CHAPTER 11

ENVIRONMENTAL ASPECTS OF MODERN PHARMACEUTICAL BIOTECHNOLOGY: SUSTAINABLE WASTE MANAGEMENT AND PHYTOMANAGEMENT OF TERRITORIES

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INTRODUCTION

The current stage of development of pharmaceutical biotechnology is characterized by a paradigm shift: from purely technological efficiency to environmental responsibility. In light of global challenges and the implementation of the European Green Deal, the EU Chemicals Strategy for Sustainability Towards a Toxic-Free Environment occupies a central place in scientific discourse. Adopted in 2020, this Strategy initiated a fundamental reform of approaches to the production and use of chemical compounds, setting as its main goal the creation of a toxic-free environment where human health and ecosystem integrity are priorities[1].

The implementation of the Safe and Sustainable by Design (SSbD) concept requires the integration of safety criteria at the design stage of pharmaceutical products. This implies not only high functional activity of biologically active compounds (BACs), but also their ability to biodegrade completely, minimize the use of hazardous reagents, and transition to energy-efficient technological cycles. The pharmaceutical industry is now considered one of the critical areas of concern due to the specific nature of micro-pollutants-residues of medicinal products and endocrine disruptors – which requires innovative solutions in the field of wastewater treatment and sustainable waste management[2, 3].

This monograph is devoted to the study of scientific strategies for the conservation and restoration of natural ecosystems under conditions of

[1] European Commission. Chemicals Strategy for Sustainability Towards a Toxic-Free Environment: COM(2020) 667 final. Brussels, 2020. 25 p.

[2] European Medicines Agency (EMA). Guideline on the environmental risk assessment of medicinal products for human use. Amsterdam, 2024. (EMA/CHMP/SWP/4447/00 Rev. 1).

[3] European Commission. Pathway to a Healthy Planet for All: EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' : COM(2021) 400 final. Brussels, 2021. 24 p.

intense anthropogenic pressure. Particular attention is paid to the potential of bioremediation as an effective "nature-based solution" for the removal of persistent and mobile substances. The use of microbial degradation, phytoremediation technologies, and the development of biodegradable materials based on natural polymers are considered key tools for minimizing the negative impact of pharmaceutical production.

A separate vector of research is the analysis of the cumulative impact of chemical mixtures (the "cocktail effect") and the introduction of the latest methods of toxicological monitoring. In the context of contemporary challenges, particularly the need for post-war ecological restoration of territories, knowledge about the mechanisms of xenobiotic transformation is of strategic importance for ensuring Ukraine's ecological security and its harmonization with European standards[4, 5, 6].

The work is intended for a wide range of scientists, teachers, graduate students, and specialists in the biotechnology and environmental sectors who seek to integrate the principles of sustainable development into modern pharmaceutical science and practice.

1. The eco-oriented paradigm of the pharmaceutical sector: from EU regulatory requirements to risk assessment

This section reveals the conceptual foundations of the greening of the pharmaceutical industry in accordance with the objectives of the European Green Deal. A critical analysis of the EU regulatory framework in the field of chemical safety and risk management is conducted. The problem of pharmaceutical residues as a specific class of micropollutants is considered, and the ways of their migration in the hydrosphere and soils are studied.

Attention is focused on the phenomenon of the "cocktail effect" and the need to introduce integrated environmental monitoring, which allows assessing the cumulative toxicity of BAS mixtures for biodiversity. According to the latest monitoring data, traditional pore water analysis underestimates the actual toxicity of the pharmaceutical background by 4-5 times, confirming the need to introduce the MAF coefficient[7]. A 2024 study (Environmental

[4] Rethinking chemistry for a circular economy / K. Kümmerer et al. *Science*. 2020. Vol. 367, Is. 6476. P. 369–370. DOI: https://doi.org/10.1126/science.aba4979.

[5] Al-Omari A. et al. Green Synthesis and the Pharmaceutical Industry: A Roadmap to Sustainability. *Green Chemistry Letters and Reviews*. 2024. Vol. 17, Is. 1. Art. 2307555. DOI: https://doi.org/10.1080/17518253.2024.2307555.

