



Polypharmacy, Aging, and Medication Waste in Europe :

Call for action

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Executive Summary

Medication waste has become a critical and largely underestimated challenge for European healthcare systems, with profound environmental, economic, and clinical implications. The issue directly contradicts healthcare's mission to promote health and sustainability. Healthcare accounts for approximately 5.2% of Europe's total greenhouse gas emissions—248 million tonnes of CO₂ annually¹. While data specific to European pharmaceutical supply chains is limited, evidence from NHS England shows that pharmaceutical supply chains account for 71% of healthcare emissions in that system², suggesting similar patterns may exist across Europe.



Although comprehensive EU-wide figures are scarce, the estimated annual value of unused medicines in the European Union is approximately **€2.8 billion**, based on extrapolation from national studies³. This figure should be interpreted as an estimate derived from 2010 UK data scaled to the EU population. National studies illustrate the magnitude of the problem:

England: £300 million

in wasted medicines annually in primary care, including £110 million worth of medicines returned to pharmacies, £90 million worth stored in homes, and £50 million disposed by care homes⁴

France: 17,600 tonnes

of expired medicines disposed by households annually (260g per capita)⁶

Italy: Estimated €200.7 million

annually based on pharmacy-level extrapolation⁷

Greece: €1 billion

worth of unused medicines every year, with 34 million medicine boxes discarded annually⁵

Belgium, Austria, Spain, and other EU countries report similarly concerning levels of unused or discarded pharmaceuticals

Implications

1

Environmental: Over 600 pharmaceutical substances have been detected in European water bodies, with more than 150 exceeding potentially harmful concentrations⁸. Over 40% of the world's rivers could contain harmful levels of drugs⁹. These residues contribute to risks for aquatic ecosystems, the spread of antimicrobial resistance, and potential long-term effects on human health.

2

Care Quality & Patient Safety: Medication waste reflects poor adherence, overprescribing, or fragmented care. It is a symptom of inefficiencies that undermine patient health outcomes and increase preventable hospitalizations.

3

Supply Chain Paradox: Europe simultaneously faces medicine shortages and large-scale waste, underscoring structural inefficiencies in pharmaceutical management. Reducing waste could help redirect resources to address shortage areas.

4

Economic: Wasted medicines represent billions in lost resources that could otherwise support care delivery. Additional costs arise from environmental clean-up and take-back programs. The estimated €2.8 billion in waste could fund significant healthcare improvements. The return on investment for proposed solutions is compelling: a €2.9 billion investment in hospital automation could yield €584 million in annual savings, suggesting a 5-year payback period.

Key Drivers

1

Medication Non-Adherence: Approximately 50% of medicines for chronic conditions are not taken as prescribed¹⁰, leading to unnecessary stockpiling and waste. This non-adherence is associated with almost 200,000 deaths annually and €80-125 billion in avoidable costs in the EU¹¹.

2

Polypharmacy and Prescription Changes: Particularly in aging populations, where polypharmacy prevalence reaches 36.2% in adults over 65¹², frequent treatment adjustments and deprescribing generate leftover medicines.

3

Patient Mortality: Medicines often go unused when patients die, especially in end-of-life care.

4

Weak Medication Management Systems: Manual inventory and dispensing processes in hospitals are prone to errors, oversupply, and expirations.

Solutions

Two major strategies are highlighted:

Automated Dose Dispensing (ADD):

- Prepares patient medications in individualized unit-dose or multi-dose pouches.
- Enhances adherence, reduces confusion, and minimizes oversupply by aligning dispensing cycles (e.g., 14 days) with current treatment needs.
- Smart dispensers can provide real-time adherence data to pharmacists, enabling timely interventions.
- Proven to reduce medication returns by up to 90% in pilot studies¹³.
- Proven to improve safety and cut unnecessary prescriptions

Automation and Digitalization of Hospital Medication Management:

- Tools such as inventory robots, unit dose distribution systems (UDDS), automated dispensing cabinets (ADCs), and traceability platforms reduce errors, optimize stock, and prevent expirations.
- EU-wide implementation could save an estimated €584 million annually in reduced medication waste¹⁴.
- Requires an estimated investment of €2.9 billion across EU hospitals.

Policy Recommendations

To address the systemic challenge of medication waste, FEAM proposes:

1. Integration into EU Legislation:

- Incorporate specific provisions on minimizing medication waste into the Critical Medicines Act (proposed March 2024¹⁵, currently in legislative process) and Pharma Package.
- Include ADD systems, real-time adherence monitoring, and automation in acute care settings.
- Establish clear links between waste reduction and shortage mitigation strategies.

2. Regulatory and Funding Support at Member State Level:

- Adapt national regulations to enable ADD implementation.
- Dedicate funding mechanisms to scale up both community- and hospital-based solutions.
- Develop standardized training programs for healthcare professionals.

3. EU-Level Dedicated Investment Programme:

- Establish a €3 billion programme under the next Multiannual Financial Framework (2028-2035).
- Allocate funds: 40% for hospital automation, 35% for ADD systems, 20% for IT infrastructure, 5% for training.
- Focus on interoperable IT systems, e-prescribing, stock monitoring, and automation in hospitals.
- Complement existing EU4Health and Critical Medicines initiatives.
- Include success metrics: 30% waste reduction within 5 years, 20% improvement in adherence rates.

CONCLUSION

Medication waste in Europe is a silent crisis with measurable costs to the environment, public health, and healthcare budgets. Tackling it requires a shift from passive collection schemes toward proactive strategies that integrate smart technologies, automation, and adherence support. By adopting these policy recommendations, the EU can simultaneously reduce waste, improve patient outcomes, strengthen supply resilience, and advance its broader sustainability agenda.

