LEGAL REGULATION OF PHARMACEUTICAL WASTE MANAGEMENT IN LITHUANIA

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Annotation

Problems of pharmaceutical waste collecting and its management in Lithuania are discussed in paper. Experience of pharmaceutical waste management in United Kingdom is analysed. Analysis of acts relating with pharmaceutical waste management and valid in Lithuania republic is carried out. Methods of research publications, acts and statistics analysis were applied. Procedure of pharmaceutical waste collecting from inhabitants and its transfer to waste manager selected by Ministry of Health in public pharmacies of Lithuania Republic is described. Pharmaceutical waste belongs to hazardous waste category; therefore most safe method of its elimination is incineration in single-purpose waste incineration devices.

Key words: medical waste, pharmaceutical waste, pharmaceutical waste management, pharmaceutical waste collecting.

Introduction

Many of chemical materials and medicaments using in health care institutions are hazardous waste (toxic, infective, unhealthy, irritant, mordant, in contact with which could be destroyed live tissues, ecotoxic, and sensitive for shaking up. Toxic materials, heavy metals, including cadmium compounds, mercury and very specific agents of contamination (various microorganisms) could be found in these materials and medicaments (Valstybinio audito ataskaita, 2010). Mostly these materials in medical waste are found in small amounts, however major amounts of this type of waste are forming when expendable or chemical materials and medicaments of expired date are utilizing.

One group of medical waste – pharmaceutical waste – is excepting from medical waste stream because of its chemical and physical characteristics. Not a few of inhabitants, especially the elderly, which bought a stock of preparations in discount prices when their date of expire are over throw on they anywhere. Outdated impracticable preparations could be reason for intoxication, if they are throwing on to dustbin or sewerage. Pharmaceutical waste, in which could be antibiotics or another preparations, phenols, disinfectants and antiseptics as well when passed into sewerage could have negative impact for work of biological treatment stations of sewage waters or toxic impact for wild ecosystems, solid waste dumps and after passing into air, soil or groundwater are causing more or less negative impact to human, fauna and flora (Farmacinės atliekos..., 2012).

Antibiotics and cytostatics - preparations, which act on all cell of organism, but cells of cancer, are more sensitive for them - are particularly hazardous for environment. After these medicaments passed into environment, they act negatively a balance of microorganisms, contaminate water, soil and could return to human organism in this way (Daunoravičienė, Griškevičius, 2011; Mačiūnas, Budginaitė, Zurlytė, Juozulynas, 2009). On purpose to protect environment, human and animal health from possible risk, is relevance to warrant management of medical waste. Inappropriate management or unsafe utilisation, though small amount of medical waste characterising by infective or chemical features, possibility of many negative consequences is remaining: environment (air, soil, water) contamination, infections spreading with blood (hepatitis B and C, HIV), intoxications, freaks, allergies, zymotic diseases, etc.

Development of health and new technologies, upturn of health care services quality and well developed production of health care products determines the increase of medical waste amount. Appropriate management of medicinal waste and pharmaceutical waste as one of its category is necessary to protect community health and clean environment and to avoid a spread of zymotic diseases.

Research goal is to evaluate legal acts of Lithuania Republic, appealing on which pharmaceutical waste is managing in Lithuania.

Research aims are to analyse the experience in waste management using case of economically developed state (United Kingdom); to discuss the problems of pharmaceutical waste management in Lithuania; to characterise a process and result of pharmaceutical waste

management in Lithuania; to discuss legal acts warranting pharmaceutical waste management in Lithuania.

Research methods are analysis of research publications, statistics and acts concerned to pharmaceutical waste management.

Results

1. Pharmaceutical waste

According to definition given in Pharmacy Law (*Farmacijos įstatymas*, 2006), pharmaceutical waste is preparations and veterinary preparations for eliminating (not qualitatively, with expired date, forfeit, collected from inhabitants, adulterate). Pharmaceutical products, which are not qualitatively packed or tare of which is damaged are attributing to pharmaceutical waste too. Dissolvable preparations are preparations with expired data, not qualitatively, forfeit and collected from inhabitants, which can not be use for purposes of health care and veterinary.