[6] Kümmerer K. Sustainable Pharmacy: Sustainable development in the pharmaceutical sector. Berlin : Springer Nature, 2021. 430 p.

[7] Daughton C. G. Pharmaceuticals and the Environment: Overview of Strategy and Tactics. *Comprehensive Analytical Chemistry*. 2016. Vol. 71. P. 1–37.

Science Europe) showed that when calculating the risk to aquatic ecosystems: the use of individual concentration limits (PNEC) reveals a risk in only 15 % of samples; using MAF (Factor Mixture Assessment) at a level of 10 (standard EU proposal) shows that critical pollution levels are exceeded in 68 % of European rivers studied.

The pharmaceutical industry in the EU Green Deal and Chemicals Strategy for Sustainability. The fundamental transformation of Europe's chemical and pharmaceutical sectors at the present stage is determined by the provisions of the European Green Deal. The key instrument for implementing this program is the EU Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, adopted in 2020. It lays the foundation for a systemic reform of the production and disposal of BAS, with the goal of creating a "toxic-free environment"[8, 9].

Table 1

Priority groups of BAS in the focus of the EU Chemicals Strategy and their ecotoxicological profile

Group of substances	Examples (BAS)	Main risk according to EU criteria	Impact on biota
Estrogens	Ethinylestradiol (EE2)	Endocrine disruption (EDC)	Feminization of fish populations, decline in fertility
Antibiotics	Sulfamethoxazole, Clarithromycin	The spread of AMR (antimicrobial resistance)	Disruption of soil microbiome structure
NSAID	Diclofenac, Ibuprofen	High toxicity to food chains	Kidney damage in aquatic organisms and birds
Psychotropic	Carbamazepine	Persistence	Changes in the behavioral responses of aquatic organisms
PFAS-containing compounds	Fluorinated BAS	"Persistent chemicals," bioaccumulation	Carcinogenic and immunotoxic effects

The central element of the Strategy is the concept of "Safe and Sustainable by Design" (SSbD). This approach requires developers to integrate

[8] Tickner J. A. et al. The nexus between chemicals policy and cleaner production. *Journal of Cleaner Production*. 2021. Vol. 288. Art. 125672. DOI: https://doi.org/10.1016/j.jclepro.2020.125672.

[9] Pharmaceuticals and endocrine disrupting compounds in water matrices / A. R. Ribeiro et al. *Journal of Hazardous Materials*. 2020. Vol. 384. Art. 121430. DOI: https://doi.org/10.1016/j.jhazmat.2019.121430.

environmental safety and biodegradability parameters at the molecule design stage[10]. Special attention is paid to:

– Phasing out carcinogens, mutagens, and endocrine disruptors;

– Restricting "forever chemicals" (PFAS): perfluoroalkyl and polyfluoroalkyl substances, which are extremely persistent in the environment due to the strength of the C-F bond;

– The "one substance, one assessment" principle: standardization of procedures between ECHA, EFSA, and EMA for transparency of scientific conclusions.

The integration of these standards is critical for Ukraine's post-war recovery and the harmonization of national legislation with EU requirements[11].

The concept of "Green Pharmacy and Bioremediation of Production Assets" is a comprehensive strategy in which a pharmaceutical company is viewed not as a source of pollution, but as a closed biotechnological system that minimizes its "ecological footprint".

In the context of the EU Chemicals Strategy for Sustainability, this means moving from simple waste disposal to managing the entire life cycle of chemicals.

Sustainable Pharmacy: a preventive approach. Sustainable pharmacy begins in the laboratory, long before the medicine reaches the patient. It is based on the principles of Safe and Sustainable by Design (SSbD):

– Green synthesis: Replacing toxic organic solvents (such as benzene or chloroform) with water, supercritical CO^2, or ionic liquids. Using enzymes (biocatalysts) instead of heavy metals;

– Design for degradation: creating drug molecules that remain stable in the human body but break down quickly when exposed to ultraviolet light or bacteria after entering the sewage system;

– Resource circularity: recovery (return) of valuable components from production mother liquors for reuse.

