing regulatory measures in the EU pharmaceutical reform.

Given its comprehensive approach, the Critical Medicines Alliance is instrumental in shaping EU policies related to pharmaceutical supply chains. The Alliance has established two working groups focused on enhancing EU manufacturing capabilities and fostering international partnerships. Their recommendations will shape a Strategic Plan, outlining multi-year actions and milestones. Drafted by the Steering Board and endorsed by the Forum, this plan will guide EU decision-makers, scheduled for adoption by the end of 2024.

This initiative could lead to the development of a Critical Medicines Act, a direct policy response to the need for enhancing the security of medicine supplies[13]. The European Commission President, Ursula von der Leyen outlined the proposition of a Critical Medicines Act in her mission letter to Olivér Várhelyi, Commissioner-designate for Health and Animal Welfare[14]. The Critical Medicines Act will combat the severe shortages of medicines and medical devices and will ensure to reduction of EU dependencies on critical medicines and their ingredients, as well as the supply of affordable medicines. It will be a pivotal upcoming policy document with the potential to set out measures for Member States to improve the visibility of the supply chain of medicines in hospitals. The Commission will launch a dedicated, preparatory study paving the way for an impact assessment. The Commission additionally announced the development of a common strategic approach to medicines stockpiling to prevent and mitigate shortages in cooperation with Member States for 2024, which is yet to be published.

**4. The revision of the EU Pharmaceutical Strategy**

In April 2023, the European Commission, through its proposals for a reformed pharmaceutical strategy, placed a strong emphasis on tackling the ever-growing problem of medicines shortages. Key elements included a new European alert system that provides earlier notifications of shortages and withdrawals by companies, standardised reporting criteria, mandatory shortage prevention plans, and coordinated management of shortages by the national competent authorities and the EMA. The reform would reinforce and strengthen the obligation of companies to ensure a proper and continuous supply.

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[13] European Commission. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions on Addressing Medicine Shortages in the EU.* Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023DC0672.

[14] European Commission. *Mission Letter to Olivér Várhelyi, Commissioner-Designate for Health and Animal Welfare.* Available at: https://ec.europa.eu/commission/commissioners/2020-2024/v%C3%A1rhelyi/mission-letter_en.

Following a successful exercise of amendment submissions to the proposed revision of the EU pharmaceutical legislation, the European Parliament's ENVI Committee voted on and adopted two reports on 19 March 2024 – the Directive on medicinal products for human use and the Regulation on the authorisation and supervision of medicinal products for human use and governing rules for the EMA[15,16]. On 10 April 2024, MEPs adopted these proposals to revamp the EU pharmaceutical legislation[17]. Among the key objectives of the regulation, is increasing access to medicines by ensuring the security of supply and addressing shortages of medicinal products.

The European Health Management Association, through the Alliance for the digitalisation of hospitals' medication management pathways (EPACT), produced several position papers advocating for key amendments on two critical healthcare issues for health managers: pharmacovigilance and patient safety and the visibility and traceability of medicine stocks in hospitals[18]. The EPACT position paper on the availability and shortages of medicines in hospital settings draws attention to pharmacists' role in both primary and hospital settings and their contribution to managing and mitigating medication shortages[19].

EHMA and the EPACT Alliance advocated for the adoption of several amendments to the pharmaceutical package. The following amendments were successfully adopted in plenary by the European Parliament's ENVI Committee:

- (Regulation – Article 121 paragraph 2 a) Facilitated the establishment of interoperable national IT systems with the European Medicines Safety Portal (ESMP), enabling automated information exchange and preventing reporting duplication.
- (Regulation – Article 121 paragraph 1 point b a) Advocated for a system allowing patients to report medicinal product shortages and requiring hospital pharmacies to electronically communicate stock data to mitigate supply shortages.
- (Regulation – Article 121) Highlighted the importance of sharing information on hospital medication stocks with regulatory agencies for the ESMP to manage and prevent shortages.
- (Directive – Recital 137) Recognised hospitals as key stakeholders in managing and mitigating the impact of shortages on patients and healthcare professionals.

Additionally, EHMA and the EPACT Alliance call on the EU Institutions to include medication errors within the definition of adverse reactions in both the proposed

[15] European Parliament. *Report on the Proposal for a Directive of the European Parliament and of the Council on the Union Code Relating to Medicinal Products for Human Use, and Repealing Directive 2001/83/EC and Directive 2009/35/EC.* Available at: https://www.europarl.europa.eu/doceo/document/A-9-2024-0140_EN.html.

[16] European Parliament. *Report on the Proposal for a Regulation of the European Parliament and of the Council Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use and Establishing Rules Governing the European Medicines Agency, Amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and Repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.* Available at: https://www.europarl.europa.eu/doceo/document/A-9-2024-0141_EN.html.

[17] European Parliament. *European Parliament Adopts Its Position on EU Pharmaceutical Reform.* Press release. Available at: https://www.europarl.europa.eu/news/en/press-room/20240408IPR20308/parliament-adopts-its-position-on-eu-pharmaceutical-reform.

[18] European Health Management Association (EHMA). *Proposed Amendments to the Pharmaceutical Legislation.* Available at: https://ehma.org/proposed-amendments-to-the-pharmaceutical-legislation/.

[19] European Health Management Association (EHMA). *Position Paper on Medication Shortages.* Available at: https://ehma.org/app/uploads/2023/11/EHMA_POSITION_PAPER_MEDICATION_SHORTAGES_V3.pdf.

Regulation and Directive. Currently both files are in the hands of the Council, which has not yet adopted its position.

5. **The European Health Data Space (EHDS)**

   The European Health Data Space is an initiative by the European Union aimed at creating a unified and secure framework for the exchange of health data across Member States and will be a key pillar of a strong European Health Union[20]. The EHDS Regulation, which was agreed upon by the European Parliament and the Council in spring 2024, aims to reconcile the regulation of the primary use of health data by European citizens and health professionals and health data's secondary use by researchers, innovators, and policymakers. The first pillar of data used in the draft EHDS regulation empowers European Union citizens to control and share their health data, granting healthcare professionals permission to access patients' health data for their treatment and care in hospitals in and across Member States (otherwise known as primary data use). Healthcare professionals will be obliged to enter and update common, interoperable, primary data in the European Health Record System.

   As levels of digitalisation in hospitals are low across the European Union, with gaps in interoperable infrastructure in individual healthcare settings, the EHDS proposals requiring hospitals to make their data available place challenging obligations on hospitals. Hospital management will be required to install and provide access to digital tools and interoperable systems to facilitate the exchange of electronic health data. Furthermore, Article 5 of the draft regulation precludes data on the availability, visibility and traceability of medications in hospitals with priority categories limited to (a) patient summaries; (b) electronic prescriptions; (c) electronic dispensations; (d) medical images and image reports; (e) laboratory results; (f) discharge reports.

6. **The European Medicines Agency's new mandate and the European Shortages Monitoring Platform**

   In March 2022, the Regulation (EU) 2022/123 reinforcing EMA's role in crisis preparedness and management of medicinal products and medical devices became applicable, making the EMA responsible for monitoring medicine shortages and reporting shortages of critical medicines during a crisis through a European Shortages Monitoring Platform to be set up by the agency[21,22]. This Regulation not only aims to provide robust protection for human health while maintaining the effective operation of the internal market for medicinal products and medical devices, but also seeks to guarantee the quality, safety, and effectiveness of medicinal products that could respond to public health emergencies. The EMA's expanded responsibilities also include the formation of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Emergency Task Force (ETF). These bodies are tasked with overseeing the management of medicine and medical device shortages, providing scientific advice during public health emergencies, and ensuring the continuous supply of critical medicines.

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[20] European Commission. *European Health Data Space (EHDS).* Available at: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en.

