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RESEARCH ARTICLE

Redispensing of medicines unused by patients: a qualitative study among stakeholders

Charlotte L. Bekker[1,2] · Helga Gardarsdottir[2,3] · Toine C. G. Egberts[2,3] · Marcel L. Bouvy[3] · Bart J. F. van den Bemt[1,4]

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Abstract *Background* Medication waste has undesirable economic and environmental consequences. This waste is partly unavoidable, but might be reduced by redispensing medicines unused by patients. However, there is little knowledge of stakeholders' views on the redispensing. *Objective* To identify the stakeholders' views on the redispensing of medicines unused by patients. *Setting* Dutch healthcare system. *Method* Semi-structured interviews were conducted with 19 Dutch stakeholders from September 2014 until April 2015. The interview guide included two themes: medication waste and redispensing of unused medicines. The latter included qualitative-, legal- and financial aspects and stakeholder involvement, with specific attention to the patient. Interview transcripts were subjected to thematic content analysis. *Main outcome measure* Requirements related to the redispensing of unused medicines. *Results* All stakeholders considered the redispensing of medicines desirable if the implementation is feasible and the requirements for the safe redispensing are met. All of them pointed out that the product quality of redispensed medicines should be guaranteed and that it should be clear who is responsible for the quality of redispensed medicines. The stakeholders stated that transparent communication to patients is essential to guarantee trust in the redispensing system and that patients should be willing to use redispensed medicines. Moreover, the redispensing system's benefits should outweigh the costs and a minimal economic value of medicines suitable for redispensing should be determined. *Conclusion* Redispensing unused medicines could decrease medication waste if several requirements are met. For successful implementation of a redispensing system, all relevant stakeholders should be involved and cooperate as a joint-force.

Keywords Medication waste · Qualitative research · Redispensing · Stakeholders · The Netherlands · Unused medicines

Impacts on practice

- Medication waste is a growing problem that should be tackled
- Stakeholders are positive about redispensing unused medicines although several requirements should be met
- Redispensing unused medicines can be considered when guaranteeing product quality, enhancing patient and stakeholder involvement, and considering financial and legal aspects

Introduction

Spending on prescription medicines has increased substantially over the past decades due to increased use and the introduction of new expensive medicines [1]. It is known that

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✉ Charlotte L. Bekker
c.bekker@maartenskliniek.nl

[1] Department of Pharmacy, Sint Maartenskliniek, PO box 9011, 6500 GM Nijmegen, The Netherlands

[2] Department of Clinical Pharmacy, Division of Laboratory and Pharmacy, University Medical Centre Utrecht, Utrecht, The Netherlands

[3] Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University, Utrecht, The Netherlands

[4] Department of Pharmacy, Radboud University Medical Centre, Nijmegen, The Netherlands

not all prescribed medicines are used. Medication waste refers to any medicine that expires or remains unused throughout the medicines supply chain [2]. These unused medicines are commonly disposed with household waste, returned to the pharmacy or collected through chemical waste programs and subsequently destroyed [3]. This waste has undesirable implications both economically, as it costs the health system hundreds of millions every year [4–6], and environmentally, as pharmaceuticals end up in the environment.

Factors that contribute to medication waste are apparent in all phases of the pharmaceutical supply chain, for instance, by producing inadequate package sizes, prescribing or dispensing more medicines than required, low adherence or the occurrence of unpredictable treatment changes due to unsatisfactory treatment response or the occurrence of side effects [7–14]. A variety of stakeholders is involved in this chain, such as the manufacturer, prescriber, pharmacist, user and regulator.

Medication waste can only be partially prevented [4]. It may be reduced by the redispensing of medicines unused by the patient that are returned to a pharmacy. An internet hotline launched by the Dutch Ministry received numerous proposals from patients on how to reduce waste in health care, the majority of which suggested the redispensing of unused medicines [15]. Moreover, it has been proposed several times that the recycling of unused medicines can be very beneficial for the healthcare budget [12, 16–20]. However, sparse information is available regarding the stakeholders' views on the feasibility of redispensing unused medicines. Moreover, the requirements, including product quality requirements and the financial aspects of a redispensing system, have not been thoroughly investigated. Consultations with stakeholders are important in facilitating health policy decision-making [21].

