

REGULATIONS ON *GREEN PHARMACY* IN EUROPEAN COUNTRIES – A COMPARATIVE STUDY

ALEXANDRA TOMA *, OFELIA CRIȘAN

Department of Pharmaceutical Legislation and Management, Faculty of Pharmacy, “Iuliu Hațieganu” University of Medicine and Pharmacy, 12 Ion Creangă Street, 400010, Cluj-Napoca, Romania

*corresponding author: alexandra85.toma@gmail.com

Manuscript received: January 2020

Abstract

Green pharmacy is a policy of protecting the environment from the risk of contamination with medicines. The aim of the paper was to compare relevant regulations from European countries in order to find solutions for such a policy in Romania. Official texts from five countries were analysed using methods of legal interpretation and the comparative method. Each country has specific regulations, but the responsibility of each stakeholder is different, from regulating, to collecting or funding. In Finland, expired medicines are collected by pharmacies and municipalities, which fund their disposal. In France, Spain and Hungary, expired medicines are collected by pharmacies, but the pharmaceutical industry is responsible for managing and funding the waste disposal. In Romania, only pharmacies and drugstores are responsible for collecting and disposing expired medicines from patients. Regulations on sharing the responsibility among all types of pharmaceutical enterprises are needed in order to develop a *green pharmacy* policy in Romania.

Rezumat

Farmacia verde e o politică de protecție a mediului față de riscul contaminării cu medicamente. Scopul lucrării a fost de a compara reglementări relevante din țări europene, căutând soluții pentru o astfel de politică în România. Texte oficiale din cinci țări s-au cercetat folosind metodele interpretării juridice și metoda comparativă. Fiecare țară are reglementări specifice, dar responsabilitatea celor implicați e diferită, de la reglementare, la colectare sau finanțare. În Finlanda, medicamentele expirate sunt colectate de farmacii și municipalități, care finanțează eliminarea lor. În Franța, în Spania și în Ungaria, farmaciile colectează de la pacienți medicamentele expirate, dar industria farmaceutică e responsabilă de gestionarea și eliminarea lor. În România, doar farmaciile și drogheriile sunt responsabile de colectarea și eliminarea medicamentelor expirate de la pacienți. Reglementări privind responsabilitatea comună a tuturor tipurilor de unități farmaceutice sunt necesare pentru a dezvolta *farmacia verde* în România.

Keywords: *green pharmacy*, pharmaceutical waste management, legal responsibility

Introduction

Constantly growing population worldwide increased medicines consumption and the amount of pharmaceutical waste which, in time, led to environmental contamination (soil, water) with pharmaceuticals (also called active pharmaceutical ingredients) [8, 10, 15, 29, 45, 49, 55, 57]. The incidence of pharmaceutical waste in the environment is due to both excretions via urine or faeces and to the improper disposal of expired or unused medicines [7, 8, 10, 31, 43, 49-53, 55, 57]. Literature shows that there are various causes for the accumulation of pharmaceutical waste generated by the population, such as prescribing and purchasing more medicines than needed, changes in treatment (because of misdiagnosis, side effects or different dosing), storing the remaining quantities of unused medicines for future use, incomplete treatment because of patients' realising the health improvement, high and easy availability of OTC medicines [10, 31, 55, 57]. In this context, competent authorities and professional organizations encourage the development of *green*

policies (green chemistry, green manufacturing, green pharmacy) implying measures and programs for protecting the environment against the risk of contamination with medicines [15, 21, 29, 51]. For example, the International Pharmaceutical Federation (FIP) prepared in 2015 the document “*Green pharmacy practice – Taking responsibility for the environmental impact of medicines*”, in order to provide pharmacists' associations useful information on this field. This reference document proposes solutions for developing *green pharmacy* policies, such as: creating an adequate legal framework at national level, establishing effective pharmaceutical waste disposal practices, organizing continuous training programs for pharmacists and other health professionals, running information and education campaigns for patients in order to reduce and properly dispose the pharmaceutical waste [29]. In the European Union (EU), the European Commission suggested in 2019 six policy areas to minimize the impact of medicines on the environment: promoting and implementing *green policies*, improving environmental

