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SHORT COMMUNICATION

# Donation programme of returned medicines: role of donors and point of view of beneficiaries

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**Background:** Donation of returned medicines is a debated health policy issue as it is discouraged by WHO, but accepted in some countries.

**Methods:** Lessons learned from a donation programme of returned medicines carried out in Europe were documented.

**Results:** The donation programme we reviewed followed a strict protocol for collection, sorting and distribution of returned drugs, in order to avoid the major limitations associated with unused medicine donations. Over a period of 3 years, 23 145 boxes of medicines were donated to 14 organizations operating in Europe, Africa and Latin America.

**Conclusions:** The donations covered about one-third of the volume of medicines used by beneficiary organizations. The programme helped to decrease expenditure by both patients and health facilities.

**Keywords:** Donation programme, Medicine donation, Returned drugs, Returned medicines, Unused medicines

## Introduction

The donation of unused medicines is not accepted worldwide, although it is legal in some countries.[1,2] A constant increase in the rate of prescription writing has prompted several charity organizations to collect a growing number of unused medicines.[3] WHO guidelines for drug donations discourage donation of unused medicines, as this may create a number of problems.[4] Detrimental effects of drug donations for use in emergency situations have been reported, as the arrival of unsorted, useless and expired medicines requires management and sorting, which may take up the time of health workers and eventually lead to the appearance of these drugs on the black market.[5–8] However, cases of regulated donations have been reported in the USA, where several states have adopted laws in order to facilitate the redistribution of unused drugs to indigent and uninsured patients.[1,2,9] As the benefit of long-term donation programmes has never been investigated, we followed and analysed one of them, and synthesized our observations in this paper.

## Materials and methods

The donation programme used special bins in the pharmacies of an Italian city to collect unused medicines. It was coordinated by local administrative, academic and health authorities. As shown in Figure 1, collected medicines were sorted by students of the School of Pharmacy of the local university and the process was supervised by pharmacists. To maximize the quality of donations, drugs with a shelf-life of less than 1 year, requiring special storage precautions (e.g. controlled temperature), with ruined packaging and/or without labels were discarded. In addition, medicines subject to legal restrictions (e.g. psychotropic) were also not accepted. Only drugs suitable for donation after sorting were registered in a database.

Local organizations supporting health facilities for disadvantaged populations in Europe or in low and middle income countries (LMICs) were identified. Those with the capacity to maintain the medicines under optimal storage conditions, to distribute them for free and according to local health regulations, and to have Italian-speaking operators in the field to manage Italian-branded products were eligible to submit a list of requests. Available drugs were