Aim of the study

The aim of this study was therefore to identify the stakeholders' views on the redispensing of medicines unused by the patient.

Ethics approval

Under Dutch law, this study did not require the approval of an Ethical Review Board. The study protocol was internally reviewed by the local scientific committee of the Sint Maartenskliniek.

Method

A qualitative study [22] was performed by conducting semi-structured interviews with Dutch stakeholders from September 2014 until April 2015. This method enables an in-depth identification of the stakeholders' views, as topics can be more thoroughly discussed. To include the relevant stakeholders that were considered most informative to the subject of the study, purposive sampling was used. Therefore, a list of stakeholders was compiled by two researchers and then thoroughly discussed with the other members of the research group. A member of each stakeholder (healthcare professionals, health authorities, health insurance companies, patient- and consumer organisations, pharmaceutical industry representatives and wholesalers) was subsequently approached by email and invited to participate. Members were chosen based on their expertise and asked to represent their organisation. Furthermore, interviewees were asked to check the list of stakeholders for completeness.

Data collection

The stakeholders' views towards the redispensing of unused medicines were examined. An interview guide (overview Table 1 and framing of questions Table 2) was developed to that end and included two themes: (1) the extent of medication waste and opportunities to decrease waste and (2) the redispensing of unused medicines (all administration forms). The study into the second theme was more in-depth, including such issues as product quality, legal- and financial aspects, patient attitude and stakeholder involvement. Beside these themes, any other issue could be addressed at the end of the interview.

The interview guide was pilot-tested on content validity and interpretation by interviewing an independent expert. The semi-structured interviews were conducted face-to-face or by phone. All interviews were conducted by a first researcher (PhD candidate, female) with training in interviewing skills and with no relation to the stakeholders. Besides the interviewee and the main researcher, no one else was present during the interviews. Interviewees gave oral consent for audio recording and anonymity was guaranteed. The interviews were transcribed verbatim and, to ensure the correct interpretation, each interviewee received a summary of the transcripts and could provide feedback on the data.

Data analysis

The transcripts were analysed thematically [23] using MAXQDA [24]. First, relevant text fragments were selected individually by two researchers and then compared to ensure no data would be missed. Second, the first researcher performed the open coding of the fragments [25]. The second researcher reviewed the open coding of ten randomly chosen codes of five transcripts. The researchers agreed on 96% of the open coding and the remaining discrepancies were resolved by consensus.

Table 1 Overview of the interview guide

1. Medication waste
Extent of the problem and perceived need for action
Opportunities to decrease medication waste
2. Redispensing of unused medicines
General view on redispensing
For which medicines applicable
Product quality
Quality criteria
Monitoring of quality criteria
Logistical aspects taken into account
Patient attitude
Factors regarding dispensing that are important to patients
Informing patients on redispensing
Patient's preferences for participating in the redispensing system
Stakeholder involvement
Consequences for stakeholders
Legal aspects
Legal constraints
Responsibility for the redispensing system
Financial aspects
Minimal economic value
Financial handling taken into account (e.g. reimbursements)

Lastly, the first researcher applied axial and selective coding [25]. Relationships between the open codes were identified with axial coding and the codes were labelled into themes. Using selective coding, the themes were sorted into the previously defined themes as used in the interview guide. This process was reviewed in its entirety by the second researcher until both researchers fully agreed on the content of the themes. Prior to the last interview, saturation of the themes was achieved as no new themes emerged. As this study aimed to broadly explore all of the stakeholders' views, no similarities or contradictions in the views of different stakeholders were explored.

Checklists were used to ensure comprehensive reporting of qualitative research [26, 27].

Results

All of the Dutch stakeholders approached were willing to participate in the study. In total, 19 interviews with stakeholders were held, one of which was conducted with two interviewees at the same time for the sake of convenience (both were representatives from two insurance companies). Stakeholders originated from the following professional fields: 3 community pharmacy employees/organisations, 3 hospital pharmacy employees/organisations, 3 medical specialists/organisations, 3 health authorities, 2 healthcare insurance companies, 2 patient/consumer organisations, 2 pharmaceutical industry representatives and 1 wholesaler. Of all interviews, 15 were held face-to-face and 4 by phone due to practical reasons (Table 3). The median duration of an interview was 32 minutes (range 12 to 56). The themes are discussed below and anonymous stakeholder quotations are presented as illustrations.

