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LOST IN DEFINITION: THE LEGAL STATUS OF PHARMACEUTICAL WASTE IN EU LAW

Abstract

The article demonstrates the increasing environmental risks associated with active pharmaceutical ingredients (APIs) and argues that current EU law lacks a coherent concept of pharmaceutical waste capable of addressing these risks. Existing practice often equates pharmaceutical waste with unused or expired medicinal products or subsumes it under medical waste, a broad category that fails to capture the diverse sources, decentralised generation, and specific chemical characteristics of APIs. As a result, legal obligations concerning waste collection, classification, and liability remain unclear. A distinct legal category of pharmaceutical waste is necessary to enable targeted regulatory measures and improve environmental and health protection. The article analyses the legal status of pharmaceutical waste in EU legislation, soft law, and academic literature, and explores its relationship to medical waste. It then develops two approaches to defining pharmaceutical waste: one based on enlisting source products and another based on the properties of source products (presence of APIs or API-like substances). The first approach mirrors current usage but poses the risk of excluding environmentally relevant products and importing long-standing classification ambiguities. A composition-based approach better reflects scientific insights from the pharmaceuticals in the environment (PiE) field, capturing contaminated materials and immediate packaging where appropriate. The paper concludes with a proposal for a definition of pharmaceutical waste.

KEYWORDS

pharmaceuticals in the environment (PiE), EU law, pharmaceutical law, environmental protection, waste law

SŁOWA KLUCZOWE

farmaceutyki w środowisku (PiE), prawo UE, prawo farmaceutyczne, ochrona środowiska, prawo odpadów

I. INTRODUCTION[1]

Active pharmaceutical ingredients (APIs), the main components of medicinal products, pose an increasing threat to the environment. Scholars from the biological, chemical, and environmental sciences are examining the presence of these substances in the environment, the risks they entail, and possible measures to prevent or mitigate their impact.[2] These scientific findings should be integrated into legal research.

At present, legal and policy discourse at international and EU level increasingly acknowledges the presence of pharmaceuticals in the environment as an issue requiring regulatory attention, while responses have thus far been developed primarily through soft law instruments (e.g., best practices) and policy initiatives.[3]

[1] The article derives from a fragment of the author's doctoral dissertation entitled 'Gospodarowanie odpadami farmaceutycznymi w prawie Unii Europejskiej' (Pharmaceutical waste management in the European Union Law), prepared in Polish and defended at the University of Silesia in 2024.
[2] Klaus Kümmerer (ed), *Pharmaceuticals in the Environment: Sources, Fate, Effects and Risks* (Springer Science & Business Media 2008); Magda Caban and Piotr Stepnowski, 'How to Decrease Pharmaceuticals in the Environment? A Review' (2021) 19 Environmental Chemistry Letters 3115; Christian G Daughton, 'Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. I. Rationale for and Avenues toward a Green Pharmacy' (2003) 111(5) Environmental Health Perspectives 757; Aib Haithem and others, 'Pharmaceuticals and Microplastics in Aquatic Environments: A Comprehensive Review of Pathways and Distribution, Toxicological and Ecological Effects' (2025) 22(5) International Journal of Environmental Research and Public Health 799 – in this last paper juxtaposed with microplastics.
[3] Various reports and best practices like: WHO, 'Safe management of pharmaceutical waste from health care facilities: global best practices' (WHO 2025); UNEP, 'An Assessment Report on Issues of Concern: Chemicals and Waste Issues Posing Risks to Human Health and the Environment' (UNEP 2020). Policies like One Health: UNEP, 'Safe disposal of unused medicines – A One Health Approach for National Systems' (UNEP 2026); Irene Cristini and others, 'A narrative review on the environmental impact of medicines: from water analysis and in vivo studies to

While ongoing discussions on amendments to Directive 2001/83/EC reflect a growing awareness of environmental concerns within pharmaceutical regulation, they have not yet resulted in measures specifically addressing pharmaceutical waste (rather focused on strengthening environmental risk assessment).[4]

However, pharmaceutical waste is rarely distinguished from the broader category of medical waste, and the concept itself is inconsistently understood. The first issue results in the marginalisation of dedicated management of pharmaceutical waste, which should account for its specific chemical characteristics, such as ecotoxicity, biodegradability, persistence, and mobility. The second issue concerns the acceptance of waste at designated collection points (e.g., liquid pharmaceuticals, pharmaceutical packaging, or syringes) and the allocation of liability, particularly under the extended producer responsibility mechanism.

Against this background, this article aims to establish a basis for distinguishing pharmaceutical waste as a distinct waste category and to propose a corresponding legal definition.

This article deliberately focuses on medicinal products intended for human use and the waste generated from them. It is acknowledged that the agri-food sector and veterinary practice also contribute to environmental pollution by APIs. However, APIs originating from veterinary medicinal products and plant protection products raise distinct and complex issues that warrant separate and more detailed analysis. These areas fall outside the scope of the present study, primarily due to their regulation under separate legal frameworks within EU law. The analysis undertaken, therefore, reflects the specific characteristics of the EU pharmaceutical market for humans, mentioning also closely related product categories such as dietary supplements.

