Introduction in medicines regulation and regulatory science

Peter Mol, University of Groningen and European Medicines' Agency (EMA)

You will be introduced the European Union's medicines regulatory network and informed on the (potential) role of RWD to support medicines evaluation. You will learn more about federated analyses, a technique that allows to study real world data from different data sets (e.g., from different countries), allowing data to stay local but make optimal use of variability in the individual data set. I will present a case study, where we will explain how such federated analyses techniques can be leveraged to study simultaneously the effects of disease-modifying therapy on patient outcomes in four multiple sclerosis patient registries from Sweden, Czechia, Denmark and Italy.

The Pharmacy of the fish- Environmental impact of Pharmaceuticals

Gerd Maack German Environment Agency

Medicines are indispensable for human and animal health; however, a large percentage of many active substances are excreted from the body unchanged and enter the environment. There, the active substances and, under certain circumstances, the metabolites or degradation products can have the same effects as the intended effects in humans and animals, but the same side effects can also occur in animals and plants. In addition, some non-expected effects occur in wildlife organisms, probably due to different exposure pathways.
Ways must therefore be found to limit releases into the environment. Examples of effects different substances, with different mode of actions are given, including their implications to the whole ecosystem, but also in “feedback- loops” to humans.
In the case of diclofenac, for example, the measured concentration in surface waters in the EU is approximately 4 µg/L, which is 10 times higher than the concentration that is potentially harmful to animals and plants. Upgrading sewage treatment plants with a so-called 4th treatment stage, as required by the EU, the so-called end-of-pipe solution, is not sufficient on its own to comply with the limit value for diclofenac and other pollutants.

Environmental Problems of and Alternatives for (Poly)fluorinated APIs and Excipients

Johanna Greinke, Robin Gundert, Michael Müller

Institute of Pharmaceutical Sciences, Albert-Ludwigs-University of Freiburg, Germany

Per- and polyfluoroalkyl substances (PFAS) are of increasing concern due to their inherent persistence and largely unknown long-term effects on human health. More than 100 active pharmaceutical ingredients (APIs) for human use are PFAS according to the current OECD definition; they are distributed across almost all indications, and ca. 85% of them are potential precursors of trifluoroacetic acid (TFA). Contrary to the assumption that polyfluorinated APIs are indispensable, we show that there are nonfluorinated alternatives for all PFAS-APIs.[1]

Nevertheless, non-fluorinated pharmaceuticals can also be sources of TFA and similar persistent compounds. This is exemplified by the use of hydrofluorocarbons (HFC) as propellants in pressurized metered dose inhalers. HFCs are under close scrutiny due to their high global warming potential, which exceeds that of CO_2 by several orders of magnitude. Pharmaceutical manufacturers have made considerable efforts to find substitutes for HFC propellants. However, some of the more climate-friendly alternative HFCs are TFA precursors.[2]

Moreover, even nature-like pharmaceuticals such as peptides can be potent sources of TFA, as their production typically involves TFA-mediated transformations, e.g., deprotection strategies. In order to achieve sustainability in drug development and manufacturing, it will therefore be essential to perform life cycle assessments not only for the APIs but for the entire process. In addition, it is important to include economic and social aspects in research and teaching to ensure that non-sustainability, such as regrettable substitutions and greenwashing, is identified as early as possible.

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Risk management & Consumer behaviour

Gerd Maack German Environment Agency

Relying on wastewater treatment plants for removing micropollutants, including pharmaceuticals, is not sufficient. Further ways must therefore be found to reduce the concentrations of active pharmaceutical ingredients in water bodies. In theory, there are options for reduction in all areas, from development and manufacture to legislation and disposal in sewage treatment plants. However, there is no single gold standard for reducing environmental pollution. Depending on the active ingredient and the form of application, there are various options that are in different stages of testing. For example, pilot projects are testing the collection of urine after outpatient administration of contrast agents for cost-effectiveness and practicability, as well as the use of filter systems for inhalation anaesthetics. The situation is more complex when it comes to outpatient medication, particularly over-the-counter drugs, as the regular use of medicines is considered part of the lifestyle by some sections of the population and is advertised accordingly.
Education is an important starting point for more environmentally conscious behaviour. It is essential to raise awareness of the problem among consumers and all those involved in the various medical fields. In particular, traditional multipliers, doctors and pharmacists are called upon to take action. In line with the precautionary principle, pharmacists therefore have a key role to play, both in independent pharmacies and in hospital pharmacies. In their advisory role, they are close to the consumers of medicines and thus have the opportunity to influence the release of medicines into the environment. However, the topic of pharmaceutical residues in the environment is currently not firmly established in the continuing education and training of pharmacists or in pharmacy studies. Selected examples at various levels illustrate that green pharmacy alone is not sufficient to reduce the release of active pharmaceutical ingredients into the environment. Sustainable pharmacy must take into account environmental aspects as well as economic, pharmacological and social aspects. Systems thinking is required to address the complexity of health, disease, sustainability, and pharmacy. High-leverage actions that address the underlying causes of diseases and barriers to health services are needed, including effective prevention and medical and non-medical treatment of diseases. Education, environment, society, economy, pharmacology, and culture as key areas to be integrated.

