FACTA UNIVERSITATIS
Series: **Working and Living Environmental Protection** Vol. 13, N° 2, 2016, pp. 121 - 128

DEVELOPMENT OF MODEL FOR HOUSEHOLD PHARMACEUTICAL WASTE MANAGEMENT

UDC 628.4.045

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Abstract. *The aim of this study is to develop a regional model of pharmaceutical waste management based on the principles of life cycle assessment. Its task is to minimize noticeable risks to human health and the environment, which are the consequence of an inadequate pharmaceutical waste management system. The research was grounded on basic eco-toxicological characteristics of ATC groups of pharmaceuticals. It is focused towards the development of a model for managing expired household medications, taking into account the fact that 90% of pharmaceutical waste is home-generated. The basis of the model comprises of multi-criteria optimization of pharmaceutical waste management process. The survey covered 2600 households in the area of the city of Nis, which is 5.24% of Serbia's total population and 5.15% of the total number of households in Serbia. A special part of the questionnaire comprises the list of household medications according to the ATC (Anatomical Therapeutic Chemical) classification system. In the households in the study area, there were 8.21 medication packages per household, of which 12.22% (slightly more than one package per household) were medicines which had expired. Based on results obtained, the projected quantities of expired medications in Serbia will be 74 920 kg / year. The main feature of a developed regional model is to allow the application of methods for treatment of small quantities of pharmaceutical waste, as recommended by the WHO. The model grounded on ATC classification system is compatible with the classification based on environmental and health risk assessment of pharmaceuticals.*

Key words: *pharmaceutical waste, ATC classification, regional model 6*

1. INTRODUCTION

Medical waste is a heterogeneous mixture of municipal, infectious, pathoanatomical, pharmaceutical and laboratory waste, disinfectants and packaging, as well as chemical waste from medical and veterinary institutions. It has been estimated that about 14,450 tonnes of bio-hazardous waste will be generated in medical institutions in 2015. If we

Received August 30, 2016 / Accepted December 15, 2016
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take into account the additional 6,610 tonnes, which are supposed to be generated in outpatient health institutions, the expected annual quantity of waste will be over 21,000 tonnes. About 3% (6,300 tonnes) of the total waste is pharmaceutical waste [1]. The World Health Organization (WHO) estimates that the quantity of medical waste will amount to about 8.5 kg per capita in the year to come [2]. In the Republic of Serbia, according to data from the Waste Management Unfortunately, over 90% of pharmaceutical waste is home-generated [3].

Disorganized system of pharmaceutical waste management in Serbia has caused the accumulation of significant quantities of pharmaceutical waste (about 200 tonnes), primarily unused or expired medications. Significant amount of pharmaceutical waste, and above all substantial risks to the environment and human health which occur as a result of an inadequate pharmaceutical waste management system, urged the authors of this article to develop a regional model for pharmaceutical waste management. The model is based on the results of multi-criteria optimization process of pharmaceutical waste management. The most important criteria for optimization are: the quantities of various groups of pharmaceutical waste, the characteristics of pharmaceutical waste treatment technologies and environmental impacts of pharmaceutical waste. A regional model developed on this basis should significantly contribute to the efficiency and effectiveness of pharmaceutical waste management system at regional and national levels.

2. METHODOLOGY

The survey was conducted in the area of the city of Nis, which comprises of the city of Niš and the municipalities of Aleksinac, Svrljig, Merošina, Ražanj, Gadžin Han and Doljevac. The examined area included six municipalities and five city municipalities, with 376309 inhabitants living in 285 settlements [4]. Figure 1 shows the area involved in the survey.

The questionnaire provides a sufficient amount of relevant data and qualitative indicators of the following issues: the structure and characteristics of households (number of age of househ old members), technical characteristics of home pharmacies (premise and storage place) and the respondents' views on the use of medications (daily dose, side effects, disposing unused or expired medicines, doctors’ and pharmacists’ consultation on the use of medications, etc.).

