

Sustainable Dispensing of Medicine

| WHITEPAPER

Dutch Association
Innovative
Medicines



This whitepaper describes...

how drug redispensing contributes to sustainability objectives, which obstacles stand in its way, what could be done to realize drug redispensing, what already has been done through the chain approach, and what is asked from politics and governance.

Sustainable Dispensing of Medicines

Medicines make a valuable contribution to society. They are vital for the daily functioning of many people, and they contribute to curing diseases and preventing death. Every year, about 420 million packages of medicines are issued in the Netherlands. More and more attention is being paid to sustainability. Social awareness of wasted medicines and environmental impact is growing.

Based on shared social responsibility, the Coalition for Sustainable Pharmacy was established in 2019, a collaboration of Vereniging Innovatieve Geneesmiddelen (VIG - Innovative Medicines Association), Bogin, Nephofarm and Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP - the Royal Dutch Society for the Promotion of Pharmacy). Its mission: **'To minimize the effects of medicines on the environment by sustainably producing, distributing and deploying medicines with the best imaginable effects on health.'**

In this context, the parties of the Coalition Sustainable Pharmacy signed the Green Deal Sustainable Healthcare, drew up the Branch Plan Sustainable Packaging and are partners of the Chain Approach to Medicine Residues from Water. Combating medicine waste is part of these social agreements.

Reducing waste of medicines

Reducing waste starts with preventing unnecessarily stocked or dispensed medication. That can be achieved by paying attention to lifestyle, reducing medication where possible, customizing dispense, optimizing package sizes and exchanging supplies between pharmacies. When opportunities to prevent waste are exhausted, redispensing can be considered. This starts with an effective collection of previously issued, unused medication.

Recovery of unused medicines

Pharmacies have long encouraged the public to hand in unused medications at the pharmacy or Municipal waste collection points. During the annual 'Collection Week' and 'Our Water Week' extra attention is paid to medicine waste. One third to a half of all the medicines that are not used find their way back to the pharmacy or Municipal waste collection points. Also in hospitals and nursing homes unused medicines are being collected.

Redispensing of medicines

A very large proportion of the collected prescription drugs turns out to be of good quality: packaging is intact, temperature requirements have been met and shelf life is sufficient. This means that, in theory, they could be redispensed to another patient after quality verification. Within the Sustainable Pharmacy Coalition, the VIG has taken the initiative to further explore the possibilities of redispensing unused medicines which are handed in by patients. We call the initiative 'Sustainable Dispensing of Medicines'.

Sustainable Dispensing of Medicines includes:

- The collection and redispensing of still usable prescription medicines in the chain ("inflow"), and
- All that is necessary to redispense medicines to the patient (the Sustainable Dispensation itself).

It is paramount that Sustainable Dispensing of Medicines should never be at the expense of quality and public health. To this end, the drug legislation includes the safeguards for the entire chain that also apply today.

From obstacles to solutions

So, if quality is no obstacle to drug redispensing, what does still stand in its way? Think of legal, logistical, financial and (ICT) technical obstacles.

Good Distribution Practices (GDP) prescribe restraint in the reuse of medicines. The Falsified Medicines Directive¹ prevents bringing back a medicine into the chain that was issued more than 10 days ago. A reimbursement system for actions of chain partners regarding collection and Sustainable Release is still lacking. ICT applications do not yet facilitate inflow and sustainable issuance. At this point, these objections still need to be tackled by appropriate solutions.

Solutions in the field

From an (ICT) technical, logistical and financial point of view, the chain could solve the obstacles that exist. For example:

- Pharmacists could check if a drug is not falsified or marked as such in the European database, they could check with a simple logger if the temperature requirements have been met, and they could check if the package is unbroken and otherwise undamaged. This way they can provide evidence that the medicine meets its quality standards and qualifies for Sustainable Release.
- Health insurers could consider appropriate reimbursements for actions under Sustainable Poisoned Medicines.
- Manufacturers could look into further shelf-life research to see if broader storage conditions are possible.
- ICT providers could update pharmacy and wholesale software.
- Logistics service providers could offer conditioned distribution or make use of robotic techniques that can help with sorting.
- Science, insurers and the supply chain could exchange and link data in order to improve and sharpen know-how and factual foundations for the project.