risk assessment of medicines (before and after marketing authorization), raising public awareness and promoting prudent and rational use of medicines (avoiding waste), minimizing and efficiently managing pharmaceutical waste, extending of environmental monitoring regarding pharmaceutical contamination, developing research and knowledge in this field [15]. Furthermore, research has been conducted in different countries emphasizing possible solutions for a better pharmaceutical waste management system, such as: creating well organized pharmaceutical waste classification systems, educating population for a rational use of medicines, implementing adequate collection schemes, organizing safe storage areas and providing sufficient financial support for pharmaceutical waste disposal. All scholars agree that there is of utmost importance to have specific regulations in this field, educational programs for healthcare professionals as well as for patients [6, 7, 10, 30, 33, 38, 45, 49, 51, 57]. Also, a study in the United States reveals that a correct standardization of doses for each hospitalized patient and a better timing for the administration of medicines could significantly reduce the quantity of pharmaceutical waste in hospitals [33]. Romanian authors have emphasized the environmental contamination with medicines in Romania, the need for better regulations and better practices of pharmaceutical waste management [7, 9, 22, 36, 43, 50-53]. We discussed those aspects in a previous paper [51] and decided to further develop and deepen our research, to provide more insight from other more advanced legislation. Taking into account all these considerations, the aim of this paper was to analyse and compare some relevant European national regulations regarding the role of different types of pharmaceutical enterprises in collecting and disposing unused and expired medicines from patients, in order to find legal solutions for adopting and implementing a *green pharmacy* policy in Romania.

Materials and Methods

We conducted a legal documentary research [14, 28] regarding the legislation related to the pharmaceutical waste management in force in five European countries [51]. We chose two Western European countries, France and Spain, for the quality of legislation, including in the field of environmental protection, and linguistic accessibility, one Scandinavian country, Finland, for its profound preoccupation concerning the environmental quality, and two Eastern European countries, Hungary and Romania, for their efforts to achieve higher standards of quality in the fields of legal and environmental quality [5, 16-20, 39]. We examined relevant laws and regulations from those five countries, and analysed their provisions, using methods of legal interpretation, then compared the five legislations, and discussed the similarities and differences between them, using the comparative method [12, 14, 51, 52,

54]. The comparison of legal provisions was based on three main criteria: the legal responsibility for disposing expired or unused medicines from patients, the legal role of each type of pharmaceutical enterprise in the waste management process, the legal source of funding for that process [52]. Considering the possibility for a performing environmental policy, including a high-quality legal framework, to diffuse in other countries [5], we provided some regulatory models and proposals that could be taken into account by the competent authorities, in order to improve the legislation regarding the pharmaceutical waste management in Romania.

Results and Discussion

In Finland, Law no. 395/1987 on medicines stipulates that hazardous waste resulting from medicines is subject to Law no. 646/2011 on waste [24, 25]. This law establishes that local authorities (municipalities) are responsible for the management of hazardous waste generated by the population [25]. The Finnish Medicines Agency (FIMEA) classifies all pharmaceutical waste as hazardous and recommends the population to return it to pharmacies or disposal points organized by municipalities, in order to protect the environment [23]. The Finnish manufacturers (Pharma Industry Finland, PIF) are responsible for assuring the quality of marketed medicines, including in terms of environmental impact [41]. Thus, PIF is involved in European research projects for minimizing the impact of medicines on the environment and in public information campaigns in terms of correct disposal of medicines, such as The Medicine-free Baltic Campaign [21, 41]. Wholesale distributors are responsible for the management of both their own pharmaceutical waste and those collected from patients through their pharmacy chains, being committed to reduce the amount of such waste [40, 42, 51]. Pharmacies are responsible for collecting expired or unused medicines from population following the rules published by FIMEA. Although municipalities have the legal responsibility for pharmaceutical waste management, including the financial one, some wholesale distributors are involved in the process of disposal, mainly through combustion with energy supply [23, 25, 40, 51, 52].