II. LEGAL STATUS OF PHARMACEUTICAL WASTE

1. EU LAW

The principal legal instrument governing waste management in the EU is the Waste Framework Directive (WFD).[5] The WFD does not contain provisions

prescribing appropriateness, based on European and Italian legal frameworks' (2025) 5 Frontiers in Drug Safety and Regulation 1681648.

[4] Proposal for a Directive on the Union code relating to medicinal products for human use, COM/2023/192 final.

[5] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives [2008] OJ L312/3.

directly addressing waste originating from pharmaceuticals. Nor does it regulate a broader category perceived as encompassing pharmaceutical waste – medical waste. References to pharmaceuticals appear in a delegated act that establishes the EU waste classification system, known as the European Waste Catalogue (EWC).[6] Under this act, waste from medicine is typically classified as waste generated by healthcare or households. While Article 20 of the WFD refers to hazardous waste produced by households, which may include pharmaceutical waste, this reference remains general and does not cover the fact that, according to the EWC, most unused medicines do not qualify as hazardous waste.

For interpretive guidance, it is possible to refer to the EU regulatory framework on medicinal products, specifically Directive 2001/83/EC.[7] This Directive mentions: the disposal of unused medicinal products, waste derived from medicinal products (Article 54(j)), and medicinal products that are unused or have expired (Article 127b). Furthermore, the Directive obliges Member States to ensure the operation of appropriate collection systems for unused or expired medicinal products (also in Article 127b). Again, the provisions concern unused or expired medicines but do not explicitly classify them as pharmaceutical waste.

Pharmaceutical waste is, however, expressly addressed in international law. The Basel Convention (1989) – the provisions of which have been adopted by the EU – recognises waste pharmaceuticals, drugs, and medicines as distinct waste streams.[8] These terms, which the Convention treats as synonymous, can collectively be understood as referring to waste originating from pharmaceuticals.

2. SOFT LAW

EU institutions have made limited use of the term *pharmaceutical waste*, or even the broader concept of *medical waste*. The expression *household medical waste* appears, inter alia, in the European Commission's Notice on the Separate

[6] Commission Decision 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council [2014] OJ L370/44.

[7] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67.

[8] Annex I in United Nations Environment Programme, Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Secretariat of the Basel Convention 1992); applied in the EU by: Council Decision of 1 February 1993 on the conclusion, on behalf of the Community, of the Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Basel Convention) [1993] OJ L39/1.

Collection of Household Waste.[9] Within this category, waste from pharmaceutical products is distinguished, limited to the obligatory take-back schemes. In a recently published document by the Health and Food Safety Directorate-General of the Commission, adopted in response to the 'EU Strategic Approach to Pharmaceuticals in the Environment',[10] pharmaceutical waste finally makes a visible appearance, although it still lacks a coherent approach, including a definition of the term.[11]

Among EU agencies, the most relevant actors in this context should be the European Medicines Agency (EMA) and the European Environment Agency (EEA). Both, however, rarely use the term *pharmaceutical waste*. A notable exception is an EEA technical report addressing the presence of pharmaceuticals in the environment, in which the authors refer to pharmaceutical waste and also mention unused or expired medicines, albeit without categorising them within a specific waste stream.[12] Interestingly, the report observes that not only unused pharmaceuticals but also *used pharmaceuticals* may be relevant to waste management – an observation that could open a discussion on waste arising from used drugs.[13] The report, however, does not clarify whether this refers to partially used medicines, their packaging, or the excretion of APIs in their original form or as active metabolites. As for the EMA, despite its efforts to address medicinal products at every stage of their life cycle, it does not address waste.[14] Instead, it supports the development of instruments such as environmental risk assessment.[15]

Beyond the EU framework, the term *pharmaceutical waste* is employed by international organisations such as the World Health Organisation (WHO), the Organisation for Economic Co-operation and Development (OECD), and the International Committee of the Red Cross (ICRC). The WHO defines pharmaceutical waste as expired, unused, and contaminated drugs and vaccines, treating it as a subset of healthcare waste.[16] Notably, the WHO distinguishes between drugs and vaccines. The concept of pharmaceutical waste has been used in WHO

[9] Commission Notice 'Separate Collection of Household Hazardous Waste' [2020] OJ C375/1.
[10] Communication from the Commission, 'European Union Strategic Approach to Pharmaceuticals in the Environment' COM (2019) 128 final.
[11] European Commission Health and Food Safety Directorate-General, 'Pharmaceuticals in the Environment: Implement the EU Strategic Approach – Compilation of Recommendations and Best Practices' (2025).
[12] EEA, 'Pharmaceuticals in the Environment: Results of an EEA Workshop' (EEA 2010) 10.
[13] Ibid 5.
[14] EMA, What we do <https://www.ema.europa.eu/en/about-us/what-we-do#monitor-the-safety-of-medicines-across-their-lifecycle-12356> accessed 20 November 2025.
[15] EMA, 'Environmental Risk Assessment of medicines' (EMA 2015).
[16] WHO, Healthcare Waste: Fact Sheet <https://www.who.int/en/news-room/fact-sheets/detail/health-care-waste> accessed 16 November 2025.

