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THE PUBLIC INTEREST AND THE RIGHT TO A HEALTHY ENVIRONMENT IN ROMANIA. THE CHALLENGE OF IMPLEMENTING THE EUROPEAN LAW

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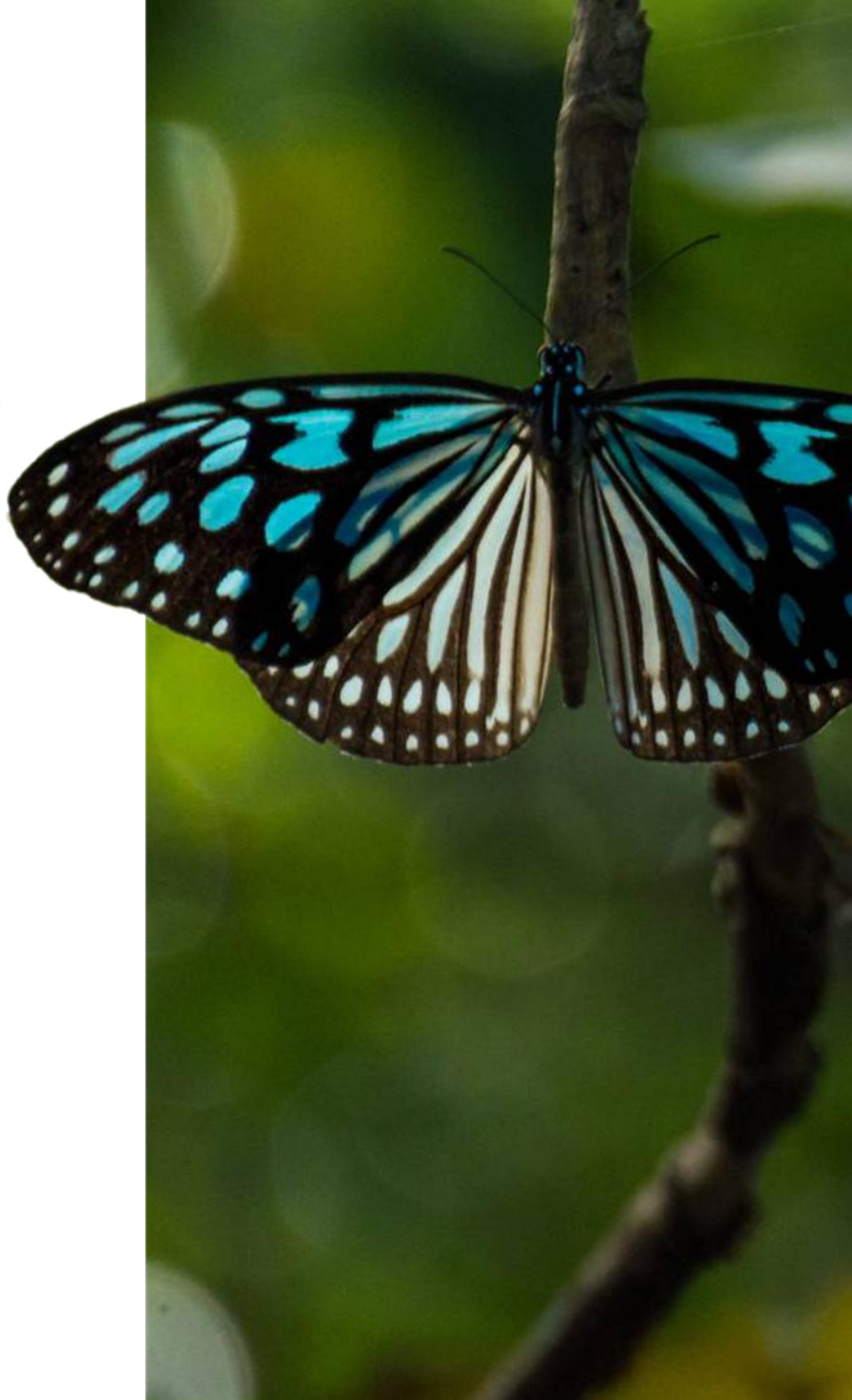

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PUBLIC INTEREST IN ENVIRONMENTAL HEALTH

- The granting of exemptions in 2022 in Romania for the use of three neonicotinoid pesticides, considered toxic pesticides, harmful to bees, is considered "the beginning of a systemic crisis for environmental health and food security in Europe and globally". That is precisely why neonicotinoid pesticides, have been completely banned from the outdoor environment by the European Commission for eight years, after the European Food Safety Authority (EFSA) confirmed their harmful effect.
- This presentation also analyzes the provisions of art. 53 of the EC Regulation no. 1107/2009 regarding the market introduction of phytosanitary products and the repeal of Council Directives 79/117/EEC and 91/414/EEC, which allows a derogation from this prohibition.