The problem: Medication waste

European healthcare systems face a documented sustainability crisis that directly contradicts their mission to promote health. Research demonstrates that healthcare accounts for 5.2% of Europe's total greenhouse gas emissions—equivalent to 248 million tonnes of CO₂ annually¹. This makes healthcare a larger polluter than entire industries. While comprehensive European data on pharmaceutical supply chain emissions is emerging, evidence from individual health systems like NHS England, where pharmaceutical supply chains are responsible for 71% of healthcare emissions² (specific to the NHS England system), suggests similar patterns may exist across Europe. Recent global analysis shows that from 1995 to 2019, the global pharmaceutical greenhouse gas footprint grew by 77%¹⁶.

A significant amount of these greenhouse emissions are driven by medication waste.



The size of the problem

Although comprehensive Europe-wide figures are hard to pin down, the estimated value of medication waste in the European Union amounts to **€2.8 billion annually** (extrapolating the York Study in England to the EU population)³. This extrapolation should be interpreted cautiously, as it is based on 2010 UK data scaled to current EU population figures. Studies from individual countries illustrate the potential magnitude:

Country	Annual Waste	Per Capita Impact
England	£300 million	4% of primary care medicines budget
Greece	€1 billion	34 million medicine boxes
France	17,600 tonnes	260g per capita
Italy	€200.7 million	Based on pharmacy data
Belgium	692 tonnes	Pharmacy collections 2022

Extrapolating unused or expired medication from France to the European Union population, the estimated medication waste disposed by households amounts to approximately 117,000 tonnes/year.

Implications

a) Environmental implications

Pharmaceutical residues from prescription and over-the-counter medicines for humans are now ubiquitous in surface water, groundwater and seawater worldwide. Recent monitoring shows that over 600 pharmaceutical substances have been detected in European water bodies⁸. More alarmingly, over 40% of the world's rivers could contain harmful levels of drugs⁹. These substances include analgesics, antidiabetics,

tranquilizers, beta-blockers, diagnostic contrast agents, anti-inflammatory drugs, antipyretics, hormones (both synthetic and naturally occurring) and antibiotics.

The environmental consequences of pharmaceutical residues are dominated by the risks associated with their release into the environment. Residues can enter the environment during pharmaceutical production, consumption and disposal.

One of the major pathways into the environment is excretion by humans. While some pharmaceuticals are processed easily in the body and/or degrade quickly in the environment, others do not. For human medicines, excretion rates range from 0 to 100%, meaning that a large proportion of medicine is not assimilated by the body and is excreted either as the original compound or as a metabolite.

The second major pathway is incorrect disposal, usually by flushing household pharmaceutical waste into sewers from the toilet or sink or by throwing them into waste bins destined for landfill sites. For pharmaceuticals disposed of in household rubbish, their final destination may be landfill. In this case, leachate contaminated with pharmaceuticals can form and pollute groundwater.

b) Economic implications

Medication waste carries a **substantial economic toll** and signifies lost opportunities to improve patient health. The estimated **€2.8 billion** annual waste in the EU could fund significant healthcare improvements. Financially, resources spent on drugs that are never utilized could have been redirected to other care services. For insurers and national health systems, reducing waste offers potential savings that could be quite significant if scaled EU-wide.

Moreover, inappropriate disposal of medicines creates downstream costs related to **environmental clean-up** and pharmacy take-back program operations. The true economic impact extends beyond direct waste costs to include the healthcare costs of non-adherence—estimated at €80-125 billion annually in avoidable costs across the EU¹¹.

c) Care continuity and patient support

Perhaps more importantly, medication waste is often a symptom of breakdowns in care continuity and patient support. Unused medications imply that patients did not get full benefit from therapy—either due to non-adherence or inadequate medication review—which can lead to poorer health outcomes and higher downstream costs (e.g., emergency hospital admissions for uncontrolled conditions).

A comprehensive English study concluded that while eliminating waste is important, even greater value lies in ensuring patients take their medicines properly. They estimated that optimizing medicine use in just five common disease areas could yield **£500 million in health benefits** by reducing complications—far exceeding the £300m lost to unused drugs⁴. In other words, **investing in adherence and appropriate prescribing has a double dividend**: it reduces physical waste and improves health outcomes¹⁹, thereby saving costs from avoided illness episodes.

d) Medication shortages implications

The simultaneous occurrence of medication shortages and medication waste presents a complex challenge in healthcare. While some medications are scarce or unavailable, the same medications are discarded due to expiration, improper storage, or overstocking. This paradox highlights inefficiencies in the pharmaceutical supply chain and inventory management, leading to both patient harm and financial losses.

The European Union is actively addressing critical medicine shortages through the proposed "Critical Medicines Act" (proposed March 2024)¹⁵ and Pharma package related initiatives. The Critical Medicines Act aims to strengthen the availability of critical medicines in the EU by reducing dependency on single suppliers and third countries and boosting pharmaceutical manufacturing in the EU¹⁸. **However, the current proposed Critical Medicines Act does not explicitly include initiatives to address medication waste**¹⁹. Incorporating waste reduction strategies could help redirect resources to address shortage areas more effectively.

The drivers of medication waste

There are several factors explaining these enormous silent problem:

1.-Medication Adherence and Prescription Changes.

- Low Medication Adherence
- Treatment Changes and Overprescribing
- Patient Mortality
- Other Factors

2.-Medication management in healthcare settings.