guidelines for the safe disposal of unwanted pharmaceuticals during and after emergencies.[17] The OECD has addressed the issue of environmental pollution from APIs by issuing guidance on the management of municipal pharmaceutical waste, although the document appears to focus primarily on waste originating from households.[18] Similarly, in its work on medical waste management, the ICRC provides a definition of pharmaceutical waste that explicitly includes drug packaging as well as spilt pharmaceuticals.[19]

3. LITERATURE

The concept of pharmaceutical waste also appears in publications, primarily within the field of Pharmaceuticals in the Environment (PiE) research. In the volume edited by K Kümmerer on PiE – addressing sources, fate, effects, and risks – a dedicated chapter by S Castensson focuses on pharmaceutical waste.[20] Castensson includes within this category waste from expired medicines, partially used test tubes and drug containers, unused intermediate products, and unfinished pharmaceutical preparations. He also classifies as pharmaceutical waste the devices used for administering and storing medicines, as well as waste resulting from the breakage or spillage of drugs, including materials that have come into sufficient contact with APIs to be considered contaminated.[21]

Similarly, Lynn Kornfeld and Ann Prouty define pharmaceutical waste through examples of source products, including unused or expired medicines, intravenous preparations and partially used intravenous lines, vials, and syringes.[22] Muhammed Jaseem and others provide one of the most comprehensive classifications, encompassing expired medicines, unwanted or discarded personal medications, residual drugs in syringes, intravenous lines, tubes, and vials, waste containing residues of cytotoxic or anticancer drugs, opened but unusable drug packaging, containers holding hazardous pharmaceutical waste characterised by acute toxicity, and contaminated clothing or materials used for cleaning up

[17] WHO, 'Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies' (WHO 1999).
[18] OECD, *Management of Pharmaceutical Household Waste: Limiting Environmental Impacts of Unused and Expired Medicine* (OECD Publishing 2022).
[19] ICRC, *Medical Waste Management* (ICRC 2011).
[20] Staffan Castensson, 'Pharmaceutical Waste' in Klaus Kümmerer (ed), *Pharmaceuticals in the Environment: Sources, Fate, Effects and Risks* (Springer Science & Business Media 2008) 489.
[21] Ibid 490.
[22] Lynn Kornfeld and Ann Prouty, 'The War on Drugs: Pharmaceutical Waste Management Challenges and Emerging Issues' (2014) 28 Natural Resources & Environment 27.

spills.[23] Verica Jovanović and others understand pharmaceutical waste to include expired, unused, damaged, and contaminated pharmaceuticals, as well as vaccines and sera that are no longer required.[24] The authors also include items used in the administration or handling of pharmaceuticals, such as bottles, boxes with drug residues, gloves, masks, tubing, and vials, within the scope of pharmaceutical waste. A narrower understanding of pharmaceutical waste, focusing on the drugs themselves, is used by, among others, Sabine Vogler and others, as well as Atum Kadam and others.[25] Eydie Pines and others also provide an extensive analysis of both the scope and management of pharmaceutical waste.[26] Justyna Rogowska and others employ the term *pharmaceutical household waste*, which not only identifies pharmaceuticals as the source of the waste but also indicates its place of origin – households.[27] Similarly, Shan-shan Chung and Bryan W Brooks refer to *municipal pharmaceutical waste*.[28] This terminology enables the conceptual differentiation of subcategories within the broader category of pharmaceutical waste, including pharmaceutical household waste, pharmaceutical industrial waste, and pharmaceutical hospital or healthcare waste.

III. RELATION TO MEDICAL WASTE

Pharmaceutical waste is classified within the broader category of medical waste. It is, therefore, necessary to examine whether this classification is appropriate or whether pharmaceutical waste should be treated as a distinct waste stream.

Medical waste, sometimes referred to also as *clinical waste* or *healthcare waste,* generally refers to waste generated through healthcare activities conducted in

[23] Muhammed Jaseem and others, 'An Overview of Waste Management in Pharmaceutical Industry' (2017) 6(3) The Pharma Innovation Journal 158.

[24] Verica Jovanović and others, 'Management of Pharmaceutical Waste in Hospitals in Serbia – Challenges and the Potential for Improvement' (2016) 50(4) Indian Journal of Pharmaceutical Education and Research 700 (probably cited after: WHO, 'Safe Management of Wastes from Healthcare Activities' (WHO 1999) 3).

[25] Sabine Vogler and others, 'Medicines Discarded in Household Garbage: Analysis of a Pharmaceutical Waste Sample in Vienna' (2014) 7 Journal of Pharmaceutical Policy and Practice 6; and: Atul Kadam and others, 'Pharmaceutical Waste Management: An Overview' (2016) 9(1) Indian Journal of Pharmacy Practice 2.

