EHMA
European Health Management Association

LEVERAGING DIGITALISATION AND AUTOMATION FOR CONTROLLED SUBSTANCES MANAGEMENT IN EUROPEAN HOSPITALS

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EXECUTIVE SUMMARY

The misuse and diversion of controlled substances in European hospitals pose significant risks to patient safety, healthcare integrity, and regulatory compliance. Despite the critical nature of controlled substances in treatment, their potential for abuse necessitates stringent oversight - yet current hospital practices across the EU remain fragmented and largely reliant on manual processes.

A recent report by the European Association of Hospital Pharmacists (EAHP) and the EHMA's survey of National Competent Authorities (NCAs) reveal widespread challenges in managing controlled substances. These include administrative burdens, inconsistent digitalisation, limited interoperability between systems, and gaps in national legal frameworks. Over 40% of surveyed pharmacists identified core management processes such as registration, administration, and dispensing as major obstacles. Storage, acquisition, and documentation issues further compound these difficulties, especially in under-resourced or smaller healthcare settings.

Disparities across EU Member States in regulation and digital adoption exacerbate the problem. While some countries, like Poland and Belgium, have made strides in digital tracking and reporting, others still rely heavily on paper-based systems, lacking real-time oversight. Without harmonised standards or sufficient infrastructure, efforts to ensure accountability and prevent diversion are undermined.

Digital transformation offers a clear path forward. Advanced technologies such as electronic prescribing, automated dispensing, and barcode tracking can improve traceability, reduce errors, and enhance compliance. A strong 88% of NCA respondents support transitioning to digital control systems, underlining the urgency for coordinated action.

To address these challenges, this paper recommends four key policy actions:

- **Accelerate the digitalisation of controlled substances management** in hospitals. The adoption of electronic prescribing, automated dispensing, and advanced tracking solutions can reduce human error, enhance regulatory compliance, and improve efficiency by streamlining workflows.
- **Harmonise EU regulations** to ensure consistent national approaches to digital record-keeping and reporting for controlled substances.
- **Provide targeted funding to support the digital transformation of controlled substances management,** particularly in smaller or resource-constrained facilities.
- **Promote good practices** by sharing successful models across Member States.

Digital solutions can significantly strengthen medication governance, improve patient safety, and enhance the overall resilience of healthcare systems across Europe. A coordinated EU-wide approach is essential to realise these benefits and mitigate the risks associated with controlled substance misuse.

INTRODUCTION

The diversion and misuse of controlled substances within hospital settings represent a growing concern across the European Union. These incidents - often involving health and care professionals such as doctors, nurses, or pharmacists - can result in the unauthorised use or distribution of prescription medications. Beyond breaching legal and ethical standards, such actions jeopardise patient safety, erode public trust, and expose health care systems to significant operational and reputational risks.

Managing controlled substances is a complex, highly regulated process that spans hospital pharmacies, wards, emergency departments, and surgical units. It requires stringent record-keeping, secure storage, and physical reconciliation of stock. Yet, many hospitals face persistent challenges - such as fragmented workflows, limited storage infrastructure, and reliance on manual systems - that increase the risk of diversion and reduce overall efficiency.

Hospital managers play a crucial role in prioritising safety and accountability in this context. Incidents of medication theft or misuse not only lead to financial and infrastructure-related losses but also compromise the quality of patient care, endanger staff, and raise operational costs, including higher insurance premiums[1]. Their leadership is vital in driving change and investing in systems that reduce these risks.

Despite the importance of robust controls, most hospitals across Europe continue to depend on disconnected or semi-digital systems for managing controlled substances. Even where digital tools are in place, key processes - such as dispensing and administration - often remain reliant on human oversight, creating gaps in traceability and compliance.

In response, the European Association of Hospital Pharmacists (EAHP) convened a Special Interest Group on Controlled Substances Management and published a report in November 2024[2]. Building on this, a survey of National Competent Authorities (NCAs) was conducted to assess national-level frameworks and identify opportunities for digital transformation in hospital settings.

This paper explores how digitalising the management of controlled substances can improve security, streamline operations, and strengthen regulatory compliance. It highlights the systemic challenges faced by healthcare institutions and offers policy recommendations to support safer, more resilient hospital environments across the European Union.

[1] 'Brasola, L., Di Giorgio, D., La Bella, F., Pani, M., & Turchetti, G. (2018). Medicine Thefts and Their Prevention: Current Approach In Italy And Future Perspectives. Medicine Access @ Point of Care, 2, 1–6.' Bing, https://www.oecd.org/en/publications/2022/09/the-economics-of-medication-safety_e79d5329.html.

[2] EAHP — European Association of Hospital Pharmacists, Final Report Special Interest Group on Controlled Substances Management, November 2024. Available at: https://eahp.eu/hospital-pharmacy-practice/sigs/controlled-substances-management/.

1. BACKGROUND INFORMATION

The management of controlled substances is a critical aspect of patient care and safety, ensuring proper oversight to prevent misuse and diversion throughout the medication lifecycle - from prescription to administration and disposal. While these substances are essential for medical treatment, their potential for abuse and illicit trafficking necessitates strict regulation and monitoring.

Across Europe, hospital managers and pharmacists play a key role in managing controlled substances, but they often face challenges due to time-consuming record-keeping processes, physical stock reconciliation, and limited storage capacity. Many hospitals still rely on disconnected manual systems, while even digitalised processes frequently require human intervention in dispensing and administration, increasing the risk of inefficiencies.

Internationally, efforts to enhance controlled substance management have also been made. The American Society of Health-System Pharmacists (ASHP) has developed a structured roadmap to guide institutions in designing and implementing controlled substance diversion prevention programmes[3]. This framework focuses on accountability and effective management at three levels: core administrative elements, system-level controls, and individual-level controls. Such structured approaches highlight the importance of proactive strategies to strengthen oversight and security in medication management.