In France, the Code of Public Health, in the section relating to human medicines unused by the population, includes the responsibilities for each type of pharmaceutical enterprise. The waste management of expired and unused medicines generated by the population is the responsibility of pharmaceutical enterprises exploiting medicines (including marketing authorization holders, manufacturers, importers, wholesale distributors), which can dispose them either directly or through an agreed intermediary [32]. In order to comply with its legal obligations, the French pharmaceutical industry has created Cyclamed, a non-profit entity, involving the collaboration of all professional associations

involved in the medicines supply chain [13, 51]. Wholesale distributors provide transportation to the pharmacy of the unfilled containers for waste collection, transportation from the pharmacy of the full ones and delivery of these containers to carriers, who take them to energy recovery centres [13]. Pharmacies are responsible for the free of charge collection of unused medicines from the population [13, 32]. The disposal of that waste is financed by Cyclamed, the contribution of each pharmaceutical enterprise being proportional with the amount of medicines marketed in the prior civil year [32, 52].

In Spain, Law no. 29/2006, on guarantees and rational use of medicines and health products, requires that the packaging of medicinal products must include a symbol, approved by the Spanish Agency of Medicines and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios*, AEMPS), which indicates that the system of pharmaceutical waste collection is applied and environmental protection is promoted [4]. By the Royal Decree no. 1345/2007, which regulates the procedure of authorization, registration and conditions of dispensation of human medicines, the marketing authorization holders must take part in collecting the pharmaceutical waste from the population [3]. Thus, in accordance with the Circular no. 3/2013, AEMPS verifies their membership in SIGRE or in another organization accredited for this purpose [2, 48]. SIGRE is a non-profit organization established at the initiative of the pharmaceutical industry and supported by the professional associations in the field [48, 51]. Pharmaceutical industry finances the work of SIGRE which is responsible for the management of pharmaceutical waste and for the implementation of ecological measures regarding the packaging of medicines [48, 52]. According to the Circular of the AEMPS no. 1/2011, the package leaflet of medicines includes instructions for the population in order to properly collect expired and unused medicines in pharmacies [1]. Pharmacies are responsible for advising, informing and encouraging the population to bring the pharmaceutical waste to SIGRE's points that are organized in their own premises [48, 51]. In doing so, they have to respect specific rules of good pharmacy practice and standard operating procedures, as recommended by the General Pharmaceutical Council of Spain [26, 48]. Wholesale distributors are responsible for the collection of pharmaceutical waste from pharmacies and its storage until disposal. The disposal is financed by SIGRE, out of the revenues of manufacturers, depending on the amount and type of medicines they placed on the market [48].

In Hungary, Law no. XCV/2005 on medicinal products of human use requires that all types of pharmaceutical enterprises participate in the disposal of pharmaceutical waste, including those originating from the population. The Minister of Health is empowered to adopt, by decree, regulations on the disposal of such waste,

on the control and enforcement of environmental protection requirements [27]. The Decree of the Minister of Health no. 20/2005, which led to the establishment of a national network for collecting medicines from the population, was replaced by the Decree of the Minister of Human Resources no. 11/2017, which imposed some new obligations for manufacturers [37, 44]. According to this decree, the management of pharmaceutical waste produced in the community is the responsibility of the manufacturers (including marketing authorization holders and importers). They must notify the national environmental authority of the way they fulfil their obligations, including financial security and public information on the management of pharmaceutical waste [35]. Manufacturers have to collect, transport and dispose of pharmaceutical waste collected from the population, directly or through intermediaries. To this end, they have created Recyclomed, a non-profit organization that collaborates with the professional pharmaceutical associations, including the Hungarian Chamber of Pharmacists [44, 51]. Wholesale distributors provide the transport of pharmaceutical waste from pharmacies to the collection centre. Pharmacies and drugstores are responsible for collecting the pharmaceutical waste from the population, in boxes specially created and supplied by Recyclomed [44]. The disposal of this waste is funded from the revenues of manufactures, depending on their market share [35, 44, 52].