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- In this situation, the Member State in question immediately informs the other Member States and the Commission about the measure adopted, providing detailed information about the situation, and the competent administrative authority (for example, the national phytosanitary authority) exercises controls on the ground. However, we are wondering what are the limits of these exceptions, when the public interest begin and what it refers to?
- Does the public interest refer to the provision of food for the population in the context of the war in Ukraine and one year's drought, or to the provision of the protection of the population's health through consistent public health measures? Are these goals contradictory? We will try to answer these dilemmas or create new questions that should lead to our final objective, namely the respect of the following human rights: the right to health, the right to a healthy environment and the right to a decent standard of living (which can include the state food security).

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PUBLIC INTEREST IN ENVIRONMENTAL HEALTH

- Regarding the recognition of the existence of the fundamental human right to a healthy environment, since 1972, the Stockholm Declaration, Principle 13 provides that, "in order to achieve a more rational management of resources, which thus leads to the improvement of the environment, states must adopt an integrated and coordinated approach to their development plans, to ensure that their development is compatible with the need to protect and improve the environment for the benefit of their own population"[1].
- The need to reorient efforts to achieve the goal of integration materialized eleven years after the Stockholm Conference, in 1983, when the United Nations established the World Commission for Environment and Development, known as the Brundtland Commission.

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PUBLIC INTEREST IN ENVIRONMENTAL HEALTH

- Romania's access to international institutions with major concerns in the field of the environment, the initiation and completion of the process of joining the European Union and the correlation of the domestic legislation with the community law of the environment stimulated the process of constitutionalizing the human right to a healthy environment, after the national referendum from November 18-19, 2003, by the Law no. 429/2003 on revision of the Constitution. In the elaboration of this normative act, the Decision no. 148/2003 of the Constitutional Court of Romania played an important role regarding the constitutionality of the legislative proposal to revise the fundamental law , which decided that in order to ensure the achievement of the purpose of the legislative proposal, it is necessary to insert the human right to a healthy environment to Chapter II of Title II of the Constitution. Also, according to art. 35 of the Romanian Constitution, the express affirmation to protect the environment raises environmental protection to the rank of fundamental duty.

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HIGHLIGHTS

- Through the presentation, we try to highlight the legal aspects that are closely and directly related to the right to a healthy environment, through the methodology of information identification, interpretation, descriptive methods and research, explanatory methods and research, as well as comparative.
- The research refers to the legal effects of the use of neonicotinoids in agriculture, in relation to the environment, by specifying the causes that led to this administrative decision at the national level, which are the deficiencies identified in the national legislation, considering the importance of its effective application, in order to reduce the impact of this activity on the health of the population. The analysis considers the identification of legal regulations in the matter, both at the European and national level, and the development of proposals for its improvement. The purpose is to emphasize the need to find solutions to respect the right to a healthy environment, concretely, as an internationally recognized individual right, but above all, the fact that this is no longer a simple individual right, but we can discuss of the existence of a public interest regarding the healthy environment and of the existence of a direct relationship with public health.

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THE RIGHT TO A HEALTHY ENVIRONMENT IN ROMANIA. CASE STUDY OF NEONICOTINOID USE

- Since 2014, Romania has continued to use neonicotinoids, toxic pesticides for bees, to treat corn and sunflower seeds, although they are prohibited in the European Union, with a series of exemptions being granted on December 17, 2021 for the use of three neonicotinoid pesticides. This aspect was considered as "the beginning of a systemic crisis for environmental health and food safety in Europe and globally, with the European Food Safety Authority (EFSA) confirming their harmful effect. Since 2014, Romania has granted a total of 20 emergency authorizations for the use of neonicotinoid products. This represents one third of all EU derogations (62) on the same period.
- Following a warning received by Romania from the European Commission in 2020, Romania has no longer granted emergency authorizations for the limited and controlled use of plant protection products from the neonicotinoid group, but in 2022, Romania reverted to the decision. The Romanian authorities have declared that the treatment of seeds with neonicotinoids is done under the strict supervision of the National Phytosanitary Authority, and European Regulation 1.107/2009 allows the granting of exemptions regarding the use of these substances in case the health of the plants is threatened by dangers that cannot be avoided by other means.

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LEGAL FRAMEWORK

- Considering the aspects reported in the public space, we mention that, according to art. 53 of the EC Regulation no. 1107/2009 regarding the introduction of phytosanitary products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, " by way of derogation from Article 28, in special circumstances, Member States may authorize, for a maximum period of 120 days, the placing on the market of phytosanitary products intended to be applied in a limited manner and under control, when it is considered that such measures are required because plant health is threatened by dangers that cannot be avoided by other reasonable means.
- The Member State concerned shall immediately inform the other Member States and the Commission of the measure adopted, providing detailed information on the situation and on all actions taken to guarantee consumer safety".

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LEGAL FRAMEWORK

- According to art. 69 of the same Regulation, "in cases where it becomes obvious that an active substance, an approved phytoprotective agent, synergistic agent or co-formulant or a phytosanitary product authorized in accordance with this regulation may constitute a serious danger to human or animal health or for the environment, and the respective danger cannot be combated satisfactorily by the measures taken by the Member State(s) concerned, measures shall be adopted without delay to limit or prohibit the use and/or marketing of the respective substance/product", in accordance with a certain regulatory procedure mentioned in the aforementioned regulation.
- We remind you that, according to art. 288 TFEU, the EU Regulations are sources of secondary law, with direct application in the internal law of the member states, it is not necessary to transpose the European legal provisions at the national level.