A special part of the questionnaire is the list of household medications with the following characteristics: name, type, dose, expiration date, number of medication packages or, the manner and frequency of medication intake (medication regimen) and the groups of medications according to the ATC classification system. According to the ATC classification system, the active ingredients in pharmaceuticals are divided into different groups, taking into account the organs or system on which they act and their therapeutic, pharmacological and chemical properties. All medications are primarily classified into fourteen main groups (the first level). Further classification indicates therapeutic subgroups (the second level) and chemical, pharmacological and therapeutic subgroups and the active The data relevant for the ATC classification, such as chemical composition and interactions with other pharmaceuticals, pharmacology and mechanism of action, therapeutic indications, etc. are extremely useful for the development and implementation of all phases of managing unwanted medications – collection, transportation, storage, neutralization, dumping.

ATC classification system provides a good basis for the selection and implementation of methods for treatment of expired medications. Characteristics of certain treatment methods (chemical-technological properties, capacity, impact on the environment and human health, etc.) are the essential data required for the development of a regional model of pharmaceutical waste management [5]. ACT classification of pharmaceuticals is as follows: A – Alimentary tract and metabolism, B – Blood and blood forming organs, C – Cardiovascular system, D – Dermatologicals, G – Genito-urinary system and sex hormones, H – Systemic hormonal preparations, excluding sex hormones and insulins, J – Antiinfectives for systemic use, L – Antineoplastic and immunomodulating agents, M – Musculo-skeletal system, N – Nervous system, P – Antiparasitic products, insecticides and repellents, R - Respiratory system, S – Sensory organs and V – Various. Reducing waste at the source is the essence of a proper system of pharmaceutical waste management. The disposal of small quantities of pharmaceutical waste is easy and relatively inexpensive, whereas large amounts of waste usually require complex and costly installations.

Table 1 Medical and pharmaceutical waste treatment methods

Pharmaceutical waste treatment methods		
Methods suitable for different categories of pharmaceutical waste	Methods suitable for small quantities of pharmaceutical waste	Methods that cannot be used for pharmaceutical waste disposal
Rotary kiln, Encapsulation, Inertization, Return expired drugs to supplier	Pyrolytic incinerator, Safe burial on hospital premises, Sanitary landfill, Discharge to sewer	Single-chamber incinerator, Drum or brick incinerator, Chemical disinfection, Wet thermal treatment, Microwave irradiation

The most important methods for disposal and treatment of small quantities of pharmaceutical waste are outlined here:

- Sanitary landfills – daily quantities of pharmaceutical waste dissolved with larger quantities of another (inert) waste may be isolated here. Cytotoxic waste and narcotics should never be landfilled.
- Encapsulation – a very small amount of pharmaceutical waste can be disposed of by this method, together with sharps if necessary.
- Safe burial on hospital premises – special programmes allow waste burial in specially equipped premises, and this disposal method considerably reduces transportation cost.
- Discharge to a sewer – moderate quantities of liquid or semi-liquid waste pharmaceuticals, such as solutions containing vitamins, eye drops, cough syrups, solution for intravenous use, etc. could be diluted in water and afterwards discharged into a sewer system; however, cytotoxic medications and antibiotics are not allowed to be discharged at any circumstance, due to possible environmental impact.
- Incineration – small quantities of pharmaceutical waste (no more than 1% of the total amount) can be incinerated together with infectious or municipal waste. The quantities are limited so as to prevent the emission of toxic gases into the atmosphere.

Large quantities of pharmaceutical waste, and in particular pharmaceutical waste after emergencies, are treated by either incineration or encapsulation [6].

3. Results and Discussion

The questionnaire contained four sections: basic data about sample households, data about household storage of medicines, the respondents' views on the management of drugs beyond their expiration date, and a list of drugs according to ATC groups. The average "home pharmacy" in the examined region is located in a cabinet (39%) or kitchen cabinet (28%), in the hallway (29%) or kitchen (21%). Only 5% of household medicines are within children's reach. In the third part of the research, we examined and analyzed the attitudes and behavior of respondents towards medications and how they dispose of expired medicines.

The results are demonstrated in the following graph (Figure 1).