In our country, Law no. 95/2006 on healthcare reform stipulates that the National Agency for Medicines and Medical Devices of Romania (NAMMDR) must ensure that there are adequate systems for collecting unused or expired medicines, but this obligation is not yet enforced [47, 51]. The Decision of the Government of Romania no. 1915/2006 establishes the obligation for patients to return unused narcotic and psychotropic medicines to the pharmacy for their disposal, based on the approval of the Ministry of Health [46]. The Order of the Minister of Health no. 119/2014 establishes that the collection of all expired medicines generated from the population is the responsibility of pharmacies and drugstores which are required to advertise the free collection on their premises, obligation not yet enforced [34, 51]. The Romanian College of Pharmacists has developed models of procedures for implementing the rules of good pharmacy practice, including one for the disposal of medicines. This procedure establishes standard operating rules for collecting, storing and handing over the pharmaceutical waste to the authorized company, based on a contract with the pharmacy [11, 52], but it is enforced only in medicines expired in the pharmacy and narcotic or psychotropic medicines returned by patients. Marketing authorizations holders (manufacturers and importers) and wholesale distributors are required to ensure that their own pharmaceutical waste (qualitatively inappropriate or expired medicines) is disposed of on the basis of a contract, in accordance

with the legislation in force [47, 51]. Therefore, in Romania, the disposal of pharmaceutical waste from the population is at the expense of pharmacies and drugstores, as mentioned in other papers, but not fully enforced yet [7, 50, 51].

Table I presents the comparative synthesis of *green pharmacy* regulations in the countries under study

based on the chosen comparison criteria: legal responsibility, the role of each stakeholder in *green pharmacy* policies, and the source of funding for the disposal of pharmaceutical waste collected from the population.

Table I

Regulations on *green pharmacy* in European countries – a comparative synthesis

Criteria Country	Legal responsibility in collecting and disposing expired/unused medicines from patients	Roles in <i>green pharmacy</i> policy			Source of funding
		Manufacturers (including marketing authorization holders, importers)	Wholesale distributors	Pharmacies, drugstores	
Finland	Municipalities Pharmacies	Research Information	Collection Transport Disposal	Information Collection	Municipalities Wholesale distributors
France	Manufacturers Wholesale distributors Pharmacies	Management Disposal	Transport	Information Collection	Cyclamed
Spain	Manufacturers Wholesale distributors Pharmacies	Management Disposal	Transport Storage	Information Collection	SIGRE
Hungary	Manufacturers Wholesale distributors Pharmacies Drugstores	Management Disposal	Transport	Information Collection	Recycled
Romania	Pharmacies Drugstores	-	-	Information Collection	Pharmacies Drugstores

The similarities between the regulations of the five studied countries are limited to establishing the responsibility of pharmacies in collecting unused medicines from the population, as well as their role in informing patients about the importance of this process. Three of the countries surveyed have similar regulations regarding the management of pharmaceutical waste generated by the population. Thus, in France, Spain and Hungary, the legal responsibility for collecting and disposal of such waste belongs to all types of pharmaceutical enterprises, as we already underlined [51]. In these countries, the pharmaceutical industry has created non-profit organizations, their income being used to finance the disposal process. These organizations are supported by professional pharmaceutical associations, involving ongoing collaboration between manufacturers, wholesale distributors, pharmacies and the general public, in order to prevent environmental contamination with medicines. The most important differences between the legislations that we analysed refer to granting a significant responsibility to local authorities in the management and disposal of pharmaceutical waste generated by the population in Finland, and to granting this responsibility only to pharmacies and drugstores in Romania [7, 50, 51]. We strongly believe, like other authors [7, 9, 43, 50, 51], that there is a need for a new legal framework for the management of pharmaceutical waste generated by the population in Romania, in which the legal