In Waste management rules (*Atliekų tvarkymo taisyklės*, 2011) unusable (dissolvable) preparations and chemical are attributing to category of hazardous waste. According to 18 chapter of Waste code list of these rules pharmaceutical waste is one of significant group of medical waste, for which codes 18 01 08 and 18 01 09 are using (18 01 08 signifies cytotoxic (they are stopping development of cancer cells) or cytostatic (they are destroying cancer cells) preparations and 18 01 09 – preparations not indicated in 18 01 08). Hazardous health care or medical waste includes infected waste; not infected sharp goods; pharmaceutical waste (dissolvable preparations and chemicals); other hazardous medicinal waste.

2. Sources of pharmaceutical waste

Medical waste can form in various places where services of human and animal health care are providing: hospitals and other institutions of health care, odontological surgeries, care institutions, laboratories, pharmacies, enterprises of veterinary services, household and others (Valstybinio audito ataskaita, 2010).

Pharmaceutical waste is forming in pharmacies, health care institutions and households. There are not accurate data on amount of collected pharmaceutical waste. In Lithuania accounting of medical waste was not organized until 2005 (Mačiūnas et al., 2009). In Lithuania the increase of medical waste is stated: from 55 tons in 2010 to 107 tons in 2013 (Kisielienė, 2015). The facts given by State waste accounting suggest that in 2007-2011 following amounts of pharmaceutical waste were formed (in thousands of tons): 2007 - 0, 12; 2008 - 0, 06; 2009 - 0, 03; 2010 - 0, 08; 2011 - 0, 07 (Valstybinis atliekų ..., 2014). There were collected 198,18 tons of dissolvable preparations in 2013 (Grigaliūnienė, 2015). But is unknown, how many unused preparations inhabitants scrap to dust hole or sewerage.

3. Management of pharmaceutical waste

The best part of human activity is concerned with waste. Waste management is concurrent of any activity process. The system of waste management by legal, administrative, economical means and their applying is formed of waste system of industrial and other economical activity, the last includes medical waste too. One group of medical waste – pharmaceutical waste – is distinguished from medical waste flow because of their chemical and physical characteristics.

3.1 Experience of pharmaceutical waste management in economically developed state (United Kingdom)

Forming of waste, possible negative their impact to environment and human health is one of most actually environment protection problem in economically developed states. Every European Union member state is undertook to protect environment of harmful factors, including tackling the problems concerned with waste forming and their management. Waste management includes the activities of waste collecting, transporting, using and eliminating as well as control of waste management activity and control of waste eliminating zones after their closing. The part of this activity is management of hazardous waste, to which pharmaceutical waste management is ascribed too. With the intention of ensuring to analysing problem European context, we shortly reviewed how pharmaceutical waste is managing in one of economical developed state – United Kingdom (Banionytė, Motiekaitytė, 2014).

In United Kingdom (UK) waste of preparations on prescription is managing sticking to *Special Waste Regulation* (1996). This regulation reflects requirements of EU *Dangerous Substances Directive* (67/548/EEC) and is close related to *The Health and Safety at Work Act* (1974). This regulation defines the hazardous waste as waste under control, which are included in hazardous waste list and is distinguishing at least by one characteristic, which determines hazardousness and is enumerated in Annex III of *EU Hazardous Waste Directive*. Environment

protection agency is prepared practical method guide how to identify special waste. Environmental protection agency is responsible for hazardous waste management (Pavojingų atliekų perdirbimo ..., 2012).

In description of pharmaceutical and medical waste a definition of pharmaceutical waste is given: there are preparations of any form and their containers, which are not sharp, when they are not using or their expiry date is issued. Ampoules, needles, syringes must be discard into special boxes for sharp waste of this type. Elimination requirements of preparations under control are stated in *Misuse of Drugs Regulations* (1985). Narcotic and psychotropic preparations can collect only these pharmacies, which have licence to trade narcotic and psychotropic materials.

In England, Northern Ireland and Wales's medical, pharmaceutical waste must be burned in special, licensee waste incineration enterprises. In Scotland pharmaceutical waste classified as cytotoxic or cytostatic pharmaceutical waste must be burned in licensee waste incineration enterprises too, pharmaceutical waste of other kinds can be burned or eliminated by alternative methods and means (NetRegs, 2012).