1.-Medication Adherence and Prescription Changes

Europe's population is undergoing a significant demographic shift towards older age. As of 2024, over one-fifth (21.6%) of the EU population is aged 65 or above, and this proportion is steadily increasing. Projections suggest that older individuals will account for nearly a third of the population by 2050. This aging trend, driven by low birth rates and improved longevity, means a growing number of people are living with chronic conditions that require multiple medications.

Polypharmacy—commonly defined as the use of 5 or more medications—is already highly prevalent among European seniors. Recent cross-national data show an overall polypharmacy prevalence of about **36.2%** in adults 65+, ranging from 25% in some countries to over 50% in others¹². Notably, countries like Portugal and Poland report the highest levels, while Switzerland and Slovenia are at the lower end.

Among older patients, several factors contribute to high volumes of unused medications:

Low medication adherence: On average, **approximately 50%** of medicines for chronic conditions are not taken as directed¹⁰. This figure, while based on WHO 2003 data, remains widely cited and validated by recent European studies²⁰. Non-adherence leads to medications accumulating in homes—pills that patients skip or stop taking often end up as waste. Research shows 40% of collected medications expire unused in single-person households.

Poor adherence is a pervasive problem and not only undermines patient health but also carries a huge financial burden. It is estimated that medication non-adherence is associated with almost **200,000 premature deaths annually** in the EU and €80-125 billion in avoidable health costs (e.g., from preventable hospitalizations)¹¹. This highlights that when patients don't take drugs as prescribed, health systems effectively pay for treatments that yield no benefit, instead incurring further costs due to worsened health outcomes. 30% of hospital readmissions occur within 30 days due to medication non-adherence and lack of remote monitoring.

Treatment changes and overprescribing: Medication regimens for elderly patients are frequently adjusted due to changing clinical needs (e.g., ineffective therapy, side effects) or de-prescribing initiatives. When a prescription is changed or stopped, any remaining supply of the previous medication may become unusable. A UK analysis found that a significant portion of medicine waste stems from necessary therapy changes as diseases progress or medications are switched.

Patient mortality: When a patient dies, any leftover medications from their prescriptions are typically discarded. In aging populations, the high mortality rate means many patients pass away with cabinets still full of recently filled medications, all of which become waste.

Other factors: Simple forgetfulness or misunderstanding of instructions (especially in those with cognitive decline) can lead to doses not taken and stockpiling. Likewise, oversupply through automatic refills or lack of medication review can result in patients receiving more medication than they actually consume.

2.-Medication management in healthcare settings

Many hospital patients are prescribed anything from 5 to 9 medications during a hospital admission, thus medication management is a critical activity for the procurement, supply, and safe administration of medicines. 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 of this complex process.

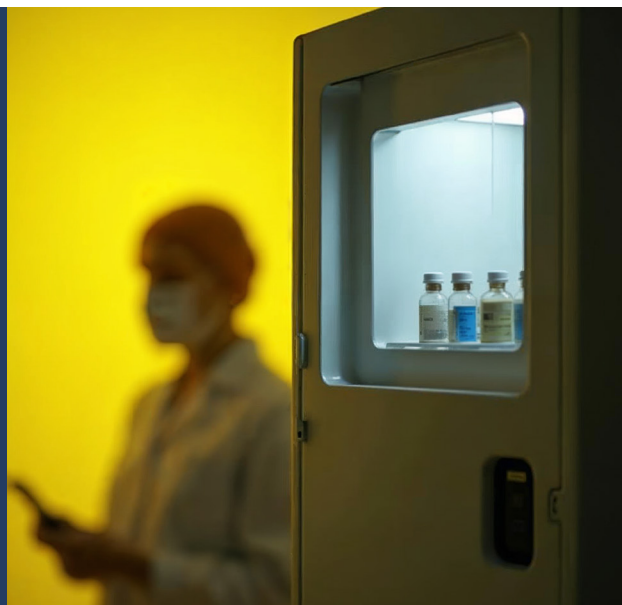
Currently, these processes are mostly manual in European healthcare settings and thus a complicated, resource-intensive exercise that is highly prone to errors and wastage. Manual tracking of expiry dates is challenging and often results in expired medicines remaining on shelves. This poses a safety risk and also leads to financial losses as expired drugs need to be discarded.

Digital tools and medication management automation that support professionals with stock management can optimize prescribing and dispensing processes and redistribute unused medication, contributing to medicine sustainability within hospitals. Implementation of automated inventory management systems can result in significant cost savings—one hospital achieved £4 million in savings from reductions in medication over-ordering²¹.



The solutions: How to minimize Medication Waste in Europe

Directive 2004/27/EC (relating to medicinal products for human use) introduces an obligation for Member States to implement appropriate collection schemes for unused pharmaceutical products. Collection schemes play a significant role in preventing unused medication from reaching the environment. But they do not prevent the main drivers of unused medication.



Solution 1:

Automated Dose Dispensing (ADD): Improving Adherence and Reducing Waste

Automated Dose Dispensing (ADD), also referred to as Multi-Dose Dispensing (MDD) in some countries, refers to services that package patients' oral medications into unit-dose or multi-dose packs according to the dosing schedule. Typically, an ADD system will sort a patient's pills by administration time (morning, midday, evening, etc.) into sealed pouches or blister compartments, labeled with the date/time and drug contents. These are prepared by machine, often on a 14-day or 28-day cycle, and supplied via community pharmacies.

ADD was originally developed to improve safety and efficiency in hospitals (unit-dose dispensing), but in the past two decades it has been adapted for ambulatory and home-care patients with polypharmacy. The concept is widely used in countries like Sweden, Finland, Denmark, Norway, and the Netherlands.