Sustainability in Pharma - Croda's ingredients and initiatives

Climate change resulting from global warming is now widely recognized as the biggest threat to global health. The climate and nature crisis is a threat that could affect mental health, for example through malnutrition, allergies, cardiovascular disease, respiratory problems, injuries and poisoning. The pharma industry is strongly positioned to tackle these environmental sustainability challenges.

As part of Croda, we are always guided by our Purpose, Smart science to improve lives. We believe growth is delivered through pairing sustainability with innovation and Our Commitment is to be Climate, Land and People Positive by 2030. We are already Land Positive: our crop and seed technologies save more land than is used to grow our bio-based raw materials. We now aspire to contribute to a Nature Positive world by 2030, working towards our goal of becoming the world's most sustainable supplier of innovative ingredients.

In 2022, Croda announced our ambition to be Net Nature Positive and aligned to our verified Science based target, supporting our customers with their Net Zero goals Positive by 2030.

- Verified in line with limiting global warming to 1.5 C°
- 2030 reduction in our scope 1 and 2 emissions by 49.5%
- 2030 reduction in our scope 3 emissions by 13.5%
- Committed to be net zero by 2050

More specifically for Croda Pharma we are delivering sustainability initiatives which support the supply chain action on sustainability. We are prioritising the replacement of at-risk ingredients with more sustainable solutions with reduced environmental impact whilst increasing security of supply (e.g. our Triton-X 100 alternative Virodex products or our non-shark derived sustainably sourced Squalene). We are decarbonising our products and operational sites to ensure we are aligned with our customer's net zero ambitions and needs. Croda remain focused on providing high purity pharmaceutical excipients, adjuvants and formulation aids which improve stability and efficiency, reducing waste, extending shelf life and reducing the need for cold chain transport and storage, contributing to reducing supply chain scope 3 emissions.

"**Regulations on sustainable packaging**" with a focus on packaging materials and regulations for pharmaceuticals.

Dr. Anja Laqua; Kuraray Co., Ltd. Tokyo, Japan; Corporate Sustainability Division, Kuraray Europe GmbH, Hattersheim Germany

Several EU political strategies (European Green Deal, Revision of paper and packaging waste directive) have pointed out that the EU's current packaging regulatory framework need to be revised and being stricter with regard to sustainability.

As a result, the regulatory criteria regarding recycling, reuse and redesign for packaging materials, food and pharmaceuticals materials are becoming increasingly challenging for the industry.

The focus of this presentation is therefore on the new EU sustainability requirements for packaging and packaging waste (PPWR – Packaging and packaging waste Regulation), its criteria on recycling; reuse; minimum recycled content in plastic packaging, and how Kuraray is handling those new challenges as opportunities.

In order to understand the associated challenges and opportunities for the industry, the presentation will sum up with practical examples from the industry.

Green and sustainable excipients in pharmaceutical formulations

Fischer, D.[1,2]

[1] *Division of Pharmaceutical Technology and Biopharmacy, Cauerstr. 4, 91058 Erlangen, Germany; dagmar.fischer@fau.de*

[2] *FAU New – Research Center for New Bioactive Compounds, Nikolaus-Fiebiger-Strasse 10, 91058 Erlangen, Germany; dagmar.fischer@fau.de*

Recent trends in pharmaceutical sciences have increasingly emphasized sustainability and environmentally friendly approaches, prompting a reassessment of traditional drug formulation methods to minimize risks to both human health and the environment. Increasing environmental awareness, rising customer demand and resource efficiency have driven the "green transition" to sustainable and environmentally friendly excipients in the manufacture of pharmaceutical drug delivery systems. For the selection and use of excipients with regard to the assessment of sustainability, the concept of "Green Chemistry" can be used [1].

Different classes of green and sustainable excipients will be discussed. Solvents and polymers, as they account for a large proportion of pharmaceutical production in quantitative terms, often pose safety and environmental limitations during their manufacture and handling, but can increasingly be produced from renewable sources such as biomass, which can also significantly facilitate the recycling [2,3]. Microorganism and plants act as sources for biotechnologically produced polymers and lipids for the preparation of micro- and nanoparticles, liposomes and micelles. The aspect of sustainability can also be extended to substances without animal origin (e.g. cholesterol, collagen), where animal welfare is also taken into consideration [1]. For cutaneous applications, sustainable prototypes of creams can be prepared by exchange of the emulsifiers by combinations of plant-derived emulsifiers, substitution of petroleum jelly by alternatives made from natural solid and liquid triglycerides or waxes, and exchange of paraffins and medium-chain triglycerides by different natural oils.

Conclusively, new excipients are available that present a significant advancement as green and sustainable alternatives in the formulation of drug delivery systems and provide access to high-quality delivery systems with reproducible quality.