In UK in contradistinction to Lithuania pharmaceutical and other medical waste management and elimination services are providing by many enterprises. They must obtain waste management licence, which enable to manage, transport, and eliminate waste harmlessly to environment and human health. Best-known are "PHS group", "Clinical Waste Collections Services", "SITA UK". In UK operate 13 enterprises, which eliminate pharmaceutical and medical waste in their own waste incineration devices, about 300 enterprises provide medical and pharmaceutical waste collecting service from health care and veterinary institutions and pharmacies and safe transportation service to waste incineration enterprises (Cylex, 2012).

Local government institutions are established effective management system of medical and pharmaceutical waste – well-run order of delivery of licensee for activity is warranting, local government collaborates with private sector constantly, through healthy conditions are capacitating for establishing and functioning of these enterprises, constant competition and better quality of offering services is promoting. When social and economic factors are changing permanently, companies, if they intend to hold down the market, must be flexible and innovative (Banionytė, Motiekaitytė, 2014).

Each pharmacy collecting waste must prepare the rule of pharmaceutical waste management, which includes all stage of waste management: collecting from inhabitants, storage and transfer to pharmaceutical waste eliminating enterprises. Marking, collecting, storage and accounting of pharmaceutical waste are describing in these rule. Particularly strict is keeping accounting of pharmaceutical waste, because real amount of emerging waste will be known (Pharmaceutical waste guide, 2012). On the basis of this data is possible to plan waste eliminating effectively and to assess necessity of new devices.

Permanent collaboration among inhabitants, pharmacies, preparation manufacturers and companies of pharmaceutical waste collecting and eliminating takes place in UK. Particularly strict attention is giving to public education and informing how to behave with unwanted or expired date preparations. Means of information are used — posters in pharmacies, advertisement in web sites of pharmacies. Companies managing pharmaceutical and other medical waste are warranting convenient collecting for inhabitants, institutions of health care, preparation manufacturers and provide them with due means: tight boxes, appropriate plastic cruets, marked bags. Pharmaceutical waste collecting from small institutions of health care, pharmacies in small towns, which collect preparations of inhabitants, is warranting, because a lot of small waste collecting enterprises are working and they are divided up in all territory.

Appropriate packing of pharmaceutical waste is main method of environment and human health protection, when waste is collecting, transporting and eliminating. In UK pharmaceutical waste is packing to tight boxes by these groups: yellow bags are using for empty plastic cruets; yellow boxes – for sharp pieces (styles, infected syringe, etc.); yellow boxes with violet cover – for sharp pieces, which interacted with cytotoxic substances (special label "cytotoxic substances" is using); yellow boxes with violet diagonal belt – for containers, tare, kids, which had contact with cytotoxic preparations; white boxes – for storage of hermetic containers of aerosols.

Thought development of health care and qualitative service determine growth of pharmaceutical waste, pharmaceutical waste management system in UK works effectively – pharmacies readily collects preparations from inhabitants, stores them in appropriate rooms and after transfer them to waste eliminating enterprises, which warrant safe eliminating. Pharmacies together with pharmaceutical waste eliminating enterprises are responsible for strict accounting of this waste. Hazardous pharmaceutical waste is incinerated in single-purpose medical and hazardous waste incineration devices.

3.2. Pharmaceutical waste management in Lithuania Republic

Hazardous waste forms separate group of waste. The main flows of this waste are waste of petrol products; waste contaminated by petrol products; hazardous waste of vehicles; waste contaminated by heavy metals; waste of chemicals; medical waste. One of most significant group of medical waste is pharmaceutical waste (Mačiūnas ir kt., 2012).

According to waste management system, stated in National waste management plan for 2014-2020, medical waste is attributed to waste management system of industrial and other economical activity. Most of pharmaceutical waste is hazardous, therefore must be collecting separately and managing according to demands of waste management and entirely hazardous waste management, so as not to menace for environment and human health. There is essential to own information on waste amount and structure classified by kinds on purpose to establish modern and effective medical waste management system.

Management of medical waste is medical waste batching in place of its formation, collecting, packing, marking, primary treatment (eliminating of noxiousness) and temporary storage in institution of health care. Management of pharmaceutical waste is activity of pharmaceutical waste collecting, treatment, transporting, using and eliminating.

Ministry of Health performs expertise of hazardous waste and its management activity impact to human and public health, determines requirements of waste batching in place of its formation, collecting, packing, marking, primary treatment and temporary storage in institutions of health care. Ministry regulates medical waste management in institutions of health care, coordinate's action of institutions of health care implementing capabilities of medical waste management.

