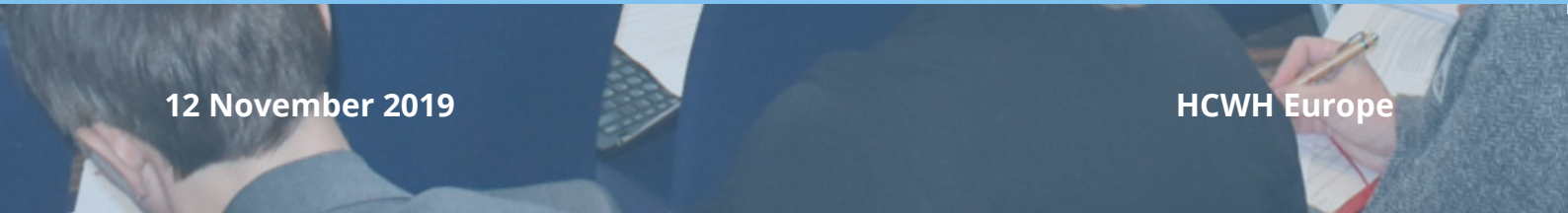
Health Care Without Harm

Safer Pharma

GLOBAL GREEN and HEALTHY HOSPITALS

A MULTI-STAKEHOLDER APPROACH TO PHARMACEUTICALS IN THE ENVIRONMENT: Working together towards effective solutions



12 November 2019

HCWH Europe

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Tuesday 12 November 2019 | 10:00 - 17:00 CET

Rue de Spa 30, 1000 Brussels, Belgium

AGENDA

09:30 - 10:00	Registration and coffee
10:00 - 10:10	**Welcome messages** **Will CLARK**, Executive Director - Health Care Without Harm (HCWH) Europe **Stefan STAICU**, Health Attaché - Romanian Permanent Representation to the EU
10:10 - 10:45	Interview **Opening session: Setting the scene** **Alistair BOXALL**, Professor in Environmental Science - University of York
10:45 - 11:45	Panel discussion **Session 1: Preventing pharmaceuticals in the environment – A regulatory approach** *Policy guidance to reduce pharmaceuticals in freshwater in a cost-effective way* **Hannah LECKIE**, Policy Analyst - OECD Division of Climate, Biodiversity and Water *Implementing the Strategic Approach to Pharmaceuticals in the Environment in a new EU mandate* **Cornelia RUDOLPH**, Policy Officer for Chemicals and Pharmaceuticals - European Commission Directorate-General for Environment *Setting sustainable procurement criteria for pharmaceuticals in Sweden* **Lena GÖRANSSON MODIGH**, Sustainability Manager - Swedish Region Västra Götaland *Recommendations to reduce emissions of active pharmaceutical ingredients in Finland and the Baltic Sea region* **Jukka MEHTONEN**, Senior Expert - Finnish Environment Institute
11:45 - 12:00	Coffee break

12:00 - 13:00	Panel discussion **Session 2: Mitigating the impact of pharmaceuticals in the environment throughout their life cycle – A multi-sectoral approach** *Promoting responsible manufacturing to curb antimicrobial resistance* 🗣 **Alba TILEY**, Global Sustainable Antibiotics Director - Centrient Pharmaceuticals *Addressing pharmaceutical residues after their release into the aquatic environment* 🗣 **Anders FINNSON**, Senior Environmental Advisor - Swedish Water & Wastewater Association *Strengthening antibiotic stewardship through innovation procurement* 🗣 **Emanuele TORRI**, Medical Director - Autonomous Province of Trento, Italy *Reducing environmental harm from pharmaceuticals in the Scottish Highlands* 🗣 **Sharon PFLEGER**, Consultant in Pharmaceutical Public Health - NHS Highland
13:00 - 14:00	Lunch
14:00 - 15:00	Presentation **Session 3: The healthcare sector as a hub for good practice** *The Mermiss project (DK): Environmentally friendly treatment of highly potent pharmaceuticals in hospital wastewater* 🗣 **Caroline KRAGELUND**, Scientific Coordinator - Danish Technological Institute *The MEDUWA project (DE/NL): Solutions to reduce or prevent the contamination of food, soil and water by medicines* 🗣 **Alfons UIJTEWAAL** & **Margarita AMADOR,** Project Developers - Foundation Huize Aarde *The PharmaSwap project (NL): Creating a marketplace for pharmacists to prevent pharmaceutical waste* 🗣 **Jelmer FABER**, Hospital Pharmacist - BovenIJ Hospital
15:00 - 15:15	Coffee break
15:15 - 16:15	Panel discussion **Closing session: The way forward - Working together towards effective solutions** 🗣 **Ines RÖNNEFAHRT**, Senior Scientist - German Environment Agency (UBA) 🗣 **Koen LAENEN**, Quality and Regulatory Affairs Manager - Medicines for Europe 🗣 **Carla CHIARETTI**, Head of Policy - EurEau 🗣 **Jean-Yves STENUICK**, Pharmaceuticals Policy & Projects Officer - Health Care Without Harm (HCWH) Europe
16:15 - 17:00	Drink reception