While the EU sets broad guidelines and legal instruments, such as the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the EU Drugs Strategy, significant variation remains in how Member States implement these regulations. These differences can lead to challenges in ensuring equitable access to necessary medications and in preventing substance misuse, with inconsistencies in hospital reporting, prescribing practices, and the management of controlled substances across various countries.

2. CHALLENGES IN CONTROLLED SUBSTANCES MANAGEMENT

Managing controlled substances is critical for patient care and safety, ensuring proper use while preventing misuse and diversion throughout the medication management cycle - from prescription to administration and disposal. However, this process remains highly complex and time-consuming. A key challenge in hospital settings, including both pharmacies and wards, is the heavy administrative burden of mandatory record-keeping and physical stock reconciliation[4]. These tasks are often further complicated by insufficient storage capacity and security measures. Across Europe, hospital managers and pharmacists predominantly rely on fragmented, manual systems for controlled

[3] Clark J, Fera T, Fortier C, Gullickson K, Hays A, Murdaugh L, Ogden R, O'Neal B, Rush J, Vest T. ASHP Guidelines on Preventing Diversion of Controlled Substances. Am J Health Syst Pharm. 2022 Dec 5;79(24):2279-2306. doi: 10.1093/ajhp/zxac246. PMID: 36208462.

[4] Kay, Liz, and Ron Pate. 'How to Handle Controlled Drugs in Hospitals Using Automation and Digital Systems'. The Pharmaceutical Journal, 6 Apr. 2022, https://pharmaceutical-journal.com/article/feature/an-advisory-document-around-the-handling-of-controlled-drugs-in-hospitals-using-automation-and-digital-systems.

substance management. Even in cases where digital solutions are in place, prescribing and administration frequently require manual oversight, increasing the risk of inefficiencies, errors, and potential security gaps. This reliance on human intervention underscores the need for more integrated and automated systems to enhance accuracy, streamline workflows, and strengthen overall medication management.

2.1. ACCESS AND TRACEABILITY OF MEDICINES

According to the EAHP Special Interest Group on Controlled Substances Management report, 48% of respondents (n=168) identified the registration process as their greatest challenge in managing controlled substances. Additionally, 42% (n=147) of respondents cited administration to patients, and 41% (n=143) pointed to dispensing as key issues. Storage was the primary concern for 25% (n=89) of respondents, while 16% (n=55) reported acquisition as their biggest challenge. Moreover, 25% (n=90) indicated that their greatest challenge was either not listed or was another issue entirely.

Among the 16% (n=56) of respondents who mentioned additional challenges, several issues were highlighted, including limited access to effective digital tools, which resulted in problems such as poor interoperability between software systems, duplication of tasks, and inconsistencies between electronic and paper prescriptions. Other recurring challenges included the destruction and return of unused medicines from wards and the management of residual substances, like half-used ampoules. In addition, many respondents identified problems within the hospital wards themselves, including difficulties with stock management, expiry date control, documentation of dispensing, borrowing between wards, and control over medications. Further issues cited included challenges in prescribing, the lack of audits, difficulties with registration processes for authorities, drug diversion, limited human resources, and medication shortages.

2.2. LACK OF COORDINATION AND FRAGMENTATION

The survey also explored the obstacles preventing respondents from overcoming these challenges. 26% (n=47) of respondents believed that controlled substances management was a priority for the pharmacy team but not for hospital management. Additionally, 23% (n=72) expressed a desire to address these challenges but lacked capacity, while 8% (n=27) lacked capability, and 22% (n=69) lacked the legislative authority to make the necessary changes.

Furthermore, respondents highlighted additional challenges in the 'Other' category, such as insufficient budget and financial resources, technical implementation issues, a lack of appropriate tools and software, and the sheer volume of controlled substances. Despite controlled substances management being a priority for hospital pharmacists, many respondents indicated that it remains a challenge for nurses and doctors, either due to their limited understanding of the requirements because it is not a priority for them or due to their limited capacity on the wards to implement these requirements.

2.3. LACK OF STANDARD LEGAL FRAMEWORK AT EU LEVEL

While EU directives and regulations provide a broad legal framework, the implementation of controlled substances policies varies significantly across Member States. National governments have the discretion to tailor regulations to their local context, which can lead to inconsistencies in enforcement and

accessibility. Disparities in regulatory approaches can undermine the effectiveness of EU strategies and create loopholes for traffickers and abusers. Individuals with substance use disorders (SUDs) often face social exclusion and stigmatisation, which can deter them from seeking treatment[5]. Policies focused solely on criminalising drug use may exacerbate these challenges. A more integrated public health approach is necessary to support recovery and reintegration, but such measures are not uniformly implemented across Europe.

Many EU Member States exhibit weak legal frameworks for managing controlled substances in hospitals, creating vulnerabilities to drug diversion[6]. For example, Slovakia's approach requiring hospitals to report consumption of controlled substances only once a year lacks the necessary frequency for effective oversight, making it easier for discrepancies to go undetected. Similarly, in Lithuania, reports on controlled substances are submitted quarterly rather than in real time. In Belgium, while there is a computerised tracking system (NARCOREG) for controlled substances until their purchase, no automatic reporting to the national authority exists afterwards, weakening post-purchase oversight. Sweden's reliance on individual caregivers to establish their procedures, without strict national enforcement on how controlled substances should be managed, creates further inconsistencies and potential gaps in security. These examples highlight deficiencies in regulatory frameworks that fail to ensure rigorous control, frequent auditing, and systematic reporting, thereby increasing the risk of diversion.