[21] European Parliament and Council of the European Union. *Regulation (EU) 2022/123 on a Reinforced Role for the European Medicines Agency in Crisis Preparedness and Management for Medicinal Products and Medical Devices.* Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0123.

[22] European Medicines Agency. *Medicine Shortages and Availability Issues.* Available at: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/medicine-shortages.

To improve demand and supply forecasting to prevent risks of critical shortages, the regulation mandates that the EMA establish an IT platform called the European Shortages Monitoring Platform (ESMP). The ESMP should enable the processing of information regarding the supply and demand for critical medicinal products during public health emergencies or significant events, as well as in normal circumstances, to ensure the reporting of shortages that could lead to public health emergencies and major events. Additionally, the ESMP should allow National Competent Authorities to submit and monitor information on unmet needs, including data from marketing authorisation holders, wholesale distributors, and other entities authorised to supply medicinal products to the public to anticipate shortages.

To support the Agency's coordination role, it is crucial that data from existing Member States' IT platforms for monitoring shortages and other relevant systems can interoperate with the ESMP, facilitating the sharing of pertinent information. Leveraging on existing IT systems, the EMA is setting up the ESMP which is expected to become operational in 2025. The launch of its minimum viable product is expected in the first quarter of 2025[23].

The EMA's expanded mandate and the implementation of the ESMP highlight the importance of visibility into medicine stocks in hospitals and the management of medicine shortages. Hospitals play a vital role in monitoring medicine supplies. The ESMP seeks to create a centralised platform for collecting and sharing information about the availability of medicines, including hospital stocks, which are essential for meeting routine healthcare demands and emergency situations. This platform aims to integrate data from multiple sources, including hospitals, to offer a comprehensive overview of medicine availability throughout the EU.

For the ESMP to be effective, the critical role hospitals play in managing crises as was in the case of COVID-19, cannot be overlooked. It is hospitals who feel the impact of medicine shortages and therefore essential that hospitals provide accurate and electronic data on medicine stocks to the ESMP. EHMA, therefore, has been conducting research with National Competent Authorities and hospital pharmacists to ascertain their level of readiness to provide accurate data for the ESMP.

To ensure the right legal environment for National Competent Authorities in Member States to request medicine stocks in electronic format to hospital pharmacies the German government modified the German Medicine Act, section 52 b, in June 2023, to incorporate the mandatory requirement for hospital pharmacies to provide medicine stocks to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM) in one electronic format:

> *"(…) Pharmacies supplying hospitals and hospital pharmacies shall, at the request of the BfArM electronically communicate data on available stocks of the respective drug to avert or mitigate an impending or existing supply shortage. The BfArM shall specify the procedure and format requirements for electronic transmission of the data and shall publish them on its web".*

No other Member State, apart from Germany, has modified the existing regulation to ensure the capacity to request medicine stock data from hospital pharmacies in one electronic format.

[23] European Medicines Agency. *European Shortages Monitoring Platform.* Available at: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/shortages.

Based on all these EU initiatives to prevent and manage medicine shortages the visibility of the supply chain downstream, especially in hospitals, become a critical priority. The lack of digitalisation and automation of medication management in hospitals represents a serious risk for the EU in achieving the objectives set by all the above initiatives. Therefore, digitalisation and automation of medication should become a key priority for EU institutions to prevent medicine shortages in the future.

## WHY THE FALSIFIED MEDICINES DIRECTIVE (FMD) IS NOT THE SOLUTION

To secure the legal supply chain of medicinal products, the Falsified Medicines Directive 2011/62/EU (FMD) and Commission Delegated Regulation (EU) 2016/161 have introduced a new end-to-end verification system for medicinal products subject to prescription. The end-to-end verification is a medicines authentication system including mandatory safety features and a repository that stores information on each pack. The new rules became applicable in the EU and EEA on 9 February 2019. From this date, prescription medicines sold in the EU need to carry a unique identifier (UI) and anti-tampering device (ATD).

The EU Falsified Medicines Directive and its Delegated Regulation provide for the establishment of interoperable repositories or database systems - the European Medicines Verification System (EMVS) - containing unique identifiers (product code, serial number, batch number, expiry date, and, where applicable, national reimbursement number) for prescription medicines. Manufacturers place the safety features (a unique identifier/2D bar code and anti-tampering device) on each medicinal pack to be sold in the EU/EEA markets. Prior to batch release into a market, manufacturers upload the information contained in the Unique Identifier into the respective national repository system, part of the European Medicines Verification System. Pharmacists are legally required to systematically verify - via the repository database - the authenticity of each unique identifier before dispensing it to the patient. Pharmacies, therefore, only dispense a product if it is verified, meaning that the information about the product is included in EMVS and all data elements of the unique identifier correspond to the correct information uploaded by the legitimate manufacturer.

Decommissioning may take place at any time the medicine is in the physical possession of an healthcare institution. Most hospitals decommission medicines at reception time and not at administration or dispensing time, considering that hospitals receive large volumes of medicinal products which are administered to the patient at ward level; that a large proportion of medicines in Europe are described as 'multi-pack' and in those cases, the UI and the ATD are placed on the bundle packaging; the use of aggregation that allows decommissioning multiple UIs from a specific shipment, instead of the individual sales packages; and that many medicines required compounding processes to be dispensed/administrated to patients[24].

The EMVS repositories system shall hold the following:

- Static data (the information listed under Article 33(2) of Commission Delegated Regulation (EU) No 161/2016) equivalent to manufacturers' uploaded data.
- Dynamic data, including *the status of the unique identifier, i.e., active or decommissioned. In the case of 'decommissioned' also the detail, e.g. recalled,*

[24] European Alliance for Access to Safe Medicines (2020). Available at Patient safety and the implementation of the FMD

*stolen, etc.; and changes to the audit trail as referred to in Article 35(1), (g) of Commission Delegated Regulation (EU) No 161/2016, which contains a record of all operations concerning a unique identifier, of the users performing those operations and the nature of the operations.*

Pharmacists decommission medicines at the point of receiving them, not when dispensing them. As a result, the European Medicines Verification System could, if designed with the right functionalities, only provide information on which medicines hospitals have decommissioned upon receipt. Since the initial stocks and the consumption of medicines would not the available in the EMVS, the single information that it can provide is the number of packs for all prescription products being supplied by manufacturers on the various EU markets and hospitals during a period of time, but not the real-time or current stock levels.

## EUROPEAN MEDICINE AGENCY SURVEY: HOSPITAL READINESS AND THE ROLE OF MEDICATION STOCK VISIBILITY IN MANAGING MEDICINE SHORTAGES IN EU MEMBER STATES

The primary aim of the survey and interviews was to gather insights from the National Competent Authorities across EU Member States regarding the role of hospitals in managing medication shortages, particularly during the COVID-19 pandemic, and their preparedness to provide real-time and accurate data on critical medicine stocks. The study also sought to understand how hospitals plan to consolidate and report demand data to the European Shortages Monitoring Platform to mitigate potential shortages in the future. [*For the full analysis, please see Annex I*]

- **Hospitals' crucial role in medication shortage management:** National Competent Authorities overwhelmingly agreed that hospitals were among the top three key stakeholders in managing and preventing medication shortages during the COVID-19 pandemic. Their role in the health ecosystem, including their collaboration with authorities, industry, and community pharmacies, was vital to ensuring a continued supply of essential medicines.
- **Ad-hoc systems for data collection during the pandemic:** The absence of standardised systems across Member States to regularly collect hospital medicine stock data posed significant challenges during the pandemic. Hospitals often had to rely on *ad-hoc* measures, such as Google forms and temporary electronic tools, to report stock levels. This lack of pre-existing infrastructure hindered efficient data gathering and highlighted the need for more robust solutions.
- **Benefits of hospital medication stock visibility:** Visibility into hospital medicine stocks during crisis periods provided several key benefits, including:
    - Oversight of medicine availability and traceability, extending beyond pandemic-related treatments to ensure continuity of care for other conditions.
    - Enabling authorities to predict, prevent, prepare for, mitigate, and manage medicine shortages.
    - Supporting more efficient and accurate inventory management and redistribution of medicines, avoiding both stockpiling and shortages.
    - Quicker response times for authorities and better-informed healthcare planning.