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PUBLIC INTEREST

- The notion of "public interest" is defined as meaning "the material and spiritual needs of citizens at a given time". It therefore follows that, although the public interest has a perpetual character within human society, its content is far from immutable, being influenced by political, economic, social and geographical factors.
- All these notions are part of the category of "undetermined legal concepts", which require certain actions of the administration to concretely determine abstract situations, to solve "those needs that particularize a public interest at a given moment", actions which represent the expression of the right of appreciation of those called to apply the law, their discretionary power to act".
- In the jurisprudence of the European Court of Human Rights regarding art. 1 Additional protocol no. 1 to the European Convention, the application of the so-called "fair balance test" was stated, in the sense that the Court must determine whether the sign of equality has been established between the requirements of the general interest of the community and the protection of individual rights.

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PUBLIC INTEREST

- The European court also showed that it respects the way a state "conceives the imperatives of the general interest", except when they do not have "a reasonable basis".
- Particularizing, at present, the national economies of the member states of the European Union are subject to exceptional factors: the COVID-19 pandemic, the price increases for electricity and thermal energy, which have caused agricultural inputs to rise by approximately 40% and the prolonged drought. The major concern of the Romanian state was to ensure the necessary resources, so that the food security of the Romanian population would not be affected.
- In order to maintain the competitiveness of agricultural activity in Romania, it was considered that these risks of using neonicotinoids represent emergency situations that require the granting of temporary authorizations, being legal instruments that states have at their disposal to ensure farmers access to plant protection products in situations where there is a phytosanitary risk on the culture.

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PUBLIC INTEREST

- However, the excessive use over time of the derogation allowed by the European Union for the use of these substances, over a repeated period of a maximum of 120 days, cannot be the direct consequence of the causes listed above, since they were subsequent to the start of the application of these legal exemptions.
- On the other hand, once these exceptions are applied at European level, it is necessary for the Member State to identify ways to control the use of neonicotinoids for agricultural crops - ways that must be undertaken at the central administrative level, in order to comply with the procedure regulated by EC Regulation no. 1107/2009, as well as to protect people's health and the environment.

MONITORING AND CONTROL PROCEDURES

- Therefore, the entire chemical treatment of the seeds must be intensively monitored, taking all necessary measures to eliminate any risks that could affect bee families and the environment.
- Thus, sowing is done only in areas and on surfaces heavily affected by the attack of soil pests Tanymecus dilaticollis and Agriotes spp.
- To reduce the risk associated with the use of plant protection products, several measures will be applied:
- a) the company responsible for the marketing of the plant protection product (the approval holder or the representative in Romania) will market the product directly or through distributors to authorized service provider operators registered at the county phytosanitary offices, who prove that the treatment will be carried out in professional facilities and with qualified personnel;
- b) Commercial operators authorized service providers who carry out seed treatment, will label the packages of treated seeds according to the provisions of EC Regulation no. 1107/2009;

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MONITORING AND CONTROL PROCEDURES

- d) Treated seed will be used only in areas and on surfaces strongly affected by the attack of soil pests;
- e) farmers have the obligation to mark the plots where corn crops have been established with treated seeds, using the warning plates received when purchasing the seed treated with neonicotinoids;
- h) The phytosanitary inspectors will carry out checks at the authorized service providers, who will keep a strict record of the batches of treated seed, the quantity of product purchased, the quantity of product used, the one left unsown and the distributor/farmer for whom the seed treatment was carried out. The situation is sent weekly, every Friday, until 12:00 p.m. to the county phytosanitary office.
- However, it is unclear how it can be verified that the treated seed will only be used in areas and areas heavily affected by the attack of the soil pests Tanymecus dilaticollis and Agriotes spp and by which criteria such areas/areas are identified.

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MONITORING AND CONTROL PROCEDURES

- From the analysis of the national legislation, it is found that, although phytosanitary inspectors have the powers to inform farmers about their obligations and verify by survey, in the field at sowing, if they comply with the requirements of the temporary authorization, the sanctions and their application are made by another public structure and not buy the National Phytosanitary Authority, as the national legislation provides.
- Therefore, we note that, in the situation where neonicotinoids are used by farmers, the procedure is very strict, subject to the control of national phytosanitary inspectors.
- However, in order to detect possible irregularities in the execution of obligations by farmers, a public authority is the one that carries out the control (the National Phytosanitary Authority, through the county departments) and the local public authority grants the sanctions (administrative-territorial units, through the mayor).

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MONITORING AND CONTROL PROCEDURES

- In relation to the above, the collaboration between the representatives of the local public administration authorities and those of the National Phytosanitary Authority is very important, regarding the careful monitoring of farmers' compliance with the obligations to inform the town hall and beekeepers in the area regarding the plots sown with neonicotinoid-treated seed, in order to ensure the effectiveness of the controls carried out, but especially in order to protect the health of people and the environment.
- That is why we propose *de lege ferenda*, the completion of the national legislation by the regulation of a procedure through which the collaboration between the representatives of the mayors is realized where deviations from the legal provisions regarding the compliance with the obligations in the actions of using neonicotinoids (inspectors who carried out the controls), are found.