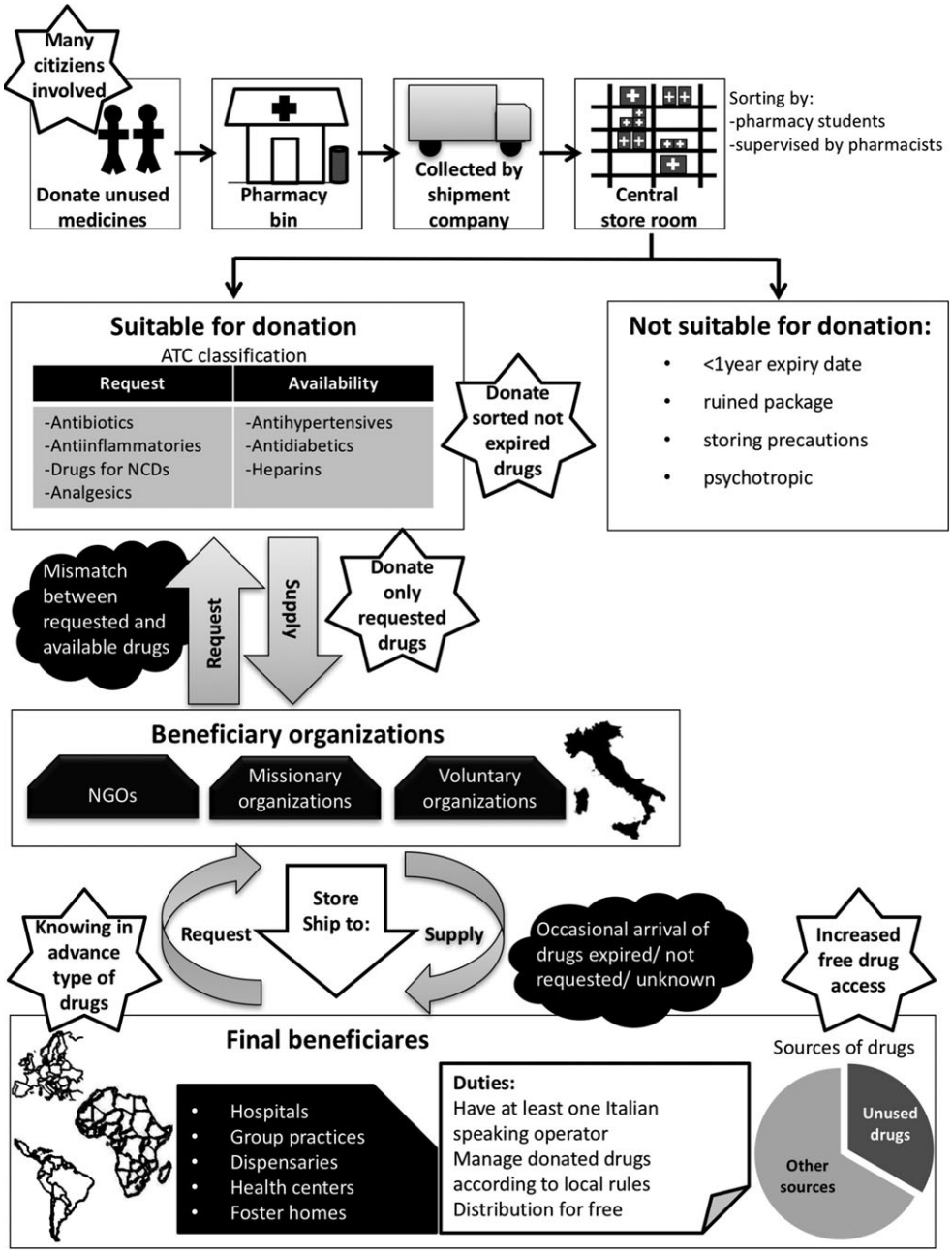


**Figure 1.** Representative scheme of the structure of the donation programme and of its main outcomes. Black clouds represent challenges and white stars represent benefits.

matched with the request and provided. The organizations managed stocking, delivery and final distribution of donated medicines.

A questionnaire was designed, validated and distributed to the organizations (see Supplementary material and methods) to collect their views on the benefit and challenges of this programme. Eight organizations responded to the questionnaire—two were non-governmental organizations, and the others were missionary or small voluntary not-for-profit organizations; three were working in Europe; and five were working in Africa and Latin America (Supplementary Table 1, I–II). The beneficiary health facilities were mostly providing primary care (Supplementary Table 1, III). Those working in Africa reported a high prevalence of infectious diseases, but also highlighted the growing incidence of non-communicable diseases (NCDs).

## Results and discussion

In the three-year period run by the programme, citizens were sensitized and involved, so that 53 644 boxes of medicines were collected; of these, 43% (23 145/53 644) were sorted out as suitable for donation and donated to 14 organizations. Fourteen

per cent (7379/53644 boxes) of medicines were suitable for donation, but were not requested (Supplementary Figure 1A). The majority of collected drugs (93%; 49 889/53 644) were prescription medicines. A large amount of medicines was sorted as 'not suitable for donation' due to short time-to-expire (less than 1 year), as also reported in other studies.[10]

Requested medicines principally included antibiotics and anti-inflammatories, but also drugs for hypertension and diabetes (Supplementary Table 1, IV), irrespective of whether the organizations were working in Europe or in LMICs. Donations did not always satisfy the requests. The returned medicines reflected the pattern of drugs dispensed by the national health system and of the most prevalent pathologies in Italy.[11] As shown in Supplementary Figure 1B, the three most frequently collected drug classes belonged to the cardiovascular system (37%; 19848/53644), alimentary tract and metabolism (14%; 7510/53644), and blood and blood-forming organs (9%; 4828/53644) ATC classes, which represent 36%, 23% and 8%, of the dispensed drugs in Italy, respectively.[12] This pattern is also comparable with that of other European medicine collection programmes.[3,13] Antihypertensives, antidiabetics and heparins constituted 31%, 25% and 14% of the donated drugs, respectively, while anti-inflammatories and antibiotics represented only 9% and 7%, respectively, due to the lack of availability.

The returned medicines programme contributed about one-third of the total volume of drugs donated by the beneficiary organizations to the local health facilities (Supplementary Table 1, V), which were also relying on other private and governmental donors. Our data are in accordance with reports showing that several health centres in LMICs are supported by small western-based voluntary organizations, which are perceived as an important source of medicines.[14] Only two responders stated that, after receiving donations, they significantly modified their order of medicines (Supplementary Table 1, VI).