Introduction

Pharmaceutical pollution is increasingly recognised as a threat to ecosystems and human health globally – 771 different pharmaceutical substances have been detected in the environment worldwide. As global consumption of human and veterinary medicines increases, this problem will only get worse.

Pharmaceuticals can enter the environment at all stages of their life cycle: manufacturing discharges, excretion during use, and improper disposal. Once in the environment, pharmaceuticals can accumulate in fish, livestock, and vegetables as well as enter our drinking water.

Pharmaceutical pollution is also closely linked to the development and spread of antimicrobial resistance (AMR) – a global health threat that is already responsible for an estimated 33,000 annual deaths in Europe alone. If no effective action is undertaken, AMR could cause 10 million deaths per year worldwide by 2050.

On 12 November 2019, Health Care Without Harm (HCWH) Europe organised the workshop *A multi-stakeholder approach to pharmaceuticals in the environment* in Brussels, with the aim to:

- Raise awareness about pharmaceuticals in the environment as a multi-sectoral issue that needs to be addressed at multiple levels
- Provide a shared understanding of the policy challenges for addressing pharmaceuticals in the environment
- Identify priorities for action in follow-up to the European Commission Strategic Approach to Pharmaceuticals in the environment
- Share best practice and identify innovative solutions that could be scaled up or replicated in other countries or regions

This event brought together key participants from EU and international institutions, national ministries, the healthcare sector, industry, civil society, and academia. It attracted attention from across Europe with half of the participants coming from outside Belgium.

The workshop comes at a time of increased attention to the threat of pharmaceutical pollution in Europe and beyond.

The European Commission released the European Union Strategic Approach to Pharmaceuticals in the Environment on 11 March 2019 (after almost three and half years of delay), which identifies six areas for action to address the environmental impact of phar-

maceutical substances.

Following this, the EPSCO Council adopted conclusions on AMR on 14 June, which called upon Member States and the Commission to "consider further legislative measures, as appropriate, to address [the] presence [of antimicrobial residues and resistant microorganisms] in the environment", and the ENVI Council adopted conclusions on a Sustainable Chemicals Policy Strategy on 26 June, which stressed "the importance to accelerate concrete and ambitious actions to reduce the risk from pharmaceuticals and their residues to the environment".

The European Parliament Committee for Environment, Public Health and Food Safety (ENVI) is currently working on a draft motion for a resolution on the Strategic Approach to Pharmaceuticals in the Environment that should be adopted in plenary in April or May 2020.

At the global level, the Interagency Coordination Group on Antimicrobial Resistance (IACG) also expressed growing concerns "about the impact of AMR on the environment and natural ecosystems due to overuse and discharge of antimicrobials and resistant micro-organisms" in their report No time to wait: Securing the future from drug-resistant infections (April 2019).

In parallel, the Organisation for Economic Co-operation and Development (OECD) published their report Pharmaceutical residues in freshwater: Hazards and policy responses a day after the workshop. This OECD report calls for a better understanding of the effects of pharmaceutical residues in the environment and outlines policy actions to prevent and remedy emerging concerns.

