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PROCEEDINGS





International Symposium on RECYCLING TECHNOLOGIES and SUSTAINABLE DEVELOPMENT

Editors: Grozdanka Bogdanović Milan Trumić

> Hotel Jezero, Bor Lake, Serbia 13 – 15 September 2017



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PHARMACEUTICAL WASTE MANAGMENT

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ABSTRACT – Pharmaceutical waste is hazardous waste generated in the production and trade of medicines and medical supplies (including pharmaceuticals, drugs and chemicals that are scattered prepared and unused or have expired expiration date or be rejected for any reason, as well as organic pollutants), as well as equipment used in handling. The pharmaceutical waste include medicines (finished, galenical and main medicines and pharmaceutical substances) which is out of date. Herbal, traditional and homeopathic remedies can also be considered as pharmaceutical waste, depending on their composition. Producer and owner of pharmaceutical waste shall be treated with pharmaceutical waste as hazardous waste. Waste Management aims to protect human health and the environment with handling and disposal of waste.

Keywords: Project, Pharmaceutical Waste Management, Pharmaceutical Waste Management, Collection, Monitoring

INTRODUCTION

Pharmaceutical waste are all drugs, including primary packaging, and all accessories used for the application of these products, which are located in, or a natural person who has been engaged in the health care of people who have become unusable due to the expiry date, failure in terms of their prescribed quality, contaminated containers, spillage, wastage, prepared and not used, returned by the end user, or cannot be used for other reasons. This waste may be: potentially hazardous pharmaceutical waste is waste that poses a risk in the event that they are not required by managed and requires procedures prescribed for hazardous

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waste management. Hazardous pharmaceutical waste is the waste of medicines and disinfectants that contain heavy metals such as barium, cadmium, cobalt, lead, mercury (including amalgam), nickel, silver and most of their compounds, and so on. And drugs whose composition cannot be determined that due to its composition requires special treatment procedures. All pharmaceutical company waste generated in health care facilities and pharmacies in Serbia is treated and disposed of as hazardous waste in accordance with the relevant legislation in the Republic of Serbia.

Pharmaceutical waste generated in health care facilities (pharmacy, hospital departments, medical clinics, dental clinics, health centers, Institutes, Divisions), health care facilities (manufacturers, wholesalers educational institutions, households). Sorting of pharmaceutical waste is carried out by: the characteristics of the active substance, controlled drugs, narcotics, collection, transport, common storage, recording, characterization, categorization, export.

Pharmaceutical waste usually dispose improperly, throwing it in the garbage can or into drains. Improper destruction of pharmaceutical waste resulting in the pollution of the environment, which certainly affects the ecosystem. Medicines that have expired and they no longer use most often remain a part of our house pharmacy. Whether it is about drugs prescribed by a physician or preparations that can be bought without a prescription they can pose a danger of potentially toxic substances in our homes. This type of disposal of pharmaceutical waste is usually the consequence of ignorance and lack of information about what to do with such drugs. This paper aims to administrators to manage, environmental impact and treatment of pharmaceutical waste.

PHARMACEUTICAL WASTE MANAGEMENT

The importance of proper management of pharmaceutical waste is being improperly pharmaceutical waste resulting in contamination of the environment, and it certainly affects the ecosystem. Numerous studies and surveys have identified a presence of drugs or their metabolites in surface water and groundwater as well as soil. When the drugs in blister such drugs must be returned in the original packaging. The original packaging must be closed with tape and stored in a container made of hard plastic and further access to the previously described manner.

Certainly it is the safest and most effective form of waste management return drugs into the hands of experts who will continue on the best way to handle them. The role of the modern pharmacist is in this segment of the pharmaceutical care and pharmacy are collection points for household pharmaceutical waste. In our country, a series of laws and regulations that treat pharmaceutical waste, directly or indirectly, and it is necessary to comply with such regulations.

The collected drugs aw on hand to care companies licensed to handle hazardous waste, according to strictly laid down procedures. The most common method of destroying drugs is burning. With regard to the pharmacy JU Sarajevo for the first time launched a project to collect pharmaceutical waste approaching

trends. In western countries, this exceptional opportunity, all we need to use and properly dispose of pharmaceutical waste from our homes.

With regard to increasing awareness and scientifically based evidence about the effects of drugs on the environment is of great importance of properly-treatment with pharmaceutical waste.

In many countries implement programs that enable the population refound of unused medicines and drugs that have expired. Most often these programs are implemented through a pharmacy that presenting a place where these drugs can be accommodated without compensation.