- Ensuring patient needs are addressed efficiently and equitably through better stock management.

- **Hospitals' limited preparedness for real-time stock reporting:** the EMA offices expressed concern about hospitals' readiness to provide real-time and accurate data on planned stocks of critical medicines. While some hospitals were somewhat prepared many faced significant challenges related to outdated IT systems, lack of investment in infrastructure, and fragmented systems that hindered efficient reporting.
- **Lack of national systems for medicine stock data collection:** Most EU Member States do not have national systems in place to collect real-time stock data from hospitals. Where such systems do exist, they are often voluntary and operate through basic electronic tools. The fragmented and inconsistent nature of these systems across Member States presents a significant obstacle to comprehensive and timely data collection for the ESMP.
- **Data consolidation challenges and fragmentation:** In many Member States, existing data collection efforts are not standardised, with hospitals often relying on manual data entry or rudimentary tools to share stock information. The reliance on voluntary data sharing (data altruism), combined with inconsistent reporting standards, has led to data quality issues that impact authorities' ability to accurately assess stock levels and predict demand.
- **Need for standardised systems and government investment:** There is broad consensus among National Competent Authorities on the need for government investments to digitise hospitals' medication management pathways. Such investments would enable real-time visibility of medicine stocks and ensure that accurate data can be collected consistently. Additionally, efforts to standardise data collection systems across Member States would be critical for improving the quality and reliability of information shared with national and EU-level authorities.
- **Planning for future demand estimation:** National Competent Authorities emphasised that estimating future demand for critical medicines, especially in times of crisis, requires the integration of sales data, hospital data, and epidemiological trends. However, most Member States currently lack the infrastructure to efficiently collect this data. Discussions are ongoing in some countries to establish national systems that could improve data collection and better meet the ESMP's requirements for crisis preparedness and medicine stock management.

In conclusion, the interviews reveal that while hospitals played a crucial role in managing medicine shortages during the pandemic, their preparedness for real-time data reporting remains limited. Addressing this gap will require significant investment in infrastructure and standardisation efforts across EU Member States to ensure the effective functioning of the ESMP in future crises.

## HOSPITAL PHARMACISTS' AND PHARMACY MANAGERS DATA SHARING SURVEY

The Hospital Pharmacists' and Pharmacy Managers Data Sharing Survey was conducted to assess the readiness of hospitals across Europe to comply with the EMA new mandate to establish a European Shortages Monitoring Platform. The survey gathered 197 responses from hospital pharmacists and pharmacy managers, examining current data-sharing practices, technological capacities, and anticipated

challenges in complying with this new requirement. Most respondents worked in general public hospitals and university hospitals, representing a wide spectrum of hospital sizes and capacities. The geographical distribution was diverse, with notable representation from Romania, Spain, Belgium, and Croatia.

Data sharing practices varied. Almost half of the respondents (47%) indicated that they shared medication stock data periodically (e.g., weekly or monthly), while others shared data on an ad hoc basis during shortages. A significant portion (23%) did not share data at all, highlighting a key area for improvement. The methods used for sharing data ranged from structured digital files to government platforms, with some hospitals even still relying on paper-based systems.

In terms of technology, 38% of hospitals had systems capable of real-time tracking for all medications, while 51% only tracked stocks stored in the pharmacy. While IT systems connecting central pharmacies to hospital wards were identified as the most common tool in use, many respondents expressed the need for further digitalisation.

The survey also revealed that many hospitals lack sufficient resources to meet the upcoming obligations. Nearly half of the respondents estimated it would take 1-10 minutes to collect stock data for any one specific medication across the hospital, while 18% reported it would take over an hour. Looking ahead, 42% of respondents indicated they had no concrete plans in place for digital reporting, while 37% were considering investing in digital tools.

Ultimately, a significant majority of respondents (76%) felt that their governments were not providing the necessary resources to comply with the EMAs new requirements.

In conclusion, the Hospital Pharmacists' and Pharmacy Managers Data Sharing Survey underscores critical areas requiring attention to support hospitals in meeting the new EMA mandate. Key findings reveal significant variation in data sharing practices, with notable gaps in digital capabilities and a lack of standardised process across European hospitals. This Survey highlights the urgent need for increased investment in digital tools and infrastructures, and regulatory support to ensure hospitals can meet the new data-sharing requirements effectively. Addressing these challenges will be essential to improve the hospital's preparedness and response to medication shortages and improve hospital pharmacy workflows associated with the collection and sharing of medication inventory data. *The detailed survey results can be found in Annex II.*

## CALL FOR ACTION

EHMA and the Alliance for the Digitalisation of Medication Management in European Hospitals call on the European Union to:

**Embed hospital digitalisation in EU funding mechanisms such as the EU4Health Programme**

The EU4Health Programme, as the EU's funding mechanism for health resilience, should prioritise the digitalisation of hospitals as a strategic initiative. We call on the EU4Health Programme to allocate funding and resources to support hospitals in adopting advanced medication management systems. This investment will not only improve data visibility for ESMP but also strengthen the EU's preparedness for public health emergencies by equipping hospitals with the tools needed to manage stocks effectively during crises.

**Prioritise digitalisation and automation in hospitals: Medicine Act & Pharma Directive**

To ensure EU hospitals are fully prepared to support the European Shortages Monitoring Platform and efficiently manage medicine shortages, the inclusion of digitalisation and automation of hospital medication management in the forthcoming Critical Medicines Act and EU Pharmaceutical Strategy are critical. Standardised digital systems across EU hospitals are essential for tracking and reporting real-time medicine stocks, as they will allow hospitals to monitor, predict, and respond to shortages effectively. We urge the European Commission to prioritise the digital transformation of hospitals in the EU's legislative agenda to enhance crisis preparedness and response.

**Focus on digitalisation in the Critical Medicines Alliance**

The Critical Medicines Alliance represents a coordinated EU-level effort to address medicine shortages and safeguard the supply of essential medicines. To maximise the effectiveness of this initiative, digitalisation and automation of hospitals should be included as a key focus area within the Alliance. This inclusion will facilitate data sharing across the supply chain, improve stock management, and prevent critical medicine shortages. Emphasizing the role of hospital automation within the Alliance will ensure that supply chain vulnerabilities are addressed comprehensively and collaboratively.

**Support the establishment of national IT systems for real-time medicine stock data**

For the ESMP to function effectively, it is essential that EU Member States develop robust national IT systems to consolidate real-time, electronic data on critical medicine stocks from hospitals. These systems will enable accurate, timely data sharing with the ESMP, supporting better coordination and preparedness across the EU. We encourage Member States to prioritise this digital infrastructure and collaborate with the EU to ensure comprehensive, standardised data collection, allowing for a coordinated response to medicine shortages and enhanced health security across the region.