Welcome messages

HCWH Europe Executive Director **Will Clark** welcomed participants to the workshop and highlighted how high the issue of pharmaceuticals in the environment is on the policy agenda at the moment.

He stressed that the workshop will both feature a range of expert stakeholders from across Europe and will provide plenty of opportunity for participants to provide input – the workshop will be engaging and solutions-focused.

Closing his introduction, Will also spoke about how this fits into the wider works of HCWH Europe, whose mission is to transform healthcare worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice.

"It doesn't matter which issue you look at, environmental impact harms human health. Environment and health are intrinsically linked and that sits at the heart of what we do."

Participants then heard from **Stefan Staicu**, Health Attaché at the Romanian Permanent Representation to the EU, who spearheaded Council conclusions on AMR during Romania's presidency in early 2019. Stefan explained that the Romanian presidency focused on three objectives on AMR:

- Improving the quality of infection, prevention, and control measures and optimising antimicrobial use across human, animal, and environmental health sectors
- Strengthening the implementation of national 'One Health' action plans
- Encouraging solidarity between countries by working together to combat AMR

Stefan also introduced the EPSCO Council conclusions on making the EU a best practice region in combatting AMR, which call upon Member States and the Commission to monitor antimicrobial residues from use and production. The conclusions also recommend monitoring resistant microorgnisms in soil, ground, and surface water and

to consider further legislative measures, as appropriate, to address their presence in the environment.

"These Council conclusions are a comprehensive document, which keeps the focus on AMR and takes into account the most recent information and developments in the area, including targeted and specific aspects of AMR such as the evolution of the presence of pharmaceuticals in the environment."

Opening session: Setting the scene

To give participants a sense of current knowledge and research priorities, **Alistair Boxall**, Professor of Environmental Science at the University of York (UK), took questions on his team's research, which focuses on emerging and future ecological and health risks posed by chemical contaminants in the natural environment.

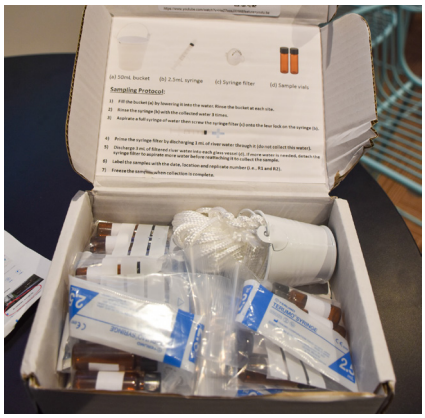
The interview began with questions about the Global Monitoring of Pharmaceuticals Project (coordinated by Alistair), which has detected dangerously high levels of antibiotics in rivers around the world.

How did the Global Monitoring of Pharmaceuticals Project come about?

In 2016, the German Environment Agency (UBA) published a literature review on pharmaceuticals in the environment, which concluded that there was no or limited data available for many regions in the world.

At that time, Alistair who was working on pharmaceuticals in the environment was in contact with the United States Geological Survey, which had developed an approach to directly inject water samples onto analytical instruments and analyse pharmaceuticals.

This method paved the way to the Global Monitoring of Pharmaceuticals Project where colleagues from around the world were invited to sample their local rivers using sampling kits. When shipped back to York, the samples were analysed for over 60 pharmaceuticals, including 20 antimicrobials; the project has now covered over 100 countries and generated a unique dataset.



What were the key findings of the study?

In the majority of sites monitored, researchers detected at least one pharmaceutical; in areas in Africa, Asia, and South America, the total concentration of pharmaceuticals were found to be very high, while in Europe the total concentration was generally lower. Alistair noted, however, that this was not always the case, as high concentrations of pharmaceuticals had been found in some cities such as Madrid for instance.

What were the most prevalent antibiotics found?

From the 20 antimicrobials analysed, the most commonly occurring antibiotics were metronidazole, trimethoprim, sulfamethoxazole, and ciprofloxacin. They found that in low- and middle-income countries, such as in Bangladesh, the concentration of antimicrobials greatly exceeded the AMR Industry Alliance discharge targets.

