Social Reverse Logistics of Used, Non-Expired Medicines (UNEM) with Public Economic Burden? An Impact Appraisal from a Municipal Program

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Abstract

There is little research on the reverse logistics of medicines, because the wastes of the pharmaceutical industry are incinerated, or undergo other forms of physical-chemical destruction, given the potential risks they pose to the environment and to public health when incorrectly disposed. This situation is more problematic in developing countries, where the management of wastes is usually neglected by governments and citizens. Whilst product innovation thrives in the pharmaceutical sector, and an ageing population represents an increase in the demand for medicines, little effort is made to avoid their incorrect disposal. The negative impacts to the water and to the soil quality derived from improper management of used medicines is a challenge in emerging economies. This research describes a local government program of reverse logistics for used, non-expired medicines (UNEM) in a small municipality in Southern Brazil. Taking as a reference the available data of collected and donated quantities of UNEM, and the number of persons that received UNEM for free from July 2015 to December 2017, it was possible to perform an environmental and socioeconomic appraisal of the program. The main findings are that reverse logistics, besides the strictly economic aspect stated by law (as return of a good to the business sector), can have a socioeconomic benefit for needy communities. In the studied case, the reverse logistics avoided environmental harms and economic spending of around US$ 1.5 million with the proper destruction of UNEM medicines; an average of 90 persons benefited every week through receiving UNEM for free; the indirect income distribution per capita, with the program, reached more than 17% of the minimum wage established by law in Brazil. However, the Public Administration carries an economic burden for the correct disposal of the medicines that expire before being dispensed. It amounted around US$ 4,000 since July 2015 to December 2017. As the population does not correctly separate and dispose used medicines, and considering that incorrect disposal of these products represents health risks that will end in the public health system as another type of economic burden, public and private, the Public Administration initiative, even ending in economic spending for the collectivity, results probably less costly than to simply do nothing and push this problem for the future. This private-public economic burden is an open issue for the current local system of reverse logistics Further investigation is necessary to enable the possibility to replicate this program to other municipalities; and it presents an opportunity worthy of investigation in other newly industrialised countries.

Keywords: *medicines wastes; impact assessment; impact appraisal; reverse logistics.*

1 Introduction

The pharmaceutical industry is a profitable business sector mainly due to the: (i) high capacity of product innovation (Hiraturba et al., 2013), (ii) increasing life expectancy, average age and illness of the world population (Akkari et al., 2016); and (iii) increase in the spending power of population subgroups that show more and more concern about health care and well-being (Teixeira, 2014).

All over the world, there is evidence of the increase of availability of pharmaceutical products, in both quantity and quality. Such products are bought and often only partially used, and then improperly discharged – either jointly with organic wastes - or straight in to a collective water system (sanitary discharge). Frequently, medicines bought by consumers have gone past their expiry date before being discharged, or are discharged as surplus to requirement after recovering before completing a treatment. For instance, in England, the costs for correct destination of such materials was estimated in a range of US$ 347 million to US$ 417 million in the last decade (Trueman et al., 2010). Unwanted pharmaceutical medicines end in domestic wastes, or water drains, or return to pharmacists, or are dispensed by doctors for incineration, and this reality is recurrent in several countries.

Patient behavior and medical prescriptions all converge for making the medicines management complex. A study performed by Abahussain et al. (2006) in a hospital in Kuwait, with 300 patients, show that almost 26% keep unwanted medicines because of the voluntary discontinuation of some health treatment they have earlier adopted, and 48% of them claim that doctors change their precriptions, so they accumulate an unexpected amount of medicines in their homes.

In the context of emerging economies (WEF, 2018), such as Brazil, where the majority of the waste is destined for landfills rather than incineration, the management of used, non-expired medicines (UNEM) is a tricky problem and presents a hazard to water and also to the soil integrity. The incorrect discharge of UNEM also threatens public health, because water and soil contaminated with such substances can reduce the biological resistance to diseases (Kotchen et al., 2009, Ruhoy and Dauchton, 2008; Seehusen and Edwards, 2006).