responsibility of all types of pharmaceutical enterprises should be established because they all make profit from marketing and selling medicines. Depending on the profit, each pharmaceutical enterprise should fund environmental actions against the contamination with medicines. Also, the role of local and national authorities in this process should be set by law since they operate in relation to taxes and fees paid by the population, in order to benefit from a healthy living environment. For example, at least in rural areas with a small number of pharmacies or drugstores, pharmaceutical waste could also be collected by local authorities, following the Finnish model [24]. In Romania, there is also a need to implement appropriate practices to prevent or minimize the elimination of pharmaceuticals in the environment, not only through recycling or better water removal [22, 36], but also through law enforcement and thorough implementation of appropriate guidelines and procedures for the waste management of medicines generated by the population, following the Spanish, French or Hungarian model [13, 44, 48, 51]. Taking into account the significant cost of pharmaceutical waste management activities [30, 31, 33, 35, 40, 44, 55] and the impact of economic development on the success of implementing high performance environmental policies [5, 19, 56], we consider that new regulations on the management of pharmaceutical wastes produced in household can be adopted and implemented in Romania. In order for

this to actually happen, there is a need for political will in reducing the environmental costs of economic growth, the participation of competent authorities, i.e. NAMMDR, and the collaboration of professional pharmaceutical associations. Manufacturers and wholesale distributors in Romania are not preoccupied with the involvement in environmental protection and the collection of pharmaceutical waste from the population. Pharmacies and drugstores, although with legal responsibility, are not fully committed to that process, and in practice there is no coherent system of collection and disposal of unused and expired medicines originated from patients, as some authors already noticed [7, 50, 51]. Pharmaceutical enterprises and pharmaceutical professionals could have many ways to contribute to environmental protection, as shown by FIP [29], the European Commission [15], authors from different countries [6, 33, 45, 49, 51, 55, 57] or some professional organizations [21, 26, 40, 41]. However, for this purpose, specific training is needed [8, 10, 15, 29, 45, 49, 51, 57]; the Romanian College of Pharmacists could be inspired by professional initiatives from other countries and could implement specific projects for the continuous education of pharmacists in the field of environmental protection. It is of utmost importance to raise the awareness of the population concerning the need to prevent the environmental contamination with medicines [8, 10, 38, 41, 45, 51, 57], through their rational use and proper disposal, and pharmacists could make an essential contribution to achieving this goal.

Our proposals are the following.

The Scientific Council of the NAMMDR, as the competent regulatory authority in the field of medicines, should adopt a decision on the organization and functioning of a national system for collecting expired or unused medicines originated from the population. This decision should include the professional and financial obligations of all types of pharmaceutical enterprises, guidelines for good practices in waste collection and disposal, implementation deadlines, control and sanction rules to be applied in the event of non-compliance.

The Ministry of Health, as the national authority in the field of public health, may decide, by Order of the Minister that in the rural area with low densities of pharmacies and drugstores, local authorities should organize disposal points for collecting expired or unused medicines from the population. The Minister's Order should include guidelines for good practices in pharmaceutical waste collection and disposal, either under the NAMMDR system or by a contract-based pharmaceutical waste disposal company.

The Romanian College of Pharmacists, as the national professional authority, should adopt a decision on a specific program of continuous training in environmental protection. This program could be organized where appropriate in collaboration with other professional associations, faculties of pharmacy or NAMMDR,

and should include lectures and training sessions on the risks of environmental contamination with medicines, methods for preventing and minimizing these risks, applying good practices in collecting pharmaceutical waste, communicating with patients about the importance of engaging in environmental protection.

