The European Health Management Association (EHMA)'s position on hospitals' medication management pathways

Introduction

The availability of medicines has been a longstanding concern in the EU.[1] Throughout the last decade, the issue of medicines shortages has become systemic. Shortages of medicines affect treatment regimens. They may also affect the health of EU citizens and, ultimately, the resilience of health systems in Member States.

The root causes of shortages are multifactorial, with challenges identified along the entire pharmaceutical value chain, from quality and manufacturing problems to industry´s competitiveness. Shortages of medicines can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. The COVID-19 pandemic has further highlighted the importance of ensuring continued supply of medicines, which is often taken for granted across Europe. This is especially true for the most critical medicines which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe.

The continued availability of safe, effective and affordable medicines for Europeans is a top priority for the European Commission. It is the foundation of the strong European Health Union established as one of the key lessons of the COVID pandemic.

Some of the actions by the European Commission are listed below:

- The launch of a European Voluntary Solidarity Mechanism for medicines (October 2023): the mechanism flags a Member State's needs for a given medicine to other Member States, that can respond by redistributing medicines from their available stock.
- A Union list of critical medicines (available by the end of 2023): Once established, this list will be the first step to analyse the supply chain of selected medicines by April 2024. This analysis will then show where additional measures are needed.
- Regulatory flexibilities: 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 effective use of these flexibilities.
- EU guidance on procurement of medicines to strengthen security of supply issued by the Commission in 2024.
- EU joint procurement for next winter for antibiotics and treatments for respiratory viruses.

Member States, the EMA and the Commission have already initiated actions that go in the direction of the proposed pharmaceutical reform to prevent and mitigate critical shortage risks.

[1] See, for instance, European Parliament, Committee on the Environment, Public Health and Food Safety, Report of 22 July 2020, Shortage of medicines – how to address an emerging problem, 2020/2071(INI).

The Commission will continue working together with Member States to accelerate elements of the pharmaceutical reform to enhance the security of supply, where possible.

Structural measures to support the long-term security of supply:

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. The Critical Medicine 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.

The work of the Alliance will focus on a targeted number of critical medicines with the highest risk of shortages and impact on healthcare systems. It will draw from a varied toolbox of policy measures to mitigate risks of shortages and increase supply, including:

- 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;
- Helping leverage and align EU and national funding.

This could pave the way for a possible "Critical Medicines Act" in the future. To that end, the Commission will launch a dedicated, preparatory study paving the way for an impact assessment. In 2024, the Commission has to also develop a common strategic approach to medicines stockpiling to prevent and mitigate shortages in cooperation with Member States.

The new EMA mandate and the ESMP

The European Medicines Agency (EMA) has been granted an extended mandate under Regulation (EU) 2022/123 to bolster its role in crisis preparedness and management of medicinal products and medical devices within the EU. This mandate is part of the broader European Health Union initiative aimed at improving the EU's capability to respond to health emergencies like the COVID-19 pandemic.

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.

Visibility of stocks in Hospitals (the downstream)

The visibility of medicine stocks in hospitals in the EU is critical to prevent and mitigate medicine shortages.

 **Efficient Supply Chain Operations:** Knowing 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 wastage.

 **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.

 **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.

a) ESMP and visibility of stocks in Hospitals

The visibility of medicine stocks in hospitals and the management of medicine shortages are crucial aspects addressed by the EMA's extended mandate and the implementation of the European Shortages Monitoring Platform (ESMP).

- **Hospitals are key stakeholders in the monitoring of medicine supplies. The ESMP aims to provide a centralized platform where data about the availability of medicines can be collected and shared. This includes stocks in hospitals, which are critical for responding to both routine healthcare needs and emergency situations. The platform is designed to integrate data from various sources, including hospitals, to provide a comprehensive view of medicine availability across the EU.**

By leveraging this platform, hospitals can report their inventory levels, and this data can be used to identify potential shortages before they become critical. This visibility allows for more effective coordination between hospitals, national authorities, and the EMA, ensuring that critical medicines are redistributed as needed to prevent local shortages.