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CONCLUSION

- The protection of the right to a healthy environment is a matter of public interest and not only a simple individual right. That is why, when public authorities invoke the public interest in the excessive use of the derogation provided by EC Regulation 1107/2009 regarding neonicotinoids, a conflict arises between two aspects that aim at the public interest. The resolution of this conflict can only take place through a reasonable and rational application of the specified exception, which should mean a limitation of the use of neonicotinoids to a term of 120 days per calendar year. That is why, beyond the measures to improve the national legislation, measures are needed to complete the EC Regulation 1107/2009 with this provision, which will prevent an EU member state from turning an exceptional situation into a rule, in the name of a declarative and hypothetical public interest.

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WHAT ABOUT EXPIRED MEDICINES?

- Regarding the collection of expired medicines that are brought to the pharmacy by citizens, it is important to determine whether or not pharmacies are obliged to take expired medicines from the population, considering the deficient national legislation in Romania.
- Thus, one opinion is the one according to which pharmacies operate according to the Pharmacy Law and not according to a ministerial order and interprets that, according to the provisions of this order, the patient is invited to the pharmacy to hand over the expired medicines, and the pharmacies are obliged to display the information according to which interested persons can do this delivery, but it is not clearly specified the obligation of the pharmacies to take over these drugs, nor who bears the costs.
- In Romania, expired medicines from the population through pharmacies have been collected, for eight years, based on a ministerial order, but which does not oblige the pharmacies to receive them. This is why people are often refused, and during this time the pollution with medical waste increases, affecting the environment and people.

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WHAT ABOUT EXPIRED MEDICINES?

- According to published information, "approximately 1,500 tons of expired medicines reach landfills or the sewage system in Romania every year, although they are dangerous waste, it is stated in the statement of reasons of a draft law aimed at combating pollution with this type of waste.
- The same project cites a study according to which in 65% of running waters, including the Danube, the level of 14 of the most common antibiotics exceeds even 300 times the maximum allowed limits. However, this pollution does not only involve the increase of resistance to antibiotics - it is also about pollution with hormones, cytostatics or antidepressants. Furthermore, wastewater treatment would only remove 60-90% of the ibuprofen that reaches the rivers, while carbamazepine - a group of anti-epileptic drugs - is removed to a much lesser extent (…). The situation has worsened during the Covid pandemic, as the amount of unused or expired medicines has increased".
- According to the provisions of art.38 letter c) of the Order no. 119/2014 for the approval of hygiene and public health norms regarding the living environment of the population "expired medicines from the population will be deposited in pharmacies or nearby pharmaceutical points, in with a view to disposal by incineration".

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WHAT ABOUT EXPIRED MEDICINE?

- In accordance with the provisions of art.872 paragraph (4) of the Health Law, "The National Agency of Medicine and Medical Devices ensures that there are adequate systems for collecting unused or expired medicines".
- Taking into account the fact that the legislation does not provide for a specific procedure regarding the return of expired medicines and considering the existence of specific legislation regarding some medicines, according to art.18 paragraph (4) letter e) of the Order no. 444/2019 regarding the approval of the rules regarding the establishment, organization and operation of pharmaceutical units, "the community pharmacy warehouse must have a special area dedicated to keeping expired medicines or those collected for destruction".
- Order no. 119/2014 does not provide for a sanction in case a pharmacy refuses to receive expired medicines from the population. Instead, natural persons who throw expired medicines in the household waste bin are fined 1000 lei. Upon accepting the receipt of the medicines, a report is drawn up, in which the patient must state all the identification data, the returned medicines (pharmaceutical form, concentration, quantity, etc.) and the reason for the return.

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HIGHLIGHTS

- From the information presented in the public space, the following results:
- - the collection of expired medicines is currently ensured with difficulty;
- - there are pharmacies that take over the waste medicines from the population and have signed contracts with specialized companies for their transport and disposal, but other pharmacies do not take over this waste;
- - the studies carried out in Romania regarding waste disposal practices revealed that the methods used by the population to get rid of drug waste were and are inadequate and incompatible with legal requirements, namely that the involvement of pharmacists in information and awareness campaigns can change significantly how the population can get rid of pharmaceutical waste;
- - in-depth studies are needed on the causes that generate the current management practices of expired medicines in parallel with the running of campaigns to raise awareness among the population regarding the impact that the random disposal of expired medicines can have on the environment.

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THE RIGHT TO A HEALTHY ENVIRONMENT IN ROMANIA. EXPIRED MEDICINES

- Thus, as part of a campaign to collect expired medicines organized in the Municipality of Braşov in 2019 in collaboration with the City Hall of the Municipality of Braşov, 550 kg of waste were collected in 2 days, which indicates the lack of a campaign to raise awareness among the population about this phenomenon.
- According to a study cited by the Ministry of the Environment, 95% of Romanians throw medicines in the trash, with consequences for the environment and people's health, considering the increase in sales of medicines.
- According to art. 887 of Law no. 95/2006 on health reform, republished, with subsequent amendments and additions, ANMDMR ensures that there are adequate systems for collecting unused or expired medicines;
- According to art.52 letters c)-d) of Law no. 211/2011 on the waste regime, republished, the Ministry of Health develops specific regulations for the management of waste from medical activities and any other activities that generate the waste provided for in class 18, subclass 18 01 of the annex to Commission Decision 2014/955/EU, with the approval of the central public authority for environmental protection; monitors and controls waste management activities, in accordance with the attributions and powers established by law.