Furthermore, according to the EHMA's survey on the state of controlled substances management in hospitals within EU Member States[6], only 6 out of 16 surveyed Member States (Poland, Finland, Belgium, Sweden, Estonia, and Spain) explicitly reference digitalisation in their national regulations on controlled substances. The lack of standardised national regulations on the digitalisation of medicines reporting and tracking across EU Member States highlights the need for harmonised EU-wide regulatory frameworks. While Poland has implemented an integrated digital system (ZSMOPL) for daily monitoring and reporting of controlled substances, other countries, such as Sweden, still rely on varying documentation methods, including paper-based records. Belgium employs an electronic system for initial control but lacks automatic reporting mechanisms, requiring hospitals to register incidents manually. These discrepancies create inefficiencies and potential risks in monitoring medicine distribution, underlining the need for a unified EU regulatory approach to digital reporting systems to ensure transparency, security, and real-time oversight across Member States.

3. CURRENT SYSTEM IN EUROPEAN COUNTRIES

The European Association of Hospital Pharmacists conducted a country-specific mapping process to thoroughly examine the regulatory frameworks for managing controlled substances across European countries[7]. The mapping aimed to identify the similarities and differences in national regulations regarding the acquisition,

[5] Norms, Committee on the Science of Changing Behavioral Health Social, et al. 'Understanding Stigma of Mental and Substance Use Disorders'. Ending Discrimination Against People with Mental and Substance Use Disorders: The Evidence for Stigma Change, National Academies Press (US), 2016. www.ncbi.nlm.nih.gov , https://www.ncbi.nlm.nih.gov/books/NBK384923/.

[6] Annex I – EHMA Survey: Controlled Substances Management

[7] EAHP — European Association of Hospital Pharmacists. Controlled Substances Management – Special Interest Group (SIG). Available at: https://eahp.eu/hospital-pharmacy-practice/sigs/controlled-substances-management/.

registration, dispensing, storage, and electronic tracking of controlled substances in hospital settings to better understand the level of digitalisation in each country and to identify any obstacles or challenges. The mapping process gathered legislative data from 16 European countries, providing a snapshot of controlled substances management practices in 2024. However, due to the limited number of responses, it cannot be considered fully representative of all legislative requirements for controlled substances management across Europe.

3.1. ACQUISITION OF CONTROLLED SUBSTANCES

According to the EAHP study, the acquisition of controlled substances in hospitals varies with three main methods observed. In most countries, the process is similar to that for other medications, with hospital pharmacists ordering directly from approved marketing authorisation holders. However, some countries, like Greece, require prior approval from the Ministry of Health or National Health Authority before purchasing certain controlled substances, which can cause delays due to backlogs. Smaller countries, such as Serbia and Malta, use a more centralised system, where controlled substances are obtained through public tenders or central repositories, although staff shortages can limit access. Portugal combines these methods based on the substance risk level.

3.2. REGISTRATION OF CONTROLLED SUBSTANCES

In all surveyed countries, hospital pharmacists are required to maintain comprehensive documentation for registering and tracking controlled substances. This includes product details, tracking information such as quantity, stock, purpose, and the person responsible for changes, as well as order forms and prescription numbers. This documentation is crucial for ensuring secure management and appropriate use, providing transparency and accountability from procurement to dispensation. Some countries, like Portugal, mandate regular reporting to health authorities, such as quarterly and annual summaries. The transition to digital systems for record-keeping is uneven, with some countries relying on manual methods. While digital tools could streamline processes, their adoption is voluntary and varies by country, leading to increased workload and potential errors in countries using paper-based systems.

3.3. DISPENSING OF CONTROLLED SUBSTANCES

In hospital settings, controlled substances are dispensed based on prescriptions, either paper or electronic, containing essential information like the patient's name, prescribed dose, active ingredient, and quantity. Hospital pharmacists or suppliers must verify the identity of the recipient before dispensing the controlled substances. They are also responsible for providing necessary information, such as usage, side effects, and disposal. Additionally, any transfer or dispensing of the substances must be recorded. A major challenge identified is the inconsistent digitalisation across hospitals, where manual dispensing and documentation increase the workload and create traceability gaps.

3.4. STORAGE OF CONTROLLED SUBSTANCES

Storage protocols for controlled substances generally focus on secure, locked storage areas such as rooms, cabinets, or safes. Slovakia is unique in requiring only narcotics to be stored in a safe, while other controlled substances follow standard medicine storage practices. Some countries, like Belgium and Greece, enforce

regular security checks, while Germany requires approval from the Controlled Substance High Authority for room plans before use.

3.5. DIGITALISATION OF REGISTRY

The digitalisation of controlled substance registries in hospital settings varies widely across European countries, with progress remaining voluntary and dependent on the availability of digital tools. Some countries, like France, have implemented a Drug Traceability Software in certain hospitals to improve transparency and accountability, while Germany allows hospitals to use electronic systems with official approval. In Belgium, from 1 September 2023, all narcotic and psychotropic drug transactions must be registered via www.narcoreg.be within 30 days, replacing paper forms. Operators must verify deliveries, report changes, and follow Good Distribution Practices (GDP) rules[8]. Pharmacies should notify the relevant authorities of any updates. In Slovakia, controlled substance movements are recorded in hospital information systems, though interoperability issues increase the workload for pharmacists. However, many countries still rely on disparate IT systems, and in Portugal, digital registries are mostly available to community pharmacists. Addressing these disparities by improving digital infrastructure, promoting interoperability, and investing in standardised systems will help streamline controlled substance management, enhance traceability, and improve regulatory compliance.

3.6. CONCLUSIONS FROM THE SURVEY

The survey reveals significant variability in the management of controlled substances in European hospitals, underscoring the limited and inconsistent digitalisation of controlled substance management processes. This lack of digital infrastructure results in increased administrative workloads for hospital pharmacists, hindering their ability to comply with legislative requirements. The process of registering and tracking controlled substances remains highly complex, relying on manual documentation that must be meticulously maintained to ensure secure and appropriate management. While some hospitals have adopted digital tools, challenges related to interoperability with existing hospital infrastructures persist, complicating processes and impacting traceability. Moreover, limited human resources, particularly in the areas of dispensing and storage, exacerbate the difficulties in managing controlled substances. These issues are particularly pronounced in smaller hospitals, where staffing limitations further complicate compliance with controlled substance regulations.