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The FAU Expired Drug Initiative (FAU EDI) – Recycled Pharmaceuticals for Research, Education and Monitoring Programs

L. Lochschmidt, M. Kuschow, L. Drees, L. Zähnle, A. Roggenhofer, M. R. Heinrich

The FAU Expired Drug Initiative aims at the recovery of active pharmaceutical ingredients (APIs) from expired drugs and their use as research chemicals or as compounds for teaching purposes. Starting in 2016, we have set up a local and national network comprising nearby pharmacies and disposal sites as well as industry, clinics and wholesalers throughout Germany. This network was recently joined by our first European partner, Luxemburg's waste disposal organization SDK. After sorting and deblistering, the APIs are separated from their excipients whereat the related recovery processes are continuously optimized. Besides typical quality control, highly purified APIs are further evaluated in certified analytical laboratories with regard to meeting the purity standards of original APIs sold on the world market. Recent applications of the recovered APIs in our group include the synthesis of novel tool compounds for antibiotic research,[1] the development of late-stage functionalization methods applicable to APIs[2] as well as their use in 3D printing.[3]

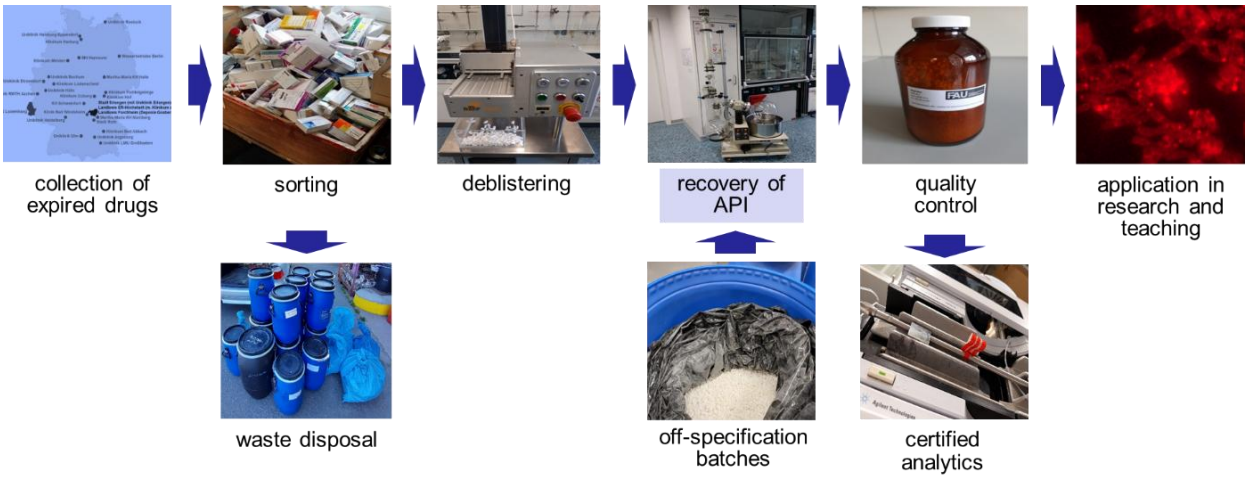

Figure 1. From the collection of expired drugs to the use of the recovered APIs as research chemicals

Due to the amounts and diversity of APIs available, which now exceed by far the demand at FAU, we have started to offer the APIs also to universities and research institutes in Germany and recently also throughout Europe.[4] In this way, our novel type of waste valorization can be combined with a broad support of research and teaching. All universities, research institutes and companies interested in the use of recovered APIs are cordially invited to contact FAU EDI at altarzneimittel@fau.de for further information.

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Acceptability of health-only versus climate-and-health framings in lifestyle-related climate-sensitive health counselling: results of a randomised survey experiment in Germany

Nicolaus C. S. Mezger, Eva Kantelhardt

Global and Planetary Health Working Group, Interdisciplinary Center for Health Sciences, Medical Faculty of the Martin Luther University Halle-Wittenberg, Halle (Saale), Germany

Climate-sensitive health counselling (CSHC) delivered by health professionals could promote individual patients and planetary health, particularly within lifestyle counselling. However, health professionals' uncertainty about the acceptability of CSHC remains a barrier to implementation. This study aimed to establish the effects of different topics and framings on patients' acceptability of lifestyle-related CSHC.

Of 3346 individuals who signed up for the HeRaCa panel between November, 2019, and June, 2020, 3163 participants of the panel (94·5%) were given the survey and 1516 (47·9%) submitted responses between April and June, 2022. 25 participants with incomplete data were excluded, and 1491 participants were included in the mixed ANOVA primary analysis. 748 participants were allocated to the diet group and 743 to the physical activity group. The mean age of the full sample was 55·6 years (SD 14·2). Excluding 62 participants with missing values, 814 (57·0%) were female and 613 (49·2%) were male; two participants (0·1%) self-identified as a diverse gender. In the whole cohort, the mean acceptability score of framing A was 4·09 (SD 0·71), was 3·67 (0·91) for framing B; and was 3·55 (0·97) for framing C. Mixed ANOVA revealed a significant and large effect of framing (partial η^2=0·18, <0·001), and a significant but negligible effect of topic (partial η^2=0·004, p=0·021) on CSHC acceptability. Stratified analysis revealed that framing effects were less pronounced among participants alarmed about climate change or positioned politically to the left.