Medication waste

All stakeholders considered medication waste to be undesirable and expressed the importance of the prevention of waste. Most of the stakeholders were aware of the large amounts of unused medicines that are returned to pharmacies and acknowledged the economic and environmental consequences of unused medicines. Many causes of waste were put forward, such as non-adherence, overprescribing and -dispensing, and the discontinuity of care related to hospital admissions. It was expressed that, in order to prevent medication waste, *"It is better to tackle the waste at the source"* (interviewee 20, male, health authority).

Redispensing of unused medicines

All stakeholders stated that the redispensing of unused medicines is desirable if the implementation in clinical practice is feasible. Possible benefits associated with the

Table 2 Leading questions of the full interview guide

1. Medication waste
What is your opinion on the waste of medicines
Which options could decrease this waste
2. Redispensing of unused medicines
What is your opinion on the redispensing of unused medicines
Which medicines would be suitable for this
Product quality
Which quality criteria are important to redispensing
Why do you think these are important
How can these criteria be fulfilled
What should be arranged logistically (e.g. track and trace)
Patient attitude
What is important to the patient when medicines are redispensed
What do you think about the possibility to choose between a new and redispensed medicine
Should the patient be informed on whether he/she receives redispensed medicine or not
Which (dis)advantages do you foresee
Stakeholder involvement
Which consequences (positive/negative) do you foresee for
I. Pharmacists
II. Manufacturers
Legal aspects
What should be changed legally to make redispensing possible
Who should take responsibility for a redispensing system
Financial aspects
What should be arranged financially to make redispensing possible
I. Patient incentive for returning medicine
II. Medicines cheaper for next patient
III. Pharmacy incentive
What would be the effect on the health care premium
How should reimbursement systems be organised
Are there other themes you want to mention

redispensing of unused medicines were stated, including containment of health care costs and reducing environmental contamination: *"It is nonsense when things are thrown away unused"* (interviewee 12, male, pharmaceutical industry). Medicines for redispensing should be selected based on price (from a cost-effective viewpoint, preferably expensive prescription medicines), storage conditions (temperature sensitive medicines are at an increased risk for quality changes) and package types (blister packs preferable to opened medicine jars). All stakeholders named several requirements that should be met for the safe redispensing of unused medicines, which are shown in Fig. 1.

Product quality

Stakeholders identified guaranteed product quality as an essential requirement. Redispensed medicines have to meet the same standard quality requirements as 'new' medicines: *"You should do it in such a way that you can guarantee an unaffected efficacy of the medicine"* (interviewee 1, male hospital pharmacist). To ensure the quality of redispensed medicines, stakeholders pointed out the need to monitor the storage conditions of medicines at a patient's home. The factors put forward as being of influence to the quality were: temperature, light, humidity, agitation, and lapsed expiration date. They mentioned that the quality of the medicine packaging and information leaflet could also be used as an indicator for storage conditions, as these should not be damaged. A health authority stakeholder suggested that concentrations of active drug substances and metabolites should be assessed in extreme conditions (e.g. extreme heat) to predict the likelihood of sustained quality.

Stakeholders from pharmaceutical industry- and pharmacy representatives pointed out that special attention should be paid to the possible introduction of counterfeit medicines within the redispensing system. Currently, the