## ANNEX I

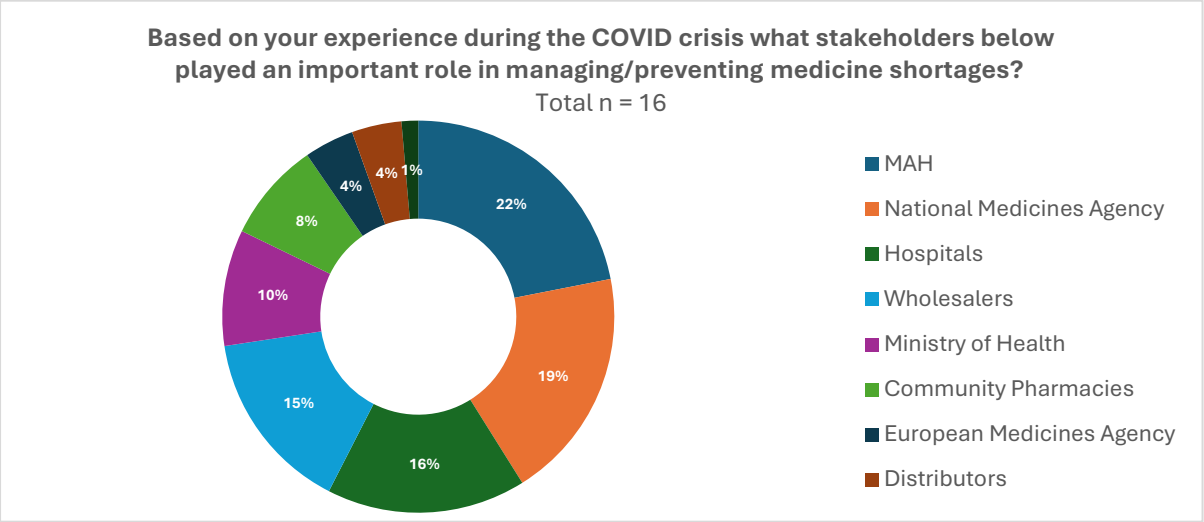
# European Medicine Agency survey: hospital readiness and the role of medication stock visibility in managing medicine shortages in EU Member States

EHMA performed a mixed-methods study using an online survey and semi-structured interviews targeting National Competent Authorities (NCA) responsible for managing medication shortages in their countries. The online survey targeted members of the European Medicines Agency (EMA) Medicines Shortages Single Point of Contact (SPOC) working party and received responses from 16 countries in the European Union. These countries were: Austria, Belgium, Bulgaria, Croatia, Cyprus, Estonia, Finland, France, Ireland, Iceland, Italy, Lithuania, Latvia, Norway, Portugal, Slovenia and Sweden. The semi-structured interviews targeted Italy, Spain, Romania, France, Poland, Belgium and Germany. Three countries participated in the semi-structured interviews: Belgium, France and Poland. The survey was conducted between May 2023 and July 2023. Semi-structured interviews were carried out in the same period.

The results below are based on NCA's experiences managing surges in medication demand during the COVID crisis, their perception of hospitals' readiness to share data on medication stocks and demand for the EMA European Shortages Monitoring Platform (ESMP). It additionally presents NCA's capacity and plans to collect real-time medication-related data from hospitals.

## Results

### Stakeholders who played an important role in managing and preventing medicine shortages during the COVID-19 crisis

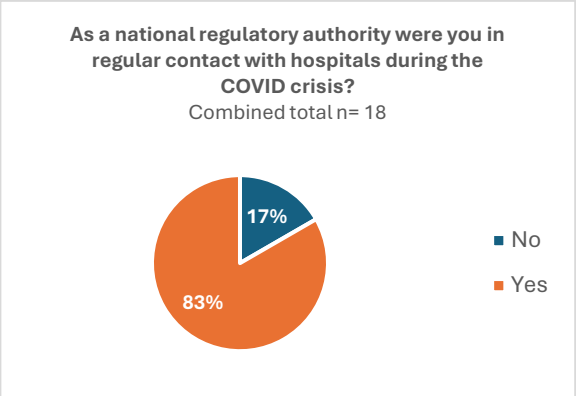



Survey responses (n=16) indicated that NCAs considered hospitals as one of the top three stakeholders who played an important role in managing and preventing medication shortages during the COVID-19 pandemic. All qualitative interviewees (n=3) discussed the importance of collaboration and communication by the entire health ecosystem and highlighted the value of close cooperation at the EU level. The importance of joint working between competent health and economic authorities, and the role of industry laboratories, wholesalers, community pharmacies, hospitals and national medicines agencies was further emphasised. Examples of innovative solutions were provided. In one country, a swift response by university-based statisticians who developed predictive epidemiological models allowed one NCA to estimate the number of medicines required to cope with

successive pandemic waves. Such innovative developments ensured that sufficient supplies of medicinal products were available on the market mitigating potential shortages.

Other examples of innovative practices to ensure the availability and accessibility of stocks throughout the pandemic included inter-agency working. In one case the competent health authority and the competent economic authority worked together to identify demand for hospital products, negotiated with laboratories and researched availability of alternative products from abroad. One country created a medicines stockpile where products were disturbed based on the priority need of hospitals. Similarly, a neighbouring country implemented controlled distribution measures amongst wholesalers where deliveries to hospitals, and pharmacies, could not exceed more than 50% of historical sales. Likewise, one national agency of strategic reserves played an important role in the distribution of key medicinal products; during the crisis, a special system for ordering medicines was created. Using this system authorities knew the quantities of medicinal products hospitals required as hospital pharmacies were obliged to send orders for medicines electronically to the system.

### Contact with hospitals during the COVID crisis




Combining responses from the online survey and semi-structured interviews showed that almost all regulatory authorities (83%) were in regular contact with hospitals during the crisis. In some instances, contact with hospital facilities was via regional authorities. In other cases, existing legislation requiring hospitals to stockpile 3 months' consumption of medicines meant NCA's only had contact with hospitals at their request. Similarly, interview respondents said they were in constant, mostly electronic, contact with hospitals. During peak crisis periods, hospitals completed weekly Google forms indicating medicinal stock levels. One NCA implemented an electronic tool (e-dispostock) where hospitals provided information on existing stock levels and predicted demand. Hospitals were required to complete this tool, otherwise were at risk of not receiving medicines. Data collected by this tool allowed the national government to create a national medicine stockpile from which medicines were distributed to hospitals based on predicted needs. In this case, the management of medicine stock for hospitals was the responsibility of the Ministry of Health.

### Benefits of hospital medication stock visibility during crisis periods

Survey responses to the question 'In your opinion, what are the main benefits of having visibility of stocks in hospitals during crisis periods such as during the COVID-19 pandemic?' showed that for respondents the overall benefits included: Oversight on the availability and traceability of medicines, including those needed to treat non-pandemic diseases.

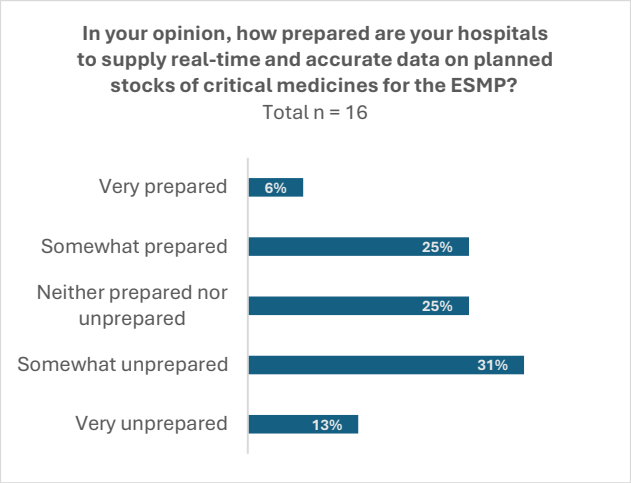
- Efficient and equitable redistribution and management of available stocks according to demand.
- Supporting efficient inventory management.
- Preventing stockpiling.
- Predicting demand.
- Planning healthcare and ensuring patient needs are addressed.
- Faster development of mitigation plans by authorities.
- Predicting, preventing, responding, mitigating and managing shortage situations.