Health-only framings of CSHC yield greater acceptability than health-and-climate framings across all subgroups. Differences are most pronounced among participants cautious or doubtful about climate change. These findings highlight tensions between the planetary health aims of CSHC and acceptability to patients, which could be alleviated by applying patient-centred communication techniques.

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Pharmaceutical and chemical aspects of sustainability in drugs Pharmaceutical and chemical aspects of sustainability in drugs

The entry of pharmaceutical residues into the environment via wastewater or by improper disposal represents a global problem.[1] Huge amounts of medications are consumed annually, and are even expected to increase significantly in the coming decades as a result of demographic change.[2] Almost 1,000 different human active pharmaceutical substances and their degradation products have been detected in relevant concentrations in the environment worldwide, including eco-critical hormones, painkillers, or blood pressure medications.[3] Currently, wastewater treatment plants are being technically upgraded with the aim of removing pharmacologically active residues to protect waterways, groundwater, and drinking water resources.[4] This *end-of-pipe* approach needs to be complemented by eco-directed measures associated with the entire drug lifecycle.

The talk delves into the complex interplay between pharmaceuticals and sustainability, focusing on medicinal-chemical aspects that influence drug development, encompassing drug design or installing metabolic stability in drugs up to the management of pharmaceutical waste. It highlights the example diclofenac[5] underscoring the urgent significance of minimizing ecological footprints in particular critical cases. The discussion strikes a balance between ensuring the accessibility of vital medications and safeguarding environmental health by developing sustainable practices within the pharmaceutical sector.

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Comprehensive approach to sustainability of pharmaceutics

Sustainability challenges in the pharmaceutical and healthcare sector are diverse and relate to the commonly identified concerns of climate change, biodiversity loss and chemicalisation. Economic and social dimensions are present alongside ecological sustainability. Research is actively addressing the environmental impact of pharmaceuticals and the development of benign-by-design APIs — biodegradable and non-toxic molecules. Also, emissions of greenhouse gases from production and transportation stress sustainability. There is a need for pharmaceutical products that comprehensively take into account sustainability in formulation, manufacture and packaging. Furthermore, the rational use of medicines plays an important role. Sustainable pharmacy is a new transdisciplinary field of research where a comprehensive approach is essential. By definition, sustainable pharmacy aims to identify and develop solutions to sustainability gaps throughout the life-cycle of medicines, from drug discovery and preclinical development to the development, production and distribution of pharmaceutical products, as well as sustainable use of medicines and their end-of-life management. As a researcher and educator, how can you contribute to sustainable pharmacy?

Metformin:

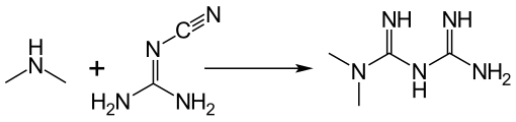
Miracle Medicine, Modern Menace and Money Cow

Peter Imming

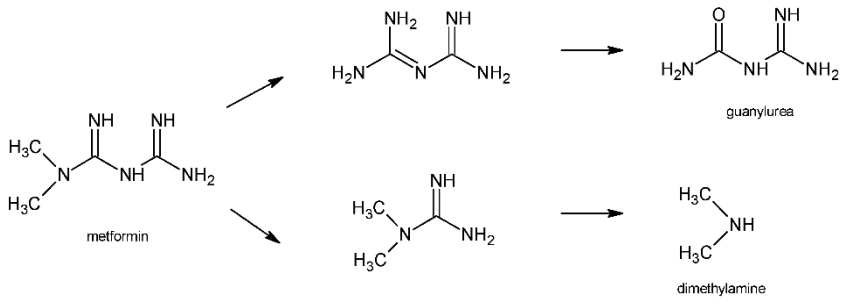
Institut für Pharmazie, Martin-Luther-Universität Halle-Wittenberg, Kurt-Mothes-Str. 3, 06120 Halle

Metformin was first synthesised in 1922. Approximately 30 years later, it was introduced as a therapeutic agent for the treatment of diabetes. Another approx. 30 years later, it was expected to be withdrawn because of the danger of lactic acidosis.[1] However, it proved to be persistent in medicine, now ranking among the most frequently prescribed drug substances in Germany, the USA and other countries, mainly against type 2 diabetes.[2] Practitioners and studies debate if metformin is essential and well tolerated. There are quite a number of alternative antidiabetic drugs. Metformin is resistant to metabolism, too. It is excreted unchanged.[3] This is favourable insofar as it does not burden liver metabolism, and it is problematic since metformin and particularly its main degradation product, guanylurea, persist in the environment. Presently, almost 90,000 tonnes of metformin-HCl are manufactured globally[4], expected to increase.[5] In 2024, worldwide sales of metformin drugs were estimated at c. 391 million US$[6] with c. 200 million people taking it.[7] Metformin-HCl can be produced simply and cheaply. The current price of c. 4 US$/kg metformin-HCl translates to 360,000 US$ globally for the drug substance only, equalling c. 0.09% of total sales. Therapeutic benefits and economical production have to be weighed against long-term environmental impact which may safely be assumed not to be beneficial.

Synthesis:



Degradation:



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Title: What is Pharmacoepidemiology and how can it contribute to the environment?