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THE RIGHT TO A HEALTHY ENVIRONMENT IN ROMANIA. EXPIRED MEDICINE DRUGS

- According to Decision 2014/955/EU/18-Dec-2014 amending Decision 2000/532/EC establishing a list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council (Decision 2014/955/EU/2014, below), are included in the category Waste from medical or veterinary assistance activities and/or from related research: "cytotoxic and cytostatic drugs" (18 01 08); "medicines other than those specified in 18 01 08" (18 01 08).
- According to Decision 2014/955/EU/2014, they are included in the category Municipal waste (household waste and assimilable waste, from commerce, industry and institutions); "cytotoxic and cytostatic drugs" (18 01 31); "medicines other than those specified in 18 01 31" (18 01 32).
- According to art.21 of the Government Emergency Ordinance no. 211/2011, in accordance with the "polluter pays" principle, the costs of waste management operations are borne by the waste producer or, as the case may be, by the current or previous owner of waste.

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THE RIGHT TO A HEALTHY ENVIRONMENT IN ROMANIA. EXPIRED MEDICINE DRUGS

- Therefore, both from the answers communicated and from the analysis of the current legislation, it is found that there is a lack of a clear regulation that provides for the management of expired medicines that come from the population and an adequate management of the situation of expired medicines. As a result, we consider it necessary to develop and implement by the Ministry of Health, in collaboration with the Ministry of Environment, Water and Forests, a public awareness program on this aspect, in order to prevent exposure to accidental medication and toxicity.
- Also, since the Ministry of Health authorizes the operation of pharmacies and elaborates by order, strict rules by which they carry out their activity, we appreciate that it is necessary to supplement the rules approved by the previously mentioned orders (Order no. 119/2014, respectively Order no. 444/2019) by imposing on pharmaceutical units their obligation to carry out constant or permanent public information campaigns on their possibility to bring expired medicines to pharmacies, as well as the obligation to conclude contracts with authorized economic operators in the collection of this category of waste, but also clear duties provided for the ministry representatives to verify compliance with this obligation.

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PUBLIC INTEREST. EXPIRED MEDICINES

- The pharmacy law no. 266/2008 and its implementing rules do not provide for and do not allow the collection of expired or unused medicines by patients, because pharmacies do not have specially designed spaces for these activities. In this context, the College of Pharmacists from Romania proposed the installation in the pharmacy office of special containers, approved by the environmental authority, in which the population can deposit these medicines, with wholesale distributors replacing these containers when necessary, the costs related to their storage or destruction proposing to be borne by the manufacturer;
- - the proposal of the College of Pharmacists cannot be implemented, since the expired or unused medicines from the population are from different manufacturers and distributed by different wholesale distributors;
- - another impediment is the fact that companies specializing in the destruction of this dangerous waste pick them up from pharmacies based on a report containing the identification data of the medicine, and in the containers, the medicines from the population are mixed together, without being separated on producers, distributors, etc.

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PUBLIC INTEREST. EXPIRED MEDICINE DRUGS

- ANMDM considers that the exposed situation is under the competence of the Ministry of Health, as it issues the authorizations for the operation of pharmacies and approves the legislative proposals.
- It is necessary to take the measures regulated by the provisions of art. 52 letters c)-d) of Law no. 211/2011 on the waste regime, republished, namely, the development of specific regulations for the management of waste from medical activities and any other activities that generate the waste provided for in class 18, subclass 18 01 of the annex to Commission Decision 2014/955/EU, with the approval of the central public authority for environmental protection; taking concrete measures regarding the collaboration with the Ministry of Environment, Water and Forests, in order to develop and implement a public awareness program regarding the collection of expired/unused medicines from the population.

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MONITORING AND CONTROL PROCEDURES

- The Government's emergency ordinance no. 92/2021 regarding the waste regime was published in the Official Gazette of Romania no. 820/26.08.2021, to come into force on September 25, 2021, with the repeal of Law no. 211/2011 regarding the waste regime. The provisions of art. 51 of the O.U.G. no. 92/2021 take over the obligations of the Ministry of Health from Law no. 211/2011 regarding waste management, these being completed with the provisions of letters d), i) and j), which regulate similar aspects to those included in Recommendation no. 174 /2020 of the People's Advocate.
- Thus, according to them, the Ministry of Health has attributions regarding the development of guidelines, instructions, rules for the management of medical waste from the population; initiates and runs in collaboration with other authorities, programs, projects and campaigns to inform the population about sustainable waste management.