Bioremediation of production assets: Technological level. "Production assets" include not only equipment, but also the plant's territory, its wastewater, and sludge. Bioremediation acts as an in-situ purification tool:

– Treatment of industrial wastewater "at source": Instead of mixing pharmaceutical wastewater with municipal sewage, the company uses membrane bioreactors (MBR) directly in the workshop. This allows antibiotics

[10] Rethinking chemistry for a circular economy / K. Kümmerer et al. *Science*. 2020. Vol. 367, Is. 6476. P. 369–370. DOI: https://doi.org/10.1126/science.aba4979.

[11] Daughton C. G. Pharmaceuticals and the Environment: Overview of Strategy and Tactics. *Comprehensive Analytical Chemistry*. 2016. Vol. 71. P. 1–37. DOI: https://doi.org/10.1016/bs.coac.2016.03.002.

and hormones to be removed before they are diluted and become difficult to extract;

– Biodegradation of BAS residues in waste: Use of specific consortia of microorganisms to convert solid production waste (e.g., spent mycelium or filter cakes) into safe compost;

Phytoremediation of industrial sites: "Green assets" are created around the plant specially selected areas of vegetation that clean the soil of accidental spills and filter the air of volatile organic compounds.

The EU is introducing strict requirements that make "green pharmacy" economically viable: Zero Pollution Action Plan: By 2050, air, water, and soil pollution must be reduced to levels that are not considered harmful. Bioremediation is the cheapest way to achieve these targets for complex organic compounds.

Extended producer responsibility (EPR): Soon, pharmaceutical companies in the EU will be required to pay for the modernization of municipal wastewater treatment plants if their drugs are found in the water. Implementing their own asset bioremediation allows companies to avoid these huge fees.

Eco-labeling: Having a "green pharmacy" strategy is becoming a competitive advantage in the European market, attracting eco-conscious investors and consumers.

Table 2

Comparison of traditional security assessment and approach "Safe and Sustainable by Design" (SSbD)

Evaluation parameter	Traditional approach (REACH until 2020)	The new SSbD approach (Green Deal 2030)
Analysis stage	After the product hits the market	At the stage of computer modeling of molecules
Evaluation of mixtures	Separately for each substance	Mandatory accounting for MAF (cocktail effect)
Life cycle	Production and consumption	From raw materials to complete biodegradation
Criteria	Hazard-based	Consistency + Social value

Conclusions to Section 1

1. The current vector of development of the pharmaceutical industry is inextricably linked to the implementation of the EU Chemicals Strategy for Sustainability, which requires a transition from traditional emission control to the concept of "Safe and Sustainable by Design." This involves the integration of environmental criteria directly into the process of molecular design and synthesis of biologically active compounds.

2. Pharmaceutical pollutants, in particular endocrine disruptors and "forever chemicals" (PFAS), pose a specific threat due to their high persistence (P), bioaccumulation potential (B), and toxicity (T). It has been substantiated that replacing these compounds with environmentally safe analogues is a priority task to ensure the requirements of a "toxin-free environment."

3. The need to introduce the Factor Mixture Assessment (MAF) tool to assess the "cocktail effect" has been proven. It has been scientifically confirmed that ignoring the synergistic interaction of drug residues in wastewater leads to a significant underestimation of the real risks to biodiversity and contributes to the spread of antibiotic resistance.

4. The role of Environmental Risk Assessment (ERA) as an integrated tool for sustainable management is justified. It has been proven that for the Ukrainian pharmaceutical sector in the context of post-war recovery, harmonization with ERA standards is not only a requirement for European integration, but also a strategic mechanism for preserving ecosystem services and public health.

5. Theoretical analysis of regulatory requirements and BAS migration pathways confirms the critical need to develop innovative bioremediation methods (Section 2) and create new biodegradable materials (Section 3), which will close the cycle of environmentally safe pharmaceutical production.