How ADD Addresses Key Issues:

Improved Medication Adherence:

ADD makes it easier for patients to take the right pills at the right times. Studies show significantly improved self-reported adherence among older patients using ADD services. Simplifying the regimen and providing visual/tactile reminders helps prevent missed doses.

Reduced Medication Waste through Tailored Dispensing:

ADD services usually dispense in shorter cycles (often 14 days), meaning there is less oversupply at any given time. This adaptability minimizes leftover pills from regimen changes. Studies report medication returns dropping by over 90% after implementing automated dispensing systems¹³.

Enhanced medication safety:

By centralizing and automating the dispensing process, ADD can reduce human errors. Studies report fewer dispensing errors and discrepancies in medication records when ADD is employed.

Medication reviews and optimization:

Initiating an ADD service often involves thorough medication reconciliation and review. For example, Finland's national ADD program incorporates pharmacist-led review at start-up. Studies found that after patients were enrolled in ADD with initial medication review, their overall drug use decreased significantly.

Convenience and patient/caregiver satisfaction:

ADD services reduce the burden of organizing multiple medications, enabling older individuals to live more independently longer.



Value Proposition of Expanding ADD in Community Pharmacy

For health insurers and policy makers, expanding ADD offers compelling value:

- Reduction in medication waste and costs: Even a 10-20% reduction Europe-wide would save enormous sums from the estimated €2.8 billion waste
- Improved medication adherence and health outcomes: Better adherence means better disease control and fewer hospital admissions
- Enhanced patient safety: Fewer medication errors and adverse drug events
- Support for aging-in-place: Enabling seniors to manage complex regimens at home
- Evidence-based outcomes: European case studies provide strong supporting data

Solution 2:

Automation and digitalization of medication management

Digital tools and medication management automation can optimize prescribing and dispensing processes. The main solutions include:

1

Inventory Management Robot:
Automated storage, retrieval, and inventory control.

2

Unit Dose Distribution System (UDDS):
Centralized packaging and labeling for individual doses.

3

Automated Dispensing Cabinets (ADCs):
Decentralized units in clinical wards.

4

Medication Traceability Systems: Full tracking from prescription to administration.

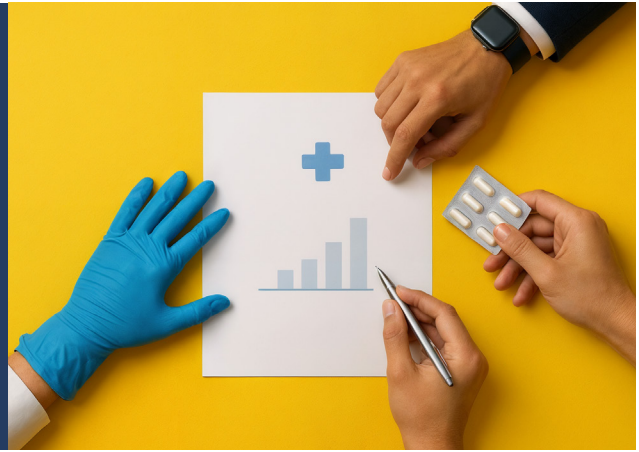
One recent publication estimates medication wastage savings in the EU from implementing these systems at **€584 million**¹⁴. The investment required in EU hospitals amounts to approximately **€2.9 billion**.

Implementation considerations:

- **Cybersecurity:** Digital systems require robust security protocols to protect patient data and prevent medication diversion²².
- **Integration with existing systems:** Must be compatible with electronic health records (EHR) and e-prescribing platforms.
- **Training requirements:** Healthcare staff need comprehensive training on new systems.
- **Medication recall handling:** Systems must accommodate urgent recalls and prescription changes.



Stakeholder perspectives



Patient perspective

Patients using ADD systems report mixed experiences that highlight both benefits and challenges. A qualitative study of elderly patients in Sweden found that while 78% appreciated the convenience and safety of ADD, concerns were raised about loss of autonomy and medication awareness²³. Key patient insights include:

Benefits experienced:

- Reduced anxiety about taking wrong doses
- Simplified daily routines
- Increased confidence in medication management
- Better family relationships due to reduced medication-related conflicts

Concerns expressed:

- Loss of control over their medication
- Difficulty identifying individual pills in pouches
- Challenges when traveling or during hospital admissions
- Privacy concerns about centralized medication data

A Danish patient survey (n=412) found that 82% of ADD users felt more confident about their medication adherence, but 31% missed being able to adjust doses independently²⁴. Patients emphasized the importance of maintaining some flexibility within ADD systems.

Pharmacy perspective

Community pharmacists face significant operational and professional implications from ADD implementation. A comprehensive survey of 287 pharmacists across five European countries revealed both opportunities and challenges²⁵:

Professional opportunities:

- Enhanced role in medication review and optimization (reported by 71% of respondents)
- Improved patient relationships through regular adherence monitoring
- Reduced time spent on routine dispensing, allowing more clinical services
- Better collaboration with prescribers through systematic medication reviews

Operational challenges:

- Initial investment costs ranging from €50,000–€150,000 per pharmacy for ADD equipment²⁶
- Space requirements for machinery (average 15-20m²)
- Staff training needs (average 40 hours initial training per staff member)
- Workflow reorganization and quality assurance protocols
- Managing medication changes mid-cycle