MONITORING AND CONTROL PROCEDURES

- The file was resolved with the monitoring of the situation, considering the following:
- - the reply address of the General Directorate of Medical Assistance, Emergency Medicine and Public Health Programs which considered the parliamentary initiative dated 30.06.2021, published by the Economic and Social Council, to supplement Law no. 95/2006 with provisions related to the elimination of drug waste and the establishment of a drug waste collection system, according to art. 712 paragraph (1) letter 6.6 in conjunction with art. 774 letter j) of Title XVIII "Medication" of the same law;
- - the response address of the Directorate of Medicine Policy, Medical Devices and Technologies, which proposed the organization of a working meeting with the representatives of the College of Pharmacists from Romania, the National Medicines Agency, the National Institute of Public Health, the General Directorate of Medical Assistance, as well as a meeting technical, with representative organizations of marketing authorization holders.

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MONITORING AND CONTROL PROCEDURES

- Also, at that time, the Government's Emergency Ordinance no. 92/2021 regarding the waste regime was published in the Official Gazette of Romania no. 820/26.08.2021, but it was to enter into force on September 25, 2021, together with repeal of Law no. 211/2011 on the waste regime. The provisions of art. 51 of the O.U.G. no. 92/2021 took over the obligations of the Ministry of Health from Law no. 211/2011 regarding waste management, regulating aspects similar to those contained in Recommendation no. 174/2020 of the People's Advocate.
- Currently, Law no. 211/2011 on the waste regime is repealed, as the Government's Emergency Ordinance no. 92/2021 on the waste regime is in force, which regulates by art. 51 letter d) and i), the following powers for the Ministry of Health :
- - elaborates guides, instructions, rules for the management of medical waste from the population;
- - establishes and manages the database regarding the programs and projects aimed at the necessary investments for the sustainable management of medical waste, the educational programs for the management of medical waste and medicine waste generated in households.

MONITORING AND CONTROL PROCEDURES

- We also specify that according to art. 18 paragraph (1) point 4 letter e) of the 2019 Norm on the establishment, organization and operation of pharmaceutical units, approved by Order of the Minister of Health no. 444/2019, the premises of the community pharmacy must has an area specially dedicated to keeping expired medicines.
- In addition, according to art. 38 letter c) of the 2014 Norm of hygiene and public health regarding the living environment of the population, approved by Order of the Minister of Health no. 119/2014, "expired medicines from the population will be deposited at pharmacies , local distribution offices or nearby drug stores, for final disposal by incineration. Pharmaceutical units will display in a visible place the notice regarding the free collection of expired medicines".
- The protection of the right to a healthy environment is a matter of public interest and not only a simple individual right. That is why, when public authorities invoke the public interest in the excessive use of the derogation provided by EC Regulation 1107/2009 regarding neonicotinoids, a conflict arises between two aspects that aim at the public interest.

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CONCLUSION

- The resolution of this conflict can only take place through a reasonable and rational application of the specified exception, which should mean a limitation of the use of neonicotinoids to a term of 120 days per calendar year. That is why, beyond the measures to improve the national legislation, measures are needed to complete the EC Regulation 1107/2009 with this provision, which will prevent an EU member state from turning an exceptional situation into a rule, in the name of a declarative and hypothetical public interest.

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THE BIOCIDAL PRODUCT Cymina Plus

- - according to art.12 paragraph (3) of OUG no.34/2012, with subsequent amendments and completions, in areas used by the public or vulnerable groups, as defined in art. 3 point 14 of Regulation (EC) no. 1.107/2009, such as parks, public gardens, sports and recreation grounds, schoolyards and playgrounds and lands in the immediate vicinity of public health institutions, it is necessary to use reduced-risk plant protection products;
- - according to art.5 paragraph (1) of EU Regulation 528/2012 on the making available on the market and use of biocidal products, the criteria for excluding active substances classified in relation to the provisions of EC Regulation no. 1272/2008 are regulated, specifying, among other things, that, in order to make an exception to this rule, the risk to humans, animals or the environment due to exposure to the active substance in a biocidal product, under the most unfavourable conditions of use realistically, is negligible, especially if the product is used in closed systems or under other conditions aimed at avoiding contact with humans and release into the environment.

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THE BIOCIDAL PRODUCT Cymina Plus

- Is Cymina Plus a product with a risky active substance according to Regulation 1272/2008 and can it be used in local disinfestation actions?
- What information and monitoring/control methods are taken in relation to the local public administration authorities, in order to ensure the performance of treatments with products that are not toxic to bees and that represent a reduced risk to the population of the respective localities?
- The biocidal substance Cymina Plus - used in disinfestation actions represents a risk not only for beekeeping activity, but also for the health of the population.
- From the point of view of EC Regulation no. 1272/2008, the product in question is dangerous, presents the following risk phrases: H351, H319, H410, and the product classification is that mentioned in Opinion no. 3272BIO/18/12.24 issued on 06.05.2015 by the Ministry of Health;
- Toxicity to bees – cypermethrin can have an effect on bees and other non-target arthropods, so there must be a recommendation on the label: apply during the bee inactivity period.