To address these challenges, the survey calls for the evolution of regulatory frameworks to better support digital advancements and adapt to workforce needs. Policy measures should prioritise the promotion of interoperability between electronic prescription systems and pharmacy databases, ensuring the seamless transmission of prescription while maintaining necessary security and privacy standards. Additionally, targeted training programmes and resources should be made available to hospital staff to enhance digital literacy, facilitating the transition to electronic workflows and improving the overall efficiency of controlled substance management across Europe.

[8] Federal Agency for Medicines and Health Products (FAMHP), Online Application for Narcotic Drugs Order Forms: Narcoreg.be. Available at: https://www.famhp.be/en/human_use/particular_products/specially_reglemented_substances/narcotics_psychotropics/reporting_national_trade.

4. RECOMMENDATIONS TO MANAGE CONTROLLED SUBSTANCES

Traditional methods of managing controlled substances in health care settings are increasingly inadequate. Manual processes, which still dominate many health care systems, consume significant time, reducing efficiency and increasing the risk of errors, misuse, and diversion. These inefficiencies hinder real-time tracking and make compliance with regulatory requirements more complex.

Survey data from National Competent Authorities further highlight these concerns[9]. Respondents reported significant barriers to effective controlled substance management, including outdated paper-based processes, inconsistent tracking mechanisms, and limited interoperability between systems. Additionally, the survey identified obstacles to moving to digital medication control systems in hospitals, such as outdated legislation, funding requirements, lack of human resources, and missing interoperability. These findings underscore the urgent need for digital transformation to address these persistent challenges.

By integrating advanced technologies into medication management pathways, such as electronic prescribing, automated dispensing, and barcode tracking, health care institutions can enhance accountability, strengthen security, and ensure regulatory compliance while reducing human error and the risk of fraud. A striking 88% of NCA survey respondents report being in favor of transitioning to digital control systems in hospitals and implementing digital reporting systems to enhance efficiency for both their agency and national hospitals[9].

To overcome these barriers and create safer, more resilient health care environments, it is essential to:

- **Accelerate the digitalisation of controlled substances management.** The adoption of electronic prescribing, automated dispensing, and advanced tracking solutions can reduce human error, enhance regulatory compliance, and improve efficiency by streamlining workflows.
- **Standardise national regulations at the EU level on controlled substances management.** The European Commission and EMA shall work with Member States to develop one standard regulation around controlled substances controls and reporting, incorporating digital record-keeping and digital reporting mechanisms.
- **Allocate dedicated funding for the digital transformation of controlled substances management.** Financial support will be critical for health care facilities, particularly smaller hospitals and pharmacies, to transition from manual to digital systems. Integration into broader health digitalisation policies at both EU and national levels will further accelerate health data interoperability and the visibility of stocks.
- **Share good practices.** Disseminate good practices from Member States, regions or hospitals in the digital management and reporting of controlled substances.

[9] Annex I – EHMA Survey: Controlled Substances Management

CONCLUSIONS

The management of controlled substances in European hospitals remains a critical yet persistently under-addressed issue, with significant variations in regulatory frameworks, digital maturity, and operational capacity across Member States. Despite the high stakes - including risks to patient safety, regulatory non-compliance, and financial losses - many hospitals continue to rely on outdated, manual processes that are ill-equipped to manage the complexity and volume of controlled substance workflows.

The findings from the EAHP Special Interest Group and the survey of National Competent Authorities reveal that pharmacists and hospital staff face mounting administrative burdens, limited digital infrastructure, and inconsistent national legislation. These challenges are particularly acute in smaller hospitals or those with fewer resources, where the lack of interoperability, staffing constraints, and manual documentation further increase vulnerability to diversion and error.

Digital transformation is not only a strategic necessity but also a clear opportunity to strengthen governance, improve traceability, and reduce the risk of misuse. However, digitalisation efforts remain fragmented, voluntary, and often unsupported by national policies or dedicated funding. While some countries have taken important steps - implementing digital registries or automated reporting systems - others continue to depend on paper-based records and isolated IT tools, creating gaps in oversight and accountability.

To move forward, coordinated action is needed at both EU and national levels. Strengthening regulatory frameworks, investing in interoperable technologies, and promoting shared best practices will be essential to ensure secure, efficient, and transparent controlled substance management across Europe.

ANNEX I – EHMA SURVEY: CONTROLLED SUBSTANCES MANAGEMENT

EHMA, on behalf of the EPACT Alliance for the digitalisation of hospitals' medication management pathways[10], conducted a survey on the state of controlled substances management in hospitals within EU Member States, targeting National Competent Authorities (NCAs). Through 18 focused questions, the survey examines national and institutional practices, including regulatory frameworks, reporting processes, satisfaction with current systems, and the potential for digitalisation. Additionally, it explores awareness of automated dispensing systems, barriers to digital adoption, and stakeholder readiness for regulatory mandates on digital systems. In total 16 NCA representatives answered the survey, representing 15 EU Member States[11].