"Antimicrobials are of pressing concern, but there are other molecules we should be thinking about in terms of ecotoxicity and environmental effects. Antidepressants are of particular concern in Europe and North America while antibiotics are potent in Africa, Asia and South America."

What are the key entry points for pharmaceuticals in the environment?

According to Alistair, in Europe the key entry points are areas with high population densities and low flow, giving the example of London where large wastewater treatment plants are emitting into relatively small streams resulting in low dilution.

In low- and middle-income countries, the project identified are a number of suspected hotspots: dumping sites for exhausters i.e. lorries emptying latrines and sceptic tanks in Kenya, pharmaceutical manufacturing sites in Bangladesh, and electronic waste dumps in Ghana.

What should be done to curb pharmaceutical pollution?

In Europe, Alistair advocates for better management of pharmaceutical prescriptions (upstream) and the introduction of tertiary treatments to existing wastewater treatments works (downstream). The situation in low- and middle-income countries, however, is very different; in areas heavily impacted by pharmaceutical pollution, more innovative and low-energy treatment solutions are more appropriate, rather than wastewater treatment plants. Better controls on the sale of pharmaceuticals would also curb inappropriate use and massive overuse of medication.

What are the next steps of the project?

Looking forward, Alistair would like to scale up the project as currently it only includes single samples from mostly urban systems. He would also like to add a temporal dimension e.g. seasonal sampling in Europe, as well as a spatial dimension to the work, particularly looking at agricultural settings and rural communities.

Session 1: Preventing pharmaceuticals in the environment – A regulatory approach

The regulatory approaches at international, EU, national and regional levels on pharmaceuticals in the environment were discussed in a panel session.

Hannah Leckie, Policy Analyst at the OECD Division of Climate, Biodiversity and Water, gave an overview of the OECD's 2019 report Pharmaceutical residues in freshwater: Hazards and policy responses, including their policy recommendations. It is estimated that 30-90% of oral pharmaceuticals administered to humans and animals are excreted as active substances, which can find their way into soil and both ground and surface water. Other pathways include the discharge of wastewater from pharmaceutical manufacturing plants, improper disposal of medicines, and diffuse pollution from agriculture.

Hannah said that *"an estimated 10% of pharmaceutical products have the potential for environmental risk"*, and the situation is set to get worse as pharmaceutical use is predicted to increase, notably due to ageing populations and intensified livestock and agricultural practices.

She added that many countries have focused on water quality monitoring, (although the vast majority of pharmaceuticals remain unmonitored) while other countries such as Switzerland have implemented end-of-pipe measures, such as upgrading their wastewater treatment plants.

OECD countries, however, face two issues with existing approaches: there is only comprehensive ecotoxicity data for approximately 10% of the 2,000 active pharmaceuticals ingredients (APIs) used worldwide, and wastewater treatment plant upgrades are limited by their removal efficiency, high investment, and operation costs, as well as increased energy consumption and carbon emissions.

The OECD therefore recommends a life-cycle

approach with actions from all stakeholders from design to disposal with a focus on four strategies:

1. Improve knowledge, reporting, and understanding on the occurrence, toxicity, and impact of pharmaceuticals in the environment, including identification of hotspots
2. Use source-directed approaches to prevent the release of pharmaceuticals in the environment, such as incentives for green pharmacy and personalised medicines, increased risk intervention and mitigation options for manufacturing of pharmaceuticals of high environmental risk, and green public procurement
3. Implement use-orientated policies to reduce inappropriate and excessive consumption of pharmaceuticals, such as improved diagnostics and restrictions or bans of excessive use of high-risk pharmaceuticals
4. Implement end-of-pipe measures to remove pharmaceutical residues after their use, such as extended producer responsibility schemes for safe disposal of pharmaceuticals and taxes to upgrade wastewater treatment plants

Participants then heard from **Cornelia Rudolph**, Policy Officer for Chemicals and Pharmaceuticals at the European Commission Directorate-General for Environment, who outlined the six areas of action in the European Union Strategic Approach to Pharmaceuticals in the Environment as well as the follow-up actions taken by the Commission.