Interview respondents shared that oversight of hospital medicinal stocks was crucial for COVID-19 patient care supporting stock redistribution between hospitals and essential for addressing drug shortages. Collated data on drug availability, the number of patients hospitalised with severe COVID-19 with data on supply levels in the national medicines stockpile provided a robust evidence base on

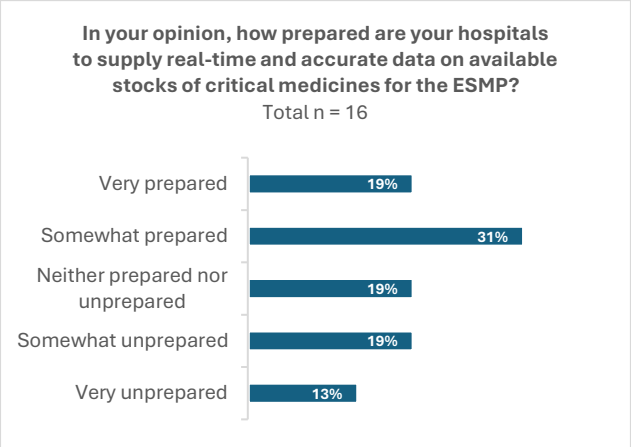
whether supplies were sufficient for demand in one EU Member State. Similarly, an integrated system of hospital stocks containing information on stock levels in hospitals, pharmacies and wholesale distributors provided authorities in another Member State with the capability to monitor trade in medicinal products. During the crisis, data on hospital stocks allowed authorities to assess medicinal stock levels and consumption dynamics supporting rapid evidence-based stock management decisions. A third Member State shared those hospitals reported stock levels on a selection of medicines every one to two weeks. This information was critical to support predictive models to manage medicinal supplies during the crisis. Overall, interview respondents indicated that access to real-time, or near-real-time, electronic information:

- Provided global information on stock levels.
- Provided data to effectively manage stock levels.
- Supported efforts to identify, mitigate and manage medication shortages.
- Strengthened decision-making for the allocation, efficient and equitable distribution of medicine stocks to hospitals.

### Hospital preparedness to supply real-time and accurate data on planned and available stocks of critical medicines for the ESMP




One survey respondent indicated that hospitals are very prepared to supply real-time, accurate data on planned stocks of critical medicines. 25% (n=4) of survey respondents shared that hospitals in their country are respectively somewhat prepared or neither prepared nor unprepared. It was highlighted that hospitals would need to invest in IT resources. Likewise, 31% (n=5) of survey respondents felt that hospitals in their countries are somewhat unprepared. 13% (n=2) indicated that hospitals are very unprepared to supply real-time, accurate data on planned stocks of crucial medicines.




In contrast, survey responses to the question 'How prepared are your hospitals to supply real-time and accurate data on available stock of critical medicines' showed that in comparison to the preceding question, 19% (n=3) of NCA's believe that hospitals in their countries are very prepared, 31% (n=5) believe that their hospitals are somewhat prepared, 19% (n=3) respectively believe that hospitals are neither prepared nor unprepared or somewhat prepared and 13% (n=2) believe that their hospitals are very unprepared to share real-time data on available stock of critical medicines for the ESMP.

Interview respondents likewise expressed concern about hospitals' preparedness to supply real-time and accurate data on planned and available stocks of critical medicines. One interviewee shared that hospitals are 'not very well prepared at the moment due to financial issues, quality of reporting and the different (fragmented) systems they have.' Likewise, for another NCA even though a national system exists to collect such information, hospitals have no regulatory obligation to do so. Interview respondents share that awareness levels need to increase amongst hospitals and that this

information will be required by NCAs. At the EU level, standardising data collection systems for hospital medication stocks will be key to improving data quality.

### What system exists in your national hospitals to collect information on available stocks and information on what is needed to restore stocks to planned minimum levels?

Presented as an open-ended question in the survey, four out of twenty-one NCAs indicated that no common national system exists to collect this information from hospitals. Two collect information at the regional level; one country (Norway) shared that some regions and organisations have real-time visibility of available medicine stocks, but this can only be shared between regions. In another country, Cyprus, hospitals have independent stock management systems, but it is unknown whether these systems are manual or electronic. In Estonia, hospital pharmacies monitor for a minimum stock level, but the system and process used for this practice were not shared. Hospitals in Slovenia and Portugal have their own unique, unconnected, solutions. Two countries stated that manual counting and calculation would need to be carried out by hospitals.

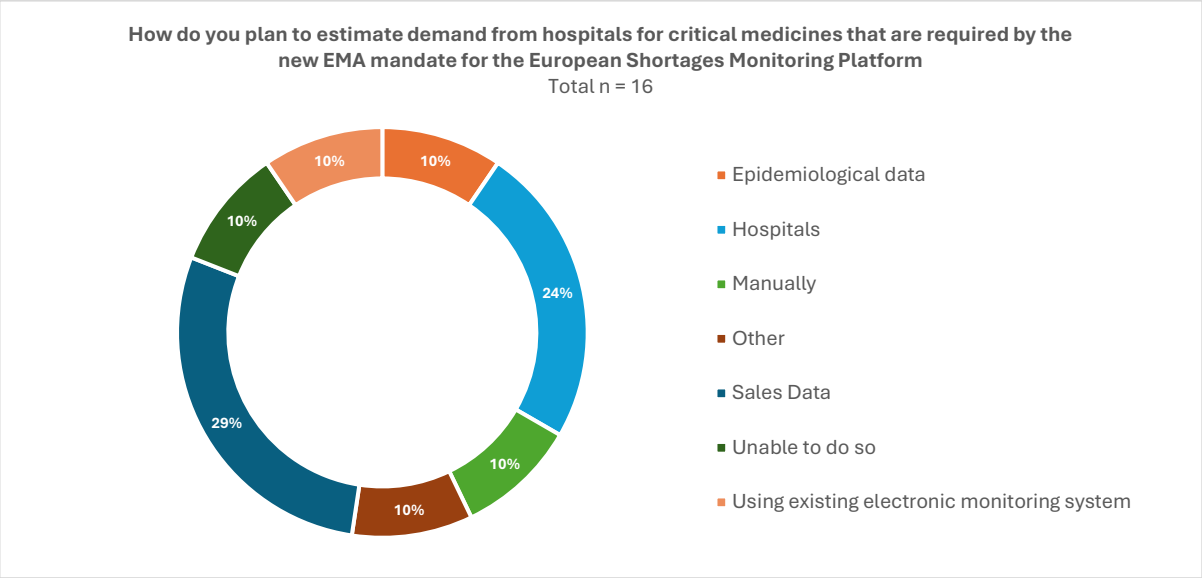
Four countries, namely France, Belgium, Bulgaria, and Poland, have some form of an electronic stock monitoring system, however, functionality varies. One respondent shared that information on hospitals' available stock is voluntarily shared via an e-tool. The voluntary nature of data sharing was identified as a barrier that impacts data volumes. The same respondent shared that data on manufacturers' available stock can also be collected to estimate planned stock but not demand. While manufacturers may have hospital demand data this information is not available for public authorities.

During the COVID-19 pandemic, one Member State developed a stock monitoring tool, initially using Excel sheets and soon to be deployed as an IT application. Users can manually download, fill, and upload a CSV file to submit information on medicine stock levels. The tool is undergoing upgrades, with plans to expand its usage to stakeholders including marketing authorisation holders, wholesalers, hospitals, and pharmacies. An electronic option will be developed permitting users to automatically submit the stock levels of the required medicines.

One survey respondent shared that a national system exists allowing hospitals to send data daily on stock and consumption levels. This system calculates nationally available stocks and determines whether stock levels will meet average demand. Finally, one interview respondent indicated that a pre-existing IT system can collect data on actual stock, but it does not have the functionality to collect data on demand or planned stock levels.