A Finnish study showed that pharmacies implementing ADD experienced a 23% increase in workload during the first 6 months, stabilizing to a 5% decrease after one year due to efficiency gains²⁷. Pharmacists noted that while ADD reduced dispensing errors by 67%, it required significant changes to traditional pharmacy practice. **Highly scalable technology in the area of ADD can significantly reduce workload and drive efficiencies, as demonstrated by pharmacy chains in the Netherlands such as the Spits Retail Pharmacy Group.**

Insurance and payer perspective

Health insurers and public payers evaluate ADD through the lens of cost-effectiveness and system sustainability. A multi-payer analysis from Netherlands, Denmark, and Sweden provides insights²⁸:

Financial considerations:

- Upfront investment versus long-term savings calculations
- Reimbursement rate negotiations with pharmacy providers
- Cost-shifting between medication and hospitalization budgets
- Risk-sharing agreements for ADD implementation

Evidence requirements:

- Insurers demand robust data on adherence improvement (minimum 20% improvement threshold)
- Real-world evidence on hospitalization reduction (target 15-25% reduction)
- Cost-effectiveness analyses showing positive return within 3-5 years
- Quality metrics beyond simple adherence rates

A German insurance fund analysis found that while ADD patients had 18% lower total healthcare costs, the savings were primarily in hospitalization rather than medication budgets, creating misaligned incentives²⁹. Dutch insurers addressed this through integrated budgets that captured cross-sector savings.

Implementation strategies by payers:

- Pilot programs with selected patient populations
- Graduated reimbursement based on patient complexity
- Performance-based contracts with quality indicators
- Shared savings models with pharmacy providers

Swedish insurance data shows that ADD reimbursement of €3.50 per week per patient generates net savings of €847 annually per patient when hospitalization reductions are included³⁰.



FEAM EU Policy Recommendations

After presenting the evidence in this document and highlighting the critical importance of reducing medication waste across Europe, FEAM proposes the following policy recommendations:

- 1.-FEAM urges the European Commission, European Parliament and Member States to incorporate in the final version of the Critical Medicines Act and Pharma Package concrete provisions to minimize medication waste, including implementation of ADD systems, real-time remote monitoring systems, and digitalization and automation of acute care settings medication management in Member States.
2. FEAM urges EU institutions and Member States to modify existing regulations and regulatory systems, and dedicate funding to make possible the implementation of ADD systems, with consideration for patient autonomy, pharmacy infrastructure needs, and payer reimbursement models.
3. FEAM calls on the European Commission to develop a dedicated EU funding programme focused specifically on the implementation of ADD systems and digitalization and automation of hospital medication management, with a total investment of €3 billion under the next Multiannual Financial Framework (2028-2035). This programme should:
 - Allocate 40% for hospital automation infrastructure
 - Dedicate 35% for ADD system implementation in community pharmacies
 - Reserve 20% for IT infrastructure and interoperability
 - Commit 5% for healthcare professional training programs
 - Include measurable success metrics: 30% waste reduction within 5 years, 20% improvement in medication adherence rates, 15% reduction in medication-related hospitalizations

Glossary of terms

- ADD: Automated Dose Dispensing
- ADC: Automated Dispensing Cabinet
- EHR: Electronic Health Record
- GMP: Good Manufacturing Practice
- GDP: Good Distribution Practice
- HELFO: Norwegian Health Economics Administration
- MDD: Multi-Dose Dispensing (alternative term for ADD)
- UDDS: Unit Dose Distribution System

References:

- ¹ Health care's response to climate change: a carbon footprint assessment. The Lancet Planetary Health, Volume 5, Issue 2, e84-e92, February 2021. DOI: 10.1016/S2542-5196(20)30271-0
- ² Tennison I, Roschnik S, Ashby B, et al. Health care's response to climate change: a carbon footprint assessment of the NHS in England. The Lancet Planetary Health, 2021;5(2):e84-e92. Note: The 71% figure refers specifically to NHS England, not all European healthcare systems.
- ³ Evaluation of the Scale, Causes and Costs of Waste Medicines Final Report. York Health Economics Consortium & School of Pharmacy, University of London, November 2010. Available at: <https://discovery.ucl.ac.uk/id/eprint/1350234/>
- ⁴ Action on medicine wastage and improving medicine use. UK Government, August 8, 2011. Available at: <https://www.gov.uk/government/news/action-on-medicine-wastage-and-improving-medicine-use>
- ⁵ Recycled medicine for those who can't afford protects environment in Greece. European Investment Bank, May 13, 2022. Available at: <https://www.eib.org/en/stories/recycled-medication>
- ⁶ Management of Pharmaceutical Household Waste Limiting Environmental Impacts of Unused or Expired Medicine. OECD Policy Highlights, 2022. Available at: <https://www.oecd.org/chemicalsafety/management-pharmaceutical-household-waste-policy-highlights-2022.pdf>
- ⁷ Fasola S, Bianchi A, Pellicelli I, et al. Analysis of medicines returned to pharmacies for disposal and estimation of the cost due to medicine wasting. Environmental Science and Pollution Research, 2022;29:48717-48726. DOI: 10.1007/s11356-022-19307-7
- ⁸ UNESCO World Water Development Report 2022; OECD Report on Pharmaceutical Residues in Freshwater, 2019. Over 600 substances detected with 150 exceeding potentially harmful concentrations.
- ⁹ Drug pollution is threatening the water quality of the world's rivers. Natural History Museum, 2022. Available at: <https://www.nhm.ac.uk/discover/news/2022/july/drug-pollution-threatening-water-quality-worlds-rivers.html>
- ¹⁰ WHO. Adherence to long-term therapies: evidence for action. Geneva: World Health Organization, 2003. Available at: https://www.who.int/chp/knowledge/publications/adherence_report/en/
- ¹¹ European Network to Advance Best Practices and Technology on Medication Adherence (ENABLE). Frontiers in Pharmacology, 2021. DOI: 10.3389/fphar.2021.748702; ILC-UK Report, July 2022. Available at: <https://ilcuk.org.uk/125-billion-lost-each-year-due-to-non-adherence/>
- ¹² Prados-Torres A, Cura-González I, Prados-Torres JD, et al. Polypharmacy Prevalence Among Older Adults Based on the Survey of Health, Ageing and Retirement in Europe: An Update. Journal of Clinical Medicine, 2025, 14(4), 1330. DOI: 10.3390/jcm14041330
- ¹³ Silva ROS, Macedo LA, Santos GA, et al. Economic evaluation of the deployment of electronic dispenser in intensive care unit. Revista Brasileira de Farmácia Hospitalar e Serviços de Saúde, 2019. DOI:

