



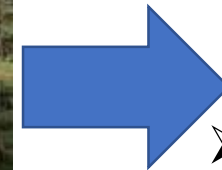
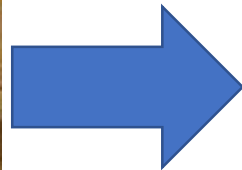
# **Current Scenario in Medication Waste Legislation**

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*Brussels, 26.06.2025*

# Why is proper handling of unnecessary/expired medications so important?



- e.g. Water pollution
- Antimicrobial resistance (AMR)

- **Scale**  
global life expectancy increased from 66.8 years in 2000 to 71.4 in 2021 and is projected to reach 78.2 by 2050 (WHO)

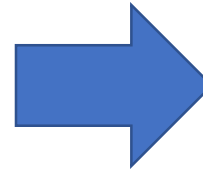
- **Properties**

- Wastewater treatment
- Interactions and degradation

AMR is a phenomenon in which microorganisms such as bacteria become increasingly resistant to antimicrobial agent

# Why is proper handling of unnecessary/expired medications so important?

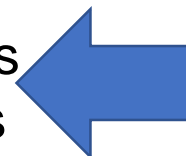
A European One Health  
Action Plan Against  
Antimicrobial Resistance  
(2017)



adopt an EU  
strategic approach  
to pharmaceuticals  
in the environment



The main objective of the strategy is to  
increase the level of knowledge both  
on the rational use of pharmaceuticals  
and the presence of pharmaceuticals  
in the environment and the risk  
resulting from this.



European Union  
Strategic Approach to  
Pharmaceuticals in  
the Environment  
(2020)

# European Union Strategic Approach to Pharmaceuticals in the Environment (2020)

Reduce waste and improve the management of waste

- Explore the possibility of reducing waste by optimising the package size of pharmaceuticals;
- Facilitate the exchange of best practices among healthcare professionals on the environmentally safe disposal of medicinal products and clinical waste, and the collection of pharmaceutical residues as appropriate;
- **Assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal;**
- Evaluation of wastewater treatment regulations, investment in new wastewater treatment technologies.

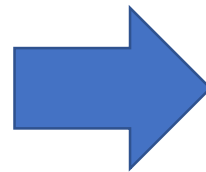
# Pharmaceutical Strategy for Europe (2020)

One of the goals of the strategy is high quality, safe and environmentally sustainable medicines.

Action: **Continue the implementation of the actions under the strategic approach to pharmaceuticals in the environment, including the environmentally safe disposal of medicines and reducing pack size and packaging.**

## Medication waste/pharmaceutical waste

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (*OJ L 312, 22.11.2008*)



No definition

# Medication waste/pharmaceutical waste

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 (*OJ L 311, 28.11.2001*)



## Medicinal product

Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.



~~Supplements~~

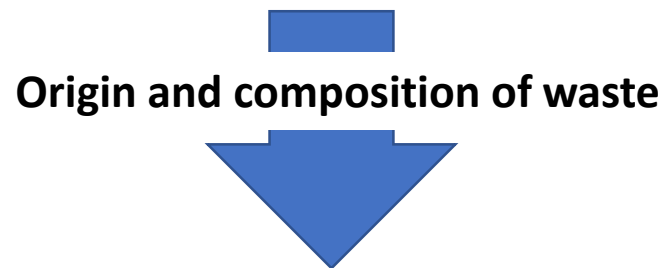
## Medicinal product waste

Waste generated from medicinal products

~~Veterinary  
medicinal  
products~~

# Medication/pharmaceutical waste

Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (notified under document number C(2000) 1147) (2000/532/EC) (EUROPEAN WASTE CATALOGUE)



WASTES FROM ORGANIC  
CHEMICAL PROCESSES



WASTES FROM HUMAN OR  
ANIMAL HEALTH CARE



MUNICIPAL WASTES

# Medication/pharmaceutical waste



**07** Wastes from organic chemical processes

**07 05** Wastes from the manufacture, formulation, supply and use (MFSU) of pharmaceuticals



**18** Wastes from human or animal health care and/or related research

**18 01** Wastes from natal care, diagnosis, treatment or prevention of disease in humans

**18 01 08\*** Cytotoxic and cytostatic medicines

**18 01 09** Medicines other than those mentioned in 18 01 08



**20** Municipal wastes (household waste and similar commercial, industrial and institutional wastes) including separately collected fractions