The ESMP's primary goal is to prevent, detect, and manage shortages of critical medicines. Here are some of the key features and processes involved:

1. Data Collection and Integration:

The ESMP collects data from national competent authorities, marketing authorization holders, and hospitals to monitor the supply and demand of medicines.

Interoperability with national and industry systems ensures seamless data exchange and reduces manual reporting efforts.

2. Real-time Monitoring and Reporting:

The platform enables real-time monitoring of medicine availability, allowing for immediate detection of potential shortages.

Hospitals and other stakeholders can report shortages and stock levels directly through the platform, facilitating timely responses.

3. Crisis Management and Preparedness:

During public health emergencies, the ESMP provides critical data to the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), which coordinates the EU's response to shortages.

Outside of crises, the platform supports preparedness activities by monitoring supply chains and anticipating potential disruptions.

4. Centralized Coordination:

Visibility into hospital stocks enables centralized coordination among healthcare providers, suppliers, and regulators. The European Medicines Agency (EMA) and national health authorities can better manage the distribution of medicines, ensuring that critical supplies are directed where they are needed most.

5. Crisis Management:

During public health emergencies, having a clear picture of medicine stocks helps in efficient resource allocation. The Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) can use this information to coordinate responses and prevent critical shortages during crises .

To ensure the right legal environment for Medicine agencies in Member States to request medicine stocks in electronic format to hospital pharmacies the German government modified the German Medicine Act, section 52 b, last June 2023, to incorporate the mandatory requirement for hospital pharmacies to provide medicine stocks to 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.**

b) HERA and visibility in Hospitals

The European Voluntary Solidarity Mechanism for medicines (October 2023): flags a Member State' needs for a given medicine to other Member States, that 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.

- **Hospitals are vital infrastructures for responding to cross-border health threats, as was the case with COVID-19, as they admit and treat patients during crises. During public health emergencies, having a clear picture of medicine stocks in hospitals, real-time and accurate, would help HERA for the efficient distribution of stockpiling among Member States and Hospitals and the implementation of the Solidarity Mechanism among Member States.**

The "European Commission staff working document on the global supply chains of medicines, structured Dialogue on the security of medicines supply", published in 2022, highlighted the important role of visibility of stocks in the downstream (hospitals):

"Participating stakeholders across workstreams agreed that more transparency on supply chains and shortages could help to address supply issues. Marketing authorisation holders repeated their desire for more clarity on actual demand from healthcare systems, in particular on anticipated changes or possible surges of demand for critical medicines, noting that such information would inform adjustments to production and supply in due time to avoid supply disruption. Representatives of wholesalers and patients argued in favour of more transparency on the supply side, focusing on downstream elements to mitigate and prevent medicines shortages."

COVID and the downstream: lessons learned

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.

Manufacturers of sedatives did not have information on where to deliver new lots of medication: country or hospital since availability of stocks were not available.

- **In summary, the visibility of medicine stocks in hospitals is a critical component in preventing and managing medicine shortages. It enhances real-time monitoring, improves coordination and response by EMA and HERA and optimizes supply chain management.**

Why 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 (DR) 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 will 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 (also called EMVS) containing unique identifiers (i.e., 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 or multiple markets, manufacturers upload the information contained in the Unique Identifier into the respective national repository system(s), part of the European Medicines Verification System.

Pharmacists are legally required to systematically verify— via the repository database(s)—the authenticity of each unique identifier (i.e., each pack), before dispensing it to the patient. Pharmacies will therefore only dispense a product if it is verified (i.e., information about the product is included in EMVS and all data elements of the unique identifier corresponding to the correct information uploaded by the legitimate manufacturer).