Conclusions

Each country has its own policy for managing pharmaceutical waste generated by the population, with responsibilities established by law, with various degrees of involvement of the state and the private sector. Romanian regulations assign pharmacies and drugstores full responsibility for the collection and the disposal of expired or unused medicines from patients.

According to the law, NAMMDR is the authority that should regulate an adequate system for collecting and disposing of such waste, but there is still no such system in Romania, yet.

An appropriate legal framework, following the model of other European countries, involving all types of pharmaceutical enterprises in the management of pharmaceutical waste originated from the population, is necessary to improve this whole process in our country.

Professional associations, in collaboration with educational institutions and with competent authorities, could organize training programs to develop the level of education of both healthcare professionals and population concerning environmental protection.

Conflict of interest

The authors declare no conflict of interest.

References

1. Agencia Española de Medicamentos y Productos Sanitarios, Circular no. 1/2011 de 24 de marzo de 2011, sobre información que deberán incluir los prospectos de los medicamentos autorizados por la AEMPS, www.aemps.gob.es/, (available in Spanish).
2. Agencia Española de Medicamentos y Productos Sanitarios, Circular no. 3/2013 de 22 de octubre de 2013, sobre exigencia de participación en sistemas que garanticen la recogida de los residuos de medicamentos que se generen en los domicilios, www.aemps.gob.es/, (available in Spanish).
3. Agencia Estatal Boletín Oficial del Estado, Real Decreto 1345/2007, de 11 de octubre, por el que se regula el procedimiento de autorización, registro y condiciones de dispensación de los medicamentos de uso humano fabricados industrialmente, www.boe.es/, (available in Spanish).
4. Agencia Estatal Boletín Oficial del Estado, Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios, www.boe.es/, (available in Spanish).