**20 01** Separately collected fraction

**20 01 31\*** Cytotoxic and cytostatic medicines

**20 01 32** Medicines other than those mentioned in 20 01 31

+18 02 animals





# Pharmaceutical waste from health care: Polish case

- Regulation of the Minister of Health of 5 October 2017 on the detailed procedure for handling medical waste (J.L. 2017, item 1975)
- Regulation of the Minister of Health of 27 October 2022 on the basic conditions for running a pharmacy (J.L. 2022, item 2363)
- Regulation of the Minister of Health of 20 February 2024 on detailed conditions and procedures for handling narcotic drugs, psychotropic substances and category 1 precursors, their mixtures or waste and medicinal products that are spoiled, counterfeit or have expired and contain narcotic drugs, psychotropic substances or category 1 precursors (J.L 2024, item 239)
- 2018 - Database on products, packaging and waste management (BDO) - a system for recording waste and tracking its fate from generation to disposal

From 2022 each pharmacy must be registered in the BDO system



# Household pharmaceutical waste

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 (consolidated version 01/01/2025)



## Article 127b

Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.

Points where residents can bring unnecessary medications:

- Pharmacies: obliged by law or voluntarily;
- Health care facilities;
- Hospitals;
- Nursing homes
- Separate waste collection points

Participation of pharmacies in the system:

**Mandatory** - Croatia, Serbia, France, Spain, Portugal

**Volunteering** - Netherlands, Finland, Poland



# Household pharmaceutical waste: Polish case

Act of 13 September 1996 on maintaining  
cleanliness and order in municipalities  
(Dz.U. 2025, poz.733)



According to the regulations, municipalities are responsible for ensuring the selective collection of municipal waste.



**PSZOKs** - points of selective collection of municipal waste

- In Poland, there are **no regulations** that would include pharmacies in the system for collecting unnecessary pharmaceuticals from residents.
- Pharmacies participate in this system on a **voluntary basis**.
- Municipalities are obliged to provide containers to pharmacies and the municipality is obliged to collect this type of waste.



# Household pharmaceutical waste

What do Polish residents do with unnecessary/expired medicines?

**Study I** - Almost 68% of respondents usually throw out expired pharmaceuticals into the municipal waste bin or pour them into the sewage system (residents of Poland).

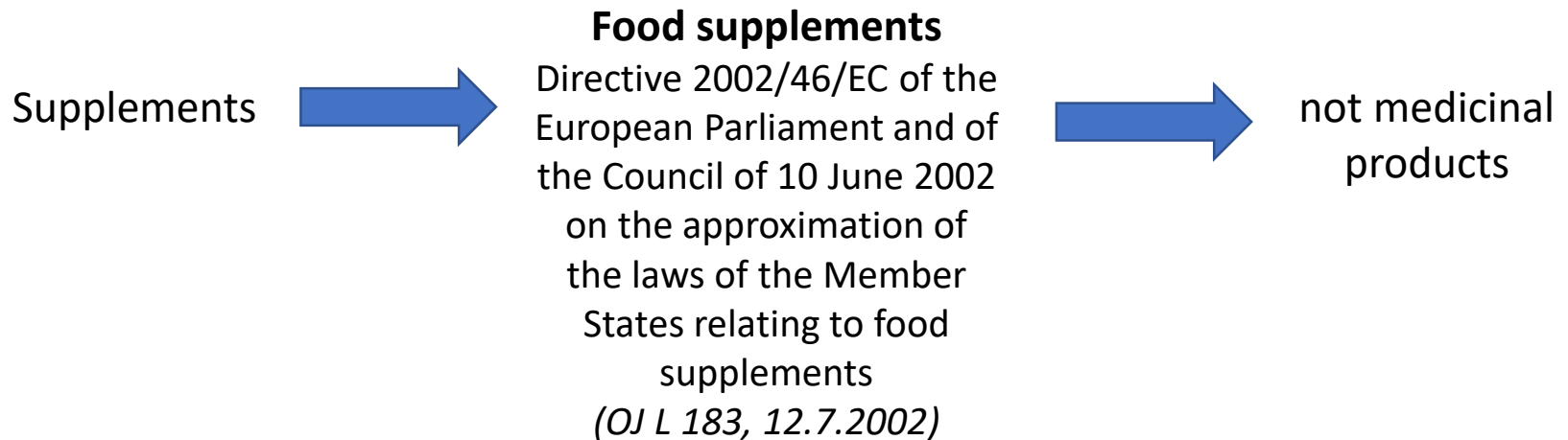
**Study II** - over 35% throw out expired pharmaceuticals into the municipal waste bin or pour them into the sewage system, 24.2% did not remember what they were doing with unnecessary medicines (pharmacy customers).