Drug utilization is far from sustainable. Issues range from overuse and inappropriate use among prescribers and patients to stockpiling and inappropriate waste management. An increasing number of studies have shown traces of medicines in water from sewage treatment plants as well as in lakes and rivers across all continents. Furthermore, climate change is predicted to change disease burden and drug utilization in most parts of the world. Sustainability, therefore needs to be considered to a much greater extent than previously done when prescribing, dispensing and using medicines in the society. Pharmacoepidemiology is the science of use and effects of medicines in populations and therefore well equipped with tools that can add value in tackling the problems. This lecture will present and discuss how pharmacoepidemiology and drug utilization studies can support reducing the environmental and health burdens from pharmaceuticals.

Impacts of micro- and nanoplastics on human health:
A snapshot of the current state of research

Lukas Wimmer - University of Vienna

Abstract

Impacts of micro- and nanoplastics on human health: A snapshot of the current state of research

Public interest in the possible impacts of micro- and nanoplastic (MNP) exposure to the human body is high. Almost weekly, news articles appear showcasing studies on MNPs in our food, drinking water, the air that we breath and even in our body. However, to detect MNPs in these different matrices, robust analytical methods and experimental designs are required to generate solid data sets on MNP quantities in the environment and in the body. The presentation will provide a brief overview of the most common techniques emerging for MNP analysis and then describe the past and current study designs, highlighting where shortcomings have led to significant learnings. In the final section, our research assessing MNP quantities in aerosols from different outdoor and indoor environments will be outlined and future research directions highlighted.

Efficient Utilization of Slaughterhouse By-products:

Introducing Keratin as a Novel Excipient for Cutaneous Application

Adina Eichner
Institute of Applied Dermatopharmacy at Martin Luther University Halle-Wittenberg (IADP) e.V.

Tons of animal waste are produced in slaughterhouses around the world every year. The use of these residues as a resource for cosmetic or pharmaceutical raw materials has so far been mostly inefficient and, apart from the production of gelatine, only poorly established. With the intention of a non-toxic and reproducible production process, keratin was extracted from chicken feather residues, whereby the upstreaming process from lab to kilograms was successfully performed. A detailed characterization of the keratin particles in powder form and in colloidal solution even exhibits diverse biological activities, which were introduced to advanced dermal delivery systems for cutaneous applications.

Pharmaceuticals in the Environment: Pathways, Hotspots, and Priority areas for Action

Pharmaceuticals are vital to modern society, safeguarding human and animal health, supporting food production, enhancing well-being, and contributing to economic prosperity. Yet, growing evidence shows that pharmaceutical residues are increasingly detected in the environment worldwide, where they can negatively impact ecosystems and human health. The life cycle of pharmaceuticals involves multiple sectors and human activities, each contributing to residue releases. Preventive measures, along with the sound management of waste and wastewater, are therefore essential to minimizing releases into the environment. Policy and regulatory frameworks play a central role in guiding effective action. Success in addressing pharmaceuticals in the environment also depends on coordinated efforts across sectors and stakeholders—including ministries, health care systems, pharmaceutical industries, civil society, agriculture, waste operators, and the public.

Tim aus der Beek

Aquatic pollution from antibiotics production sites - evaluation of occurrences in wastewater, runoff and water bodies

Antibiotic resistance is increasingly jeopardizing the effectiveness of prevention and medical treatment of an increasing number of infectious diseases and is causing a high number of premature deaths worldwide. By now, it is widely recognized that the release of antibiotics into the environment via production wastewater discharged from the pharmaceutical industry constitutes an important factor. Evidently, tackling such point sources through appropriate treatment of production wastewater would be a decisive step towards achieving a substantial reduction in antibiotic pollution and consequently in a reduction of occurrences of resistant pathogens. The here presented pilot study addresses the overall feasibility of implementing maximum permitted API concentrations in production wastewater and how to verify compliance. Wastewater from 19 production sites from Europe, India and China has been investigated. The sites selected previously agreed to comply with the PNEC values for certain antibiotics in their wastewater and to permit independent inspections. In addition, wherever possible, supplementary environmental investigations were conducted in water bodies adjacent to the production sites.
So far, > 27 different antibiotics have been detected, some of them repeatedly and at several sampling locations. Antibiotic concentrations exceeding PNEC limits were found at ten production sites - both in wastewater samples and in affected environmental samples. Maximum environmental concentrations ranged from 0.1 µg/l up to 18.5 mg/l, wastewater concentrations from 0.1 µg/L to 22.5 µg/L. In the total number of environmental water samples analysed, more than 60 % of antibiotic concentrations exceeded the ecotoxicological PNEC value, whereas no reliable, scientifically derived effect threshold was available for other antibiotics in these samples.
The results of our study confirm and quantify that wastewater from pharmaceutical production sites, as well as surface runoff and thus the general handling of active substances at these sites, contribute significantly to high concentrations of antibiotics in the environment and thus to the potential emergence of antibiotic resistance. Moreover, in view of the current intention to regulate the emissions of antimicrobial substances via the environmental risk assessment for human pharmaceuticals, it should be borne in mind that an effective system for verifying the values or explanations provided by the companies is required