When asked about the procedures for controlling and reporting on controlled substances managed by hospitals in their respective country, the responses revealed a wide range of approaches. Key themes include regulatory frameworks, monitoring mechanisms, record-keeping practices, and the extent of digitalisation in the processes:

- Regarding regulatory frameworks, all countries operate under specific national legislation or guidelines to regulate controlled substances. For example, Italy and Spain emphasise adherence to comprehensive legal requirements, ensuring every movement of controlled substances is meticulously documented and recorded. In Cyprus, pharmacists oversee narcotics management, and regulatory inspectors conduct regular checks.
- Concerning monitoring mechanisms, several Member States employ structured systems to ensure compliance. Poland's ZSMOPL program exemplifies a centralised, daily monitoring system that integrates retail and wholesale distribution data. Similarly, Spain uses automated systems (SADME) integrated with electronic prescribing and logistics systems. In contrast, Luxembourg mandates annual reporting, reflecting less frequent but detailed oversight.
- Pertaining to record-keeping practices, manual and digital records are both in use, depending on the country. Latvia's strict accounting journals and Malta's designated registers signify traditional approaches, where every transaction is logged and validated. By contrast, countries like Belgium and Finland incorporate electronic systems to varying extents, although manual processes still coexist in many cases.
- Lastly, regarding the state of digitalisation, responses revealed that the integration of digital systems varies significantly. Countries like Poland and Spain have advanced systems enabling electronic tracking and reporting, while Estonia and Finland highlight partial digitalisation. Estonia's use of electronic medicine drawers and unique identifiers underscores the potential of technology to enhance accuracy and security. However, countries such as Sweden note that digitalisation is not yet universally adopted, with some caregivers still relying on paper-based documentation.

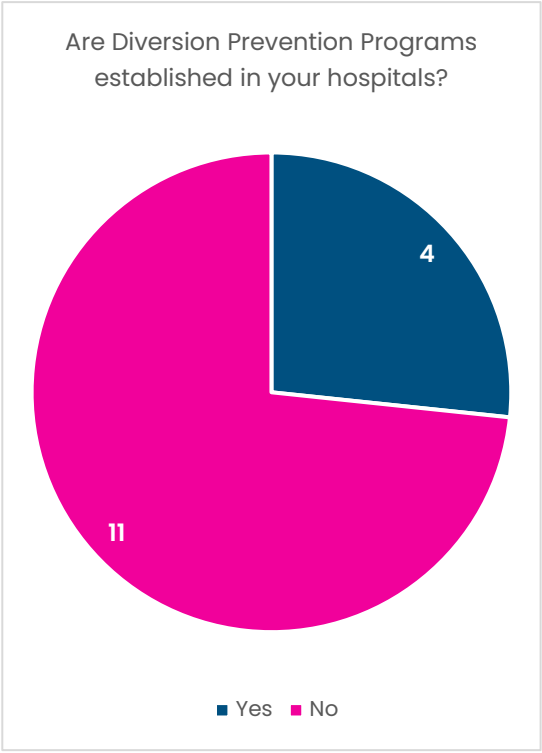
All respondents mentioned that their countries have national regulations ruling over the controlling and monitoring of controlled substances. For instance, Lithuania's framework is governed by the Narcotic Drugs and Psychotropic Substances Law of 1977 and complemented by ministerial orders, such as the 2006 directive on the storage and recording of controlled substances. Similarly, Estonia enforces a comprehensive regulatory system under the Act on Narcotic Drugs and Psychotropic Substances and Precursors, which includes licensing requirements, strict security measures, detailed record-keeping, reporting obligations, and

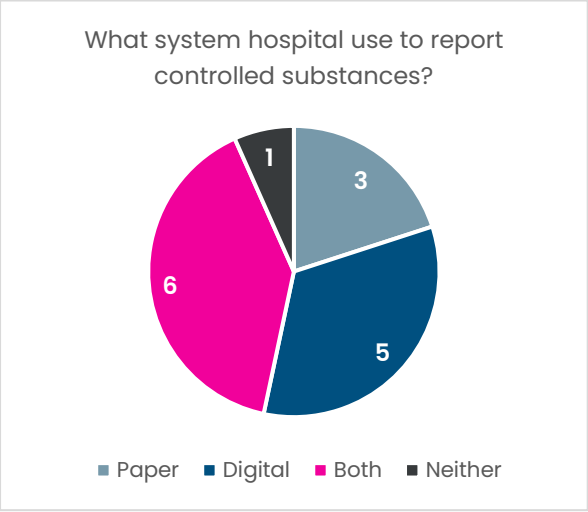
[10] EHMA, 'EPACT - The AlliancE for the Digitalisation of hosPitAls Medication Management Pathways'. https://ehma.org/projects/epact/.

[11] Belgium, Bulgaria, Cyprus, Estonia, Finland, Italy, Latvia, Lithuania, Luxemburg, Malta, Poland, Portugal, Slovakia, Spain, Sweden.

regular inspections by the State Agency of Medicines. Belgium implements stringent measures, legally requiring both handwritten and electronic prescriptions secure storage of narcotics, and specific procedures for transportation and inventory maintenance under the pharmacist's responsibility. Spain's Royal Decree 1675/2012 requires comprehensive tracking of controlled substances and annual reporting by hospitals, which use automated security cabinets integrated with electronic prescribing systems. Italy's DPR 309/90 legislation demands detailed documentation and periodic inspections, with validated registers for hospital departments. Other responses referenced general legal provisions, such as Luxembourg's Grand-ducal regulation of 1974 and Malta's Dangerous Drugs Ordinance, which collectively highlight the universal emphasis on monitoring, documentation, and safety in handling-controlled substances.