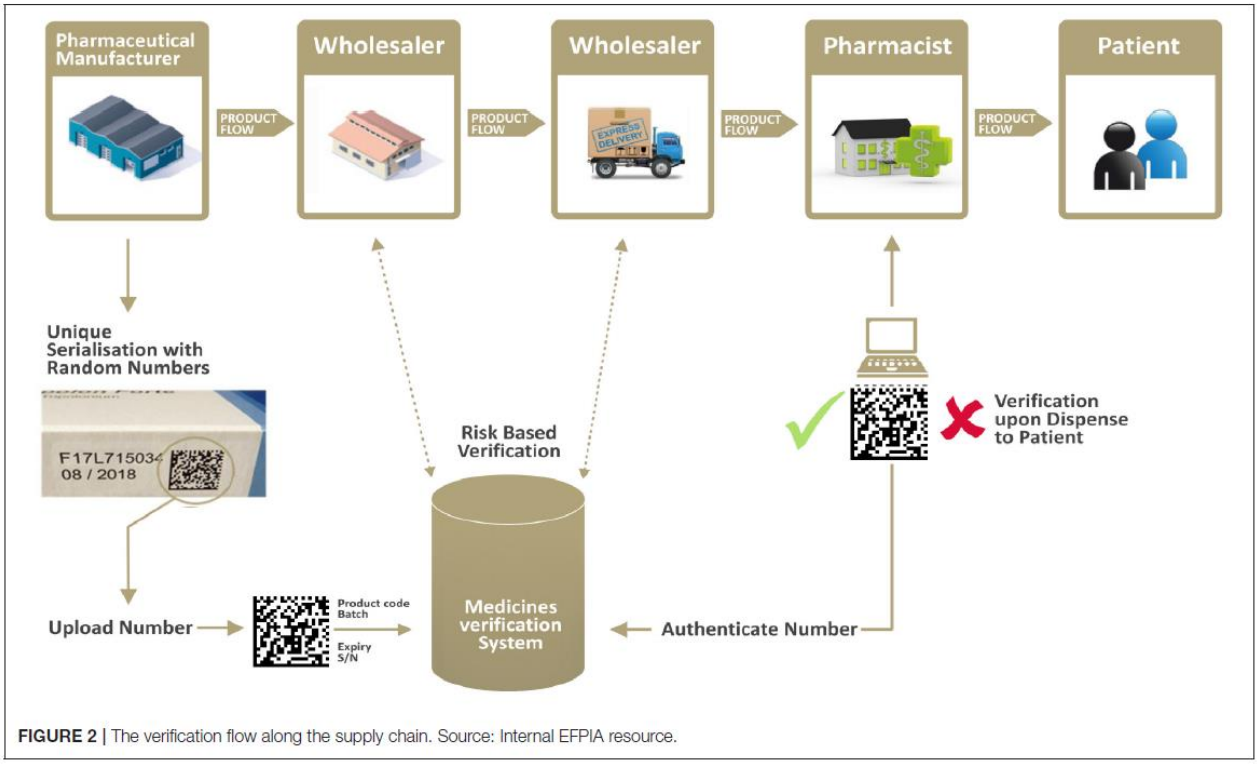

FIGURE 2 | The verification flow along the supply chain. Source: Internal EFPIA resource.

Decommissioning may take place at any time the medicine is in the physical possession of the healthcare institution, not necessarily when the medicines are dispensed to patients.

Considering that :

- hospitals receive large volumes of medicinal products which are administered to the patient at ward level.
- a large proportion of medicines in Europe are described as "multi-pack" (the outer packaging as that of the bundle and the single packs as not for individual sale (the text 'can't be sold separately' or equivalent is present on the packs)) and in those cases, the UI and the ATD are placed on the bundle packaging, not on the individual single packs (pills, ampoules, vials, etc.,).
- the use of aggregation that allows decommissioning multiple UIs from a specific shipment, instead of the individual sales packages.
- many medicines required compounding processes to be dispensed/administrated to patients.