The "Urban Waste Water Treatment Directive" implication to access to medicines - the Industry Perspective

Elmar Kroth

Deputy General Manager, Pharma Deutschland e.V., Geschäftsstelle Bonn, Ubierstrasse 71-73, 53173 Bonn, Germany

The revised Urban Wastewater Treatment Directive (UWWTD) entered into force on January 1, 2025. This directive exclusively requires manufacturers of human pharmaceuticals and cosmetic products to finance at least 80% of the costs for the construction and operation of the fourth stage of treatment in wastewater treatment plants in all EU member states. According to the EU Commission, both sectors are responsible for 92% of all harmful micropollutants found in urban wastewater. Several scientific reports have since shown that this EU Commission assessment massively overestimates the contribution of pharmaceutical and cosmetic active ingredients.[1,2,3] In contrast, the resulting costs for wastewater treatment plant expansion were massively underestimated.[4] This also leads to an incorrect assessment of subsequent effects such as the loss of profitability of numerous generic pharmaceuticals and their subsequent market exit. Funding by the pharmaceutical and cosmetics industry can no longer be justified on this basis. Policymakers should initiate a fundamental revision of the UWWT Directive.

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Urban Wastewater Treatment Directive and extended producer responsibility

Nathan Obermaier, Gerd Maack *German Environment Agency*

One of the primary objectives of the European Urban Wastewater Directive 91/271/EEC (UWTD) is to protect the environment from the harmful effects of inadequately treated urban wastewater. To achieve this, the EU directive places requirements on the member states. In addition to the collection and purification of wastewater from residential areas of a certain size, these also include the comprehensive collection of data and new planning of the so-called 4th purification stage for the removal of micropollutants, such as pharmaceutical residues and other substances difficult to break down. The requirements of the UWTD now also apply to sewage treatment plants with a population equivalent of 1,000 or more. It obliges local authorities to draw up wastewater management plans and to reduce the discharge of inadequately treated wastewater (combined sewer overflows). It tightens limit values for nitrogen and phosphorus – key contributors to the eutrophication of water bodies and it Introduces an extended producer responsibility (EPR), which anchors the polluter pays principle in water management and thus creates incentives to reduce the harmfulness of products to water bodies.

The specific costs for the upgrade cannot yet be precisely quantified. They depend in particular on the number of sewage treatment plants to be upgraded and the risk assessment. It should also be noted that the UWTD envisages a gradual upgrade of the affected sewage treatment plants by 2045, meaning that the costs will be spread over almost 20 years. The introduction of the extended producer responsibility aims to strengthen the polluter pays principle enshrined in the EU Treaty in water law and to make manufacturers of pharmaceuticals and cosmetics contribute financially to the costs of removing trace substances from municipal wastewater. At least 80% of the investment and operating costs for the fourth stage of purification must be covered by the manufacturers of pharmaceuticals and cosmetics, regardless of where the company is based and where the production takes place. The contribution is based on the quantity and hazardousness of the substances placed on the market. The specific, enforceable details of how the contribution obligation is to be calculated have not yet been finalised.

At present, it is completely unclear how the costs of advanced wastewater treatment will affect the prices of medicines. This cost change depends on the number and structure of manufacturers liable for payment. *Until this scope is clear, any estimates relating to individual medicines or cosmetics are unreliable.* Exactly which medicines are affected depends on the assessment system for hazardousness and quantities, which is still to be developed. It can be assumed that many medicines will be affected, leading to a broad distribution of costs among manufacturers. Existing social security systems, such as co-payment limits for those with statutory health insurance, will remain in place. Nevertheless, certain medicines are likely to become more expensive, as drug manufacturers will pass on the additional costs to consumers. The implementation of the directive will be designed in such a way that the supply and diversity of medicines are guaranteed. Legal regulations on drug costs remain in place and ensure social justice. The EHV does not weigh up different treatment options against each other, but refers to the harmfulness of the respective drug to water bodies. Wastewater fee payers will be relieved of the burden of having to finance only 20% of the additional costs for the fourth treatment stage, rather than 100%.

Anja Autzen Virtanen [a], Satu Lakio [b], Atif Madi [c], Mia Sivén [a,d]

[a] Division of Pharmaceutical Chemistry and Technology, Faculty of Pharmacy, University of Helsinki, Finland
[b] Orion, Finland
[c] SK biotek Ireland, Ireland
[d] Helsinki Institute of Sustainability Science, HELSUS, Finland

Title

Excipient and process sustainability in the manufacture of oral solid dosage forms - Targeted literature review as complementary method to life cycle assessment

Background information

Pharmaceutical dosage forms exert their impact on the environment throughout all stages of their life cycle: from raw material acquisition to waste disposal. Addressing this interdependent complexity, life cycle assessments are inherently intricate, requiring extensive knowledge in the generation and application of life cycle inventory data.

Purpose

Focusing on generic excipients and common manufacturing processes, this study aims to investigate the environmental impact of these throughout the life cycle of a model tablet formulation of a poorly water-soluble active pharmaceutical ingredient. Thereby, emphasizing what can be discerned about its environmental impact without specific empirical data or software calculations. The goal is to inform pharmaceutical product development and enable the targeting of sustainability optimization efforts to areas in which the greatest impact can be achieved.