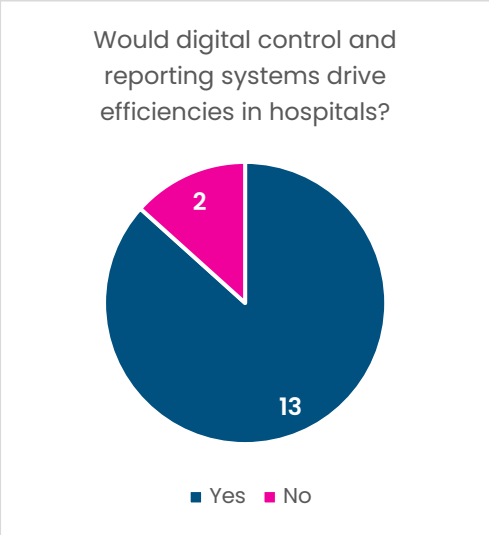
Regarding Diversion Prevention Programmes (DPP), the majority of respondents, from 11 out of 15 Member States, reported that DPPs are neither mandatory nor established in national hospitals. The four countries that have DPPS established in hospitals due to them being mandatory, are Spain, Latvia, Finland, and Poland. Poland demonstrates a comprehensive approach to diversion prevention in hospitals, underpinned by its mandatory ZSMOPL tele informatic system, which ensures real-time tracking of controlled substances. Hospitals are further supported by mandatory procedures aimed at preventing drug diversion, aligned with clinical guidelines, pharmacotherapy rationalisation, and legal requirements. Continuous training for hospital staff, the establishment of specialised committees such as those for pain pharmacotherapy rationalisation, and the integration of psychological and therapeutic support reflect a multifaceted strategy.





The format used to report controlled substances most frequently consists of a mixture of paper-based and digital systems (n=6), followed by fully digital systems (n=5), and fully paper-based systems (n=3). Belgium is the only Member State to report not having either system in place.

Regarding the frequency of reporting controlled substances to NCAs, most respondents mentioned that this information is passed on annually (n=9), followed by monthly (n=3), and quarterly (n=2). In Sweden, no reporting takes place between hospitals and the NCA.



Half of all respondents believe their current system is efficient, while the other half perceives their system as inefficient. Additionally, half of all respondents are aware of new automated dispensing systems for controlled substances and their capabilities to electronically manage and report. The vast majority of NCA representatives (88%, n=13) believe that transitioning to digital reporting systems would enhance efficiency for both their agency and national hospitals. However, respondents mentioned the current lack of digital systems in place in hospitals, funding requirements, as well as a lack of personnel as the main barriers to transitioning to digital management and reporting.

75% of respondents (n=12) mentioned being in favour of promoting a regulation to mandate the digital management and reporting of controlled substances in hospitals in their respective countries. While all countries have national regulations governing these processes, the extent of digitalisation and efficiency varies widely. Some EU Member States, such as Poland and Spain, showcase advanced digital systems, while others rely on a mix of manual and electronic methods. Most respondents see potential in transitioning to fully digital systems to improve efficiency and compliance. However, barriers such as funding constraints, personnel shortages, and the lack of existing digital infrastructure hinder progress. Encouragingly, the vast majority of respondents support the introduction of regulations to mandate digital systems, signalling readiness for a harmonised and modernised approach to controlled substances management in European hospitals.

ANNEX II - EXISTING TOOLS TO SUPPORT AND ADVANCE THE DIGITALISATION OF THE MEDICATION PROCESS AND THEIR LEVEL OF USE

HEALTHCARE TECHNOLOGIES

CENTRALISED ROBOTIC PHARMACY SYSTEMS

A solution that stores medications in large quantities and automates retrieval. It tracks inventory, stock levels, expiration dates, and usage in real-time. Integrated with pharmacy systems, it manages automatic ordering and replenishment, while ensuring secure access for authorised personnel.

Purpose: The robot is integrated into a broader management software that allows seamless tracking of medication stored inside and outside of a dispensing robot.

Impact

1. **Enhanced security:** Medication robots provide secure storage with controlled access through user authentication, such as biometric scanning or PIN codes, ensuring only authorised personnel can access medications.
2. **Reduced human error:** By automating dispensing processes, these systems minimise errors and ensure precise handling, reducing risks associated with manual intervention.
3. **Improved inventory management:** Robots track medication quantities, expiration dates, and lot numbers in real time, enabling the detection of discrepancies. Software extends inventory management to medications stored outside the robot.
4. **Auditing and reporting:** Systems generate detailed records of all transactions, including dates, times, and user information, allowing for analysis to identify irregularities.

AUTOMATIC CABINETS (ADCs)

These cabinets are automated and computer-controlled, allowing healthcare staff to access medications via secured login. They track medication usage, manage inventory, and generate reports for auditing purposes. They often have barcode scanning and integrated software to track and verify medication dispensation.

Purpose: They are typically located in patient care areas, such as nursing units, emergency departments and operating rooms, and are accessed through individual user accounts with unique credentials.

Impact

1. **Enhanced security:** ADCs securely store medications, granting access only to authorised personnel via fingerprint or badge authentication.
2. **Controlled access and auditing:** ADCs log user, time, and medication details for each transaction, supporting monitoring and investigation of irregularities.
3. **Inventory management:** ADCs track medication quantities, alerting staff to restock and minimising shortages or overstocking.
4. **Restricted access to high-risk drugs:** ADCs limit access to controlled substances, requiring witness confirmation for certain medications to prevent unauthorised use.
5. **Electronic Health Record (EHR) integration:** ADCs integrate with EHRs for real-time data exchange, ensuring accurate medication dispensing and efficient management.
6. **Electronic registers:** ADCs enable digital tracking of medication movement, reducing paperwork and providing a transparent, centralised record.

ANAESTHESIA DRUG CABINETS OR CARTS

Anaesthesia drug cabinets or carts are typically designed with compartments tailored for anaesthetic agents, sedatives, muscle relaxants, and other medications specific to anaesthesia care. They often include features like lockable drawers, clear labelling, and secure, organised storage to prevent medication errors during high-stakes procedures.

Purpose: Anaesthesia drug cabinets play a critical role in operating rooms, providing anaesthesiologists with immediate, organised, and secure access to anaesthetic medications, sedatives, and emergency drugs. They help ensure safe drug administration, support compliance with medication regulations, and reduce the risk of errors.