Ministry of Environment regulates and administrates management of all waste, controls implementation of stated requirements and tasks. Ministry of Environment coordinates activity of others institutions and municipalities in waste management field.

Means of waste management, tools, and legal aspects are discussed in environment protection literature (Spruogis, Jaskelevičius, 2000; Bakas, 2008; Grité, 2014, Venckus, 2008, 2015). Medical and pharmaceutical waste management and elimination are analysed in publications and research papers devoted to these problems (Mačiūnas et all., 2009; Daunoravičienė, Griškevičius, 2011; Jakaitienė, 2011; Grigaliūnienė, 2015).

It was began to talk about pharmaceutical waste, its collecting and eliminating importance till *Pharmacy Law* (2006) was become effective. Now, though valid acts regulating pharmaceutical waste management are enough, pharmaceutical waste emerging problems remains. One of them is irresponsible usage of preparations, when inhabitants obtain and entirely not use or used only partly compensatory preparations prescribed them. There are expensive preparations as often as not, which basic price is paid by state from bugged funds. Second, more or less management problem, is rarely obtainable preparations, which expire date ends, but they stay not sold, because former regular not buys their through various reasons.

3.3. Collecting of pharmaceutical waste

In 42 article of Pharmacy Law attitude is fixed: Public pharmacies must take dissolvable preparations from inhabitants free. Waste manager collects accepted dissolvable preparations from public pharmacies and pursues other activity of their managing according to order defined in Waste management Law of Lithuania Republic and other law. Government defines order of accepting of dissolvable preparations from inhabitants and reimbursement of their management.

For management of dissolvable preparations accepted from inhabitants and veterinary preparations is reimbursing to appropriate institutions, which are responsible for implementation of this law, from general vote confirmed in state bugged.

Body, in whose activity pharmaceutical waste is forming this pharmaceutical waste manages by order of Waste management Law of Lithuania republic and other law.

Inventory of order of dissolvable preparations accepting from inhabitants and reimbursing for their management (2012) ascertains order of dissolvable preparations accepting from inhabitants in public pharmacies and production public pharmacies, order of their registration and reimbursing for their management. Dissolvable preparations accepting from inhabitants are managing according to requirements of hazardous waste management and must be to release for management to waste managers selected by order of Inventory of Ministry of Health and having right to manage hazardous waste by order of Waste management Law and other law.

Head of pharmaceutical activity is responsible for dissolvable preparations accepting from inhabitants, accounting and releasing to waster manager having right to manage of them. Pharmacy must release dissolvable preparations accepting from inhabitants to waste manager selected by order of Inventory no latter than 6 month from their accepting day.

By order of *Waste management rule*, enterprise, which is using or eliminating waste, must have waste using or eliminating technical order. In technical order using and eliminating waste kinds and characteristics, procedures of waste accepting and control, waste transfer from site of collecting to site of its using or eliminating must be defined.

Head of enterprise, which owns public pharmacies and production public pharmacies, formulates interior document how to manage pharmaceutical waste in filial of enterprise. According to this document head of pharmaceutical activity of filial or pharmacy specialist appointed by order of head of pharmaceutical activity transfers pharmaceutical waste to enterprise of pharmaceutical waste management (V. Motiekaitytė pers. comm.). If enterprise, which owns pharmacy, is prepared *Quality guide of pharmaceutical activity*, head of pharmaceutical activity of filial is organizing pharmaceutical waste management by appropriate procedure described in this guide. Head of pharmaceutical activity warrants, that not pharmaceutical waste (food supplements of expired data, medical goods, cosmetic and others good of pharmacy assortment, not attributing to preparations) will not be collected. Only pharmaceutical waste (dissolvable preparations and unusable chemicals) formed in pharmacies and accepted from inhabitants is transferring to manage.