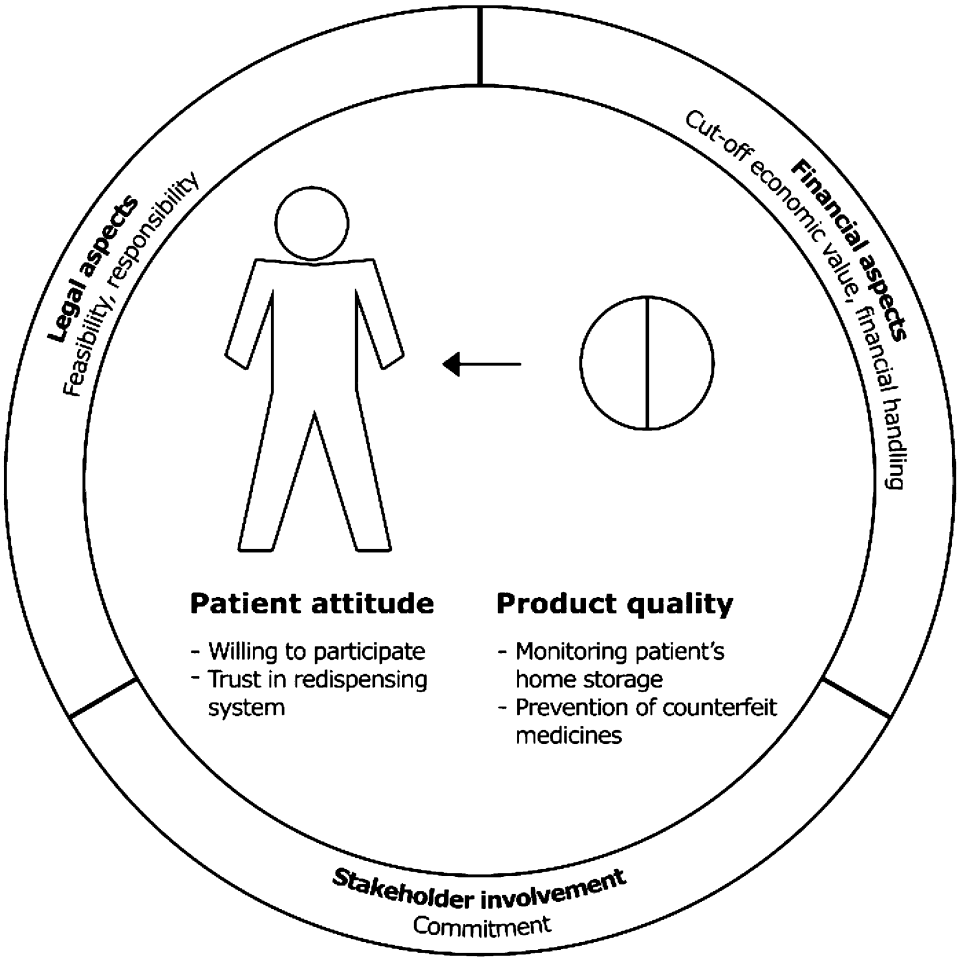

Fig. 1 Two central requirements related to the redispensing of unused medicines could be identified from the analysis: patient willingness to use and trust redispensed medicines and guaranteed product quality of redispensed medicines (all administration forms). These are surrounded by the requirements of the redispensing system: legal feasibility, financial aspects that should be taken into account and the roles stakeholders can fulfil

complete chain from manufacturers to wholesalers is regulated according to the Good Distribution Practice (GDP) guidelines. GDP should also apply to redispensing. In addition, some stakeholders, such as a wholesaler, specialist- and pharmacist organisation, pointed out that a track and trace system could be used to decrease the chance of errors within the system. It was suggested that manufacturers should play a role in the quality control, for instance, by adding a track and trace system to the packages. A health insurance company remarked that monitoring the quality of medicines should not expand too much, as this would make it almost impossible to design a practical redispensing system.

Patient attitude

Stakeholders commonly mentioned the importance of the patient's trust in the redispensing system. According to them, guaranteeing the patient's privacy (which medicines they use) and the quality and safety of the medicines are important to patients. A redispensing program is only successful if patients are willing to participate, as they have to return unused medicines to the pharmacy and must be willing to accept redispensed medicines. Furthermore, patient's awareness regarding medication waste should be increased. Communication about the redispensing system and product quality to patients was therefore important. Stakeholders agreed that information should be provided in a transparent manner, with all healthcare professionals disseminating the same message.

Several stakeholders suggested the possibility of using incentives to stimulate patients to participate in the program, such as lowering health premiums with discounts or granting refunds directly. One comment reads, *"If the patient is not interested in bringing it back, and the benefit goes to the health insurances or the pharmacy or whoever, there is no reward for the patient for bringing it back"* (interviewee 16, male, wholesaler). A health authority and pharmaceutical industry representative remarked that using incentives also has drawbacks as it may imply a second-best medicine, whereas redispensed medicines should become standard. Another interviewee stated, *"There is no difference in the quality. That is the starting point. There is no difference in the quality, so why should we compensate*