Impact

1. **Secure storage:** Medication safety cabinets provide locked storage for anaesthesia drugs, featuring controlled access through electronic locks or biometric authentication to ensure only authorised providers can access them.
2. **Limited access:** Designed for anaesthesia professionals, these cabinets use individual credentials like PINs or badges to restrict access, documenting all transactions.
3. **Enhanced tracking and auditing:** Advanced tracking features log user, time, date, and medication details for every transaction.
4. **Integration with documentation systems:** Some cabinets connect with anaesthesia documentation systems or EHRs, linking medication administration to records for improved accountability.
5. **Dose verification:** Technology ensures accurate dose dispensing, minimising risks from incorrect or manipulated doses.
6. **Audits and inventory management:** Regular audits and robust inventory practices help detect discrepancies, shortages, or unusual patterns in medication use.

NARCOTIC CABINETS

Narcotics are drugs, mainly opioids, used to relieve pain by acting on the central nervous system and are strictly regulated due to their potential for addiction and misuse. Such technology solutions make it easier to safely and securely store these drugs while simultaneously limiting and monitoring access.

Purpose: Narcotic cabinets have stricter security measures than other medication storage units, requiring reinforced locks, biometric access, and automated tracking. They are subject to stricter regulations, with real-time monitoring and auditing.

Impact

1. **Secure storage:** Medication cabinets provide locked, tamper-resistant storage for narcotics, using electronic locks, biometric authentication, or PIN codes to allow access only to authorised personnel.
2. **Limited access:** Access is restricted to trained health and care professionals, such as pharmacists and nurses, reducing opportunities for unauthorised use.
3. **Controlled dispensing:** Cabinets with automated systems require user authentication and track transactions, creating an audit trail to detect irregularities.
4. **Controlled cooling:** Cabinets can include secure refrigeration for controlled drugs, allowing single-item access with user authentication.
5. **Auditing and monitoring:** Electronic logs and reports enable regular audits, helping identify discrepancies or patterns of potential misuse.
6. **Inventory management:** Cabinets provide real-time stock monitoring, including expiry dates, ensuring accurate tracking and timely restocking.
7. **Education and training:** Training healthcare staff on risks and signs of diversion promotes accountability and a culture of reporting.

MEDICATION CABINETS FOR EMERGENCY WARDS

These cabinets offer secure storage with controlled access for authorised personnel, pre-organised compartments for quick retrieval, and real-time inventory tracking to monitor stock levels and prevent shortages. Some models integrate with hospital systems for automated restocking and may include temperature control for sensitive medications.

Purpose: Medication cabinets for emergency wards are designed to provide immediate access to essential medications needed for urgent and life-threatening situations. They ensure rapid retrieval of critical drugs to support emergency treatments while maintaining security and organisation.

Impact

1. **Secure storage:** Medication cabinets securely store drugs, including controlled substances, with reinforced construction and electronic locks, biometric authentication, or PIN codes to prevent unauthorised access.
2. **Limited access:** Cabinets restrict access to authorised health and care professionals using unique credentials like PINs or badges, reducing the risk of diversion.
3. **Controlled dispensing:** Automated systems require user authentication and record transactions, creating audit trails to identify irregularities and ensure medications are dispensed only for patient care.
4. **Enhanced inventory management:** Cabinets provide real-time stock visibility, tracking usage and expiration dates to identify discrepancies and prevent misuse.
5. **Emergency-specific medication configuration:** Cabinets prioritise quick access to essential medications, including controlled substances, while maintaining security.
6. **Auditing and monitoring:** Cabinets track all transactions, supporting regular audits to detect suspicious activities or patterns indicating potential diversion.

MEDICATION DISPOSAL CABINETS

These cabinets have tamper-resistant, locked compartments to prevent unauthorised access, segregated sections for different types of medication waste (e.g., hazardous, non-hazardous, controlled substances), and tracking systems to log disposals for compliance purposes. Some models integrate with waste management systems for automated disposal scheduling and regulatory reporting.

Purpose: A medication disposal cabinet is designed for the secure and compliant disposal of expired, unused, or controlled medications within health care facilities. It helps prevent drug misuse, contamination, and environmental harm while ensuring adherence to regulatory guidelines for safe pharmaceutical waste management.

Impact

1. **Secure design:** Disposal medication cabinets must feature tamper-resistant construction, electronic locks, or similar mechanisms to ensure only authorised personnel can access their contents.
2. **Limited access:** Access should be restricted to authorised staff using unique credentials like PINs or biometric authentication to prevent unauthorised entry.
3. **Controlled disposal:** Cabinets should include mechanisms like irreversible openings or destruction features to ensure safe disposal and prevent medication diversion.
4. **Monitoring and auditing:** Cabinets should track disposal activities, recording details like date, time, type, quantity, and personnel involved, with regular audits.
5. **Staff training:** Health and care professionals must be trained in proper disposal procedures, recognising diversion risks, and reporting suspicious activities.
6. **System integration:** Linking disposal cabinets to inventory systems enables real-time tracking, accurate documentation, and rapid identification of any issues.

E-PRESCRIPTION (eRx)

E-prescription systems include secure electronic transmission to pharmacies, real-time drug interaction checks, automatic dosage verification, integration with Electronic Health Records, and compliance with regulatory standards. Some systems also support refill management, controlled substance e-prescribing and clinical decision support.

Purpose: E-prescription systems are designed to digitise and streamline the prescribing process, allowing health care providers to electronically send prescriptions directly to pharmacies. They enhance patient safety, reduce medication errors, prevent prescription fraud, and improve workflow efficiency automating prescription tracking.

Impact

1. **Enhanced security:** E-prescriptions are harder to forge than handwritten ones, with digital signatures and encryption ensuring authenticity and preventing drug diversion.
2. **Real-time monitoring:** E-prescription systems provide real-time access to patient medication histories, helping detect drug interactions, duplicate prescriptions, or excessive quantities to prevent misuse.
3. **Accountability:** Digital prescriptions, including details of prescribers, patients, and medications, enable tracking and investigation of unusual patterns to detect diversion.
4. **System integration:** Integration with pharmacy and dispensing systems ensures real-time updates, reducing errors and manipulation, and promoting accuracy and accountability.
5. **Data Analytics:** E-prescription data can be analysed to detect anomalies, such as frequent prescriptions, early refills, or inappropriate combinations, aiding in identifying and addressing potential diversion.