### Plans to estimate demand from hospitals for critical medicines for the ESMP

29% (n=6) of NCA's plan to estimate demand for critical medicines by hospitals using existing sales data. 24% (n=5) of respondents identified hospital data as key information for estimating demand. In some cases, a combination of sales and hospital data, or hospital data and other data will be required. 10% (n=2) of respondents shared that, while time-consuming, information for the demand of critical medicines would be collected manually. 10% of respondents will use an existing electronic system, 10% are unable to collect this information and one country shared that data would be collected on individual demand, while another NCA highlighted that estimating 'demand is not feasible unless you have historical data'.




Combined data sources included cases such as sales data with hospital demand and supplies. In some situations, e.g. times of crisis, data on hospital stocks would be combined with epidemiological data. Another NCA will combine epidemiological data with historical consumption data.

One interview respondent shared that while sales databases exist, they are mostly in the ownership of private organisations. During times of shortages, manufacturers must declare usual sales levels, and in some instances, they are asked to distinguish between sales to hospitals and sales to community pharmacies. However, while some manufacturers know hospital stock levels, facilitating the redistribution of stock when needed, saving this data is not common practice. Another interview respondent shared that determining demand will be based on data collected by their integrated electronic system taking historical consumption and supply patterns into account. A limitation of this approach is that data shared by hospitals to this system depends on the availability of e-prescribing systems of which penetration is low. Where they are available, they are heterogeneous and non-standardised impacting data quality. Additionally, while hospitals are legally required to report stock levels, reporting is not consistent; some hospitals share the number of tablets they have rather than the number of packages. It was highlighted by this interviewee that incorrect, non-standardised data sharing, impacts the accurate assessment of available medicinal stocks and the ability to determine the severity of a shortage. Finally, within the survey, one respondent identified that a *'new electronic system would be required to collect additional or timely information from hospitals'*, one shared that a national supply and demand system is awaiting approval. Equally two interview respondents agreed that the availability and deployment of an interconnected, national country database, would be beneficial and enable consistent, standardised data collection and accurate visibility of global medicine stocks.

### Plans to consolidate demand data from hospitals to be reported to the ESMP

Two interview respondents indicated that either they have no information on actual demand and needs will be estimated based on normal, or global, sales volumes. One respondent shared that information on stocks will be collected through their monitoring tool and the sum of this data will be given to the ESMP. A third interview respondent was unsure but believed that they would use data from their existing integrated system. However, challenges were foreseen with updating this system to meet this new obligation as changes in national pharmaceutical law would be required.

Currently, as seen from the responses, many countries lack a national system for real-time demand data collection, leading to reliance on historical consumption patterns, which may be adjusted for recent trends or specific situations, such as seasonal peaks or public health emergencies. In one country, discussions are ongoing with relevant stakeholders to establish a standardised approach, with a final solution expected soon. Due to national confidentiality regulations, detailed information

about demand and crisis preparedness may not be fully shared with international authorities. Instead, aggregated or summary data may be provided to ensure compliance with local laws while fulfilling reporting obligations.

In the absence of automated systems, data collection often involves manual processes, such as contacting hospital pharmacies via email or phone. This method poses challenges, including data accuracy and the timely availability of information. One respondent stated that efforts are underway to streamline these processes, potentially using electronic formats like Excel for data submission. The lack of uniform digitised record-keeping systems across hospitals complicates data consolidation efforts. In many cases, hospitals do not use standardised medicine registration numbers, making it difficult to compile and report data accurately. During normal times, routine data collection is not practised, with data gathering being reserved for public health emergencies or major events.

One country has implemented a shortage monitoring system that functions continuously, covering the entire supply chain from manufacturers to pharmacies. This system provides daily and monthly consumption data, helping to estimate demand more accurately. However, the implementation of such systems requires significant coordination and infrastructure development. While the collection and consolidation of hospital demand data present challenges, especially concerning real-time reporting and technological infrastructure, the focus on critical medicines means that the expected volume of shortages may be relatively low.

Ongoing discussions and collaborations with relevant authorities should therefore aim to improve data collection methods and ensure compliance with ESMP requirements. Continued monitoring and development of solutions are essential as the ESMP evolves.

**Poland – Best practice example from the community**

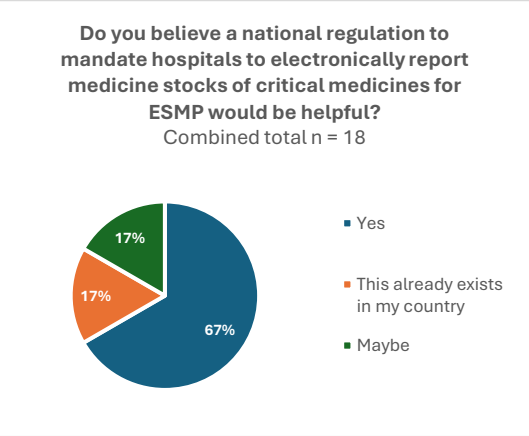
Commercial websites exist which have direct access to the stocks of community pharmacies (useful for patients when searching for medications). An example of a commercial website is Gdziepolek.pl ktomalek.pl. It is connected with the main provider of the software for community pharmacists. 90% or more community pharmacists have this system, and they are connected. Poland has about 12,000 community pharmacists - ktomalek has about 10,000 of them. Technically it is not impossible or difficult to exchange this information. When the interviewee worked in a pharmacy, they could see the stocks in wholesale distributors. Hospitals would use a similar system to ktomalek (API) – There wouldn't be a big resistance from hospitals – financial investment to set up such a system could be an obstacle. Hospitals having to deal with financial issues – upfront financial investment.

### Benefits and Limitation of ePI to collect data on hospital medication stocks and demand

Half of the survey respondents identified multiple benefits from ePI including enabling the accessibility, availability and faster allocation of medicinal supplies between countries during shortage periods. Other benefits highlighted by respondents included mitigating the imprudent use of prescriptions and broadening the supply variety of medicines. 27% stated that ePI will be of very limited support, if any and will not facilitate data collection on stocks and demand. One survey respondent stated that ePI '*does not help to collect data on medicine stocks and demand in hospitals (can be considered to be even opposite, when there are multiple different packages of the same medicinal product without proper ID')*'. An equal percentage were unclear about what benefits ePI will have on collecting this type of data and could not identify a connection between ePI and stock and demand data collection. In response to this question, one survey respondent stated that '*a new electronic system for information exchange*' is needed while another respondent thought that ePI is useful as the NCA needs data that be collected rapidly in a structured format to enable analysis and projects.

## Mandating hospitals to electronically report medicine stocks of critical medicines

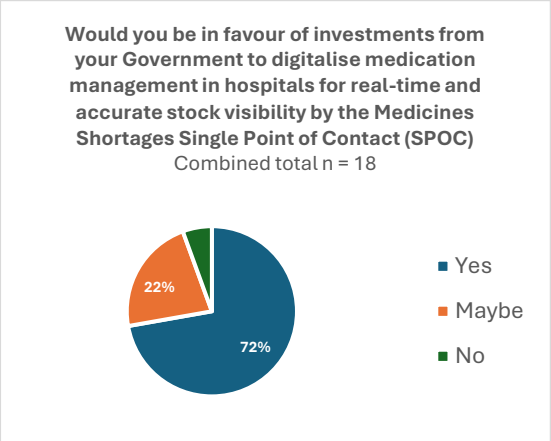
Combined data from the survey and interviews shows that the majority of respondents (67%, n=12) indicated that a national regulation mandating hospitals to electronically report medicine stocks of critical medicines would be helpful. One country shared that they are currently working on such an obligation, but no law has been officially approved to ensure consistent, transparent data sharing with the NCA. Another respondent believed that such an obligation would be helpful as long as data is available in a standardised, structured format. Such data would support rapid, equitable, evidence-based decision making by NCAs to manage and mitigate shortages.