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THE BIOCIDAL PRODUCT Cymina Plus

- Monitoring of public administration authorities for the purpose of applying/monitoring disinfestation treatments does not fall within the remit of other public authorities.
- We note, in this regard, that no competences have been identified regarding the obligation to inform and monitor/control in relation to local public administration authorities, in order to ensure the performance of appropriate treatments with products that are not toxic to bees and that represent a reduced risk to the population of the respective localities.
- Biocidal products are placed on the Romanian market if they hold an opinion (as is the case with the Cymina Plus product) or certificates of mutual recognition of authorization, according to art.6 of H.G. no.617/2014;
- - if at EU level, the procedure for approving active substances is completed (Cymina Plus has 3 active substances), biocidal products are evaluated and the certificate of recognition of authorization is issued according to art.89 paragraph (2) of regulation no.528/2012;

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THE BIOCIDAL PRODUCT Cymina Plus

- - on 25.11.2020, the National Commission for Biocidal Products (CNPB) within the Ministry of Health issued an Extension Notice for the Cymina Plus product, which is supplemented with more specific information, including the concentration of the working solution/application dose, as well as the Biocidal product label, with all risk phrases. The risk phrases are the following: H351 Suspected of causing cancer; H319 Causes serious eye irritation; H410 Very toxic to the aquatic environment with long-term effects;
- - the extension is valid for the period of validity of the notice, until 31.12.2024.
- It is therefore noted that, until the issuance of the Extension Notice in the case of the Cymina Plus biocide, the characteristics contained in the authorization notice regarding the risks that this substance poses to the population were not consistent with those found at European level. Following the issuance of the Extension Notice, a higher risk to the health of the population, but also to the activity carried out in the beekeeping field, was recognized at the national level, which is why, as the authorities competent in carrying out disinfestations with the biocidal product Cymina Plus, they must inform themselves about these new characteristics of the product, in order to respect them in future disinfestation actions.

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THE BIOCIDAL PRODUCT Cymina Plus

- Thus, disinfestation actions with Cymina Plus must be carried out during the period of bee inactivity, and the recognition of the risk phrases (including H351 - likely to cause cancer) denotes the special attention that the authorities applying these substances must pay to the concentration used in disinfestation actions, especially in areas used by the public.

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Improving Environmental Protection Legislation from the Perspective of Identifying Pestilential Odors

- The study follows the analysis of European legislation and national legislation in Romania on the olfactory discomfort noticed in the open air, starting from the situation of City of Brasov from Transylvania, where residents often noticed in 2019, the existence of pestilential odors in certain areas of the city, which led to numerous complaints to public authorities. This particular case requires the identification of mechanisms by which substances with an olfactory impact can be identified and subsequently correlated with ambient air quality, in order to determine whether it represents a real danger to the health of exposed inhabitants. These mechanisms can be applied more or less by different competent authorities in the field, but the applicable legal framework must be sufficiently elaborated to allow concrete results to be obtained. Therefore, beyond a potential subjectivism related to the sensitivity to odors and implicitly to the regulation of their monitoring and the establishment of measures in order to prevent and reduce the olfactory discomfort, certain aspects (identification of the source of smell, establishment of measurement/determination methods, technical possibilities monitoring and measurement of odors) requires a thorough analysis of the situation created, the article notes certain shortcomings in the legal framework governing this area and brings proposals to improve it.

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Improving Environmental Protection Legislation from the Perspective of Identifying Pestilential Odors

- The right to health care is unanimously recognized by international regulations and is found under the protection of constitutional norms in most states of the world. At the Council of Europe level, there is no separate article in the European Convention on Fundamental Rights and Freedoms, but the jurisprudence of the European Court of Human Rights, through its creative spirit, has often referred to the existence of the right to a healthy environment, indirectly, by integrating it into other rights already enshrined at European level, such as the right to private property, the right to life or the right to privacy. In most cases, European case law has extended the protection of privacy provided for in Article 8 of the Convention to the healthy environment in which man has the right to live. Thus, in Guerra and Others v. Italy, the Court held that there were direct consequences of the production of noxious substances by the activity of a neighboring chemical plant on privacy, and in López-Ostra v. Spain, the Court ruled that by placing a treatment plant of wastewater, with adverse effects on the applicant's private and family life, in the vicinity of her home, the State concerned did not ensure a fair balance between the general interests, embodied in the present case by the need to build such a station and the applicant's right to benefit from a healthy environment, as defended by art. 8 of the ECHR.

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Improving Environmental Protection Legislation from the Perspective of Identifying Pestilential Odors

- More recently adopted, the Charter of Fundamental Rights of the European Union regulates environmental protection in Article 37, stating that "Union policies must provide a high level of environmental protection and quality improvement, to be ensured in accordance with the principle of sustainable development".
- Directive 50/2008 of the European Parliament and of the Council of the European Union on air quality and cleaner air for Europe also deals with ways to combat pollutant emissions at source and to identify and implement the most effective pollution control measures reducing emissions at local, national and Community level. Accordingly, the preamble to the Directive states that emissions of harmful atmospheric pollutants should be avoided, combated, or reduced and appropriate targets for ambient air quality should be set, taking into account World Health Organization standards, guidelines, and programs.
- At the national level, Romanian legislation protects the right to a healthy environment through art. 35 of the Romanian Constitution and has transposed Directive 50/2008 by Law no.104/2011 on ambient air quality (Romanian People`s Advocate Recommendation no.34/2020).