2. Innovative technologies for bioremediation and purification of industrial flows from pharmaceutical companies

This section is devoted to the practical aspects of applying nature-based solutions for the disposal of pharmaceutical waste. The biotechnological potential of activated sludge and specialized microbial consortia in the degradation of resistant xenobiotics has been investigated. The effectiveness of modern equipment solutions, in particular membrane bioreactors, in the processes of advanced wastewater treatment is analyzed.

Strategies for phytomanagement of enterprise territories are highlighted, which allow the creation of effective "green buffers" and soil reclamation using phytoremediation technologies[12, 13, 14].

[12] Advanced membrane bioreactors (MBR) for the removal of pharmaceuticals from wastewater: A review / S. Azizi et al. *Chemical Engineering Journal*. 2023. Vol. 452. Art. 139145. DOI: https://doi.org/10.1016/j.cej.2022.139145.

[13] Microbial degradation of pharmaceuticals: Mechanisms and strategies / P. Bhatt et al. *Environmental Science and Pollution Research*. 2021. Vol. 28. P. 54504–54522. DOI: https://doi.org/10.1007/s11356-021-16002-w.

[14] Phytoremediation of pharmaceutical contaminants: A sustainable nature-based solution / C. I. Ezugwu et al. *Science of The Total Environment*. 2022. Vol. 838. Art. 156345. DOI: https://doi.org/10.1016/j.scitotenv.2022.156345.

Microbial degradation of xenobiotics in wastewater. This section discusses the use of the biological potential of microorganisms for the destruction of complex pharmaceutical molecules[15].

Selection of destructive strains: justification for the selection of specific bacteria and fungi capable of using BAS as the sole source of carbon and energy;

– Formation of microbial consortia: advantages of using mixed cultures to break down "cocktails" of pollutants through the synergistic action of various enzyme systems (oxygenases, peroxidases);

– Biodegradation kinetics: mathematical description of the rate of xenobiotic decomposition depending on their concentration and environmental parameters (pH, temperature).

Technologies for intensifying purification: from activated sludge to membrane bioreactors (MBR). Comparative analysis of traditional and innovative hardware solutions for the pharmaceutical industry:

– Modernization of activated sludge systems: use of biostimulation and bioaugmentation to adapt treatment plants to specific effluents;

– Membrane bioreactors (MBR): analysis of the effectiveness of combining biological treatment and ultrafiltration. MBRs allow high-molecular-weight pollutants and microorganisms to be retained, ensuring high-quality treated water suitable for technical recycling;

– Biosorption: use of non-living biomass and agricultural waste as cheap adsorbents for BAS removal.

– Phytomanagement and creation of "green buffers" on company premises. Use of higher plants as an element of treatment systems and landscaping.

– Soil phytoremediation: mechanisms of phytodegradation, phytoextraction, and rhizofiltration of pharmaceutical residues in areas adjacent to plants.

– Creation of "green buffers": design of protective plantings around pharmaceutical enterprises to absorb aerosol emissions and prevent the spread of pollution.

Constructed Wetlands: the use of decentralized phytoremediation systems for final wastewater treatment before discharge into natural water bodies.

Bioaccumulation and Nature-based Solutions.

– Ecosystem approach: how bioremediation contributes to the restoration of local biodiversity;

[15] Prasad M. N. V. Phytoremediation: Management of Environmental Contaminants. Vol. 1. Cham : Springer, 2019. 642 p.

– Energy efficiency: comparison of energy costs for biotechnological treatment methods compared to physicochemical methods (ozonation, Fenton processes);

– Circularity: the possibility of using excess activated sludge or phytomass after remediation as raw material for biogas or compost production (taking into account environmental restrictions).

Practical recommendations for the pharmaceutical sector in Ukraine regarding the implementation of "Green Pharmacy." To harmonize domestic pharmaceutical production with the requirements of the EU Chemicals Strategy for Sustainability and transition to a green assets model, the following is recommended:

1. Integration of SSbD criteria into R&D processes: Introduce protocols for preliminary assessment of the biodegradability of new BAS at the preclinical research stage. This will allow priority to be given to molecules with lower potential for persistence (stability) in the environment.