Table 3 Demographic characteristics of the interviewees

Interviewee	Gender	Profession	Representative of organisation
1	M	Hospital pharmacist	–
2	F	Pharmacy technician	–
3	M	Chairman	Pharmaceutical industry
4	F	Advising pharmacist	Healthcare insurance company
5	M	Healthcare purchaser	Healthcare insurance company
6	M	Healthcare purchaser	Healthcare insurance company
7	M	Campaign manager	Consumer organisation
8	M	Manager	Pharmacy organisation
9	M	Hospital pharmacist	Hospital pharmacists' organisation
10	F	Director	Outpatient pharmacists' organisation
11	M	Project leader	Health authority
12	M	Senior advisor	Pharmaceutical industry
13	F	Senior assessor	Health authority
14	F	Senior advisor	Medical specialists' organisation
15	M	Senior advisor	Medical specialists' organisation
16	M	Pharmacist	Wholesaler
17	M	Senior advisor	Patients' organisation
18	F	Board member	Community pharmacy employees
19	M	Chairman	Medical specialists' organisation
20	M	Senior assessor	Health authority

someone? You are getting a good medicine" (interviewee 17, male, patients' organisation).

Some of the stakeholders mentioned that patients are worried about the affordability of healthcare, and will agree to use redispensed medicines. On the other hand, some stakeholders expect difficulties as patients might be less willing to use medicines that were already stored at another patient's home.

Stakeholder involvement

Stakeholders mentioned several roles that some stakeholders could fulfil in the redispensing of unused medicines. If pharmacists were to fulfil a major executive role in the redispensing, stakeholders acknowledge that this would include extra tasks for which they should be financially compensated. Nonetheless, a wholesaler, pharmacist- and patient/consumer organisation highlighted that caution is warranted for creating a negative image of pharmacists. Their involvement in the redispensing of unused medicines should be based on an intrinsic motivation to decrease waste and not to benefit from the potential cost savings. Stakeholders considered health insurance companies eligible for stimulating redispensing. For manufacturers, some stakeholders foresaw negative consequences like declines in turnovers, while others saw this as a relative decrease with little impact. Stakeholders mentioned social involvement as the primary reason for manufacturers to contribute to a redispensing system. Some stakeholders had opposing views on each other's opinions on the redispensing of unused medicines. Non-pharmacy related stakeholders supposed that pharmacists are less motivated to redispense medicines, while the latter said that they are motivated. Pharmacy related stakeholders felt that health insurance companies would be less prepared to compensate them for redispensing of medicines. The insurance companies reported to be willing to provide financial compensation for the redispensing of medicines.

Legal aspects

Opinions on the legal feasibility of redispensing unused medicines were divided. A health authority stakeholder said that, according to current legislation, it is legal to redispense medicines. However, some pharmacy organisations and a health insurance company mentioned that all medicines that are returned to pharmacies have to be destroyed, as stated in professional standards. Therefore, even if legislation does not prohibit redispensing, professional standards need to be adjusted as health care professionals follow both.

Virtually all stakeholders stated that it is critical to identify which stakeholders are responsible for the redispensing system, and especially for the quality of redispensed medicines. The majority of stakeholders indicated that pharmacists are capable of fulfilling this role, as they

are already responsible for the quality of dispensed medicines. A pharmacy organisation also identified wholesalers as a responsible stakeholder.

Financial aspects

Stakeholders frequently named cost aspects of the redispensing system as an important requirement. Namely, the financial benefits of a redispensing system must outweigh the costs of implementing such a system. Therefore, a minimal economic value of the medicines that could be redispensed should be determined: *"But the most important thing is to make a model with the financial benefits"* (interviewee 1, male, hospital pharmacist). The financial benefits could be shared among patients, pharmacists and health insurance companies or used for research.

Lastly, stakeholders mentioned that financial handling, with declaring and crediting the redispensed medicines, should be properly organised. This implies the adaption of pharmacy information systems and reimbursement software of health insurance companies.