Procedure of transferring of pharmaceutical waste to enterprise of pharmaceutical waste management includes arrangement of pharmaceutical waste accumulated in pharmacy, correct processing of documents and transferring to store of enterprises or to waste manager. Pharmaceutical waste formed in pharmacies is discarding, after that they are transferring to storage site special site marked *Dissolvable preparations*, where it is keeping grouping (having narcotic materials, having psychotropic materials, having mercury; other dissolvable preparations, including not identified; preparations accepted from inhabitants); by dissolvable preparation groups accounting acts/assignments are preparing, dissolvable preparations accepted from inhabitants are registering in separate journal indicating datum of accepting of dissolvable preparations, kind of waste, code and weight. For transferring dissolvable preparations are putting to boxes by groups together with appropriate accounting acts/assignments, the labels of group marking are gluing on boxes. After transferring of pharmaceutical waste to carrier, head of pharmaceutical activity registers accounting acts/assignments in *Pharmaceutical waste accounting/assignments journal* and in *Dissolvable preparations accepted from inhabitants accounting/assignments journal*.

Primary health care institution, with witch pharmacy is compacted commission agreement concerning inhabitant's supply of preparations through primary health care institution situated in rural districts and with witch the same pharmacy is compacted agreement concerning accepting dissolvable preparations, can accept dissolvable preparations from inhabitants free and transfer them to pharmacy.

In Lithuania Republic dissolvable preparations are accepting from inhabitants free, though polluters (consumers) must reimburse all social and economical detriments arising from contamination and resource exploitation (Meškys, 2006).

State waste management plan for 2014-2020 years ascertains: public pharmacies and public production pharmacies according regulation order must accept preparations from inhabitants free. Government of Lithuania Republic or institution appointed by its order – Ministry of Health - ascertains order of accepting of preparations from inhabitants and payment of their management. For accepted preparations and veterinary preparations from inhabitants is paying from general subsidies approved in state budget. Ministry of Health from general subsidies approved to it in state budget is paying to selected managers of hazardous waste by real amount of accepted dissolvable preparations from inhabitants.

According to *Inventory of order of dissolvable preparations accepting from inhabitants and reimbursing for their management* (2012), pharmacy must transfer accepted dissolvable preparations from inhabitants to hazardous waste manager selected by Ministry of Health – company "Tekasta" only not later than 6 months from data of their accepting (Farmacines atliekas surinks…, 2012).

4. Acts regulating pharmaceutical waste management

Management of pharmaceutical waste is implementing according to General acts: Waste management law (Atliekų tvarkymo įstatymas. 2014), Waste management rule (Atliekų tvarkymo taisyklės, 2011) and acts of Health system: Pharmacy law (Farmacijos įstatymas, 2006), Hygiene rule HN 66:20132013, Safety requirements of medical waste management" (Higienos norma HN 66:2013 "Medicininių atliekų tvarkymo saugos reikalavimai), Inventory of order of dissolvable preparations accepting from inhabitants and reimbursing for their management (Naikintinų vaistinių preparatų priėmimo iš gyventojų ir apmokėjimo už jų tvarkymą tvarkos aprašas", 2012).

According to *Waste management law*, enterprises, which collect, store, eliminate or use hazardous waste, must get licence, which certify Agency of Environment protection. Therefore enterprises has right to pursue pharmaceutical waste management activity only after obtaining two licences.

Waste management law obliges to manage waste not exceeding environment protection marks fixed in acts for water, air or soil pollution and not inducing significant negative impact to public health, animals or vegetation.

Basic requirement of *Waste management rules* is to collect, store and sort waste so as they not induce risk to human health and environment.

Pharmacy law regulate pharmaceutical and other activity related with preparations, research preparations, veterinary preparations, active and other medicinal materials and implement government and control of this activity too. Pharmacy law regulate management of pharmaceutical waste. This law allows that pharmaceutical waste management (except for eliminating) is pharmaceutical activity under licence, which is certificate by State drug control agency.

Pharmacy law ascertains that juridical person can manage pharmaceutical waste if it has pharmaceutical waste management (except for eliminating) licence certificated by determinate order only. This law obliges pharmaceutical waste managers to have appropriate premise, equipment, which will meet the requirements and to warranty: appropriate store of pharmaceutical waste and their management; that pharmaceutical waste will be manage by Technical regulation, which in detail characterizes how waste must be collected, sorted, stored and included to accounting. Juridical person, in whose activity pharmaceutical waste is forming, this pharmaceutical waste is manage according to Waste management law and other acts determinate order. Dissolvable preparations can not be using in human or animal health service.