Solutions at legal and regulatory level needed

To execute these solutions, and successfully implement Sustainable Issuing of Medicines, adjustments in Dutch and European laws and regulations need to be made:

- **Necessary amendments to laws and regulations should be brought forward at national and European level.** This focuses in particular on adapting the legislation to prevent counterfeiting of medicines, which - in our view - unnecessarily dictates that after a period of 10 days, a medicine may not be included into the chain again. This restriction of 10 days should be replaced by the criterion that a judgment by a pharmacist should be made whether or not a drug is (still) of good quality

to be reissued. Here, the consultation on revision of the EU's general medicines legislation EU³ comes into play. We call on the government to raise, together with the pharmaceutical industry, the issue of Sustainable Dispensing and to contribute to the above.

- **Responsible flexibility for authorities to gain experience with Sustainable Medicines Release should be extended.**

This could entail making exceptions to current regulations and supervisory policies. As mentioned, this currently happens in relation to scientific research, and only recently the pilot has been extended. The initiators advocate extending this exception of drug redispensing to regular flows, starting in the controlled environment of hospitals and nursing homes.

A widespread acceptance of redispensing is needed to realize these necessary adjustments. Both patients and caregivers have expressed a positive attitude towards drug redispensing⁴ and several political parties have included this position in their parties' manifestos.

Shared social responsibility

At the same time as removing the obstacles, all parties in the medicine chain must join forces to make the re-dispensing of medicines successful. The first step taken was a stakeholder table, which was organized as part of the Sustainable Dispensing of Medicines initiative. Invited were all chain members (companies, wholesalers, prescribers, dispensing physicians, hospitals, wholesalers, patients), but also scientific researchers and health insurers. The Ministry of Health, Inspectie Gezondheidszorg en Jeugd (IGJ - Healthcare and Youth Inspectorate) and College ter Beoordeling van Geneesmiddelen (CBG - Medicines Evaluation Board) have expressed their interest in following the process.

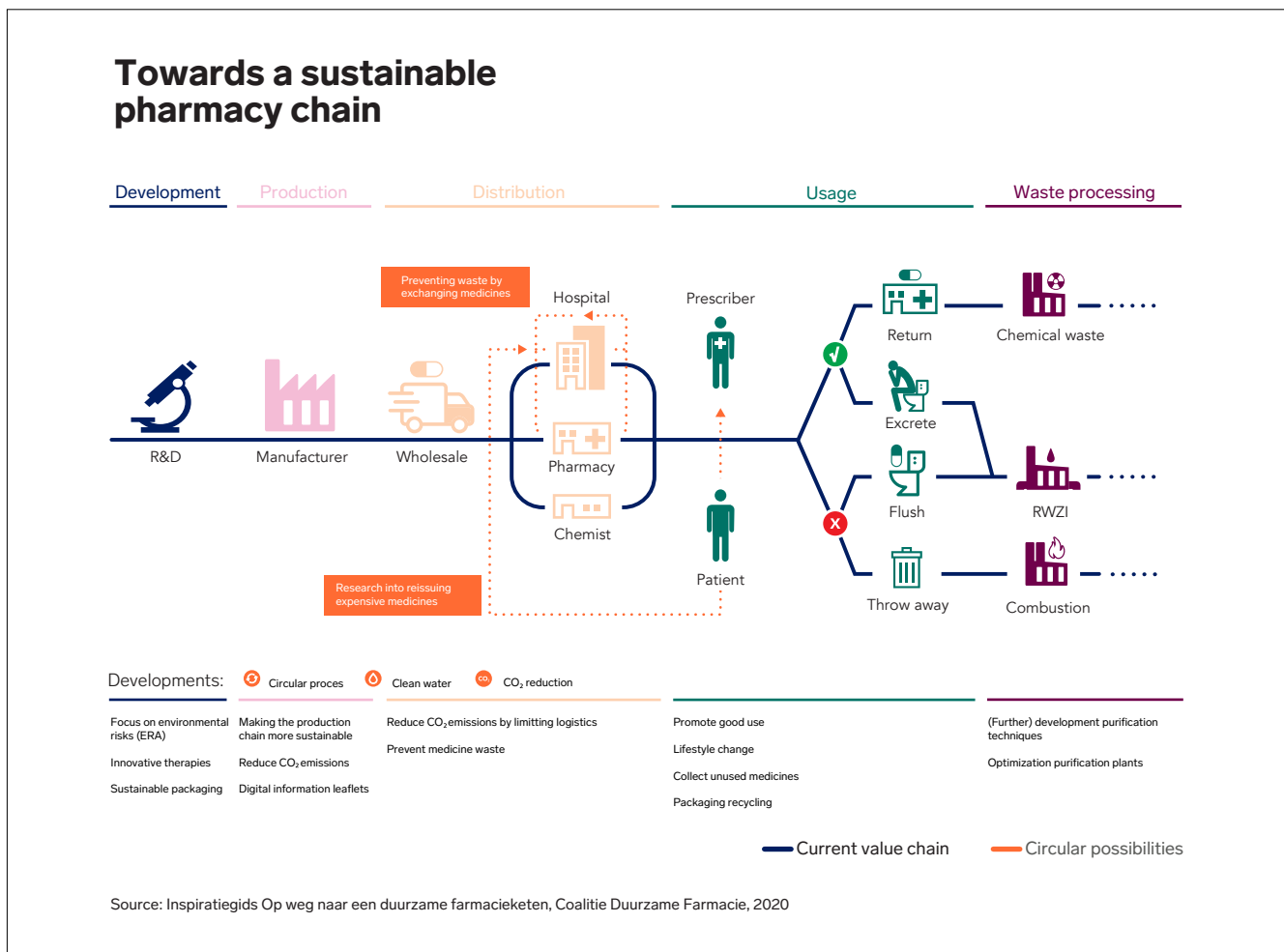
The first meeting, held in September 2021, generated enthusiasm, support and ownership. There appeared to be a great need to make a joint effort. All the possible solutions, mentioned in the previous paragraphs, have been discussed. There is great willingness to make things concrete. Already, Radboudumc is demonstrating results in this field. A substantial waste reduction is realized when redispensing unused oral anticancer drugs. Through extended stakeholder cooperation, this could lead to even greater impact.²