[26] Eydie Pines and Charlotte Smith, 'A 10-Step Blueprint for Managing Pharmaceutical Waste in US Healthcare Facilities' 2022 Edition (US EPA 2022).

[27] Justyna Rogowska and others, 'Pharmaceutical Household Waste Practices: Preliminary Findings from a Case Study in Poland' (2019) 64 Environmental Management 97.

[28] Shan-shan Chung and Bryan W Brooks, 'Identifying Household Pharmaceutical Waste Characteristics and Population Behaviors in One of the Most Densely Populated Global Cities' (2019) 140 Resources, Conservation & Recycling 267.

hospitals, clinics, pharmacies, laboratories, and similar facilities.[29] S Chartier and others define medical waste as encompassing all waste arising from healthcare institutions, research centres, and laboratories related to medical procedures. They further emphasise that this category also includes similar waste generated from smaller and more dispersed sources, such as waste produced during home healthcare.[30] *Medical waste* is typically distinguished by reference to the activity during which it is generated.

The classification of pharmaceutical waste within the broader category of medical waste may raise several concerns.

First, there is the issue of the dispersion of pharmaceutical waste sources. Classifying pharmaceutical waste as medical waste primarily associates its generation with healthcare facilities. Within this group, hospitals and pharmacies are the principal generators. However, pharmaceutical waste is also generated in households.[31] Similar waste arises from entities that neither provide healthcare services nor are directly related to medical practice but manage pharmaceuticals, such as shops, petrol stations, and online platforms. Comparative empirical data on pharmaceutical waste from households and healthcare facilities remain limited, though national examples offer some insight. In France, households disposed of approximately 17,600 tonnes of unused or expired medicinal products in 2018 (around 260 g per capita).[32] By contrast, a study of 210 hospitals reported that over two tonnes of medicinal products were discarded within a single week.[33] These figures suggest a notable disparity. However, they should be interpreted with caution, as healthcare waste is subject to strict regulatory controls, whereas household pharmaceutical waste remains more diffuse and less systematically managed.

Second, comes the issue of the dispersion of pharmaceutical distribution channels. Historically, pharmaceuticals were dispensed primarily by specialised entities such as pharmacies and hospitals. However, market liberalisation has led to the widespread availability of medicines in supermarkets, beauty supply stores, petrol stations, and through online sales.[34] The growing availability of over-the-counter (OTC) pharmaceuticals has decoupled the acquisition of medicine

[29] WHO (n 16).
[30] WHO, 'Safe management of wastes from health-care activities 2nd edition' (WHO 2014).
[31] Rogowska (n 27) 102 and WHO (n 30) 3.
[32] OECD (n 18) 4.
[33] Résomédit, C2DS, 'Médicaments à l'hôpital : [ré]agir pour moins jeter', 2026. With approx. 52 weeks in a year, it adds up to 104 tonnes. The study does not include all of the facilities.
[34] Rogowska (n 27).

from healthcare services.[35] As a result, basing waste classification on the source of generation – namely, healthcare provision – is increasingly inadequate. The COVID-19 pandemic has further accelerated this trend, as remote healthcare and online medical consultations have expanded access to medicines beyond traditional medical institutions.

Third, the category of medical waste fails to account for the specific characteristics of pharmaceutical waste. Effective waste management policies must reflect the specific environmental and health risks associated with different waste types. Medical waste encompasses a broad range of materials that share only the common feature of being associated with healthcare-related activities. This link is insufficiently precise to support uniform regulatory treatment.

Under subcategory 18 01 of the EWC,[36] corresponding to medical waste, the following are included:

- Medicines, with a distinction of cytostatic and cytotoxic medicines;
- Sharps;
- Body parts and organs, including blood bags and blood preserves;
- Infectious waste;
- Waste not subject to special requirements in order to prevent infection (e.g. dressings, plaster casts, linen, disposable clothing, diapers);
- Amalgam waste from dental care;
- Chemicals.

This extensive and heterogeneous catalogue makes it challenging to design coherent and specialised procedures for medical waste management. Generalised approaches risk regulating fundamentally different waste types under the same framework, without accounting for their distinct properties. Referring to pharmaceutical waste as medical waste thus obscures its specific chemical and environmental characteristics. The COVID-19 pandemic has further shifted attention within the context of medical waste management toward personal protective equipment (PPE), such as masks and gloves. For example, the WHO's Global Analysis of Healthcare Waste in the Context of COVID-19 focuses predominantly on PPE-related waste.[37]

[35] Colin P Bradley and Christine M Bond, 'Increasing the Number of Drugs Available over the Counter: Arguments for and against' (1995) 45(399) British Journal of General Practice 553.
[36] Commission Decision (n 6).
[37] WHO, 'Global analysis of healthcare waste in the context of COVID-19: status, impacts and recommendations' (WHO 2022) 6.