Method

The study is based on previous work detailing the direct compression manufacture of minitablets from a spray-dried amorphous solid dispersion of indomethacin (BCS II) in polyvinylpyrrolidone or hydroxypropyl methylcellulose acetate succinate with the use of lactose, microcrystalline cellulose and magnesium stearate as tablet excipients. Our study employs a mixed-method methodology using the PRISMA -framework to conduct a systematic literature review and comprehensive analysis of literature describing the environmental impacts of these excipients and manufacturing processes throughout the life cycle of the formulation.

Results

Environmental hotspots related to manufacture of excipients and tablets, and the end-of-life scenarios were identified. Despite identical nomenclature, excipients provided by different suppliers may differ significantly in their resource and energy consumption. Moreover, data on the environmental performance of different manufacturing process alternatives was found to be inconclusive. When considering the end-of-life scenario, excipients generally regarded as safe (GRAS) are not necessarily harmless to the environment.

Conclusion

Targeted literature reviews focusing on specific excipients and processes are a useful complementary method to full life cycle assessment of the environmental impacts of pharmaceuticals. Being a quick and low barrier method, it provides valuable insights that can provide perspectives on choices in formulation development or product review, thereby promoting sustainable product development.

In vitro culture of adventitious roots in bioreactors – a sustainable approach for the utilisation of mediterranean MAPs biodiversity

Maria Androudi[1,2], Katerina Grigoriadou[1] and N. Aligiannis[2]

[1] Hellenic Agricultural Organization DIMITRA (ELGO-DIMITRA), Institute of Plant Breeding and Genetic Resources, Balkan Botanic Garden of Kroussia, P.C. 570 01 Thermi, Thessaloniki, P.O. Box 60458, Greece. mairi.androudi@gmail.com

[2] National and Kapodistrian University of Athens, Faculty of Pharmacy, Department of Pharmacognosy and Natural Products Chemistry, Panepistimioupolis Zografou, P.C. 15771, Athens, Greece.

Abstract

The continual search for new attractive and innovative natural medicinal products is a central focus of pharmaceutical industries worldwide. Recent years, documentation, conservation, evaluation, and sustainable exploitation of European medicinal and aromatic plants (MAPs) has been the main concern for researchers, conservation managers, and policy makers, especially in the Mediterranean basin. Greece, in particular, is one of the richest floral diversity regions with 6,764 native species, including 22% indigenous endemics. Among them, species of the *Iris* genus, apart from their use as ornamental plants, have been noted in the texts of ancient physicians (Hippocrates, Dioscorides) for their widespread use of dried roots as abortifacients, emmenagogues, and for improving bone health. Previous studies revealed that extracts from the roots of four different species of genus *Iris* (*I. germanica, I. attica I. unguicularis ssp. cretensis and I. Pseudacorus*) are capable to promote osteoblastic differentiation, with *I. germanica* extracts being the most promising one. To date, the use of bioreactors for the *in vitro* culture of plant tissues in liquid nutrient medium with growth regulators and elicitors, being independent of climatic and geographical constraints, could provide an incessant and viable production of secondary metabolites, easier extraction and purification of the generated products, aiming at holistic exploitation and development of innovative products that combine safety and effectiveness. Considering all the aforementioned, an *in vitro* adventitious root production protocol using a balloon bubble type bioreactor in liquid media was developed as an alternative way of production secondary metabolites in *I. germanica*, particularly those with potential phytoestrogenic properties. From our results, tissue culture of *I. germanica* could serve not only for propagation but also for production of species-specific secondary metabolites such as isoflavone and iridales derivatives, through adventitious root cultures. This study, could help set the basis for enhancing *in vitro* root biomass production and, in parallel, the large-scale biosynthesis of secondary metabolites in bioreactor systems, with potential applications also in other *Iris* species of pharmaceutical relevance. Overall, this approach demonstrates the potential of bioreactor systems for the sustainable exploitation of MAPs, bridging conservation and innovation in biopharmaceutical and nutraceutical applications.

Keywords: medicinal and aromatic plants; *in vitro* culture; balloon bubble type bioreactor; secondary metabolites; adventitious roots