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Improving Environmental Protection Legislation from the Perspective of Identifying Pestilential Odors

- In the context of the right to a healthy environment, we question whether the existence of olfactory discomfort may, under certain conditions, be a possible harm to the right to a healthy environment, since there are currently no international limit values for this type of discomfort, and at the level of the World Health Organization were published only the indicative values for limiting olfactory discomfort, but for a small number of individual compounds and not for all odor-generating compounds.
- The situation is of particular importance, as there may be various organic and inorganic chemical compounds with an olfactory impact in the atmosphere, which are not covered by Directive 50/2008 on ambient air quality and clean air for Europe: sulfur compounds; nitrogen compounds; oxygen compounds; hydrocarbs.

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Deficiencies in Legislation

- The link between olfactory discomfort and public health is made through legislative changes that have taken place recently at the national level and which we will refer to in detail. For the time being, we will limit ourselves to specifying the content of art.64^6 of Law no.123/2020 according to which, "in the situation where following the investigations the central public authority for health, through subordinated structures, finds the olfactory discomfort and the state of health of the population, notifies the competent authority for environmental protection responsible for issuing the regulatory acts in the field of environmental protection for the re-examination and updating of the respective acts".
- For the evaluation of odor concentration, chemical analysis techniques of odor-generating compounds or sensory methods that provide information can be used, and the choice of method must take into account certain factors (purpose, location, type of source, odor frequency). The quantification of the sensory properties of the odor sources can be achieved objectively, the odor concentration being the targeted parameter, based on the indicative values used at European / international level, in the absence of nationally regulated values.

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Deficiencies in Legislation

- Also, specific equipment is needed to identify and determine odors, but the national competent authorities, namely the National Environmental Guard and the National Agency for Environmental Protection, must detain the necessary equipment to carry out measurements of these odors and thus eliminate, beyond any doubt of the existence in the air of substances which endanger the health of the population (Florea 2020, 209).
- In the Municipality of Braşov in Romania, unpleasant odors in the air were found several times during 2019 by the population and, subsequently, by the competent authorities, which imposed actions to determine their cause, as well as to remedy the situation created.
- Although EU legislation does not include regulations on olfactory discomfort, it is indirectly regulated by establishing measures to prevent and reduce emissions and airborne concentrations of air pollutants that can cause olfactory discomfort.

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Deficiencies in Legislation

- If there is an olfactory discomfort, the operator must find solutions to prevent the persistence of the olfactory discomfort. For example, Implementing Decision (EU) 2017/302 establishing conclusions on best available techniques under Directive 2010/75/EU of the European Parliament and of the Council for the intensive rearing of poultry and pigs, provides that odor emissions can be monitored using EN Standards: dynamic olfactometry in accordance with EN 13725 to determine odor concentration; ISO standards, national standards or other international standards that ensure the provision of data of an equivalent scientific quality.
- Considering a potential subjectivism related to odor sensitivity and implicitly regulating their monitoring and establishing measures to prevent and reduce olfactory discomfort, certain aspects (identifying the source of odor, establishing measurement/ determination methods, technical possibilities for monitoring and odor measurement) require a more in-depth analysis and on the other hand given the many complaints reported on olfactory discomfort situations,
- the Romanian Ministry of Environment, Waters and Forests considered it appropriate to introduce clear regulations on monitoring and measuring olfactory discomfort.

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Recent regulation of olfactory discomfort

- In this regard, this ministry submitted a series of amendments to the draft law amending the Government Emergency Ordinance no. 195/2005 on environmental protection, approved with amendments by Law no. 265/2006, which among other things establishes additional measures for prevention of the reduction and control of olfactory discomfort that must be respected by economic operators, so as not to affect the health of the population and the environment.
- The law on odors introduces in the Romanian legislation the term "olfactory discomfort" and introduces several control attributions and obligations on the part of the local public administration authorities for olfactory monitoring.
- As a result, on July 16, 2020, the amendments adopted by Law no. 123/2020, also known as the "Law of Smells", which, in art. 2 point 23^1, defines the notion of olfactory discomfort as "the generated effect of an activity that may have an impact on the health of the population and the environment, which is subjectively perceived on different scales of odors or is objectively quantified according to the national, European and international standards in force".

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Recent regulation of olfactory discomfort

- The notion of olfactory discomfort management plan is also introduced: a plan of measures comprising the steps to be taken in specified time intervals, in order to identify, prevent and reduce olfactory discomfort that occurs both in the case of new facilities/ activities or existing installations/activities, as well as in case of substantial modifications of existing installations/activities.
- Regarding the attributions of the public authorities, the law brings additions regarding the environmental authority, but also regarding the central public authority for health. Thus, the latter, through subordinated structures, imposes, in the framework of regulatory procedures for projects or activities that may create olfactory discomfort in residential areas, the operating conditions for compliance with hygiene and public health rules on the living environment of the population, and the authorities Competences for environmental protection responsible for issuing regulatory acts in the field of environmental protection shall include the conditions imposed by the authorities subordinated to the central public health authority in those regulatory acts. The effective application of these procedures therefore requires interinstitutional cooperation at central level.

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Thank you!

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