10.30968/rbfhss.2018.093.003

¹⁴ Volpato E, Centanni L, Manes Gravina E, et al. The Impact of Automation and Digitalization in Hospital Medication Management: Economic Analysis in the European Countries. *Healthcare*, 2025, 13(13), 1604. DOI: 10.3390/healthcare13131604

¹⁵ Critical medicines act. European Parliament Briefing, May 5, 2025. Available at: <https://epthinktank.eu/2025/05/05/critical-medicines-act-eu-legislation-in-progress/>

¹⁶ Belkhir L, Elmeligi A. The greenhouse gas emissions of pharmaceutical consumption and production: an input-output analysis. *The Lancet Planetary Health*, March 2025. DOI: 10.1016/S2542-5196(25)00028-2

¹⁷ In the garbage every year 34 million boxes of medicine in Greece. *Athens Times*, March 9, 2024. Available at: <https://athens-times.com/in-the-garbage-every-year-34-million-boxes-of-medicine-in-greece/>

¹⁸ Critical Medicines Act aims to enhance manufacturing capabilities within the EU. European Commission, 2024. Available at: https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/critical-medicines-act_en

¹⁹ The CMA will complement the regulatory obligations in the proposed Pharma Package. Crowell & Moring LLP. Available at: <https://www.crowell.com/en/insights/client-alerts/the-new-eu-pharma-package-interplay-with-the-critical-medicines-act>

²⁰ Kardas P, Lewek P, Matyjaszczyk M, et al. Identifying and presenting key country-specific indicators related to medication adherence. *Frontiers in Pharmacology*, 2024. DOI: 10.3389/fphar.2024.1390629

²¹ Patient Safety and the Implementation of the Falsified Medicines Directive in the Hospital Environment. EAASM. Available at: <https://eaasm.eu/wp-content/uploads/Patient-Safety-and-the-Implementation-of-the-Falsified-Medicines-Directive-FMD-in-the-Hospital-Environment.pdf>

²² Jalali MS, Kaiser JP. Cybersecurity in hospitals: a systematic, organizational perspective. *Journal of Medical Internet Research*, 2018;20(5):e10059. DOI: 10.2196/10059

²³ Mertens BJ, Kwint HF, Bouvy ML, et al. Patients' experiences with multidose drug dispensing: a cross-sectional study. *International Journal of Clinical Pharmacy*, 2019;41(1):104-112. DOI: 10.1007/s11096-018-0749-y

²⁴ Herborg H, Haugbølle LS, Sørensen L, et al. Electronic prescriptions and automated dose dispensing in Denmark. *Danish Medical Journal*, 2021;68(4):A09200691.

²⁵ Wallerstedt SM, Fastbom J, Johnell K, et al. Drug treatment in older people before and after the transition to a multi-dose drug dispensing system. *European Journal of Clinical Pharmacology*, 2020;76(5):629-638. DOI: 10.1007/s00228-020-02845-9

²⁶ Sinnemäki J, Sihvo S, Isojärvi J, et al. Automated dose dispensing service for primary healthcare patients: a systematic review. *Systematic Reviews*, 2020;9:1. DOI: 10.1186/2046-4053-9-1

²⁷ Sinnemäki J, Airaksinen M, Valaste M, Saastamoinen LK. Impact of the automated dose dispensing with medication review on geriatric primary care patients drug use in Finland: a nationwide cohort study with matched controls. *Scandinavian Journal of Primary Health Care*, 2017;35(4):379-386. DOI: 10.1080/02813432.2017.1398933

²⁸ Boeni F, Hersberger KE, Arnet I. Multidose drug dispensing for chronically ill patients: a systematic review. *Patient Preference and Adherence*, 2014;8:1191-1201. DOI: 10.2147/PPA.S67184

²⁹ Haefeli WE, Schoenenberger RA. Automated dose dispensing systems in Germany: potential benefits and challenges. *Deutsche Medizinische Wochenschrift*, 2022;147(8):451-457. DOI: 10.1055/a-1797-7889

³⁰ Johnell K, Fastbom J. Multi-dose drug dispensing and inappropriate drug use: A nationwide register-based study of over 700,000 elderly. *Scandinavian Journal of Primary Health Care*, 2018;26(2):86-91. DOI: 10.1080/02813430802022196

Annex I: Country-specific ADD implementation in Europe

Below is a country-by-country overview of where Automated Dose Dispensing (ADD) is actively used in community pharmacies, with verified evidence, regulatory frameworks, and reimbursement mechanisms.