Practice is to return when medication keeps a register which aims to record the medications that are returned (Rp / Br.Rp) and ultimately financial value. Many governments across the relevant authorities developed information leaflets about how to manage household pharmaceutical waste. Thus, the solid forms recommends that removed from the original packaging and store in a container made of hard plastic. Some programs recommend that these drugs dissolved with Amal water to prevent their misuse. When it comes to liquid medicinal forms , they must be in the original packaging placed in a container made of hard plastic. Problem of drugs and their impact on the environment is becoming a popular early twenties when he proved that fluokoetin from the group of antidepressants dangerous to living organisms in the water and was found in fish tissues (eg. Carp), similar toxicity shows diazepan Given that some drugs may be obtained without a prescription, it is clear that due to the frequent use of a large and can be found in the vicinity. For diclofenac the drug was found to have a toxic effect on algae.

In Pakistan and India, it was confirmed that diclofenac in surface waters is one of the main patterns of death of different species of birds of prey, as to cause nephrotoxicity. Beta blocker (propanol, metaprolol), which is a membrane stabilizers, have been found in surface waters, indicating toxicity to planktonic species. Producer and owner of pharmaceutical waste is obliged to treat it as hazardous waste .Pharmacies and medical institutions are obliged to useless drugs (drugs with expired shelf life, bulk drugs, defective drugs in terms of quality, etc.) Returned to the manufacturer, importer or dealer for safe treatment whenever possible, especially cistotatics and narcotics .In case it is not possible to submit the pharmacies that are required to collect unusable drugs from citizens.

Pharmacies and medical institutions keep and maintain records of pharmaceutical waste and data submitted to the Agency in accordance with the regulations governing integral cadastre of polluters. Minister in charge of Health and the Minister shall prescribe the manner of pharmaceutical waste management, a list of pharmacies that are required to collect unusable drugs from citizens .

The Ministry will in this case to provide all the help and support especially in speeding up legal procedures in order to process medical waste management in Serbia improved .Although it sounds strange in this area, developing countries have a lot to be and praise. In fact in most there is no separation of the infectious waste noninfectious, but statistics show that the total medical waste in these countries ranges 0.5 - 3 kg per person per annum.



Figure 1. Disposing of expired drugs duration

PHARMACEUTICAL WASTE COLLECTION

Annually collect 460,000 tonnes of hazardous waste, in which one of the medical and the zravstvenih the lips in Belgrade during the same period, remove the 2,314 tons of medical waste.

Ademonstration of pharmaceutical waste incinerators, and many institutions are obliged to pay large sums of money to medications with expired shelf life or those who were withdrawn from circulation and destroyed exported abroad. Although it was once announced to a plant that emits harmful gases, our country will soon need to get, it will not be possible in the next five years.

A number of health facilities, pharmacies, pharmaceutical manufacturers and pharmaceutical companies have a big problem with accumulated stocks of medicines and consumable materials obtained from humanitarian aid over the past decades. At the same time, inventories are piling up in the homes of citizens who purchase drugs for "God forbid", and then when it expires thrown into drains, containers, on the garbage without thinking about the consequences. It happens that some people throw medicines in boilers and burning them with coal and firewood, which represent an attack on human health. Pharmaceutical waste depending on the species, must be packed in special boxes, containers and destroyed at high temperatures (1200° C) in furnaces with special filters that exist in the vicinity of Vienna, where many pharmaceutical companies from Serbia destroying their waste.

In pharmacies no special bins in which to dispose of medications that people are not in use. Instead of people take drugs with expired shelf life, in pharmacies for now people can just get a piece of paper with a phone number and Transfer station hours when citizens can submit written off drugs for a certain period when citizens can submit written off drugs for a certain period .

Novi Sad is praised by the minister for drugs that people are bringing passed all measurement procedures, classification according to pharmacological groups and were transported specially marked vehicle to the Transfer Station, which is in the center of Novi Sad. He's also called on all citizens not to throw drugs where they do not belong because it is a hazardous waste that threatens the environment, on this occasion and appealed to other towns and municipalities throughout Serbia to engage in this activity and organize the collection of medical

and pharmaceutical waste to prevent that the hazardous chemical waste not reach where it should not (in groundwater and thus threaten not only humans but also wildlife.

Waiting for the state to divide containers launched a project sorting and collection of pharmaceutical waste. In the past two years in the warehouse were collected and classified nearly two tons of drugs with expired shelf life, while once a month and collect up to 200 pounds.