The reverse logistics of medicines represents an opportunity to avoid such negative impacts and to create socio-economic benefits for persons that cannot afford the costs of health treatment that depends on the acquisition of medicines. According to Hiratuka (2013), such type of reverse logistics – the return of UNEM to the consumption chain, under the supervision of health professionals – is an opportunity for a new business that is nowadays equivalent to around U$776,000,00 in Brazil. The few initiatives that exist in the reverse logistics of UNEM or expired medicines in Brazil, are performed by retailers' chains (Hiratuka, 2013). Nevertheless, the retailers do not keep records of the quantities and types of medicines they collect, because this material is sent to incineration or another type of physical-chemical treatment to avoid soil or water contamination that otherwise would occur with inapproapriate disposal. A full impact assessment, or even an appraisal of these initiatives, especially with regard to the possibility of donating or reselling UNEM, is therefore lacking.

The Brazilian government, at the beginning of this decade, enacted a Federal Law that regulates reverse logistics and other actions for solid waste management (Federal Brazilian Govenrment, 2010). Nevertheless, this law (number 12350/2010) does not provide specific procedures for the reverse logistics of UNEM. In practice, the National Health Surveillance Agency (ANVISA) and the National Council of the Environment (CONAMA) are in charge of the regulation of the management of health wastes, but such control does not include individuals' decisions and actions regarding the discharge of used medicines. It is primarily targeted at the distributors and retailers of medicines, and to health institutions, such as clinics and hospitals.

This paper explores gaps in the current practices of UNEM's reverse logistics (that is, the lack of systematic procedures, and lack of accurate information on the quantities and the types of returned medicines) by describing an experience that takes place in the South of Brazil. In the municipality of Farroupilha, Rio Grande do Sul State, the local public administration decided to create a system for the collection and donation of UNEM that started to work as a reverse logistics system in July 2015. The experience, called Solidare Pharmacy, has already benefited more than 8,000 inhabitants of the municipality and has avoided the discharge of around 2 tonnes of hazardous wastes into the environment. The following sections will present: (2.1) a short review about the impact assessment/appraisal undertaken; (2.2) the reverse logistics of UNEM; (3) the methodological design of the case study; (4) the preliminary findings and discussion; (5) some final remarks.

2 Review

This review intends to summarize pivotal concepts of impact assessment/appraisal, and reverse logistics for the case of UNEM.

2.1 Impact Assessment/Appraisal

According to the International Association for Impact Assessment (IAIA, 1996), the process of identification, forecasting, assessment and mitigation of the relevant outcomes of any project, policy or program, regarding the physical and biophysical environments, and other aspects, such as social and economic ones, is named impact assessment (IAIA, 1996). "Impact assessment (IA) is carried out as an *ex ante* process to inform decision-making" (Bond et al., 2018: 16). Although the tradition of IA has leaned on rationality and on the predominance of technical procedures since its inception in the 1970s, the evolution of methods and experimentation on IA has lead to the development of more participatory processes and application at more strategic levels of decision-making. One such evolution is the appraisal as a form of policy analysis with the use of multiple procedures (Owens et al., 2004). Such appraisal entails multiple methods and perspectives in order to produce politically relevant information for decision making. According to Vatn (2009), appraisal brings to the scene a collective endeavour in which communicative action works, putting together individuals and groups with parallel roles, as citizens, consumers, experts, stakeholders, and policy-makers. In this paper, it is assumed that appraisal will consider the observable and measurable environmental, socio-economic and economic effects of a public program of reverse logistics of UNEM. The distinction between socio-economic and economic aspects is here justified taking in account the different nature of the subjects involved in the appraisal. For the individuals that receive UNEM, social and economic effects were taken together, as they are difficult to separate, because economic benefits are indirectly earned with the participation in the program (social aspect), and probably will reverberate more in the determinants of their wellbeing (surplus to buy goods other than medicines) than in the economic aspect itself. For the municipality, the economic savings through avoiding the generation of waste are tangible, while the social effects are more difficult to elicit, as they are shared throughout the whole local community. At the same time, there is an economic burden on the municipality for the destination of unwanted medicines that reach to the public pharmacy and become expired, and it is simultaneously an environmental gain for the local community, as the regulatory requirements for public agent are more stringent than for members of the public.

