Re-dispensing of High-Cost medicines under strict conditions

Re-dispensing of high-cost medicines is a feasible and necessary measure to reduce wastage of high-cost medicines and patient safety is ensured. In addition, available stocks can be used more efficiently, thereby contributing to a more sustainable and efficient medicines supply. The Dutch Association of Hospital Pharmacists (NVZA) supports the controlled re-dispensing of high-cost medicines, but only if product safety and integrity is ensured. The process must be fully managed by the dispensing pharmacist, who has the expertise to assure quality, traceability, and logistics of high-cost medicines.

Rationale

Preventing pharmaceutical waste starts with prescribing and dispensing appropriate quantities. Nevertheless, medicines that remain unused despite these precautions are still frequently destroyed. The destruction of usable high-cost medicines is avoidable and is socially and economically unacceptable. European and national legislation currently prohibits the re-dispensing of medicines. This leads to increased healthcare costs and unnecessary environmental burden.

Although re-dispensing does not offer a structural solution to medicine shortages, it contributes to a more efficient use of resources and can mitigate the impact of the shortage.

European framework

Re-dispensing of medicines is currently not permitted under European legislation per Directive 2001/83/EC and the Falsified Medicines Directive (2011/62/EU), which set requirements for packaging integrity, safety features, and traceability of medicines. These provisions have been implemented in national legislation and form the legal basis for the current ban on re-dispensing.

With the revision of the European pharmaceutical legislation, Article 207a introduces a controlled exception. This provision will allow re-dispensing of medicines under strict conditions. Member States will be authorised, but not obliged, to permit re-dispensing. Article 207a stipulates that re-dispensing may only take place if all individual conditions are met, including:

- limitation of the medicines to specific categories established by the Member State
- verification of the authenticity of the safety features referred to in Directive 2001/83/EC and the Falsified Medicines Directive
- storage of the medicines within the required temperature range during the period in which they were in the possession of the patient, as verified through continuous temperature monitoring devices
- unopened and sealed outer and inner packaging
- ensurance of the integrity of the safety features
- collection and re-dispensing by only the same pharmacy that initially dispensed them
- recording of batch numbers to ensure full traceability
- written informed consent by the patient
- limiting the returned medicinal product to only one re-dispense

The NVZA supports these conditions to ensure patient safety and product integrity. These safeguards also ensure that re-dispensing can only take place within a strictly regulated and professionally organised healthcare framework. However, the NVZA emphasises that the requirement for written informed consent would impose a substantial administrative burden. The NVZA therefore advises against this obligation: the risk of increased administrative workload when implementing these conditions in practice, may jeopardise the purpose

National safeguard and implementation
For safe implementation, all steps from initial dispensing and return to quality verification and re-dispensing must be carried out within the same pharmacy. This ensures that the above conditions for safe re-dispensing are met.
Furthermore, re-dispensing requires a solid legal framework, including clear allocation of responsibilities, defined liability arrangements, and oversight at the national level.

The ROAD study 1.0 pilot and the broader ROAD study 2.0, conducted in 14 hospitals, demonstrated that re-dispensing can be technically and organisationally feasible, under specified conditions. These practical experiences offer valuable insights for designing a safe and responsible system, and legal changes are essential to ensure the continuity and further rollout of such initiatives.

Call to action
The NVZA calls on the European Union, the Dutch government, and other relevant stakeholders to adopt Article 207a in full into European legislation and implement it swiftly into law.

The responsibility for implementation of re-dispensing practices should be assigned to pharmacists, who have the expertise to organise this process safely and professionally.

If the proposed amendments to European legislation are not adopted, large amounts of valuable medicines will continue to be destroyed unnecessarily. Efforts to reduce pharmaceutical waste and improve the efficient use of medicines will then only be possible in a future revision of European pharmaceutical legislation, which is not expected for another two decades.

Conclusion
Re-dispensing of high-cost medicines under strict conditions is a proven safe and responsible approach to substantially reduce pharmaceutical waste. The ROAD study[1] has shown that re-dispensing not only results in considerable cost savings but can also be carried out without additional risk to patients when strict conditions are met.

If the proposed amendments to pharmaceutical legislation are adopted, re-dispensing could be introduced on a voluntary basis under the conditions set out in Article 207a. Any delay in the adoption of Article 207a will result in the unnecessary destruction of usable medicines, whereas timely implementation under the right conditions will support responsible medicine use and help ensure future-proof healthcare.

[1] Smale EM et al. Cost Savings and Waste Reduction Through Redispensing Unused Oral Anticancer Drugs: The ROAD Study. JAMA Oncol. 2024;10(1):87-94. doi:10.1001/jamaoncol.2023.4865