Old drugs are collected from citizens, pharmacies and pharmaceutical companies to store in a safe place. Pharmaceutical waste means waste that is grouped into two main groups according to place of origin: the waste generated in the production cycle of drugs, medicinal products and medical devices, ie. Industrial framework, waste originating from drugs with expired shelf life that can be found in the warehouses of wholesalers, pharmacies and so on, or on humanitarian aid. Drugs are considered preparations established quality and quantitative composition of the produced industrial or laboratory, and placed on the market in the form and packaging manufacturers especially as finished drugs. Drug substance specific chemical composition of mixtures of drug substances, as well as herbs and medicinal substances of plant and animal mineral and synthetic origin used for the development and production of Products in pharmacies made of medicinal substances in quantities to which the finished packs per day according to the recorded needs based on individual recipes and galenical preparations highway.In addition to the problems of waste treatment that arises from the production cycle of the pharmaceutical industry, a particular problem and makes a substantial amount of drugs with expired shelf life as in warehouses and those from humanitarian aid. Given that Serbia wants to join the European Union, it is the convergence of their standards and thus solving the problem of waste. Also a number of international conventions in the field of environmental protection which is a party and our country, obliges us to act with the waste products that they prescribe.

If the composition of the wastes is not known, it is necessary to examine the composition of the waste, in order to determine whether the waste has characteristics of hazardous waste. If the waste has any of the following characteristics of hazardous waste (H1 to H14 , with limits that were previously given), considered to be hazardous waste :Explosiveness H1, H2 ability oxidation substances, H3A Highly flammable (flash point below 21 $^{\circ}\text{C}$), H3 flammability (flash point < 55 $^{\circ}$ C), IritancionH4, H5 harm, H6 toxicity, carcinogenicity H7, H8 corrosivity, the infectivity of H9, H10 toxicity to the reproductive system, mutagenicity H11 , H12 Substances and preparations which, in contact with water, air or acid releaseyoxic gases, H13 Substances and preparations that create a product that erosion has any of the above properties, H14 ecotoxicity.

Pharmaceutical waste can contain substances in supplements Directive on Dangerous Substances Directive (65/548/EC/) which includes other hazards besides H9- infectious. With the following types of waste must also be treated as hazardous waste (it is necessary to be stored as hazardous waste)barium, cadmium, cobalt, lead, mercury (including amalgam) nickel, silver and most of their compounds (but not barium Cytotoxic and cytostatic waste is hazardous medical waste generated in connection with the implementation and production of

pharmaceutical products with cytotoxic properties including primary packaging of all the equipment used for the preparation and implementation of such products, as well as blood and body fluids contaminated with the above mentioned drugs.

Cytostatic pharmaceuticals, formerly called antineoplazmatici or anticancer drugs, they have the ability to kill or inhibit the growth of living cells . They are used in chemotherapy, which is carried out in specialized institutions in Serbia .If released into the environment can create serious problems in their effects on reproductive processes in various life forms. Therefore their disposal must be carried out with particular Cytostatics must be segregated from other drugs and stored separately in clearly marked containers with solid walls. Ideally should be securely packed and returned to the supplier for disposal.

Cytostatic drugs should never be disposed of in a landfill in the untreated state, but only after encapsulation or deactivation. Working team that handles these drugs in a medical institution must avoid puncturing the packaging or remove products from their packaging. They can only be discharged into drains after chemical decomposition, and must not be discharged untreated into surface water or natural waterways. This category belongs to any pharmaceutical product that has one or more hazardous properties of toxic, carcinogenic, toxic for reproduction, mutagenic. This can include drugs and pharmaceuticals in certain classes, such as antineoplastic agents , antivirals, immunosuppressants and other drugs .

Where there is a certain cytotoxic agents (eg . Fluorouracil, Cisarabine..) Protocol for waste management must include a risk assessment which must take into account the fact that when using this drug and when it comes to waste, there is a risk from the effects of toxic substances (eg . agents are teratogenic, mutagenic and carcinogenic) on the human body . If we are talking about citototoksičnim drugs and devices (eg fluorouracil 5FU - Cisarabin, etc.), the risk assessment is necessary to note that there is a danger of toxic substances (for example , to indicate that the cytotoxic agents teratogenic , mutagenic and carcinogenic).

SITUATION IN THE REPUBLIC OF SERBIA IN TERMS PHARMACEUTICAL MANAGMENT

Medical waste in health care institutions in the Republic of Serbia is created in uneven amounts, depending on the type of facility, number of beds, type of diseases and conditions that are disposed of, and the types of services oje in health care facilities are provided.