The organizations mostly followed their internal guidelines to order and donate medicines (Supplementary Table 1, VII–VIII). Medicines were usually checked and registered by the organizations and/or by the local health centre, were not kept separated from drugs received from other sources and were distributed for free in the original package, which did not constitute a barrier due to the Italian-speaking operators, the high frequency of illiterate patients and the handwriting of the posology on the box (Supplementary Table 1, IX–X).

Despite the sorting process, occasional arrivals of medicines that had expired, were not requested, were not known to local health staff, or in dosage or formulations that were not useful were reported (Supplementary Table 1, XI). This indicates that even a structured programme may face issues related to the management of drug donations.[10] Responders appreciated the fact that they were able to know the quantity and type of medicines to be received, as this is one of the most critical issues in drug donation practices.[5–8] The availability of medicines through drug donations helped to reduce costs for both patients and health facilities (Supplementary Table 1, XII–XIII).

## Conclusions

This study documents some lessons learned from a donation programme of unused medicines. Returned drugs can be useful for some populations that otherwise would not have access to those medicines, suggesting that guidelines and policies that interdict this practice can create hindrances for drug donation. Safety concerns may be raised because of uncertain quality of medicines stored at home by individual donors. Thus, further studies are necessary to provide more insight on the quality of donated drugs and ways to safeguard the final beneficiaries.[3] In addition, this is a case study of one donation programme and may not represent all donations; evaluations of more programmes, taking into account the impact of long-term donations on health systems, compliance issues with local laws and their effect on rational prescribing should be carried out.

There are risks that organizations may not have required expertise or may lack a standardized protocol to manage returned medicines; there is also a risk of a mismatch in the need vs supply of returned medicines.[14] This study documents potential problems and how they may be minimized. The programme also served as an example and demonstrated the importance of collaboration between organizations in the donating (e.g. Italy) and recipient countries, suggesting the value of organized donation programmes over ad-hoc donations or emergency supplies.

## Supplementary data

Supplementary data are available at International Health Online (http://inthealth.oxfordjournals.org).

**Authors' contributions:** FN, DR and AS designed the study. FN, DR and GB collected the data. FN, DP, DR and AS analysed the data and wrote the manuscript. All authors reviewed and approved the final manuscript.

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## References

1 Patrick PA, Jibilian A, Herasme O et al. The efficacy of a US-based medicine recycling program delivering antiretroviral drugs worldwide. J Int Assoc Physicians AIDS Care (Chic) 2009;8:25–9.

2 Kuehn BM. States try medication recycling programs. J Am Med Assoc 2008;300:28.

3 Mackridge AJ, Marriott JF. Returned medicines: waste or a wasted opportunity? J Public Health (Oxf) 2007;29:258–62. http://www.who.int/medicines/publications/med_donationsguide2011/en/.

4 WHO. Guidelines for medicine donations. 2010.

5 Bero L, Carson B, Moller H et al. To give is better than to receive: compliance with WHO guidelines for drug donations during 2000–2008. Bull World Health Org 2010;88:922–9.

6 Berckmans P, Dawans V, Schmets G et al. Inappropriate drug-donation practices in Bosnia and Herzegovina, 1992 to 1996. N Engl J Med 1997;337:1842–5.

7 Bonn D. Call made for application of drug-donation guidelines. Lancet 1999;353:2131.

8 Quaglio GL, Mezzelani P, Cuchillo C. Drugs arriving in Kosovo need checking. Br Med J 1999;319:1007.

9 Conis E. Recycling unused cancer drugs. Health Policy Monitor 2009. http://www.hpm.org/us/a13/2.pdf.

10 Reich MR, Wagner AK, McLaughlin TJ et al. Pharmaceutical donations by the USA: an assessment of relevance and time-to-expiry. Bull World Health Org 1999;77:675–80.

11 http://www.federfarma.it/Documenti/spesa/2013/Italia.aspx [accessed 15 January 2018].

12 Federazione nazionale unitaria titolari di farmacia. Spesa farmaceutica. http://www.federfarma.it/Farmaci-e-farmacie/Spesa-e-consumi-farmaceutici-SSN/I-consumi-nazionali/Consumi-per-ATC-I-livello.aspx [accessed 15 January 2018].

13 Osservatorio Donazione Farmaci, 1°rapporto Donazione Farmaci e Povertà sanitaria. Osservatorio Donazione Farmaci, 2014. http://www.bancofarmaceutico.org/default.asp?id=367&id_n=1776&Pagina=12.

14 Mariacher GG, Mtasiwa D, Wiedenmayer K et al. In-kind drug donations for Tanzania. Stakeholders' views—a questionnaire survey. World Health Popul 2007;9:74–99.