17% (n=3) of countries shared that some type of system already exists. It is unclear, however, if a legal obligation on hospitals to share data on the supply and demand of medicines exists, as one respondent stated that *'This is in use after the Covid-19 pandemic and in order to be on a more permanent basis, should be included in the national legislation'*.

Similarly, 17% of respondents stated that such a regulation could be useful but would need to incorporate all stakeholders in the supply chain and if all systems are coordinated with each other. Limitations identified to the implementation of such a regulation included the availability and quality of data and the cost of human resources associated with collecting data on available stock.

## Government investments in hospitals' medication management pathways to enhance real-time and accurate stock visibility of medicines




Combining data from the survey and interviews, 72% (n=13) of respondents indicated that they would be in favour of government investment to digitalise hospitals' medication management pathways. 4 were unsure, and 1 respondent opposed making investments to digitalise hospital medication management pathways aimed at supporting real-time visibility and accurate medication stock tracking.

## ANNEX II

# Hospital pharmacists' and pharmacy managers data sharing survey

The Hospital Pharmacists' and Pharmacy Managers Data Sharing Survey was conducted in the context of the European Medicine Agency's (EMA) expanded mandate to establish the European Shortages Monitoring Platform (ESMP). This new obligation, part of the EU's strategy to build a stronger European Health Union following the COVID-19 pandemic, requires hospitals to share medication stock data with national and regional authorities. The survey was designed to assess hospitals' current capacities to meet these requirements, identify potential barriers, and evaluate the impact on workloads.

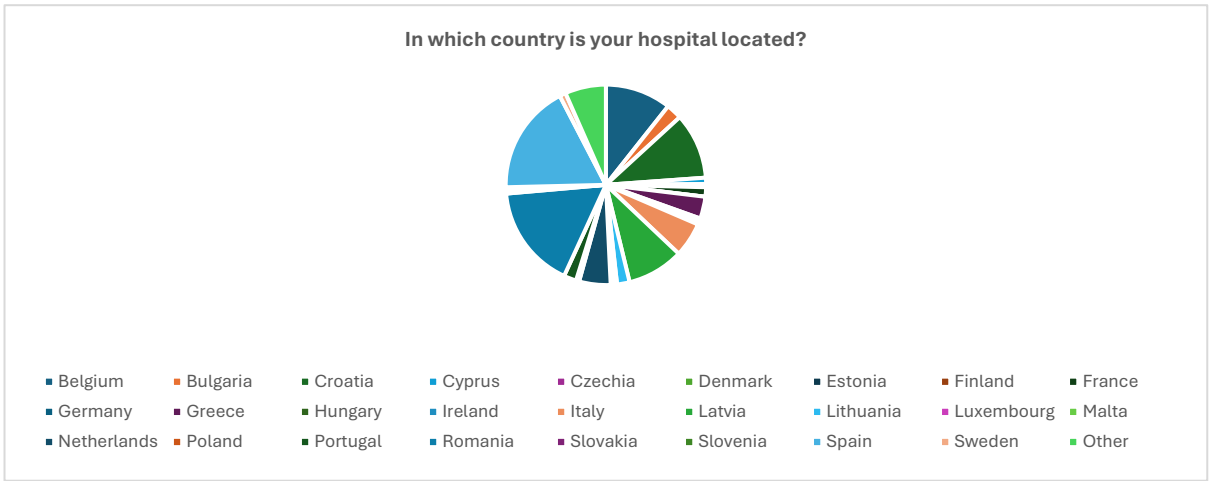
Key objectives of the survey include:

- Identifying how hospitals collect and share data on medication stocks and demand.
- Highlighting barriers to gathering accurate and timely stock information.
- Understanding the workload impact and the need for digitalisation in hospital pharmacy workflows.

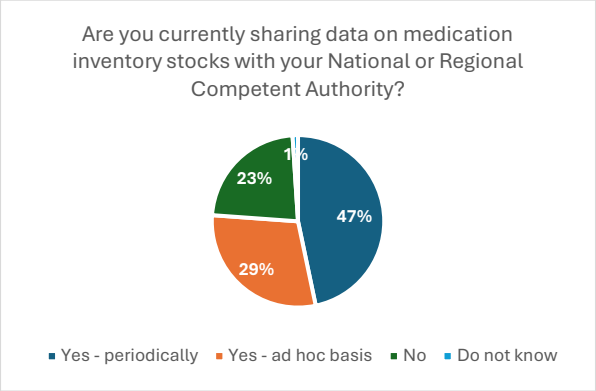
The survey questions were structured to gather specific information on existing data-sharing practices, the technological tools used, the frequency of data collection, and the estimated time required for these tasks. Additionally, it explored whether respondents had sufficient resources—staffing or digital tools—to comply with the ESMP and what investments might be necessary moving forward.

Questions also explored the effectiveness of monitoring hospital medication stocks in both emergency and routine settings and whether hospitals feel supported by their national pharmacy associations or governments in meeting this new obligation. This information is essential for shaping future strategies to ensure hospitals are adequately prepared for the EMA's new data-sharing requirements.

The survey was predominantly answered by hospital pharmacists (77%, n=151), while pharmacy managers constituted the remaining 22% (n=44). The respondents represent a diverse range of hospitals, with most working in general public hospitals (37%, n=72) and university hospitals (19%, n=37). Other respondents were from general teaching hospitals (public) (14%, n=28), specialist hospitals (10%, n=20), and smaller numbers from community hospitals and psychiatric hospitals. Regarding geographical representation, respondents were distributed across EU member states, with Romania (17%, n=33) and Spain (18%, n=35) representing the largest contingents. Notably, Belgium and Croatia each had a significant share, with 11% (n=21) respondents each. Other countries with notable representation included Latvia (9%, n=18) and Italy (6%, n=11).

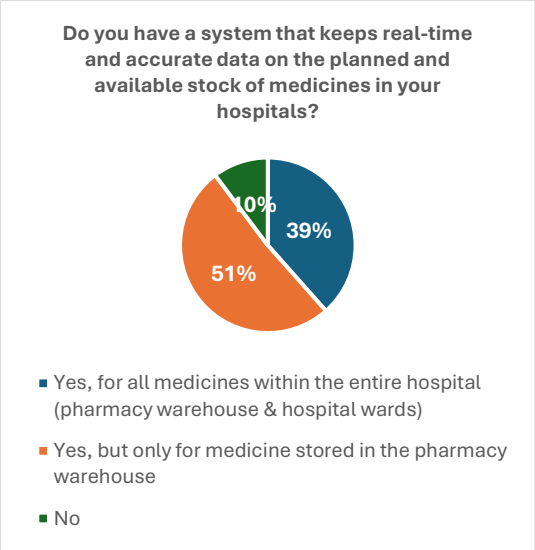


Hospitals varied in size, with 36% (n=71) of respondents coming from facilities with 0-250 beds, followed by 251-500 bed hospitals (28%, n=56). Hospitals with over 1000 beds made up 15% (n=29), indicating the participation of institutions of varying capacities. Regarding the ICU bed capacity of hospitals, only 6% (n=12) of respondents provided answers which ranged from zero to 150.