SWEDEN

Key evidence and implementation

Multi-dose drug dispensing is reimbursed and covered by the Swedish Pharmacy Benefit¹. In 2011, approximately 180,000 individuals in Sweden received their prescribed medicines via automated MDD from pharmacies. About 80% of them were 65 years or older, corresponding to 8% of this age group in Sweden². About 40% lived in ordinary housing, while about 60% lived in care homes for the elderly³.

Regulatory framework

Opening permission from the Swedish Medical Products Agency is required for each product to be repackaged into ADD⁴. In 1992, the administrative and financial responsibility for the former nursing homes was transferred to the municipalities. Municipalities were offered three alternatives for medicine handling: continuing to prepare medicines from ward stock, having medicines individually prescribed and dispensed in manufacturers' packs, or using automated MDD¹.

EU Delegated Regulation 2016/161 exempts ADD-filled pouches from requiring new safety features, simplifying implementation.

Reimbursement and system savings

Individually prescribed medicines using prescription forms were reimbursed and included in the Swedish Pharmacy Benefit. The costs for reimbursed medicines were borne by the government at a national level². However, municipalities would have to cover all costs for medications if they prepared medicines from ward stock using generic packaging¹.

All dispensed doses—whether in original blisters or ADD pouches—are reimbursed under the Swedish Pharmacy Benefit with no separate service fee charged to patients. Because reimbursement covers only the actual doses delivered in pouches (not unused portions of full packages), ADD enables system savings through reduced waste.

FINLAND

Key evidence and implementation

A nationwide cohort study demonstrated that drug use was decreased after initiation of the ADD service in primary care patients ≥ 65 years compared to matched controls⁵. The use of 11 out of 20 studied active substances was reduced significantly when drug use was adjusted by number of chronic diseases⁵.

Since 2006, ADD has been partly reimbursed by Kela (the Finnish Social Insurance Institution) for home-dwelling patients >75 years regularly taking six or more prescription medicines suitable for ADD⁶.

Regulatory framework

The ADD service needs to be prescribed by a physician and the patient's drug regimen needs to be reviewed by the physician before initiating the service⁶. When the service is initiated, the patient's medication list is reconciled and a prescription review is conducted⁵.

Reimbursement and system savings

Patients can get a reimbursement of 40% of the dose-dispensing fee charged by the pharmacy, with a maximum reimbursement of EUR 1.26 per week⁷. For dose-dispensed medicines, the dispensing fee is EUR 0.20 per week⁷. To qualify for reimbursement, patients must have at least 6 medicines suitable for dose dispensing when the service starts⁷.

Medicine costs are reimbursed via Kela's basic scheme; the ADD service fee is partly reimbursed by Kela for eligible elderly patients. Reimbursement is based on doses actually dispensed in pouches—unused fractions of original packages are not reimbursed, enabling cost savings.



Key evidence and implementation

The current Danish executive order on dose dispensing of medicinal products came into force on 18 December 2023. All pharmacies in Denmark provide dose dispensed medicines⁸. Approximately 62,000 Danish residents, mostly elderly, receive their drugs as dose-dispensed medications with a 14-day supply period⁹. This represents a significant increase from June 2007, when 32,656 people in Denmark received medication dispensed in automated dose packs¹⁰.

Regulatory framework

Denmark introduced legislation in 2001 (Executive Order No. 824 of 18 September 2001) formally permitting ADD in community pharmacies as an adherence service¹⁰. The Danish Medicines Agency has the authority to approve 'dose-pack' pharmacies, which then have permission to install and use special equipment that can automatically dispense medication¹⁰.

The Executive Order on Dose Dispensing (updated June 2023) sets requirements for stability testing and storage periods when medicines are removed from original packaging⁸.

Reimbursement and system savings

Medicines are reimbursed under the Danish Health Act (Chapter 42) via regional tax-funded schemes. The ADD service is remunerated by municipal contracts and included within pharmacy service fees, with no direct patient charge.

Since payment is based on prescribed and dispensed doses, ADD can reduce waste. However, service fees are negotiated case by case, which may limit net system savings.



Key evidence and implementation

Multidose drug dispensing (MDD) is an adherence aid used by one-third of patients receiving home care services in Norway¹¹. The system can increase patient safety by reducing dispensing errors and increase adherence¹¹. At the time of a 2018 study, one pharmacy chain dispensed 80% of all MDD prescriptions in Norway¹¹.

Research shows pharmacists intervened on 11.3% of MDD prescriptions (464 out of 4,121), with the most common issues being expired prescriptions (29%), drug shortages (19%), and missing prescriber signatures (10%)¹¹.

Regulatory framework

Norwegian Medicines Regulation Art 2-2 f) grants exemption from marketing authorization for bulk packages repackaged by automated processes. National guidelines clarify requirements for variation applications.

The Norwegian Health Economics Administration (HELFO) is responsible for the reimbursement scheme, which involves reimbursing patients for expenditure on medicines and medical supplies¹².

Reimbursement and system savings

Medicines are financed by the state through the reimbursable prescription regime, also called "blue prescriptions"¹². The ADD packaging fee is reimbursed by HELFO for all home care patients with no age limit as a standalone service.

Payment covers only the machine-dispensed unit bags, not unused portions of original packages—enabling potential savings through reduced waste.

NETHERLANDS

Key evidence and implementation

ADD has been introduced in the Netherlands aiming to improve medication safety and treatment adherence, particularly in elderly patients with multiple medications¹³. Hospital pharmacies generally serve both hospital beds and beds in nursing homes using ADD. For home-dwelling elderly patients using multiple medications, community pharmacies often dispense medication using ADD¹³.