most hospitals decommission medicines at the reception time and not at dispensing time not at the administration/dispensing time.[2]

The EMVS repositories system shall hold the following:

- Static data (i.e., the information listed under Article 33(2) of Commission Delegated Regulation (EU) No 161/2016) equivalent to manufacturers' uploaded data;
- Dynamic data i.e.:

◦ *the status of the unique identifier, i.e., active or decommissioned. In the case of "de-commissioned" also the detail, e.g. recalled, stolen, etc.;*

[2] European Alliance for Access to Safe Medicines (2020) *Patient safety and the implementation of the FMD*

◦ *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.*

- **Since pharmacists decommission at medicine reception and not at medicine dispensation the information that EMVS could provide (if the right functionalities are in place) is the medicines that hospitals have decommissioned at the reception time. 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 available stocks.**

How to improve the visibility of stocks in hospitals in the EU?

The medication management pathway in hospitals is a complex activity, covering ordering, reception, storing, prescription, compounding, distribution among wards and departments, dispensing/ administration to patients, and monitoring.

Medicine stocks are received and stored in the hospital pharmacy warehouse and then distributed to wards to be administrated/dispensed to patients. Hospital Pharmacists compound some infusion preparations for critical areas like oncology and intensive care units.

Manual shelves and traditional inventory systems in hospitals often face several inefficiencies that can impact the overall management of medicine stocks. Here are some key challenges associated with manual shelves and their implications:

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 continuously and to respond promptly to emerging shortages.

Delayed Response to Shortages: Without real-time data, it is difficult to anticipate and manage shortages effectively. Hospitals may not realize they are running low on certain medications until it is too late, 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 not only poses a safety risk but 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 wastage.

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 data leads to silos, where different departments may not have visibility into each other's inventory levels, hindering efficient resource sharing and redistribution.

The best way to eliminate the inefficiencies coming from the manual management of medication inventory in hospitals is the automation and digitalization of the process.

1. Inventory Medicine Management Robots

These robots are generally placed in the Pharmacy warehouse to receive and store most of the medication ordered by the hospital.

Integration of Inventory Medicine Management - Robots with Pharmacy Inventory Management Systems Pharmacy Software

- **Automated Inventory Management:**
  - Medicine robots are equipped with advanced sensors and software to track inventory levels in real-time. They can automatically update the pharmacy system with the current stock status, including the quantity, location, and expiration dates of medications.

- **Seamless Order Processing:**
  - When a medication order is placed in the pharmacy system, the integrated robots can retrieve the correct medication from storage and prepare it for dispensing. This process reduces manual handling and speeds up order fulfilment.

- **Real-Time Data Synchronization:**
  - The integration ensures that both the medicine robots and the pharmacy systems share real-time data. This includes updating inventory levels, tracking medication usage, and monitoring restocking needs.

- **Automated Restocking:**
  - Based on inventory data, the robots can autonomously move medications to and from storage areas, ensuring that frequently used medications are readily available and that stock levels are maintained efficiently.

- **Enhanced Accuracy and Safety:**
  - Robots can use barcoding, RFID, and other identification technologies to verify medications during dispensing. This reduces the risk of errors and ensures that patients receive the correct medications.

- **Integration with Electronic Health Records (EHR):**
  - The robots can be connected to EHR systems to verify patient prescriptions and ensure that the right medications are dispensed according to physician orders.

2. Automated Dispensing Cabinets (ADCs)

Automated Dispensing Cabinets (ADCs) are systems used in healthcare settings, primarily in hospital wards, to securely store, dispense, and manage medications.

Integration of ADCs with Pharmacy Inventory Management Software

- **Communication and Data Sharing:**
  - ADCs communicate with pharmacy management systems in real-time, ensuring that all medication orders, inventory updates, and patient information are synchronized across both systems.