2.2 Reverse Logistics of Used Non-Expired Medicines (UNEM)

Reverse logistics is defined as "[...] a tool for economic and social development characterized by a set of actions, procedures and means addressed to make feasible the collection and the return of solid wastes to the business sector, for its reuse, in the same or in another productive cycle, or other environmentally proper destination" (Federal Brazilian Government, 2010). It is noticeable that this definition, given by the Brazilian National Policy of Solid Wastes (Law 12305/2010), does not consider the return of solid wastes straight to consumers for social harnessing, but to the business sector.

In Brazil, medicines are classified as a type B health waste: those that contain chemical substances that can threaten the environment or public health through inflammability, corrosivity, reactivity, or toxicity (Alencar et al., 2014).

There is a considerable number of studies focusing on the reverse supply chain of medicines (Weraitak et al., 2016a; Weraitak et al., 2016b; Kongar et al., 2015; Xie and Breen, 2012; Hiratuka, 2013; Kumar et al., 2009; Ko and Evans, 2007; Hunter et al., 2005; Ritchie et al., 2000). Some of the research on medicines as wastes does address the impacts on the soil or water environments (for example, Sheehusen and Edwards, 2006; Ruhoy and Daughton, 2008; Kotchen et al., 2009; Vazquez-Roig et al., 2013).

When reverse logistics are considered in relation to businesses, Weraitak et al. (2016a) estimate a likelihood of a return tax of at least 6.5% for the producer. They argue that is possible to have economic gains in cases of medicines with long (more than two years), medium (from two to one year), and short (less than one year) terms of expiration under a system of incentives for donors. Once the potential donors are aware of the economic value of the incentive, they can make their offering in the amounts they are willing to accept. Such a process keeps on running until the collection is completed. This is just an example of a business model that can be tried by the stakeholders in the reverse supply chain. Several others, with profit or non-profit aims, can possibly be designed.

Knowing that medicines are not amongst the types of solid wastes targeted by Brazilian federal law on solid waste management, and knowing that the main focus of reverse logistics is directed at the business sector, at least two questions are asked: (i) what to do with UNEM rather than collect and promote their physical-chemical destruction? (ii) how to turn reverse logistics directed at business into reverse logistics for social ends as well? In this paper, we will provide some evidence that it is possible to make reverse logistics of UNEM a reality, starting at a small scale, and to perform a social type, or socio-economic type, of reverse logistics, in order to benefit people that cannot otherwise afford health treatment but nevertheless depend on regular access to medicines.

3 Methods

This research is designed as a simple case study with exploratory aims (Yin, 2014). The unit of analysis is a not-for-profit, public organization, called Solidare Pharmacy. It was created in 2015 through a public municipal law in the city of Farroupilha, located in the Southern State of Rio Grande do Sul, Brazil. Farroupilha covers an area of 359.3 Km^2, has 69.5 million inhabitants, and its economic yield is ranked in the 19th place amongst 496 municipalities of the State (IBGE, 2017). The research started with awareness of the findings of Hiratuka et al. (2013) in their report about the position of Brazil regarding waste medicines. This report mentions that reverse logistics of medicines was about to be established in Farroupilha. The researchers accessed the report in 2017, thereby raising the potential for four years of data to be available. The local authority confirmed the existence of the reverse logistics process, and an appointment was arranged in order to conduct interviews with the managers. The first interview was informal, addressed to a pharmacist and her assistant, who manage the program. The goal of the research was to understand the reasons for the project, determine the routines of the pharmacy, and identify the main outcomes in terms of environmental, socioeconomic, and economic impacts. An appraisal, related to environmental, economic and socioeconomic impacts of the program, was then designed. The results are presented in the following section.

4 Results

According to the pharmacist and her assistant, the first idea was to avoid the uncontrolled discharge of used, non-expired, medicines (expired or not) into the environment. Only non-expired and with assured preserved integrity medicines are accepted as donations. After this initial insight, they worked out a plan to organize a system for free distribution of UNEM. It was a challenge because a physical space was needed, and all the legal requirements must be followed. The local public administration has provided a space (more or less 70 square meters) in the Public Administration building for the classification, storage, separation (where necessary – into component parts), and other necessary routines that are similar to the functioning of a regular pharmacy.