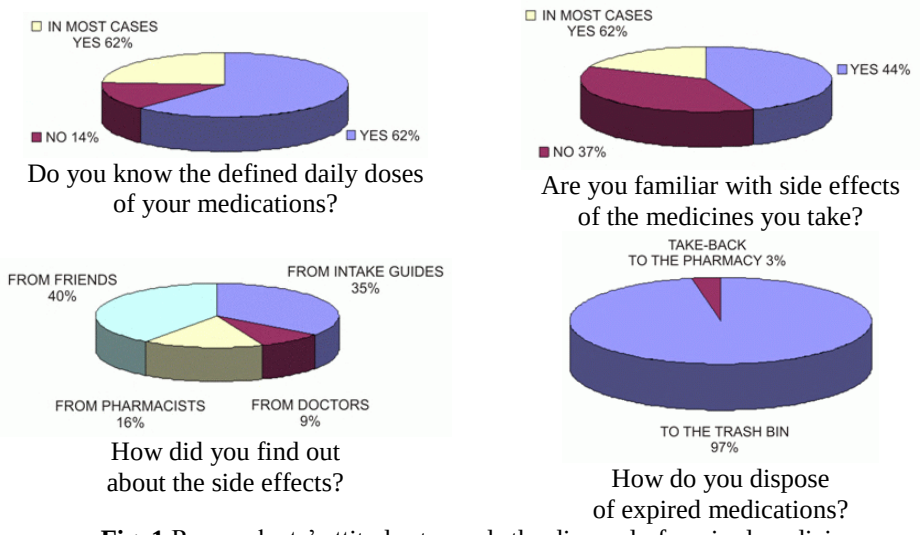

Fig. 1 Respondents' attitudes towards the disposal of expired medicines.

Over 62% of respondents know the defined daily dose of medication they take, whereas 37% are not familiar with the side effects of the medicines they use. The majority of respondents (40%) were warned about side effects by the friends who take the same or similar medications, while only 9% were warned by the doctors. Almost all respondents (97%) throw the expired and unused medications in the household trash, and only 3% of the respondents take them back to the pharmacy. 41% related they consult a physician only. Of all people surveyed, 48% do not fully understand the information about the medicines they receive from their doctors or pharmacists.

Table 2 shows the percentage of expired medications in the total amount of medications in "home pharmacies", by ATC groups and municipalities.

More than two thirds (68.03%) of the total number of packages in examined households has been classified into five ATC groups. The most common are group N - nervous system (16.81%) and group C – cardiovascular system (13.78%). 21,356 packages of medications were found in the households involved in the survey, which is 8.21 items per household, of which 2610 or 12.22% (slightly more than one package per household) were expired medications.

Table 2 The proportion of medications beyond expiration date in the total amount of household Medications (%)

ATC group	Expired medications (%)							
	Niš	Aleksinac	Svrljig	Doljevac	Merošina	G. Han	Ražanj	Total
A	12,85	13,53	14,37	12,78	13,73	12,36	13,64	13,32
B	11,53	11,63	8,70	9,76	13,79	11,54	10,00	10,99
C	7,28	7,06	7,56	8,09	6,86	6,67	7,46	7,28
D	20,00	22,14	20,83	20,00	20,69	18,52	20,00	20,31
G	14,13	14,29	18,75	15,38	20,00	11,11	16,67	15,76
H	10,32	9,68	0,00	11,11	14,29	16,67	0,00	8,87
J	18,13	17,60	19,85	17,27	19,23	18,06	18,52	18,38
L	0,00	0,00	0,00	0,00	0,00	0,00	100,00	14,29
M	11,93	11,67	12,50	11,90	11,70	12,94	12,70	12,19
N	7,05	6,67	6,64	7,23	7,14	7,27	8,43	7,20
P	12,43	14,12	15,63	16,00	5,26	11,76	16,67	13,12
R	12,24	11,83	11,54	11,63	12,31	12,50	11,90	11,99
S	22,69	25,49	18,18	25,00	23,08	18,18	22,22	22,12
V	16,08	16,49	14,41	16,09	15,87	16,67	15,91	15,93
TOTAL	12,19	12,22	12,26	12,23	12,35	12,16	12,83	12,22

The results are shown in Table 3. Estimated annual amounts are based on the assumption that people cleanup or restock medications in "home pharmacies" three times a year.