- **Order Processing:**
  - When a physician prescribes medication, the order is entered into the Electronic Health Record (EHR) system, which is then transmitted to the pharmacy system. The pharmacy verifies the order and sends the dispensing instructions to the ADC.

- **Inventory Management:**
  - ADCs continuously update the pharmacy system with current inventory levels, medication usage, and expiration dates. This real-time data helps the pharmacy manage stock levels more effectively, reducing the risk of stockouts or overstocking.

- **Automated Replenishment:**
  - Based on the inventory data from ADCs, the pharmacy system can automatically generate restock orders. These orders are sent to the pharmacy or central supply, ensuring that the ADCs are consistently stocked with the necessary medications.

- **Patient Safety and Accuracy:**
  - The integrated system verifies patient information and medication orders, ensuring that the correct medication is dispensed. Barcoding and scanning technologies further enhance accuracy by cross-referencing the medication with the patient's prescription.

3. Pharmacy Inventory Management Software

Advanced software solutions are used to monitor medicine stocks in real time. They connect data from inventory management robots and automated dispensing cabinets in the wards, allowing real-time and accurate visibility of the medicine stocks in the hospital. These systems can track usage patterns, predict future needs, and alert staff when stocks are running low. This proactive approach helps in maintaining adequate supplies across all departments.

4. Data Analytics

By analysing historical data and usage trends, hospitals can forecast demand and adjust stock levels accordingly. This helps in optimizing inventory and ensuring that critical medicines are available when needed.

What is the situation in Europe?

The single reference is the study conducted by the ECAMET Alliance (www.ecamet.eu) in 13 European countries. The study shows that the penetration of pharmacy information systems, inventory robots and automated dispensing systems in wards is very low:

- **Pharmacy Information Systems**

  Survey results:
  - Only **66%** of hospitals have pharmacy information systems.

- **Inventory management robots**

  Survey results:
  - Only 25% of hospitals have inventory medication management robots. 75% of medication inventory in hospital pharmacies is managed manually , through manual shelves and manual counts.

- **Automated dispensing cabinets**

  Survey results:
  - Availability of automated drug cabinets is very limited. This is especially true in critical care areas such as ICUs, only **25%**, and Oncology wards **16%** and **12%** in Oncology-Ambulatory or One-day hospitals.
  - In those hospitals where they are available the average number varies between 2.2 - 2.5. Considering the number of different wards in a hospital where medication is administrated/dispensed to patients, the average number looks very low.

Conclusions

The role of hospitals will be critical in future healthcare crises as the COVID crisis has demonstrated. Visibility of critical medicines in hospitals, real-time in electronic systems is fundamental to ensure data included in the ESMP is accurate and proper allocation of medicine stockpiles and the solidarity mechanism among Member States is properly deployed.

Since pharmacists decommission at medicine reception and not at medicine dispensation the information that EMVS could provide (if the right functionalities are in place) is the medicines that hospitals have decommissioned at the reception time. 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 available stocks.

It is not possible to get real-time and accurate medicine stock level information without automation and digitalization of medication management: inventory robots and automated dispensing cabinets connected to Pharmacy inventory management software, supported if possible by Data analytics. The level of penetration of this system in the EU, as the ECAMET survey suggests, is very low.

RECOMMENDATIONS FOR HERA

Therefore, we recommend HERA to :

1) Incorporate in the Critical Medicines Act the need to digitalise and automate medication management systems in EU hospitals to drive real-time and accurate stock and demand visibility in the ESMP;

2) Include within the Medicines Alliance, one project around digitalization and automation of medication management in the EU hospitals with the aim of achieving 90% penetration by 2026, supported by one specific chapter in the EU4Health program;

3) Disseminate best cases of Member states, Regions or Hospitals investing in digitalization and automation of medication management to generate real-time and accurate data on stocks and demand of medicines in hospitals.

For any inquiries, please contact Ms. Eleonora Varntoumian, Policy Officer at the European Health Management Association (EHMA) at eleonora.varntoumian@ehma.org.