Public campaigns were organized in municipal schools and in the overall community to seek donations of medicines. According to the pharmacist, all collected medicines are strictly supervised regarding the quality and the expiry date. All products are classified and stored. There is an accounting system to calculate and record quantities that are received, stored and given. A biannual inventory is performed, and expired medicines are destined for incineration. The pharmacy only donates medicines once a week (on Tuesday afternoons) in order to avoid any accusation of competition with commercial retailers in the same sector, and only under medical prescription of the public health system (SUS). An average of 90 persons benefit every week.

4.1 Environmental Impacts

There are basically four environmental impacts monitored in the program of reverse logistics. The first one refers to the amounts of recyclable paper from packages of medicines and the quantities of UNEM that were collected from donors and expired before the opportunity arose to use them. A small decrease in the physical amount of recyclable paper (3%) was observed in 2017 compared with 2016 (Figure 1). Using a biannual comparison, the percentage of recycled paper was higher in the second semester of 2016 compared with the same period of 2015 (28%) and higher in the second semester of 2017 compared with the corresponding months of 2016 (10.8%).

Fig 1 – Amounts of recycled paper with the program

Semester/year	Recycled paper (Kg)	Comparison (%)
July-Dec 2017 (1)	133.6	(1) X (2) 10.8
July-Dec 2016 (2)	120.5	(2) X (3) 28.0
July-Dec 2015 (3)	94.1	
Full year 2017 (4)	243.6	(4) X (5) – 3.0
Full year 2016 (5)	251.2	

Source: Field Data (2018)

The second tracked environmental impact refers to the physical amounts of solid expired medicines that were collected before expiring but not could be distributed before product expiry. An increase of 50.48% in the physical amount of solid medicines expiring after collection was recorded (from 501.6 Kg in 2016 to 754.8 Kg in 2017). It refelcts the increasing volume of medicines received from one year to the next and, whilst illustrating some inefficiency in the distribution system, reflects a significant benefit in terms of improvements to waste management approaches.

The third impact refers to the liquid medicines collected and not distributed (an increase of 262.5% from 2016 to 2017). Figure 2 compares on an annual and biannual basis and shows that, since the start of the program, until December 2017, 3,100 litres and 1,467 Kg were diverted from inappropriate disposal routes in the environment because they remained under professional care.

The fourth impact are the quantities effectively distributed from July 2015 to December 2017 (approximately 548 Kg). These two last impacts are arguably significant, as they represent around 2 tonnes of solid wastes that did not contaminate the soil or the water.

Fig 2– Amounts of expired medicines after reaching the pharmacy

Semester/year	Expired medicines (Kg)	Comparison (%)	Expired medicines (litres)	Comparison (%)
July-Dec 2017 (1)	431.3	(1) X (2) 77.8	1,100	(1) X (2) 275
July-Dec 2016 (2)	242.5	(2) X (3) 15.3	400	(2) X (3) 200
July-Dec 2015 (3)	210.3		200	
Full year 2017 (4)	754.8	(4) X (5) 50.5	2,100	(4) X (5) 262.5
Full year 2016 (5)	501.6		800	

Source: Field Data (2018)

4.2 Economic Impacts or Avoided Environmental Impacts

Considering both solid and liquid medicines that have expirated after reaching the pharmacy, Solidare calculated a monetary increase of almost 400% from 2016 to 2017. This equates to an economic value of unusable stock equivalent to US$ 1.32 per kilo only in the last year (Figure 3). It corresponds to the ratio between physical quantities received in 2017 (754.8 Kg, Figure 2) and the respective net value of such quantities (US$ 571,728, Figure 3), given the average market values of the sum of all medicines that reached the pharmacy. Such estimates are based on the average selling price of all brands of medicines performing the same functions as those donated.