Hygiene rule HN 66:2013 "Safety requirements of medical waste management" is prepared with aim to harmonize regulation of medical waste management in health care institutions with acts regulating general waste management system (Atliekų tvarkymo įstatymas, 1998), Atliekų tvarkymo taisyklės, 1999), Atliekų susidarymo ir tvarkymo apskaitos ir ataskaitų teikimo taisyklės, 2011) and to ascertain obligatory regulations of public health safety warranting appropriate medical waste management in health care institutions. This Hygiene rule ascertains requirements for medical waste (excluding radioactive medical waste) sorting in their forming places, collecting, packing, marking, primary treatment (noxiousness eliminating) and temporal storing in health care institutions.

Because of exceptional features of pharmaceutical waste its management requirements are very strict, therefore holder of pharmaceutical waste has to allocate a separate lockup place or premise to dissolvable preparations.

5. Pharmaceutical waste elimination

Waste or materials, which can not be used repeatedly and after to process or to use differently, is permitting to eliminate in waste eliminating devices tooled and exploiting according to requirements ascertained in acts.

In *Pharmacy law* eliminating of pharmaceutical waste is not ascertained. Eliminating pharmaceutical waste, it is processing. Physical (including sorting), chemical or biological processes are using, when characteristics of pharmaceutical waste are changing than its size or hazardousness will reduce and will be easy to manage it. Is forbidden to depose waste in landfills and to incinerate in devices not fulfilling requirements ascertained in environment protection and other acts.

EU practice shows that most medical and pharmaceutical waste is eliminating using incineration because of its human and environmental hazard (Atliekų deginimo aplinkosauginiai reikalavimai, 2003). Most popular elimination method of medical waste is its incineration. Incineration is one of main elimination method of most medical waste and widely using yet. It is possible to take out remains of incinerated waste to landfills. Hazardous pharmaceutical waste must be to incinerate in single-purpose incineration devices for medical or hazardous waste.

Incineration is high temperature dry oxidation process, which changes organic and easily ignitable waste to inorganic, flameproof and thus weight and size (amount) of waste very decreased. Modern incineration technologies decrease waste size and mass to 95 pct. There is incinerating this waste, which can not be repeatedly used, processed or deposited. In 2011 most (0,067 thousands of tons) pharmaceutical waste was exported to incinerate to single-purpose hazardous waste incineration devices in Germany (Valstybinis atliekų tvarkymo..., 2014).

Conclusions

Statistic data on amount of forming in pharmacies and collected from inhabitant's pharmaceutical waste is not published. *Pharmacy law* obliges pharmacies to collect, sort and appropriately store not only their own pharmaceutical waste, but to accept from inhabitant's inconsumable preparations. Management of pharmaceutical waste is pharmaceutical waste collecting, process, transport, use and eliminating activity.

Management of pharmaceutical waste is implementing according to Waste management law (Atliekų tvarkymo įstatymas, 2014), Pharmacy law (Farmacijos įstatymas, 2006), Waste management rules (Atliekų tvarkymo taisyklės, 2011), Inventory of order of dissolvable preparations accepting from inhabitants and reimbursing for their management (Naikintinų vaistinių preparatų priėmimo iš gyventojų ir apmokėjimo už jų tvarkymą tvarkos aprašas, 2012), Hygiene rule HN 66:2013 "Safety requirements of medical waste management" (Higienos normos HN 66:2013 "Medicininių atliekų tvarkymo saugos reikalavimai") attitudes and requirements, following to interior documents of pharmacy enterprises. Management of pharmaceutical waste is regulating by Pharmacy law.

Dissolvable preparations are accepting from inhabitants for free in pharmacies. Ministry of Health from general subsidies approved to it in state budget is paying to selected managers of hazardous waste by real amount of accepted dissolvable preparations from inhabitants. Pharmacy must transfer accepted dissolvable preparations from inhabitants to hazardous waste manager selected by Ministry of Health – company "Tekasta" only not later than 6 months from data of their accepting.

Practice of economically developed states (United Kingdom) shows that most medical and pharmaceutical waste must be eliminating using burning in single-purpose medical or hazardous waste incinerating devices because of human and environmental hazards.

Analysis of law regulating pharmacy activity in public pharmacies related to pharmaceutical waste management allows to state that there are sufficient acts for management of pharmaceutical waste. However, was stated that the problem of pharmaceutical waste forming in households and partly in pharmacies own remains actually.

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