Redispensing of expensive oral anticancer medicines: a practical application

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What was done?

- Defining quality criteria for redispensing of returned oral anticancer medicines (OAM)
- Implementing these criteria using a standard operating procedure (SOP) in daily pharmacy practice

Why was it done?

- Increasing use of expensive, newly introduced OAM
- NKI-AVL: ± 17,300 dispenses/year, ± €3200 monthly/patient, ± €56 M total value/year
- Approximately 33% of patients discontinue therapy, 50% of them have redundant OAM at home
- Discard of unused OAM leads to an unnecessary environmental and financial burden

How was it done?

- A systematic risk analysis to determine eligibility of returned OAM for redispensing
- Redispensing was quantified over a one-year period
- Defined quality criteria were laid down into a SOP and implemented (see flowchart assessment for redispensing OAM)

Product presentation

- **Returned OAM → On eligibility list?**
- **Criteria eligibility list:**
  - Stability demonstrated for 6 months at 40°C/75% relative humidity (RH) based on registration dossier
  - Integrity of package for protection against light and humidity
  - 75% of OAM on eligibility list (N = 40)

Physical condition

- **Unopened secondary package**
- **Opened secondary package**
  - Unopened primary package ID = opened secondary package ID
- **Visual quality aspects:** good condition package + no stains, cracks, damages

Authentication

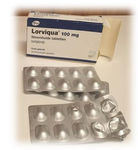
- **Label/patient identity**: confirm initial dispense, to correct financial reimbursement
- **Falsified Medicines Directive (FMD)**
  - European regulation: verify whether returned OAM was successfully authenticated by our pharmacy initially before dispensing
- **No recall**

Additional aspects

- **Uncontrolled storage** at patients' home without monitoring of storage conditions:
  - Remaining stability at accelerated conditions is considered sufficient to bridge an "uncontrolled" storage period of **<3 months**
- **Residual shelf-life** (to cover at least the period of use when redispensed):
  - **Unopened: ≥3 months**
  - **Opened: ≥6 months**

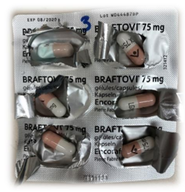
OAM accepted for redispensing

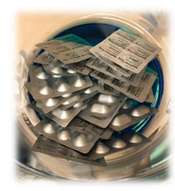
Primary package:
- Container or blister
- Direct contact with the dosage form



Secondary package:
- Packaging in which the blister or container is dispensed

Validation visual examination of integrity:
- Integrity study using a vacuum leak-test
- 1,896 dose units, 262 blisters





What has been achieved?

Results of a one-year period (05/2021–04/2022)
- Assessment according to a Standard Operating Procedure (SOP)
- Feasible to implement in daily pharmacy practice
- After acceptance: adding to stock, correcting billings to health insurers by financial department
- **79%** of returns accepted for redispensing; **0.9%** of total costs of OAM dispensed
- Waste reduction: **1132.1 g** (highly) potent drug substance

Figure 1: Total amount of OAM returns

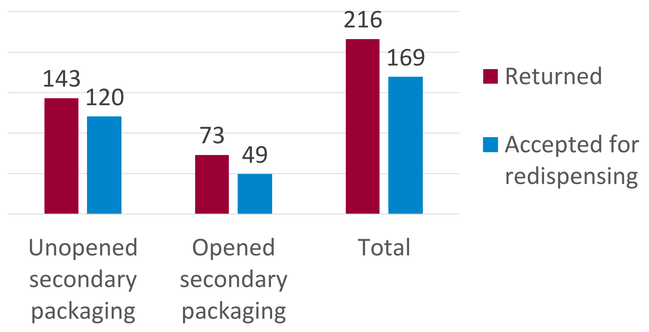
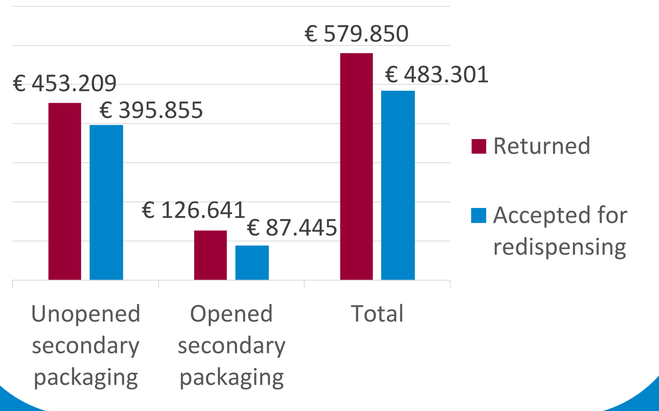


Figure 2: Value of returned OAM



What is next?

- Redispensing of OAM can be successfully implemented in daily pharmacy practice
- All relevant quality aspects should be considered by implementing strict procedures
- Wide implementation of this approach would result in a significant reduction in financial waste and environmental burden

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