Fig 3 – Monetary values of the expired medicines after reaching the pharmacy

Semester/year	US$*	Comparison (%)
July-Dec 2017 (1)	99,636	(1) X (2) 85.9
July-Dec 2016 (2)	53,596	(2) X (3) 84.1
July-Dec 2015 (3)	29,118	
Full year 2017 (4)	571,728	(4) X (5) 392.3
Full year 2016 (5)	116,132	

*US$ values were calculated from amounts in reais (R$, Brazilian currency) considering 1 US$ as R$ 3,22 according to the official Central Bank of Brazil exchange in Feb 16th 2018.

Source: Field Data (2018)

Current stocks of expired medicines (with accounting updated in January 2018, and related to 2017) amount to US$ 25,465, and correspond to 44.9 Kg (Figure 4). Such quantities will necessarily enter into the legal disposal system that demands segregation, and storage in bottles for hazardous wastes, that are kept in a storage area. Costs for final disposal of expired medicines using legally acceptable processes present high variability. There are several authorized forms of destruction of expired medicines, such as incineration, pyrolysis, autoclaving, microwave, ionizing radiation, electrothermal deactivation, and chemical treatment, so the values of such wastes' destructions are highly variable, depending on the conditions of each signed contract. In the case of Farroupilha, the Public Administration currently pays US$ 2.76 per kilo for physical-chemical destruction of wasted medicines. Considering the data in Figure 2, since the beginning of the program, in July 2015, until December 2017 (last available data), the physical amount accounted 1.46 tonnes. It represented total costs around US$ 4,000 for final disposal This is a significant economic value as impact for the Public Administration because it is not provided by public budget planning, therefore it is accounted as extra expense. Nevertheless, at least two non-economic counterparts need to enter in consideration: socioeconomic impacts for the benefited persons (subsection 4.3) and avoided negative environmental impacts that could be generated through the incorrect discharge of such medicines.

Fig 4 – Current expired and not expired stocks

Physical stocks (December 2017)	Physical value (Kg)	Monetary value (US$)*
Not expired	111.416	90,460
Expired	44,947	25,465

*US$ values were calculated from amounts in reais (R$, Brazilian currency) considering 1 US$ as R$ 3,22 according to the official Central Bank of Brazil exchange in Feb 16th 2018.

Source: Field Data (2018)

From another perspective, a positive economic impact relates to the whole value of donations. In physical amount, it has increased from 301.2 Kg in 2016 to 469.7 Kg in 2017 (a 56% increase). The corresponding monetary value has also jumped from US$ 191,785 in 2016 to US$ 293,481 in 2017 (a 52% increase). Figure 5 details the quantities of donations.

Fig 5– Donated quantities by local community of UNEM since the beginning of the program

Semester/Year	Physical amounts (Kg)*	Comparison (%)	Monetary amounts (US$)*	Comparison (%)
July-Dec 2017 (1)	179.8	(1) X (2) 1.18	135,433	(1) X (2) 24.66
July-Dec 2016 (2)	177.7	(2) X (3) 3.47	108,633	(2) X (3) -17.74
July-Dec 2015 (3)	171.7		132,065	
Full year 2017 (4)	469.7	(4) X (5) 55.97	293,481	(4) X (5) 53.02
Full year 2016 (5)	301.2		191,785	

*It refers to pills or medicines bottles
**US$ values were calculated from amounts in reais (R$, Brazilian currency) considering 1 US$ as R$ 3,22 according to the official Central Bank of Brazil exchange in Feb 16th 2018

Source: Field Data (2018)