IV. HOW TO DEFINE PHARMACEUTICAL WASTE?

1. APPROACH

Legal definitions fulfil two principal functions: they reduce ambiguity and prevent unnecessary repetition (as in Directive 2001/83/EC).[38] By proposing a definition of pharmaceutical waste, one implicitly identifies a new category of waste. This category will encompass several sub-streams, as pharmaceutical waste does not constitute a homogeneous stream but rather comprises multiple sub-streams that reflect the diversity and complexity of the chemical substances contained in pharmaceutical products.[39] Frequently cited examples include waste from anticancer medicines (identified by their high toxicity), waste from liquid formulations (classified by physical state), waste from antibiotics (classified by the associated risk of antimicrobial resistance), and waste from syringe preparations (distinguished by the route of administration). Nonetheless, these substreams remain part of the overarching pharmaceutical waste category.

In WFD, individual waste streams are typically distinguished by:

1. the source product of the waste, i.e. the object or substance from which the waste originates – like food waste (Article 3(4a));
2. the physicochemical properties of the source product – like bio-waste and its biodegradability) (Article 3(4));
3. the activity or process generating the waste, like construction and demolition waste (Article 3(2c));
4. the suitability or unsuitability of the product for its initially intended purpose, like waste oils (Article 3(8)).

These criteria can guide the development of a definition for pharmaceutical waste. The first conceptual approach is to rely on a catalogue of source products through delineating the product categories covered by the definition. Existing definitions of pharmaceutical waste typically rely on its generation from medicines. Analogous to the definition of food waste, pharmaceutical waste could be defined by reference to the legal definition of a medicinal product contained in Directive 2001/83/EC. However, this approach is limited in scope, as it excludes other product categories capable of generating similar contaminants, such as medical devices, dietary supplements, and cosmetic products, and it imports interpretive

[38] Mario Hernández Ramos and Volker Heydt, 'Legislative Language and Style' in U Karpen, H Xanthaki (eds), *Legislation in Europe: A Comprehensive Guide for Scholars and Practitioners* (Hart Publishing 2017) 134.
[39] Pines (n 26) 31.

challenges associated with the EU concept of a medicinal product into the definition of pharmaceutical waste.

A second approach is to focus on the properties of the source product rather than on the product category itself. This method better reflects the primary concern in preventing environmental pollution: the presence of APIs (in chemical, not legal, meaning) in both medicinal and non-medicinal products.

A third approach is to identify the activities or processes that generate pharmaceutical waste. Currently, pharmaceutical waste is implicitly included within medical waste, which is defined primarily by its origin. As discussed earlier, defining pharmaceutical waste through these processes is problematic because it obscures its distinct environmental significance and ties it too closely to healthcare delivery.

The fourth criterion employed by the EU legislator pertains to the loss of suitability for the originally intended purpose. In the context of pharmaceutical waste, however, this approach is difficult to justify given the specific nature of APIs. One conceivable approach would be to draw on the definition of a medicinal product and classify waste as material that has lost its pharmacological, immunological, or metabolic activity. Yet determining the precise point at which such activity ceases remains highly complex. While expiry dates may serve as a proxy, it is well established that many medicinal products retain effectiveness beyond the indicated date.[40] Moreover, reliance on the expiration date as the decisive criterion would fail to capture medicinal products arising from unfinished or discontinued therapies, before expiration.

Under WFD, the EU legislator provides criteria operating in the opposite direction – namely, from waste to product – through the concept of end-of-waste status (Article 6). A substance may cease to be waste where it is intended for specific use, meets technical and regulatory standards, has a market or demand, and does not pose adverse environmental or health impacts. By analogy, reverse criteria may be constructed to assess the transition from product to waste. In the pharmaceutical context, this could include situations where: (1) the API can no longer be used for its primary purpose; (2) the product fails to meet relevant technical or regulatory standards; and (3) its use may pose risks to human health. In practice, however, such determinations are frequently made by consumers, who, lacking specialised knowledge, are generally unable to identify these transitional thresholds.

[40] Gurmeet S Sarla, 'Efficacy and disposal of drugs after the expiry date' (2019) 31(4) The Egyptian Journal of Internal Medicine 431–434.

2. DEFINITION BASED ON THE WASTE SOURCE PRODUCT

Defining pharmaceutical waste by reference to the source product (which becomes waste when meeting the conditions under WFD) requires not only a precise understanding of the legal concept of a medicinal product (as defined in Article 1(2) of Directive 2001/83/EC) but also an assessment of other product categories that may fall within the scope of the definition. The characteristics of medicinal products and their relationship to other regulated product groups have been analysed extensively in the literature.[41] Given that APIs posing environmental risks are predominantly found in medicinal products, treating medicines as the core source product of pharmaceutical waste is an intuitive and commonly applied approach.

A source product-based definition of pharmaceutical waste could be formulated as follows: 'pharmaceutical waste means medicinal products, as defined in Article 1 of Directive 2001/83/EC of the European Parliament and of the Council, that have become waste'. Such a definition would offer a clear, legally anchored criterion that consumers and waste management entities should easily identify.