Poster 05: Nhomsai Hagen

The course „Pharmacy in Global Health" is organised by the Pharmaceutical Institute of Tuebingen University in collaboration with the non-profit organisations APOTHEKER HELFEN e.V. (www.apotheker-helfen.de), Apotheker ohne Grenzen Deutschland e.V. (https://www.apotheker-ohne-grenzen.de) and Difäm Weltweit (https://difaem.de). It offers participants the opportunity to learn and gain insights about the many pharmaceutical aspects of development cooperation and disaster relief and, if desired, to prepare for future voluntary or full-time work in this field. The central objectives of pharmaceutical development cooperation are to ensure access to effective and safe medicines for all patients in economically poor countries and to guarantee the correct use of these medicines as far as possible. Qualified pharmacists are also in demand for international disaster relief operations. In the course, more than 15 experienced international lecturers from various development cooperation and disaster relief organisations teach about the various tasks involved and report on their practical experience. The course will take place for the 10th time from 16th until 25th of March 2026 (16th-20th of March 2026 on-site in Tuebingen, 23rd-25th of Match 2026 virtual via zoom). The eight-day seminar is followed by two weeks of independent project work, usually a literature review in pairs, and a final presentation (13th of June 2026 via zoom). The project work is compulsory for students of the University of Tuebingen, but voluntary for other participants. Target group is primarily pharmacy students and licensed pharmacists, others interested in Pharmacy in Global Health may attend in case of availability. Maximum number of participants is 25. Course language is German and English.
For more information see: https://uni-tuebingen.de/fakultaeten/mathematisch-naturwissenschaftliche-fakultaet/fachbereiche/pharmaziebiochemie/teilbereich-pharmazie-pharmazeutisches-institut/pharmazeutische-biologie/ak-heide/kurs-pharmacy-in-global-health/

Abstract to the 4th Summer School on Sustainable Pharmacy (22.–25.9.2025, Halle)

Authors: Sanja Riikonen[a,*], Johanna Timonen[b], Mia Sivén[c], Mirella Miettinen[a]
Affiliations: [a]University of Eastern Finland, Law School; [b]University of Eastern Finland, School of Pharmacy; [c]University of Helsinki, Faculty of Pharmacy
*Doctoral Programme in Drug Research, School of Pharmacy, UEF
Contact email: sanja.riikonen@uef.fi

Title: Measures taken by different pharmaceutical actors to implement green transformation – the impacts of EU chemicals policy and legislation

Background: Environmental impacts caused by the pharmaceutical sector have raised increasing concern in recent decades.[1] The European Commission has stated that there is a need for deeply transformative policies to increase the value given to protecting natural ecosystems, to sustainable use of resources and to improving human health.[2] To support this, many legislative changes have been proposed or adopted to EU chemicals legislation affecting the actors in the pharmaceutical sector in different ways. The term 'green transformation' is a concept with interpretative flexibility, and it is hypothesized that different actors may have different views on green transformation(s) needed, which can be reflected in their measures and lead to multiple pathways to achieve green transformation(s).

Objectives: The aim of this study was to examine the measures taken by different pharmaceutical actors towards green transformation and how recent changes in EU chemicals policy and legislation may have influenced their practices.

Method: 26 semi-structured interviews were conducted with pre-defined groups of actors: interest groups incl. 2 non-governmental organizations (NGOs) n=8; pharmaceutical industry n=7; public authorities n=6, and researchers n=5. The interviewees chose the legislative changes to be discussed in the interview from the given themes. The data was analyzed using qualitative content analysis.

Results and conclusions: The measures taken included actions to reduce environmental impacts from production and supply chain (industry), supporting the industry in the transformation (industry interest groups), developing environmental criteria for public procurement (authorities & NGOs), conducting research and educating future generations on green principles (researchers). The views on the legislative changes, working as drivers of green transformation for the different actors, varied both across and within actor groups. The results provide new information on the concrete impacts of legislative changes to green transformation(s) in the pharmaceutical sector.

References:

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Universidad del País Vasco Euskal Herriko Unibertsitatea
FACULTY OF PHARMACY
UNIVERSITY OF THE BASQUE COUNTRY
Basque Sustainable Pharmacy & Biotherapy

Pharmaceutical Pollution Postgraduate

Introduction: The concept of sustainable pharmacy, although not a new one, remains largely unrecognised by healthcare professionals and specialists engaged in the drugs' supply chain. The training of new healthcare professionals is paramount for bringing about an environmentally friendly, sustainable and green pharmaceutical sector. We present a postgraduate course offered by the University of the Basque Country (UPV/EHU) which aims to increase knowledge and awareness of the environmental impact of pharmaceuticals, particularly among healthcare professionals, and also give an introduction of basic concepts on sustainable pharmacy. Secondly, the initiative aims to foster collaboration between healthcare and environmental professionals to develop solutions to the problem.

Method: The postgraduate course is 100% online and has 15 ECTS credits: 10 theory and 5 practice (personal work). The theoretical part is divided into two blocks. The first is related to the existing environmental issue and the second to the possible solutions for the mitigation of pharmaceutical pollution and the implementation of sustainability in their daily work. The final evaluation will take into account the note of the exams grade of each block and the personal work, which will be supervised by the organizers. The international teaching panel has consisted on more than 30 different professionals, 13 of which belong to the world's top 2% scientists ranking according to the Stanford University. It is an interdisciplinary and transversal group of lecturers, some of which come from the environment world and others from the healthcare setting.

Results: The third edition has finished last June. So far, 33 different students from five different countries (Spain, Mexico, Germany, Italy and Ecuador) and have cursed it. The majority of students (81%) have been pharmacists, but other backgrounds (medicine, chemical & environmental engineering, chemistry, environmental science) have participated too. The final coursework of some students has been the source of high impact research articles, and also, they are having been awarded with national and international prizes

Conclusions: The postgraduate course aims to contribute to solve the problem of drug pollution, via education especially to healthcare professionals, and may also help to build bridges between the environment and the health-care world.