E-COMPOUNDING: GRAVIMETRIC SYSTEMS

These systems use high-precision electronic scales to measure and verify each ingredient in real-time, ensuring exact dosage and formulation. They provide automated tracking and documentation, integrating with pharmacy management systems for compliance and audit purposes. Some models feature barcode scanning and Radio Frequency Identification (RFID) verification to prevent ingredient mix-ups, as well as closed-system workflows to maintain sterility and reduce contamination risks.

Purpose: Gravimetric e-compounding systems are designed to automate and enhance precision in pharmaceutical compounding by measuring ingredients based on weight rather than volume. They ensure high accuracy, consistency, and compliance with regulatory standards while minimising human error in preparing customised medications, especially in sterile and hazardous drug compounding.

Impact

1. **Accurate compounding:** Gravimetric systems ensure precise medication measurement by weight, reducing errors and variations, with full documentation to minimise risks of diversion.
2. **Controlled substances:** These systems offer precise handling of controlled substances, reducing the risk of diversion through inaccurate or manipulated doses.
3. **Audit trail:** Electronic records of compounding processes create a detailed audit trail, enhancing accountability and aiding in the detection of potential diversion.
4. **Inventory integration:** Integration with inventory systems enables real-time tracking of medication usage and stock, reducing the risk of unauthorised removal or manipulation.
5. **Regulatory compliance:** Gravimetric systems support compliance with compounding accuracy and controlled substance regulations, ensuring quality and safety standards.

BAR CODE MEDICATION ADMINISTRATION (BCMA)

BCMA uses barcode scanning technology to match the patient's wristband with the prescribed medication, ensuring accuracy. It integrates with electronic health records for automatic documentation and alerts health care providers to potential drug interactions, allergies, or incorrect dosages. The system also provides audit trails for tracking medication administration, improving compliance with safety protocols and regulatory requirements.

Purpose: BCMA is designed to enhance patient safety and reduce medication errors by ensuring that the right patient receives the right medication at the right dose, time, and route. It provides real-time verification of medications before administration, preventing errors related to mislabelling, incorrect dosing, or wrong patient identification.

Impact

1. **Patient-specific administration:** BCMA ensures the 'five rights' of medication administration by verifying patient and medication barcodes, reducing risks of errors or diversion.
2. **Documentation:** It records medication administration details electronically, creating a full audit trail to enhance accountability and detect potential diversion.
3. **Real-time tracking:** Integration with pharmacy systems enables real-time monitoring, ensuring accurate usage and identifying discrepancies or unusual patterns.
4. **Medication reconciliation:** BCMA reconciles prescribed medications with those administered, helping to spot missing or extra doses that could indicate diversion.
5. **Alerts and reports:** BCMA generates alerts and reports for unusual patterns or missed doses, aiding in timely investigations of potential diversion.

CONTROLLED SUBSTANCE MANAGEMENT SOFTWARE

A comprehensive management solution designed to centralise, automate and track the chain of custody for controlled substances.

Purpose: Controlled substance management software streamlines and automates documentation and chain of custody tracking, reducing the administrative burden on both pharmacy and ward staff. It enhances governance, ensures regulatory compliance and improves overall operational efficiency.

Impact

1. **Enhanced tracking and auditing:** Provides a centralised view of controlled substances records with built-in support for discrepancy resolution.
2. **Paperless system:** Enables fully electronic records through a multi-register platform, allowing each hospital location to manage the receipt, issuance, administration, return and destruction of controlled substances efficiently.
3. **Improved accuracy and efficiency:** Reduces processing time by streamlining receipt, removal, balance management and handover. Eliminates certain manual tasks, enhancing register accuracy.
4. **Diversion prevention:** Facilitates the identification and reporting of potential controlled substances diversion, strengthening security measures.
5. **Seamless integration:** It integrates with dispensing and inventory systems to ensure the end-to-end chain of custody tracking. Supports Patient Administration System (PAS) integration for effective controlled substances management across patient admissions, stays, and discharges. Compatible with hardware such as Automated Dispensing Cabinets (ADCs) and controlled substances storage units.

SMART PUMPS

Smart pumps are equipped with safety features such as built-in dose error reduction systems (DERS) that alert health care providers to potential dosing errors or improper infusion rates. They integrate with electronic health records for automatic tracking and documentation, ensuring accurate records of medication administration. Some models offer wireless connectivity for real-time data monitoring, programmable drug libraries, and alarm systems for safe medication delivery and easy error detection.

Purpose: Smart pumps are designed to automate and safely administer intravenous (IV) medications and fluids by controlling flow rates, volumes, and dosages. Their primary purpose is to reduce human error, improve medication accuracy, and enhance patient safety, particularly in critical care settings where precise delivery of medications is essential.

Impact

1. **Dose accuracy:** Smart pumps deliver medications precisely, using drug libraries with dose, concentration, and rate limits to prevent errors and reduce diversion risks.
2. **Electronic Health Records integration:** Seamless communication with electronic health records ensures accurate programming of prescribed doses, reducing unauthorised or incorrect administration.
3. **Custom drug libraries:** Tailored drug libraries restrict medication choices and set dose limits, triggering alerts or requiring authentication for deviations, deterring unauthorised use.
4. **Audit trails:** Detailed records of drug, dose, rate, and time create an audit trail for monitoring and investigating irregularities, aiding in diversion prevention.
5. **Alerts and alarms:** Notifications for deviations from programmed parameters alert staff to unusual practices, allowing timely intervention.
6. **User authentication:** Access controls like PINs or biometrics ensure only authorised personnel can interact with the pump, minimising diversion risks.