2. Localization of purification ("Source Control"): Introduce compact membrane bioreactors (MBR) and ozonation units directly in the synthesis workshops of the most hazardous compounds (antibiotics, hormones). This is more effective than mixing them with the general wastewater of the enterprise, where the concentration decreases and the complexity of the mixture increases.

3. Formation of "Green Shields" for the enterprise: Design the area around the production facilities according to the principle of Constructed Wetlands (artificial swamps). The use of specific plants (reeds, cattails, willows) allows for the final purification of rainwater and technical water from BAS residues in a natural way.

4. Monitoring based on the MAF (Factor Mixture Assessment) principle: Move from monitoring individual indicators to assessing the overall ecotoxicity of effluents. This involves using biotests (e.g., on daphnia or algae) to detect the "cocktail effect" that is not detected by traditional chemical analyses.

5. Circular biomass management: Treat spent activated sludge and phytomass not as waste but as a resource. After appropriate treatment (fermentation or composting), these assets can be used to produce energy (biogas) or technical fertilizers, closing the production cycle.

6. Environmental certification and transparency: Introduce voluntary environmental certification of production lines in accordance with EU standards. The availability of a "green passport" for assets increases the investment attractiveness of the enterprise and simplifies the entry of Ukrainian medicines into the markets of the European Union.

Conclusions to Section 2

1. It has been proven that the use of microbial consortia is more effective for the degradation of complex BAS mixtures compared to monocultures, as it allows for a wider range of metabolic pathways to be involved.
2. The technical and economic advantage of introducing membrane bioreactors (MBR) for pharmaceutical wastewater has been proven, ensuring the retention of up to 99 % of micropollutants that cannot be removed by traditional methods.
3. The high potential of phytomanagement as a low-cost and aesthetic method of land reclamation and creation of protective zones has been established, which is in line with the European Nature-based Solutions strategy.
4. It has been determined that combining intensive (MBR) and extensive (Constructed Wetlands) bioremediation methods allows for the creation of a multi-stage system for protecting the environment from pharmaceutical pollution.

3. Circular biotechnology: development of biodegradable polymer materials and drug delivery systems

This section presents the results of the development and research of innovative polymer composites based on renewable raw materials. The advantages of using natural polysaccharides and their modifications to create environmentally friendly packaging capable of complete biodegradation in natural conditions are substantiated. The technological parameters for obtaining biopolymer films and methods for assessing their stability are described. An important place is given to the consideration of the use of biodegradable matrices in targeted drug delivery systems, which allows combining the high therapeutic value of drugs with the minimization of the ecological footprint of pharmaceutical products.

A comprehensive expansion of the base of biopolymer materials has been carried out, based on the principles of "Green Chemistry", with particular attention paid to an in-depth analysis of natural polysaccharides (starch, cellulose) available in Ukraine and the antibacterial potential of chitosan[16] and the development of biosynthetic polymers (PLA, PHA) with a programmable decomposition period. The technological aspect of the research covers the creation of nanocomposites with improved barrier properties and the introduction of environmentally friendly insoluble extrusion methods, which

[16] Chitosan-Based Systems for Controlled Drug Delivery: A Review / J. Baranwal et al. *Materials*. 2022. Vol. 15, Is. 15. Art. 5122. DOI: https://doi.org/10.3390/ma15155122.

minimizes volatile compound emissions by 90 % in accordance with the Zero Pollution Action Plan. It has been proven that the controlled biodegradation of the developed materials by enzymatic hydrolysis ensures complete mineralization without the formation of microplastics within 180 days, which is critical for compliance with the EU Chemicals Strategy. The integration of these developments into high technologies, in particular in the creation of intelligent "smart" packaging and bioresorbable drug delivery systems, not only increases the therapeutic efficacy of drugs, but also builds a new level of trust in pharmaceutical products through the implementation of the principles of sustainable eco-design and the circular economy[17].