5. Arbolino R, Carlucci F, De Simone L, Ioppolo G, Yigitcanlar T, The policy diffusion of environmental performance in the European countries. *Ecological Indicators*, 2018; 89(4): 130-138.
6. Bekker CL, Gardarsdottir H, Egberts ACG, Bouvy ML, van den Bemt BJJ, Pharmacists' Activities to Reduce Medication Waste: An International Survey. *Pharmacy*, 2018; 6(3): 94: 1-14.
7. Bungău S, Tit DM, Fodor K, Cioca G, Agop M, Iovan C, Nistor Csepto DC, Bumbu A, Bustea C, Aspects Regarding the Pharmaceutical Waste Management in Romania. *Sustainability*, 2018; 10(8): 2788: 1-14.
8. Carvalho MA, dos Prazeres KC, Klepa RB, Cortellazzi Franco MA, Silva Filho SC, Curvelo Santana JC, Assessment of consumer knowledge in two cities of greater Sao Paulo, Brazil about the impacts caused by the incorrect disposal of medicines. *Interciencia*, 2018; 43(8): 580-584.
9. Chertes A, Crişan O, Standards for good pharmacy practice – a comparative analysis. *Farmacia*, 2019; 67(3): 545-550.
10. Chung SS, Brooks BW, Identifying household pharmaceutical waste characteristics and population behaviours in one of the most densely populated global cities. *Resources, Conservation & Recycling*, 2019; 140: 267-277.
11. College of Romanian Pharmacists, 2011, Iacob S. (coordinator), Legislation and models of standard operating procedures for applying the rules of good pharmacy practice, <http://colegfarmbv.ro/legislatie/>, (available in Romanian).
12. Constantinesco LJ, Treaty of comparative law, tome 2: Comparative method, Ed. All Educational, Bucharest, 1998; 4-39, 52-109, (available in Romanian).
13. Cyclamed, www.cyclamed.org/english/.
14. Delnoy P, Éléments de méthodologie juridique: 1. Méthodologie de l'interprétation juridique; 2. Méthodologie de l'application du droit, 3^e édition, Larcier, Bruxelles, 2008; 23-31, 155-180 (available in French).
15. European Commission, 2019. Communication from the commission to the European Parliament, the Council and the European economic and Social Committee, European Union Strategic Approach to Pharmaceuticals in the Environment, <https://ec.europa.eu/>.
16. European Commission, The Environmental Implementation Review 2019, Country Report Finland, <http://ec.europa.eu/environment/>.
17. European Commission, The Environmental Implementation Review 2019, Country Report France, <http://ec.europa.eu/environment/>.
18. European Commission, The Environmental Implementation Review 2019, Country Report Hungary, <http://ec.europa.eu/environment/>.
19. European Commission, The Environmental Implementation Review 2019, Country Report Romania, <http://ec.europa.eu/environment/>.
20. European Commission, The Environmental Implementation Review 2019, Country Report Spain, <http://ec.europa.eu/environment/>.
21. European Federation of Pharmaceutical Industries and Associations (EFPIA), Pharmaceuticals in the Environment (PIE), www.efpia.eu/about-medicines/.
22. Fierăscu RC, Dinu-Pîrvu CE, Fierăscu I, Țărmure V, Stanică N, Nicolae CA, Somoghi R, Trică B, Anuța V, Inorganic/organic core-shell magnetic materials for removal of endocrine disrupting pharmaceuticals from water. *Farmacia*, 2018; 66(2): 316-322.
23. FIMEA, How to dispose of medicines, www.fimea.fi/.
24. FIMEA, Medicines Act 395/1987 Unofficial translation; Amendments up to 1340/2010 included, www.fimea.fi/documents/.
25. FINLEX, Waste Act (646/2011; amendments up to 528/2014 included), www.finlex.fi/.
26. General Pharmaceutical Council of Spain, Good Pharmacy Practice in Spanish Community Pharmacy, Medicines Waste Management, Expiry Dates and Returns from the Community Pharmacy, 2016, www.portalfarma.com/Ciudadanos/.
27. Hungarian Parliament, Act XCV of 2005 on Medicinal Products of Human Use and on the Amendment of Other Regulations Related to Medicinal Products, <https://net.jogtar.hu/>, (available in Hungarian).
28. Hutchison T, Duncan N, Defining and Describing What We Do: Doctrinal Legal Research. *Deakin Law Rev.*, 2012; 17(1): 83-119.
29. International Pharmaceutical Federation (FIP), 2015. Green pharmacy practice: Taking responsibility for the environmental impact of medicines. www.fip.org/.
30. Kermenidou M, Voudrias EA, Konstantoula AC, Composition and production rate of cytostatic pharmaceutical waste from a Greek Cancer Treatment Hospital. *Global NEST J.*, 2019; 21(2): 131-140.
31. Kujala V, Salimaki J, Siisalo S, Sandler C, Kalsta K, Quantification of pharmaceutical waste, environmental and economic burden in Finland. The Association of Finnish Pharmacies, Helsinki, 2016, <https://fip.org/>.
32. Legifrance, Code de la santé publique, www.legifrance.gouv.fr/, (available in French).
33. MacBrayne EC, Williams CM, Obermeier H, Child J, Heizer JW, Millard M, Pearce K, Dugan C, Parker SK, Anti-infective waste in a pediatric institution: pinpointing problems in the process. *Hosp Pharmacy*, 2019; 55(4): 220-223.
34. Minister of Health, Order no. 119/2014 on approval of the norms of hygiene and public health on the living environment of the population, Official Journal of Romania, part I, no. 127/2014, latest consolidated version, (available in Romanian).
35. Minister of Human Resources, Decree no. 11/2017 on waste management activities regarding waste pharmaceuticals produced in community medical product supply, www.recyclomed.hu/, (available in Hungarian).
36. Moisa C, Copolovici L, Bungău S, Pop G, Imbrea I, Lupitu A, Nemeth S, Copolovici D, Wastes resulting from aromatic plants distillation – bio-sources of antioxidants and phenolic compounds with biological active principles. *Farmacia*, 2018, 66(2): 289-295.
37. Nagy-Kopanny K, Hungary: New Hungarian Legislation on Pharmaceutical Waste Management, Mondaq, 26 January 2018, www.mondaq.com/, (available in Hungarian).
38. Niyongabo E, Jang YC, Kang D, Sung K, Generation, management practices and rapid risk assessment of solid medical wastes: a case study in Burundi. *J Mater Cycles Waste*, 2019; 21(4): 950-961.
39. OECD (2019), Better Regulation Practices across the European Union, OECD Publishing, Paris.
40. Oriola, Recycling, <https://www.oriola.com/>.