It is essential to ensure that consumers can readily determine whether a product, once discarded, constitutes pharmaceutical waste, as this classification shapes subsequent disposal behaviour. The possibility of purchasing medicinal products in non-pharmacy settings, such as petrol stations or supermarkets, may weaken consumers' perception of these products as belonging to the healthcare domain. As a consequence, consumers may treat waste arising from such products similarly to ordinary household waste, including food waste, rather than as a separate, environmentally relevant waste stream. Conversely, purchasing a product in a pharmacy – including not only medicines but also dietary supplements or cosmetics – may lead consumers to assume automatically that the resulting waste falls within the category of pharmaceutical waste.

Within a definition constructed around the medicinal product as the source product, several sub-categories require particular attention due to their environmental or regulatory significance. These include cytostatic and cytotoxic medicinal products, controlled substances, vaccines and serums, and medicinal products administered in pre-filled syringes.

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[41] Joanna Haberko (ed), *System Prawa Medycznego. Tom 4: Prawo farmaceutyczne* (CH Beck; Institute of Legal Sciences, Polish Academy of Sciences 2019) 345; Jarosław Kocot, *Prawo Unii Europejskiej wobec procederu fałszowania produktów leczniczych* (Instytut Wydawniczy Euro-Prawo 2018) 40; Magdalena Krekora and others, *Prawo farmaceutyczne* (Wolters Kluwer Polska 2020) 31.

A further question is whether products similar to medicinal products may pose comparable environmental risks. Dietary supplements and specific medical devices can serve as an example. Dietary supplements often contain substances identical to those present in medicinal products, albeit at lower doses; in some cases, empirical findings indicate that supplements may contain even higher levels of such substances.[42] Regarding medical devices, manufacturers typically indicate whether their product falls within this regulatory category.[43] Some products are on the borderline, such as eye drops.[44] Although regulatory authorities may verify and correct misclassifications, such control is selective and, therefore, not comprehensive.

The principal advantage of defining waste through reference to specific products or product groups is transparency.[45] On the other hand, defining pharmaceutical waste by enumerating its source products risks transferring the classification and interpretative uncertainties associated with these products directly into the definition of pharmaceutical waste. Mainly, when attempts include non-medicinal products that may contain substances identical, in physicochemical terms, to APIs, this approach may lead to creating an overly expansive definition. In categories such as medical devices or dietary supplements, only some products contain such substances; therefore, only those specific items should potentially fall within the scope of pharmaceutical waste. Furthermore, the rigidity of product lists renders them susceptible to obsolescence, particularly in rapidly evolving markets.[46]

3. DEFINITION BASED ON THE PROPERTIES OF THE WASTE

Focusing on products rather than the materials from which they are made can hinder the effective regulation of waste streams.[47] This critique is especially rel-

[42] Małgorzata Korzycka and others, 'Suplementy diety i żywność specjalnego przeznaczenia medycznego' in J Haberko (ed), *System Prawa Medycznego. Tom 4: Prawo farmaceutyczne* (CH Beck; Institute of Legal Sciences, Polish Academy of Sciences 2019) 409; also Katarzyna Stoś, 'Suplementy diety czy leki?' Narodowe Centrum Edukacji Żywieniowej <https://ncez.pzh.gov.pl/abc-zywienia/suplementy-diety-czy-leki/> accessed 20 November 2025.

[43] Case C-219/11 *Brain Products GmbH v BioSemi VOF and Others* ECLI:EU:C:2012:742, para 33.

[44] Medical Device Coordination Group, 'Manual on Borderline and Classification for Medical Devices under Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices', Version 2 (2022) 37.

[45] Ilona Cheyne, 'The Definition of Waste in EC Law' (2002) 14(1) Journal of Environmental Law 63.

[46] Ibid.

[47] Based on the Commission actions: Geert Van Calster and Leonie Reins, *EU Environmental Law* (Edward Elgar Publishing 2017) 267.

evant in the context of pharmaceutical waste, where environmental harm arises from the chemical properties of APIs and similar compounds rather than from the formal regulatory status of the products containing them.[48]

A second approach worth considering is to define pharmaceutical waste based on the properties of the waste itself, in particular the presence of APIs, which in Directive 2001/83/EC should be matched with *active substance*, since there is no separate definition of *active pharmaceutical ingredient*.[49] Such an approach shifts the focus away from the legal classification of the source product and towards the substances responsible for environmental risk. This does not necessarily require amending Directive 2001/83/EC. A parallel definition could be introduced in environmental (in case of choosing a separate legal instrument to regulate the matter) or particularly waste law, capturing substances based on their chemical identity and environmental relevance. This would allow pharmaceutical and environmental law to operate in a complementary manner: the former remains product-centred, while the latter addresses substance-related risks at the waste stage.