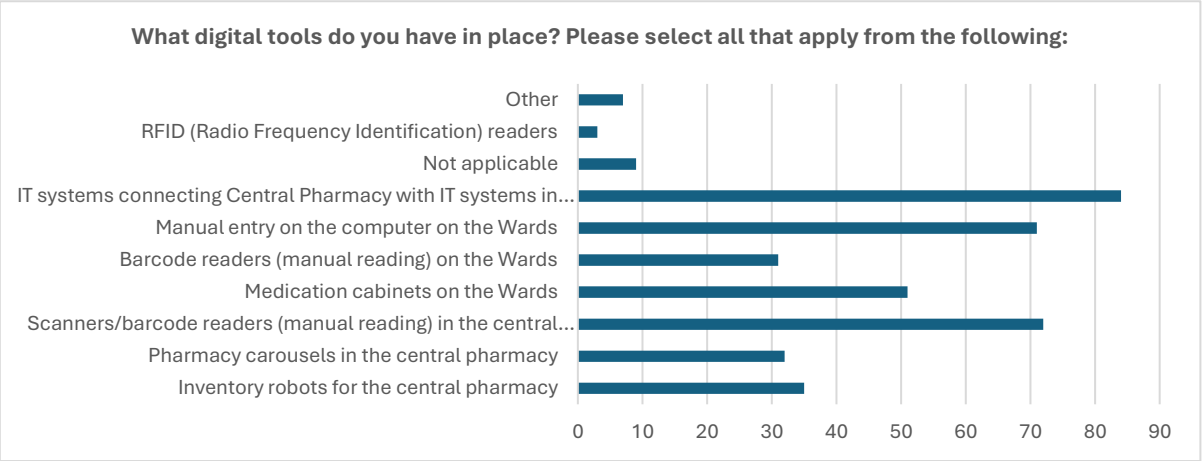

Regarding current data sharing practices, a significant portion of hospitals is already engaged in some form of medication inventory data sharing practices. 47% (n=92) of respondents indicated that they share inventory data periodically (weekly or monthly). 29% (n=58) share data on an ad hoc basis, typically during shortages or other crises. However, **23% (n=45) reported not currently sharing any data** with their National or Regional Competent Authorities.

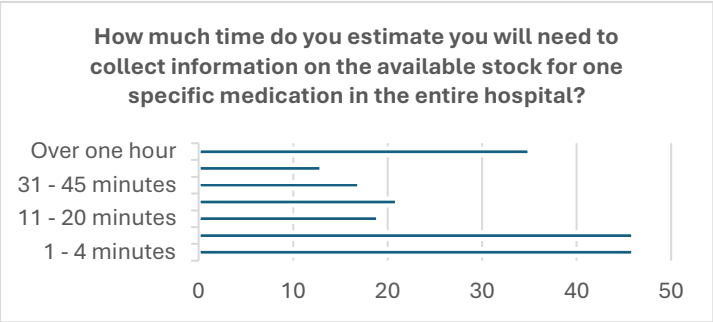
The methods for sharing medication data varied widely. 30% (n=60) use structured digital files (e.g., Excel, CSV). 25% (n=50) report using government platforms or public web portals, and a smaller number still rely on manual paper-based methods, such as fax (6%, n=11). 23% (n=32) are using system-to-system integrations, indicating a more advanced level of digitalisation.




Regarding the availability of systems for tracking medication stocks in real time, 38% (n=75) of respondents reported that their hospitals had systems in place for all medicines, including those stored both in central pharmacies and hospital wards. 51% (n=100) indicated that their systems only covered medicines stored in pharmacy warehouses and **10% (n=20) of hospitals reported having no real-time systems for medication tracking**. Additionally, regarding the level of medication stock monitoring in their hospitals, a small portion of 6% (n=11) of respondents reported monitoring stocks at the packaged medicinal product level. Meanwhile, 22% (n=43) monitor the medicinal product level, which includes individual items such as vials, tablets, or bottles. An additional 22% (n=44) stated that their hospitals monitor stock at both.

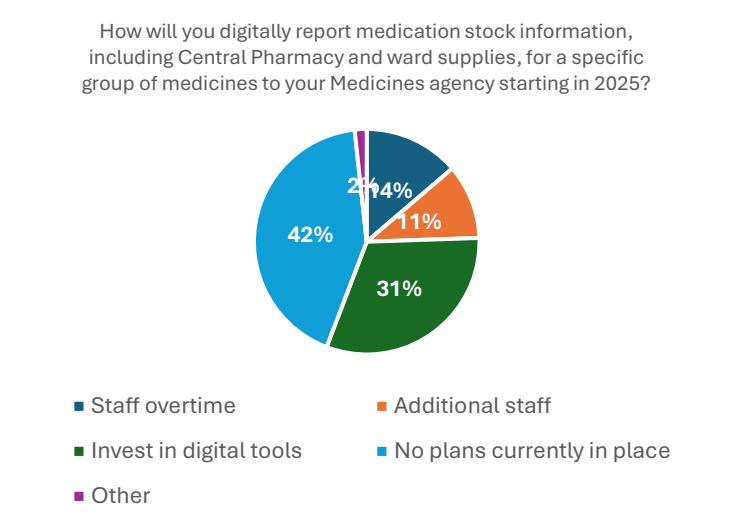
Regarding the use of digital tools that are being used to monitor medication stocks in hospitals, the survey revealed significant variation. IT systems connecting central pharmacies with wards were the most commonly used tool, reported by 43% (n=84) of respondents. Scanners or barcode readers in central pharmacies are used by 37% (n=72), followed by a manual entry on the computer on the wards (18%, n=71). Medication cabinets in hospital wards were reported by 26% (n=51). More advanced tools, such as inventory robots and RFID readers, were less frequently used, with only 18% (n=35) and 1.5% (n=3) reporting their use, respectively. For those without a system that keeps real-time and accurate data on the planned and available stock of medication, data collection frequency was varied. 20% (n=40) collect data daily. 16% (n=32) collect data weekly, and 15% (n=30) report monthly collection. Quarterly and yearly collections were less common, at 5% (n=10) and 6.5% (n=13) respectively.




Regarding the estimated time that it takes to collect information on the available stock of one specific medication in the entire hospital, 47% (n=92) estimated 1-10 minutes and 18% (n=35) reported that it would take over one hour, suggesting considerable variability in efficiency. All remaining answers scored in-between the two.

To the question 'How will you digitally report medication stock information, including central pharmacy and ward supplies, for a specific group of medicines to your medicines agency starting in 2025?', 42% (n=99) responded that they currently have no plans in place. 37% (n=73) plan to invest in digital tools, 16% (n=32) anticipate relying on staff overtime, and 11% (n=25) report planning on hiring additional staff. Regarding the need for additional staff to meet the new requirements, 47% (n=92) are unsure of how many full-time equivalents (FTE) they would need. 26% (n=52) believe that 1 additional FTE would be necessary, 14% (n=27) believe that 2 additional FTEs would be necessary, and 8% (n=15) believe that 3 additional FTEs would be necessary. Of those planning to invest in digital tools IT systems connecting central pharmacies with hospital wards are the most sought-after tool (54%, n=108). Medication cabinets in the wards (18%, n=67), robots in central pharmacies (18%, n=65), and bedside scanning (16%, n=60) also ranked highly, indicating a clear trend toward increased automation and digitalisation.




When asked if respondents' local pharmacist association was involved in the overall topic, the readiness of hospitals across Europe to comply with the EMAs new mandate to establish an ESMP, 37% (n=72) reported that they were actively involved, and 34% reported no active involvement (n=67).

Ultimately, **a large majority of respondents—76% (n=149)—felt that their governments were not providing the necessary resources to comply with the new EMA obligations.** Only 24% (n=48) believed that adequate resources were available.

The survey highlights significant variability in hospitals' preparedness for the new EMA mandate, with many hospitals lacking real-time systems for medication stock management and a large proportion uncertain about the resources required for compliance. The data reveals a clear need for increased investment in digital tools and staffing, alongside stronger governmental support to ensure hospitals are equipped to meet the upcoming obligations. Monitoring hospital medication stocks is generally seen as effective for managing shortages, both in emergency and routine contexts, but substantial work remains to be done in terms of infrastructure and planning.