**Only about 30% give unnecessary/expired medicines to pharmacies**

# Problems

## 1. What to do with waste from supplements?



Main reasons for the withdrawal of supplements from the Polish market by the Chief Sanitary Inspector in 2020–2023:

- contamination with chemical compounds such as ethylene oxide, 2-chloroethanol, chlorpyrifos (pesticide) or polycyclic aromatic hydrocarbons (PAH) (in concentrations above permissible values)
- the presence of active substances in supplements: yohimbine, ibutamoren, sildenafil or tadalafil

**Should be treated  
as medicinal  
products?**

# Problems

## 2. Should pharmacies be included in the system on a mandatory basis?

Question	Total answers	Percentage of group (%)
The survey (I)	Investigated group (n=450)	
Do you know that expired/unused pharmaceuticals can be taken to a pharmacy for disposal?		
Yes	293	65.1
No	157	34.9
Do you think the pharmacy is obliged to accept expired/ unused pharmaceuticals for the purpose of disposal?		
Yes, but only selected pharmacies	57	12.7
Yes, each pharmacy	256	56.9
No, pharmacy does not have such an obligation	16	3.5
I don't know	121	26.9
The survey (II)	Investigated group (n=635)	
Is in your opinion pharmacy is a place which should accept expired/unused pharmaceuticals?		
Definitely yes	415	65.4
Rather yes	100	15.7
I haven't opinion	70	11.0
Rather no	42	6.6
Definitely no	8	1.3

### 3. Should pharmaceutical manufacturers be included in the system under the Extended Producer Responsibility concept?

responsibility of producers for their products along the entire lifecycle, including at the post-consumer stage

Art. 20 ust 4 Waste Framework Directive - By 5 January 2020, the Commission shall draw up guidelines to assist and facilitate Member States in the separate collection of hazardous waste fractions produced by households.



Commission Notice  
Separate Collection of Household Hazardous Waste  
(2020/C 375/01)

BEST PRACTICES IN HOUSEHOLD HAZARDOUS WASTE  
COLLECTION

## 3. Extended Producer Responsibility

France and Spain

### **France - CYCLAMED:**

- 1993, non-profit organisation associating pharmacists, distributors and pharmaceutical companies;
- Pharmacies are obligated to collect expired or unused medicines (for human use) from individuals (legal obligation);
- Financial resources for the operation of the system come from producer contributions;
- Effects: collecting 77% of the unused medication (in 2024) (71% in 2023).

**Spain – SIGRE**

**Portugal - VALORMED**

**One of the goals of the activity: conducting educational campaigns!!!**



## 4. Should medicine packaging include information about the appropriate waste collection system?

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 (consolidated version 01/01/2025)



### Article 57

The following particulars **shall appear** on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate **collection system** in place;

# Problems

## 4. Markings/information on packaging



<https://sigre.es>

Spain



Czech Republic



Nepoužitelné léčivo vraťte do lékárny.  
Any unused medicinal product should be  
returned to the pharmacy

<https://www.magistra.cz/cs/produkt/>

# More information...

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- Rogowska, J., Piątkowska, K., & Głowacz, Z. (2024). Societal involvement in household waste sorting behavior in the context of the circular economy: a case study of Poland. *Sustainability*, 16(5), 1841.
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