Basing the definition on the substance rather than the product also ensures a more coherent response to environmental concerns identified in PiE research. It would be incorrect to say that APIs are present in products other than medicinal products, but it is correct that some products contain substances with the same chemical structure and, therefore, properties as APIs. Substances identical to APIs may occur in products classified as non-medicinal, such as dietary supplements, medical devices, or cosmetic products, often due to regulatory or market distinctions rather than chemical differences. In some cases, the distinction depends on dosage rather than substance identity.[50] A composition-based approach avoids overlooking such cases. The assessment of environmental relevance should remain evidence-based, and differentiated waste management measures may be introduced, for example, to ease handling requirements for environmentally benign substances. Extending regulatory coverage to such cases does not require redefining *active substance* in pharmaceutical law. It can instead be achieved through a series of references made in the regimes regulating the above-mentioned products, together with an indication of the conditions under which waste from such products should be considered pharmaceutical waste. At the same time,

[48] Cheyne (n 45).

[49] Article 1(3a): *any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.*

[50] E.g., for dietary supplements: Małgorzata Korzycka and others (n 42).

classifying waste from non-medicinal products as pharmaceutical waste should remain exceptional and contingent on the presence of relevant substances.

Building on the above, it must be acknowledged that clearly delineating the boundaries between environmental law – particularly waste law – and product-specific regulation, such as that governing medicinal products, is difficult in practice. The increasing reliance on a life-cycle approach means that regulatory frameworks addressing products cannot avoid engaging with their end-of-life stage, including waste. As a result, a degree of overlap is inevitable. General principles of waste management are laid down in WFD, while more specific rules concerning the handling of waste derived from particular product categories remain embedded in sectoral legislation, including Directive 2001/83/EC. Rather than constituting a contradiction, this dual structure enables the integration of product-specific characteristics into waste management regimes, thereby, in author's opinion, enhancing their effectiveness. Moreover, such an approach is consistent with the principle of integration enshrined in Article 11 TFEU.

A crucial issue arises when defining pharmaceutical waste by reference to APIs content: whether items contaminated by APIs should fall within the definition. Personal protective equipment, cleaning agents, absorbent materials used to manage spills, and similar items may become contaminated through contact with broken, spilt, or improperly handled medicinal products.[51] Equipment used in administering medications may likewise acquire APIs residue. S Castensson extends this logic further, noting that materials contaminated during pharmaceutical manufacture should also be regarded as pharmaceutical waste.[52]

The EU legislator can draw guidance for addressing this issue from Y Chartier and others, who classify discarded items *heavily contaminated* during the handling of pharmaceuticals – such as bottles, vials, boxes containing pharmaceutical residues, gloves, masks, and connecting tubes – as pharmaceutical waste.[53] The key element is the qualifier *heavily*, which introduces a threshold concerning the degree of contamination sufficient to justify classification as pharmaceutical waste. Incorporating a contamination-based criterion would allow for a more nuanced regulatory approach. In opting for the flexible yet inherently indeterminate notion of *heavily* as a threshold criterion, it is appropriate to briefly consider an alternative approach based on the use of quantitative benchmarks. EU chemical legislation provides a relevant point of reference in this regard, among others in Regulation (EC) No 1272/2008 (CLP), where numerical thresholds – such as

[51] Castensson (n 20) 489.
[52] Ibid.
[53] WHO (n 30) 5.

0.1% and 1% – are employed to assess the health hazards posed by substances and mixtures.[54] These thresholds effectively operationalise the graduality by translating it into measurable criteria. However, the transposition of such an approach into the present context raises important feasibility concerns. First, within the chemicals regulatory framework, manufacturers typically possess the technical capacity and procedural infrastructure necessary to determine substance concentrations at the production stage. By contrast, any threshold adopted here would need to be ascertainable not only by professional healthcare operators but also, at least in principle, by end-users such as households, thereby introducing practical limitations on measurement and verification. Secondly, the determination of contamination levels may be complicated by the heterogeneity of contaminated items (here, it is not the substance that is 'contaminated', like in chemical legislation). The relative proportion of a contaminant may vary considerably depending on the nature and scale of the object in question – for example, between small-volume pharmaceutical applicators, such as tubes, and larger items such as contaminated garments. These factors suggest that, while numerical thresholds offer conceptual clarity, their practical implementation in this domain may prove significantly more complex.

A definition centred on APIs content evokes parallels with the EU's chemicals regulatory regime, which focuses on the properties and hazards of substances rather than on the specific products containing them. Such an approach would shift attention from the category of source products to the chemical characteristics of the waste, treating pharmaceutical waste as a stream defined by the presence of environmentally relevant compounds.

4. PACKAGING

Packaging may be regarded as an integral part of the medicinal product;[55] this is reflected, among others, in the legal definition of an excipient, which presupposes the existence of packaging material alongside the excipient and the APIs (Article 1(3b) of the Directive 2001/83/EC). Two categories of packaging are generally distinguished: immediate packaging and outer packaging. *Immediate packaging* refers to the container or other form of packaging immediately in contact with the

[54] Annex 1, OJ L 353 of 31 December 2008.