41. Pharma Industry Finland, PIF, Medicines and the environment, www.pif.fi/responsibility/.
42. Phoenix Group, Areas of responsibility, Environmental protection, www.phoenixgroup.eu/.
43. Popescu DE, Bungău C, Prada M, Domuta C, Bungău S, Tit DM, Waste management strategy at a public University in smart city context. *J Environ Prot Ecol.*, 2016; 17(3): 1011-1020.
44. Recyclomed, Our waste collection activity, www.recyclomed.hu/, (available in Hungarian).
45. Rogowska J, Zimmermann A, Muszyńska A, Ratajczyk W, Wolska L, Pharmaceutical household waste practices: preliminary findings from a case study in Poland. *Environmental Management*, 2019; 64: 97-106.
46. Romanian Government, Decision no. 1915/2006 approving the Methodological Norms for the application of the provisions of Law no. 339/2005 on the legal regime of narcotic and psychotropic plants, substances and preparations, Official Journal of Romania, part I, no. 18/2007, latest consolidated version, (available in Romanian).
47. Romanian Parliament, Law no. 95/2006 on healthcare reform, republished. Official Journal of Romania, part I, no. 652/2015, latest consolidated version, (available in Romanian).
48. SIGRE, The role of each stakeholder, www.sigre.es/, (available in Spanish).
49. Singleton JA, Lau ETL, Nissen LM, Waiter, there is a drug in my soup – using Leximancer® to explore antecedents to pro-environmental behaviours in the hospital pharmacy workplace. *Int J Pharm Pract.*, 2018; 26(4): 341-350.
50. Tit DM, Bungău S, Nistor-Cseppento C, Copolovici DM, Buhas C, Disposal of unused medicines resulting from home treatment in Romania. *J Environ Prot Ecol.*, 2016; 17(4): 1425-1433.
51. Toma A, Crișan O, Activities related to human medicines in Romania: Legal environmental protection issues. *Environ Sci & Policy*, 2020; 106(4): 22-28.
52. Toma A, Crișan O, European pharmaceutical initiatives in environmental protection. *Medic Pharm Rep.*, 2019; 92(Suppl.1): S81.
53. Toma A, Crișan O, Green pharmacy – A narrative review. *Clujul Medical*, 2018; 91(4): 391-398.
54. Van Hoecke M, Legal doctrine: Which method(s) for what kind of discipline?, in: Van Hoecke M., Ed., Methodologies of legal research. Which kind of method for what kind of discipline?, Hart Publishing, Oxford and Portland, Oregon. 2011; 1-18.
55. Vogler S, de Rooij RHPF, Medication wasted – Contents and costs of medicines ending up in household garbage. *Res Social Adm Pharm.*, 2018; 14(12): 1140-1146.
56. Wood J, These are the OECD's most productive economies, 15 February 2019, World Economic Forum, www.weforum.org/.
57. Zorpas AA, Dimitriou M, Voukkali I, Disposal of household pharmaceuticals in insular communities: social attitude, behaviour evaluation and prevention activities. *Environ Sci Pollut Res.*, 2018; 25: 26725-26735.