Table 3 Estimated amounts of expired medications in Serbian households, by ATC groups

ATC group	Number of packages	Quantity (t/year)	Percent of total amount (%)
A	364570	10,94	14,60
B	91860	2,76	3,70
C	204772	6,14	8,20
D	166497	5,00	6,67
G	39232	1,18	1,57
H	18181	0,55	0.73
J	404760	12,14	16.20
L	957	0,03	0.04
M	314813	9,44	12,60
N	241133	7,23	9,65
P	67938	2,04	2,72
R	211470	6,34	8,46
S	78464	2,35	3,14
V	292805	8,78	11,72
Σ	2497452	74,92	100,00

According to WHO, between 0.3 and 0.4 kg / capita / year of hazardous medical waste is generated in middle-income countries occurs. The results obtained in this study are correlated with data from the National Waste Management Strategy which claims that 2410 tonnes of hazardous medical waste, or 0.33 kg / capita / year, are generated in The Republic of Serbia every year. Due to the fact that pharmaceutical waste comprises 3% of total amount of hazardous medical waste, and that calculated annual generation of pharmaceutical waste in Serbia is 72.3 tonnes, the calculated quantities obtained in this study are slightly different (our calculation is 74.92 tonnes / year).

Based on survey results, we can propose the basic framework of the regional model of pharmaceutical waste management:

- More than two thirds (64.77%) of the total quantity of expired medications are ATC group medications S, A, M, V and N, and in terms of waste disposal they are comprise particularly significant amounts of pharmaceutical waste. These five ATC groups generate about 48.5 tonnes of pharmaceutical waste in Serbia per year. Taking into account the amounts of waste and chemical-technological characteristics of waste disposal methods, a developed waste management model predicts regional systems of waste collection and treatment for this group of pharmaceuticals. The regional treatment allows the application of methods for disposal and treatment of small quantities of pharmaceutical waste (Table 1).
- The following three ATC groups (R, C and D) annually generate about 17.5 tonnes of waste pharmaceuticals, which is 23,33% of total pharmaceutical waste tonnage. A developed cost effective and eco friendly model suggests the establishment of a network of regional collection centers, as well as the possibility of treatment at the national level. Regardless of the treatment at the national level, it is possible to use the method for treatment of small quantities of pharmaceutical waste (Table 3).
- The remaining six ATC groups (B, S, P, G, H and L) generate 11.9% of total pharmaceutical waste or 8.91 tonnes annually. For pharmaceuticals in these groups, the proposed model predicts the collection and treatment at the national level, or export to treatment in other countries.

Figure 2. shows the fundamentals of a regional model for pharmaceutical waste management.