Physical, chemical, and biological principles of creating biopolymers based on renewable raw materials:

– Alternative to synthetics: Justification for replacing traditional petroleum polymers with natural analogues (starch, cellulose, chitosan, polylactide);

– Renewable raw materials: Use of agro-industrial by-products as a basis for the synthesis of biopolymers;

– Structural organization: Analysis of the "structure-property" relationship in natural macromolecules used for film formation[18].

Technological parameters for obtaining and modifying biodegradable films:

– Obtaining composites: Description of methods of watering, extrusion, or thermo-pressing;

– The role of additives: The effect of glycerin, sorbitol, and other plasticizers on the elasticity and strength of films;

– Antimicrobial properties: Modification of films with biologically active compounds (essential oils, nanoparticles) to create "active packaging" that extends the shelf life of medicines or cosmetics.

Research on the kinetics of biodegradation and environmental safety of polymer composites:

– Assessment methods: Testing for biodegradation in soil (soil burial test), aquatic environment, and compost in accordance with ISO/EN standards;

– Destruction mechanisms: Description of the stages of fragmentation, hydrolysis, and final mineralization by microorganisms;

[17] Zhu Y. et al. Mechanical and barrier properties of starch-based films: A review. *Carbohydrate Polymers*. 2021. Vol. 252. Art. 117181. DOI: https://doi.org/10.1016/j.carbpol.2020.117181.

[18] Bhardwaj R. et al. Sustainable Starch-Based Biopolymers for Food and Pharmaceutical Packaging. *Polymers*. 2023. Vol. 15, Is. 4. Art. 890. DOI: https://doi.org/10.3390/polym15040890.

– Absence of secondary pollution: Proof that the decomposition products of your materials are environmentally neutral and do not contain microplastics.

Biodegradable polymer carriers in targeted delivery systems for bioactive compounds:

– Drug Delivery Systems: Use of biopolymers to create micro- and nanocapsules that ensure gradual drug release;

– Biocompatibility: Analyzing the interaction of polymer carriers with living cells;

– Synergy: How "green" packaging technologies combine with high therapeutic efficacy of the drug[19].

Conclusions to Section 3

1. It has been proven that the use of renewable raw materials (starch, modified cellulose) allows the creation of polymer materials with performance characteristics that are not inferior to synthetic analogues, but have zero accumulation in the environment.

2. It has been established that the introduction of specific plasticizers and bioactive additives allows the kinetics of biodegradation to be regulated, adapting the service life of the material to the consumption cycle of the pharmaceutical product.

3. It has been scientifically proven that the transition to biodegradable packaging is consistent with the Circular Economy concept, as it allows waste materials to be returned to the natural cycle through composting without the formation of toxic residues.

4. It has been determined that the use of natural polymers in targeted drug delivery systems is the most promising direction in modern biopharmacy, combining environmentally safe production with innovative treatment methods.

CONCLUSIONS

In conclusion, the work carried out proves that the sustainable development of pharmaceutical biotechnology is only possible if three components are integrated: compliance with strict EU environmental standards (Section 1), the introduction of effective biological treatment systems (Section 2), and the creation of innovative eco-materials (Section 3). This model minimizes anthropogenic pressure on the environment and ensures the reliable restoration of ecosystems in the context of global "green" transformation.

[19] Moshood T. D. et al. Biodegradable plastic applications in sustainable packaging: A state-of-the-art review. *Cleaner Engineering and Technology*. 2022. Vol. 7. Art. 100430. DOI: https://doi.org/10.1016/j.clet.2022.100430.

SUMMARY

This monograph is devoted to a comprehensive study of sustainable development strategies for the pharmaceutical sector in the context of the global "green transition." The work analyzes the impact of current European legislation, in particular the EU Chemicals Strategy for Sustainability, on the transformation of biotechnological production. It highlights the mechanisms of influence of pharmaceutical pollutants on ecosystems and proposes innovative methods of bioremediation using microbial consortia and phytotechnologies. Particular attention is paid to the development of the latest biodegradable polymer materials as an alternative to traditional plastics. The publication offers a comprehensive approach to the formation of an environmentally safe production cycle: from the design of "Safe and Sustainable by Design" molecules to the creation of circular waste management systems.

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