“ We are responsible for working together within the whole chain to find solutions, but we also need support from the government. ”

The stakeholder table will take follow-up steps to get national and European government including VWS, European Commission, IGJ, CBG, European Medicines Agency (EMA) and Rijksinstituut voor Volksgezondheid en Milieu (RIVM - National Institute for Health and Environment) to join.

Finally, we like to illustrate the support in the chain by listing the participants at the stakeholder table Sustainable Dispensing of Medicines:

- **Scientific researchers:** Radboud universitair medisch centrum, Universiteit van Utrecht
- **Hospitals:** Erasmus Medisch Centrum, Elisabeth Twee Steden Ziekenhuis
- **Nursing homes:** Algemene Stichting voor Zorg en Dienstverlening (ASVZ)
- **Patients:** Patiëntenfederatie Nederland
- **Health Insurers:** Zorgverzekeraars Nederland, VGZ, Zilveren Kruis
- **Logistics:** Logistic Community Brabant
- **Sustainability:** Coalition Sustainable Pharmacy
- **Pharmacists:** Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP), Nederlandse Vereniging van ZiekenhuisApothekers (NVZA)
- **Wholesale:** Alliance Healthcare, Brocacef Industry
- **Pharmaceutical sector:** Vereniging Innovatieve Geneesmiddelen (VIG)



¹ View: [Commission Delegated regulation 2016/161](#) of 2 October 2015 to supplement Guideline 2001/83/EG of the European Parliament and the Council by establishing detailed rules on safety features on the packaging of medicinal products for human use

² Smale, E.M. (2023) Cost Savings and Waste Reduction Through Redispensing Unused Oral Anticancer Drugs The ROAD Study, JAMA Oncol. doi: [10.1001/jamaoncol.2023.4865](https://doi.org/10.1001/jamaoncol.2023.4865) [jamaoncol.2023.4865](https://doi.org/10.1001/jamaoncol.2023.4865)

³ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Herziening-van-de-algemene-geneesmiddelenwetgeving-van-de-EU_nl

⁴ Bekker C, van den Bemt B, Egberts TC, Bouvy M, Gardarsdottir H. Willingness of patients to use unused medication returned to the pharmacy by another patient: a cross-sectional survey. BMJ Open.