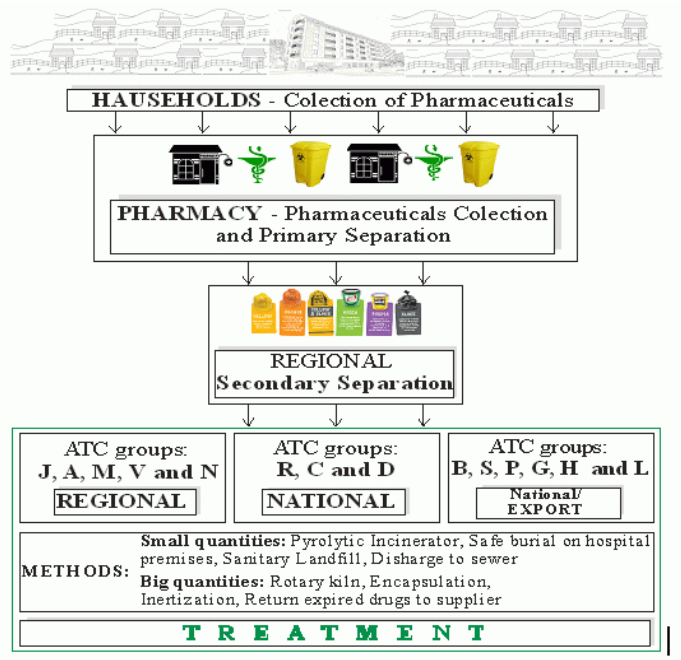

Fig. 2 The fundamentals of a regional model for pharmaceutical waste management

The key feature of this model is that it allows the implementation of disposal methods for small quantities of pharmaceutical waste recommended by the WHO. The application of methods for treating larger quantities of pharmaceutical waste is conditioned, exclusively, by chemical and technological characteristics and significant impacts on the environment and human health [7]. The research is based on primary eco-toxicological characteristics of individual ATC group of pharmaceuticals, or their combinations. In addition, we have also considered the complexity of the physical and chemical monitoring and control of pharmaceuticals in the environment [8]. The solutions presented in the paper take into account the fact that per capita consumption of medications is constantly increasing. To develop a consistent system of management of expired pharmaceuticals, it is significant to provide pharmaceutical waste labels.

Moreover, the model and disposal methods should be developed in line with ATC classification of pharmaceuticals. This classification is fully compatible with the classification based on environmental and health risk analysis of pharmaceuticals.

4. CONCLUSION

The research results show that it is of paramount importance to develop national programmes for effective and efficient management of pharmaceutical waste, more exactly the expired medications in the possession of consumers. The ideal outcome will be the implementation of these programmes at the local and regional level, as close as possible to the site where this type of pharmaceutical waste gets generated. The programmes intended for collection of unused and expired medications and their safe disposal and / or treatment must exclude or minimize adverse impacts on the environment and health of the population and employees in waste management sector. Moreover, these programmes should be designed so as not to create additional cost burdens on household residents. Life cycle assessment of pharmaceutical products is the most efficient tool for managing home-generated pharmaceutical waste and should be used as the basis for integrated sustainable management of pharmaceutical waste flows.

The model of treatment, which has been presented in this article, provides a continuous evaluation of the management programme in terms of safety, effectiveness, efficiency and sustainability of funding this programme. A particularly important feature of this model is the prevention and management of accidents when dealing with expired medications, which has been achieved by managing the flows of household pharmaceutical waste. The model predicts the responsibility of informing the public or the household residents about the negative impacts of expired medications on the environment and human health.

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RAZVOJ MODELA UPRAVLJANJA FARMACEUTSKIM OTPADOM IZ DOMAĆINSTAVA

Cilj rada je razvoj regionalnog modela upravljanja farmaceutskim otpadom, zasnovanog na principima analize životnog ciklusa, sa zadatkom minimizacije izraženih rizika po životnu sredinu i zdravlje ljudi, koji nastaju kao posledica neadekvatnog sistema upravljanja farmaceutskim otpadom. Istraživanje je zasnovano na osnovnim eko-toksikološkim karakteristikama pojedinih ATC grupa farmaceutskih proizvoda. Usmereno je na razvoj modela upravljanja lekovima sa proteklim rokom trajanja iz domaćinstava, jer 90 % farmaceutskog otpada potiče iz domaćinstava. Osnovu modela čini višekriterijumska oprtimizacija procesa upravljanja farmaceutskim otpadom. Istraživanjem je obuhvaćeno 2600 domaćinstava u Niškom regionu u kojem živi 5,24% ukupnog stanovništva Srbije u 5,15% ukupnog broja domaćinstava u Srbiji. Poseban deo upitnika čini popis lekova u domaćinstvima prema ATC (Anatomical Therapeutic Chemical) sistemu klasifikacije. U domaćinstvima na istraživanom području evidentirano je 8,21 pakovanje po domaćinstvu, od kojih je 12,22% (nešto više od jednog pakovanje po domaćinstvu) lekova sa proteklim rokom trajanja. Na osnovu dobijenih rezultata izvršena je projekcija količina lekova sa proteklim rokom trajanja u Srbiji, na 74,92 tona/godina. Osnovna karakteristika razvijenog regionalnog modela je da omogućuje primenu metoda tretmana koje su, od WHO, preporučene za tretman manjih količina farmaceutskog otpada.

Ključne reči: *farmaceutski otpad, ATC klasifikacija, regionalni model upravljanja, WHO*