Discussion

To our knowledge, this is the first study that provides insights into stakeholders' views on the redispensing of medicines unused by patients. In general, medication waste was considered to be an expanding problem that occurs in all parts of the pharmaceutical supply chain. Stakeholders therefore addressed that interventions aiming to avoid this waste should be implemented in the complete chain. Recently, key themes aligned with solutions for minimising medication waste were identified, namely practitioner effects (medication review and better communication), patient effects (reassurance of medication availability), political effects (implementing solutions) and societal effects (awareness and education) [28]. Our findings align with what others have concluded, namely that medication waste is a multi-causal problem that requires a multi-factorial approach for minimization. Nevertheless, all stakeholders had a positive attitude towards the redispensing of the non-preventable part of medication waste. The most important requirements of a redispensing system that were identified were related to the quality assurance of redispensed medicines, the responsibility for this quality and it was highlighted that patients' trust and willingness in a redispensing system was crucial. Furthermore, the benefit-cost ratio of redispensing should be evaluated to define a minimal economic value of medicines suitable for redispensing. The proposed requirements are in line with views of others on the redispensing of unused medicines [19]. Pharmacists' criteria on the redistribution of medicines have been assessed and the quality and safety of the medicines was of most importance here as well [28]. This study contributes to the sparse information regarding the redispensing of unused medicines and provides key points for the implementation of such a system.

Stakeholders had comparable opinions on the redispensing of medicines and related requirements. Most importantly, they unanimously stated that the product quality of redispensed medicines should be guaranteed. Furthermore, the following factors that can affect the quality should be ensured: temperature, light, humidity, agitation, and lapsed expiration date. According to guidelines on packaging for pharmaceutical products [29], packages must protect the products against light and moisture. Agitation, such as shaking, may affect liquid drug formulations but not the quality of solid dosage forms like tablets. Light, humidity and agitation are therefore unlikely to affect the quality of these medicines when packed properly. As for the quality assurance of solid dosage forms, only temperature monitoring is needed, which can easily be done using a temperature sensitive label, we consider these type of medicines the most appropriate for redispensing (blister packs and unopened medicine jars).

Besides consensus on discussed themes, some controversies were also identified. First, we observed differences in stakeholders' views on legal constraints. In The Netherlands, medical practices are based on the Dutch Medicines Act, which refers to the European GDP with respect to the (re)distribution of medicines [30]. The latter states that medicines that have left the distribution centre can return in stock if several factors concerning good product quality control can be confirmed. Thus, according to the law, medicines can be redispensed as long as their quality is guaranteed.

Second, different views existed on whether incentives should be used to stimulate patient participation in a redispensing program. On the one hand, triggering patients to return unused medicines and rewarding this willingness might increase the amount of returned medication. However, on the downside, incentives might imply inferior product quality. Before medicines can be redispensed in practice, the use of incentives in a redispensing system requires further investigation.

Lastly, some stakeholders had misperceptions of the views of other stakeholders. Health insurance companies and pharmacists were perceived as negative towards the redispensing of unused medicines. However, on the contrary, these stakeholders had a positive view towards the redispensing of unused medicines. Some stakeholders thought that patient willingness to participate in a redispensing program would be minimal. In contrast, patient related stakeholders emphasised that patients are highly willing to participate. Stakeholders should clarify their

willingness for redispensing unused medicines among one and another to facilitate a strong collaboration.

Although we aimed at involving all relevant stakeholders, some stakeholders still may have been missed. Interviewees, however, confirmed the completeness of our stakeholder list and all stakeholders agreed to participate. Moreover, no new themes emerged in the final interviews and therefore we consider the collected data to be comprehensive. As the main researcher subjectively interpreted the data, researcher bias could have occurred. However, as the data were also independently analysed by the second researcher and discussed until both fully agreed about the content, the risk of researcher bias was minimised. To succeed with a redispensing system, patients have to be willing to participate. In this study, only the views of patient/consumer organisations were identified, which might differ from individual patients' views on the redispensing of medicines. Furthermore, the study was performed in The Netherlands, which might hamper generalizability of our results to other countries. Reimbursement systems in particular can differ among countries. However, in our view, medication waste is an international problem and the two major themes, namely product quality and patient's trust, will be of importance in each setting.

Conclusion

Medication waste is a general problem that requires a multi-dimensional approach. Nevertheless, unused medicines can be redispensed to reduce medication waste if several requirements are met. This enhances the idea of diminishing medication waste by redispensing unused medicines, eventually decreasing health care expenditures and environmental harm. The future development of a redispensing system needs criteria to define the product quality and minimal economic value of medicines that are suitable for redispensing. Moreover, possible legal constraints should be solved. Eventually, all requirements for redispensing unused medicines should be integrated into clinical and regulatory guidelines.

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