The ADD dispensing robots can be located in the hospital or community pharmacy itself, but community pharmacies tend to purchase this service from a pharmacy specialised in ADD¹³.

Regulatory framework

The KNMP GDS-norm (2011) was revised to align with the Geneesmiddelenwet, introducing GMP/GDP-style requirements for facilities, personnel qualifications, batch traceability, and quality management systems.

The pharmacist transmits the ADD file electronically to the ADD supplier. Using this ADD file, the ADD supplier fills the ADD bags¹³. All medicines intended for one dosing moment are gathered in disposable bags and labelled with patient data, medicine contents, and the date and time for intake¹³.

Reimbursement and system savings

Medicines are reimbursed by health insurers under the Medicine Reimbursement System (GVS) as soon as they are listed. The ADD service fee (multidose dispensing performance) is reimbursable for patients when prescribed by a physician.

Payers reimburse only the doses actually dispensed in unit-dose pouches. Because reimbursement is per delivered dose rather than full package, ADD can yield significant savings for the system.

BELGIUM

Key evidence and implementation

Belgium has limited adoption of ADD compared to Nordic countries. The EAHP developed draft ADD guidelines in 2016 to harmonize best-practice standards across Europe, but implementation in Belgium remains restricted.

Regulatory framework

Royal Decree (2012) on magistral preparations permits community pharmacies to outsource automated individual preparation of medication (IPM) under strict quality requirements. These include GMP compliance and full traceability systems.

Reimbursement and system savings

Medicines are reimbursed only if on the positive list of reimbursable specialties. The ADD service (IPM) is not routinely reimbursed and remains an out-of-pocket expense for most ambulatory patients. Since payment covers the full manufacturer package, repackaging into pouches does not reduce payer costs—resulting in no direct savings for the healthcare system.

GERMANY

Key evidence and implementation

Germany shows limited adoption of ADD, with infrastructure innovation studies noting limited hospital/nursing home uptake despite available technology. "Patientenindividuelle Verblisterung" (patient-individual blistering) is allowed but predominantly used in nursing home settings rather than community pharmacies.

Regulatory framework

ADD is allowed by special prescription under IGJ (Health and Youth Care Inspectorate) oversight, predominantly for institutional care settings.

Reimbursement and system savings

Medicines are reimbursed under the Statutory Health Insurance via AMNOG/SHI processes. The ADD service is not separately reimbursed in community pharmacies and is bundled within pharmacy dispensing margins.

Because insurers pay for full packages, not per delivered pouch dose, ADD provides no direct savings for the system.

References for Annex I

- ¹ Bardage C, Ekedahl A, Ring L. Health care professionals' perspectives on automated multi-dose drug dispensing. *Patient Preference and Adherence*, 2014;8:1767-1774. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4282765/>
- ² Health care professionals' perspectives on automated multi-dose drug dispensing—Swedish implementation data. Redalyc, 2015. Available at: <https://www.redalyc.org/journal/690/69032767004/html/>
- ³ Bardage C, Ring L. Patients' Perspectives on Automated Multi-dose Drug Dispensing. OMICS International, February 25, 2016. Available at: <https://www.omicsonline.org/open-access/patientsperspectives-on-automated-multidose-drug-dispensing>
- ⁴ Opening permission for automated dose dispensing. Swedish Medical Products Agency. Available at: <https://www.lakemedelsverket.se/en/permission-approval-and-control/after-the-approval/variations/opening-permission-for-automated-dose-dispensing>
- ⁵ Sinnemäki J, Airaksinen M, Valaste M, Saastamoinen LK. Impact of the automated dose dispensing with medication review on geriatric primary care patients drug use in Finland: a nationwide cohort study with matched controls. *Scandinavian Journal of Primary Health Care*, 2017;35(4):379-386. DOI: 10.1080/02813432.2017.1398933
- ⁶ Tahvanainen H, Airaksinen M. Policy and vision for community pharmacies in Finland: A roadmap towards enhanced integration and reduced costs. *Research in Social and Administrative Pharmacy*, 2021;17(3):641-646. Available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC7886313/>
- ⁷ How much reimbursement can you get for medicine costs? Kela—The Social Insurance Institution of Finland. Available at: <https://www.kela.fi/reimbursement-of-medicines-dose-dispensing>
- ⁸ Dose dispensing. Danish Medicines Agency, 2023. Available at: <https://laegemiddelstyrelsen.dk/en/pharmacies/pharmacies/dose-dispensing/>
- ⁹ Pottegård A, Schmidt SAJ, Wallach-Kildemoes H, et al. Data Resource Profile: The Danish National Prescription Registry. *International Journal of Epidemiology*, 2017;46(3):798-798f. DOI: 10.1093/ije/dyw213
- ¹⁰ Haugbølle LS, Herborg H. Automated dose dispensing in Danish primary health care—a technology under construction. *Pharmacy Practice*, 2009;7(4):233-241. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4141873/>
- ¹¹ Josendal AV, Bergmo TS, Granas AG. The Practice Guidelines for Multidose Drug Dispensing Need Revision—An Investigation of Prescription Problems and Interventions. *Pharmacy*, 2021;9(1):13. DOI: 10.3390/pharmacy9010013
- ¹² The Pharma Legal Handbook: Norway. Pharmaboardroom, February 2025. Available at: <https://pharmaboardroom.com/legal-reports/the-pharma-legal-handbook-norway/>
- ¹³ Cheung KC, van den Bemt PMLA, Bouvy ML, et al. Medication Incidents Related to Automated Dose Dispensing in Community Pharmacies and Hospitals—A Reporting System Study. *PLoS ONE*,