4.3 Socioeconomic Impacts

The most interesting aspect of the social reverse logistics of UNEM in the case under study is arguably the socioeconomic benefits it brings to the community that participates in the program. The dispensation of medicines in Solidare has risen 53% in monetary value between 2016 and 2017 - from US$ 116,132 to US$ 177,555, respectively (Figure 6). In physical amounts it corresponds to a 67% increase, from 187.2 kg (of pills or medicines bottles), in 2016, to 313.4 kg in 2017. Since the beginning of the program, in July 2015, 8,015 persons have benefited: 929 in the first year (six months), 3,621 in 2016, and 3,465 in 2017 (full year accounted in 2016 and 2017). It means that in 2016 the average income, indirectly distributed, amounted to US$ 32.07 per capita. Taking just the last year, this value increased to US$ 51.24 per capita, which corresponds to 17.29% of the minimum wage that is established by federal law in Brazil. Such values are gains that the benefited persons could readdress to other than medicines' purchasing, i.e., it represents an amount of money that could be, and likely was, spent on other essential needs, such as food, clothes, education, transportation, and leisure activities. Another socioeconomic impact is of a collective nature. It relates to avoided costs that would be incurred if UNEM had not be redistributed and were instead destinated for incineration and other forms of physical-chemical destruction. Considering that dispensed quantities reached to 547.6 Kg since the beginning of the program, the avoided costs sum US$ 1,511. This quantity represents savings that the Public Administration can invest in social improvements. Here only the savings of reverse logistics of UNEM are included, rather than the overall monetary amount spent in the correct final disposal of the medicines that was incurred through expiry after being collected, as stressed in the section 4.2.

Fig 6 – Dispensed quantities of UNEM to needy people since the beginning of the program

Semester/Year	Physical amounts (Kg)*	Comparison (%)	Monetary amounts (US$)*	Comparison (%)
July-Dec 2017 (1)	142.396	(1) X (2) 78.18	99,636	(1) X (2) 85.89
July-Dec 2016 (2)	182.131	(2) X (3) 87.31	53,596	(2) X (3) 84.06
July-Dec 2015 (3)	47.024		29,118	
Full year 2017 (4)	313.383	(4) X (5) 67.36	177,555	(4) X (5) 52.89
Full year 2016 (5)	187.247		116,132	

*It refers to pills or medicines bottles
**US$ values were calculated from amounts in reais (R$, Brazilian currency) considering 1 US$ as R$ 3,22 according to the official Central Bank of Brazil exchange in Feb 16th 2018

Source: Field Data (2018)

5 Discussion and final remarks

The pharmaceutical industry has a high capacity for innovation and it is a highly profitable sector that will keep on growing mainly with the aging of the population and with the discovery of new drugs and treatments for diseases. Incorrect discharge of used medicines is a global negative impact for the environment and for the public health. It represents waste in all perspectives – environmental, economic, and social. It also projects itself to future generations in terms of a heritage of environmental and health problems.

In emerging economies such as Brazil, the incorrect discharge of used, non-expired medicines, is a wicked problem. Brazil has had a federal law for the reverse logistics of solid wastes since 2010, but it does not specify procedures for used, non-expired medicines (UNEM) to re-enter the consumption chain.

Some isolated solutions are taking place for the reverse logistics of UNEM amongst nets of retailers, but most of them have not collected records of benefited persons. In Farroupilha municipality, situated in Southern Brazil, the Public Administration created a program for collecting and donation of UNEM in July 2015. Due to professionalism and management capacity, this program has recorded all amounts of collected and dispensed medicines. Therefore, an assessment/appraisal of the impacts is feasible.

Through this case study, it was shown that the program (Solidare Pharmacy) has distributed UNEM in a total amount of US$ 322,8 from July 2015 to December 207. This is a monetary saving attributed to the initiative of the reverse logistics that represent an indirect socioeconomic earning for people that participated in the program. Under such initiative, a total physical amount of 547.6 Kg of UNEM re-enter to local consumption system. Besides such indirect economic and environmental positive impacts, a brief socioeconomic appraisal can show that around 90 persons are benefited every week, receiving UNEM at no cost, subject to possession of a public medical prescription. In 2017, the indirect distribution of income with the program reached US$ 51.25 per capita, around 17% of the minimum legal wage in Brazil.

Nevertheless, the Public Administration increased its economic spending with the physical-chemical destruction of collected medicines that expired before have the chance of being dispensed. As the individuals do not use to proper dispose medicines wastes, this economic burden for the municipality is justifiable from the point of view of avoiding further environmental and health damages.

Reverse logistics is not a simple set of tasks. When it relates to medicines, this reality is especially difficult. The program of the Solidare Pharmacy faces many challenges to keep on receiving/collecting the necessary types of medicines to fulfill the weekly demand and to remain open to new needs. It relies on the continued support of donors. Another challenge is to improve the management capacity,

receiving support of researchers for the development of new tools that facilitate the donor campaigns close to the community.

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