[55] Noticeable in Annex to the Regulation of the Minister of the Environment of 22 October 2013 on the Exemplary List of Products that Are or Are Not Considered Packaging [2013] Journal of Laws 2013 item 1274 (PL) – in which packaging is expressly considered to be an integral part of the product and necessary for storing, maintaining or protecting the product throughout its entire cycle and period of operation.

medicinal product (Article 1(23) of the Directive 2001/83/EC). In contrast, *outer packaging* refers to the packaging that contains the immediate packaging (Article 1(24) of the Directive 2001/83/EC). Immediate packaging can correspond with the *pharmaceutical packaging* sometimes used in literature.[56]

From the perspective of defining pharmaceutical waste, packaging should be included only to the extent that it has come into contact with APIs. On this basis, the inclusion of immediate packaging within the scope of pharmaceutical waste appears intuitive, as direct contact with APIs increases the likelihood of contamination. However, immediate packaging should not automatically be classified as pharmaceutical waste; rather, it should be considered as such only when it is heavily contaminated with APIs. Outer packaging, by contrast, generally lacks direct contact with APIs and should be treated as pharmaceutical waste only in exceptional circumstances – namely, where heavy contamination has occurred.

V. CONCLUSIONS: PROPOSAL OF DEFINITION

Although the term pharmaceutical waste does not appear in EU legislation, it is increasingly used in academic and policy documents. The current, implicitly applied understanding of pharmaceutical waste tends to focus on unused or expired medicinal products. This approach is too narrow to address environmental pollution caused by active pharmaceutical ingredients (APIs). Moreover, the classification of pharmaceutical waste under the broader category of medical waste is insufficient, as it fails to account for the dispersed sources of pharmaceutical waste generation, the decentralised distribution of products that become such waste, and the specific environmental characteristics of APIs.

Is the definition of pharmaceutical waste necessary? Establishing pharmaceutical waste as a distinct category would enable the development of targeted strategies, policies, and legal instruments tailored to its unique characteristics and needs. It would also draw greater regulatory attention to this waste stream than is possible when it is subsumed under the broad and diffuse category of medical waste, often equated with waste from protective equipment or healthcare consumables. These factors demonstrate the need to develop a distinct and coherent concept of pharmaceutical waste.

Regarding the shape of the definition, the approach based on enlisting products that later fall into the category of pharmaceutical waste naturally leads to an emphasis

[56] Castensson (n 20) 494.

on medicinal products. However, other products containing substances of the same environmental significance should not be excluded from the scope. Moreover, a definition based on a list of source products would import the interpretative difficulties associated with distinguishing between medicinal products, dietary supplements, cosmetics, and medical devices into the category of pharmaceutical waste.

To avoid these problems, pharmaceutical waste can instead be defined by reference to the composition of the source product – namely, the presence of APIs or substances with API-like characteristics (second approach). This approach requires introducing, or extending, the definition of APIs so that it also encompasses substances found in products other than medicinal products. A composition-based approach would capture all environmentally relevant products and substances that contribute to environmental pollution, as described by researchers from the PiE area. Materials containing high levels of APIs as a result of contact with pharmaceutical products would also be considered pharmaceutical waste, for example, items contaminated through spillage or during handling. Immediate packaging should likewise be included within the definition if contaminated. The treatment of outer packaging depends on the design of pharmaceutical waste collection systems; however, generally, such packaging should be excluded and managed according to paper, plastic, or glass waste streams.

A final proposal for the definition of pharmaceutical waste can, therefore, be formulated as follows: *Pharmaceutical waste means waste from products containing an active pharmaceutical ingredient.* Given that Directive 2001/83/EC contains a definition of active substance, two options are available. Option one – introducing a separate definition of APIs for environmental protection purposes, or option two – treating active substance and active pharmaceutical ingredient as equivalent terms, and broadening the scope of its understanding through references made in the regimes regulating similar products that contain substances with a chemical structure equivalent to APIs. The first approach is viable where the definitions are placed in separate legislative acts; otherwise, clarity and transparency may suffer. The second approach supports legal coherence and recognisability, particularly given the centrality of APIs to the discourse on PiE.

To facilitate the application of the definition and reflect both scientific knowledge and societal understanding, the following clarification may be added: *Waste from a medicinal product as defined in Article 1 of Directive 2001/83/EC of the European Parliament and of the Council is presumed to be pharmaceutical waste.* As the definition applies only to products that have become waste, it remains consistent with the general EU concept of waste, which concerns substances or objects that the holder discards, intends to discard, or is required to discard (as in Article 3(1) of the WFD).

In light of the considerations regarding packaging, it may be appropriate to add: […] *along with packaging in direct contact with the substance* or […] *along with immediate packaging.*

Finally, to address the inclusion of items contaminated by APIs, the following provision may be considered: *A product containing an active pharmaceutical ingredient also means an object or substance that, through contact with a product originally containing an active pharmaceutical ingredient, has been heavily contaminated by it.* Although the term heavily introduces a degree of vagueness, it is the most reasonable threshold for capturing contamination levels relevant to environmental and health protection. This addition would address concerns raised in the literature regarding materials contaminated with APIs during manufacturing, handling, clinical use, or accidental damage.

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