Disposal of various categories of medical waste in Serbia until 2008, performed in different ways in different health institutions. The Ministry of Health in 2007 launched specific actions to introduce a uniform system of medical waste management, and in particular the category of infectious medical waste.

Certain categories of medical waste can be a significant threat to the health of employees in health care institutions .In addition to the health risks that result from direct contact, medical waste can have irreversible indirect health effects through contamination of water and soil during the treatment and final disposal and air pollution through the emission of highly toxic gases during incineration.

It has been proven that there is no method of waste treatment or disposal that completely eliminates all risks of medical waste carries a population of street

environment. Generani depending on the type of technology the treatment of medical waste, residues can be transferred from one phase to the treatment of waste to another. For example, during the incineration process ,ie. Incineration of medical waste, combustible waste components are converted into gaseous byproducts (CO_2 , H_2O , CO) and other gases and noncombustible components remain as ash. Ministry of Environment supervises the work of the said hospital incinerators, and the process of closing them if they do not meet the criteria for rad. Samo in certain medical institutions perform sterilization of infectious medical waste and the already mentioned autoclaves that are very old.

After sterilization, sharps are disposed of in the ordinary municipal waste containers. Used needles, syringes, swabs of cotton wool, bandages and other categories mainly infectious waste management issue, then to the landfill. Such institutions in Serbia is almost gone. The reform of the healthcare system in our country is aimed at improving the quality of health services, both in the state and private sector health care.

An important element is the improvement and proper disposal of medical waste, which is in accordance with national legislation and with the fundamental principles of professional practice of medical waste management, prevention of communicable diseases and health promotion. The introduction of a unified system of medical waste management in the health sector in the Republic of Serbia, is a prerequisite for the regulation system of medical otpadomu whole.

Consensus within the working group composed of eminent professionals in the field, it was agreed that the use of the European Waste Catalogue, which defines the basic categorization of medical waste, and attitudes in relation to segregation or separation, labeling and treatment of different categories of medical waste, for use in medical institutions.

The ultimate goal is to contribute to the protection and promotion of health as well as reduce and control pollution of the environment. Lose their estimates show that the lager Sbiji currently about 200 tons of pharmaceutical waste, or medicines that are out of use. As many as 90 percent of pharmaceutical waste, estimated to be generated in the household. Although it is potentially toxic wastes whose destruction requires special procedures. Disconcerting is that the drugs that are donated arriving nineties from around the world were stale or they are nearing the end of its serviceable life for a few months, so the Serbian served as pharmaceutical waste landfill which is now not easy to get rid of. Inventories usually unnecessary piling up due to procurement of drugs, threw usually in containers, hence the landfill and end up in waterways, where it became a danger to future generations of drinking water in which are dissolved antibiotics, sedatives, analgesics.

There are times that the medication thrown in boilers and burned together with wood and coal, not knowing that thereby threatening not only the environment but also your health. Safe storage and destruction of drugs in Serbia is not possible, because there is no adequate incinerator. Pharmaceutical companies, wholesalers and pharmacies generally adhere to strict regulations.

There were chemicals and drugs adulteration, to charities, and cleared everything he stood for years at the facilities. Now at the facility are not only procedures for waste management, but also its prevention.

CONCLUSION

Improvement of appropriate handling and disposal of medical and pharmaceutical waste is put the preservation of public health. Every member of the community has a right to be informed of the potential hazards to health.

The development of the pharmaceutical industry and an aging population on Earth has led to a widespread production and use of drugs, and this, in turn, to the generation of pharmaceutical waste.

Even minor concentrations of certain substances in medicines can have adverse effects on water quality, and consequently to human health. Medicines should not be disposed of via wastewater and municipal garbage, which, unfortunately, often the case.

As a state with one of the goals set to join the European Union, Serbia will have to make a series of institutional changes, but also a number of changes in the socio - cultural patterns that will (in some areas) necessarily lead to a change in the way of life of its citizens. One of these areas is the protection of the environment.

In addition to the adoption of environmental principles at the institutional level, it is necessary to strengthen the environmental awareness of citizens, not only for the purpose of joining the EU, but also to the adoption of such values that will enable sustainable survival of our society as a whole .

For this purpose, it is necessary to inform citizens about environmental problems, promote ecological values, but, as importantly, to encourage their local activism and participation, both in environmental and in all other spheres of social life .

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