As a first step, the Commission hosted a workshop with Member States to collect information about available national strategies and organised meetings with various stakeholders to discuss their experiences of tackling pharmaceuticals in the environment. The Commission is also in the process of establishing working groups for pharmaceuticals in the environment (notably within the Pharmaceuticals Committee), and is in internal discussions with several units to implement actions from the Strategic Approach, for instance regarding the Urban Wastewater Treatment Directive.

The European Green Deal will also include different actions related to chemicals, including a zero-pollution ambition in water and air with a chemical aspect. Cornelia concluded *"there are a lot of opportunities to get pharmaceuticals into all of these strategies, which are still in development."*

Lena Göransson Modigh, Sustainability Manager from the Swedish Region Västra Götaland (a HCWH Europe member) then provided a national perspective to pharmaceuticals in the environment.

For over ten years, Sweden has been using social procurement criteria for pharmaceuticals and environmental criteria in the form of contract terms for five years. More recently, in 2017, the Swedish National Agency for Public Procurement, together with an expert group and a procurers working group, began developing new criteria (available in Swedish). In this process, criteria were developed in award form so that the market could be driven forward.

Lena admitted that setting up new criteria hasn't been an easy ride – there have been challenges to address transparency, especially in long and complex supply chains. It was also a challenge to include award criteria on emission effluent control – the new criteria do not yet address this specifically, but work is continuing on this aspect.

Lena's closing message was that *"collaboration is key for countries who would like to set up sustainability procurement criteria for pharmaceuticals; these countries should look at what has already been done"*. She added that Nordic countries are currently investigating whether it is possible to harmonise their criteria sets and called for harmonised criteria at an EU level.

The last panellist **Jukka Mehtonen**, Senior Expert at the Finnish Environment Institute (SYKE), presented the policy brief Environmental drug load can be reduced and preliminary findings and recommendations from the CWPharma project in the Baltic Sea.

Jukka stressed that *"it is crucial to have information on emissions from different sources (including primary sources) as this is the cornerstone to develop cost-efficient measures to reduce the levels of pharmaceuticals in the environment in the Baltic Sea"*, adding that there was a particular lack of information on emissions due to the use of veterinary medicinal products in livestock and pets.

He also highlighted the need to implement rational prescription and use of pharmaceuticals to reduce quantities of unused medicines and waste; information campaigns targeting citizens, farmers, and veterinarians are very important in that sense.

Finally, he welcomed the development of an environmental classification system for pharmaceutical products in Finland to support public procurers and medicine prescribers. The challenge, however, is for the database underpinning the classification to be based on reliable and transparent information. He also called for a common EU-wide classification system instead of separate national sys-

Session 2: Mitigating the impact of pharmaceuticals in the environment throughout their life cycle – A multi-sectoral approach

In this second panel session representatives from the healthcare, pharmaceutical industry, procurement, and water sectors discussed approaches to curb pharmaceutical pollution.

Alba Tiley, the Global Sustainable Antibiotics Director at Centrient Pharmaceuticals, provided the pharmaceutical industry perspective. She discussed the AMR Industry Alliance – the private sector coalition that seeks to provide sustainable solutions to curb AMR. In 2018, the AMR Industry Alliance launched two work products:

- The Common Antibiotic Manufacturing Framework – a framework that sets out minimum expectations for business policies, practices, and behaviours to minimise the release of antibiotics into the environment from drug production and formulation
- A list of Predicted No-Effect Concentrations (PNECs) for use in Environmental Risk Assessments (ERAs) of antibiotics – Alliance members have voluntarily committed to targets in this list of safe discharge levels for antibiotic manufacturing.

"Manufacturing companies should be responsible for the products that they produce, but we need collaboration across the whole value chain. Procurers and regulators need to understand the role that they play – the price is often

a driving factor in antibiotic procurement, while environmental and social standards are often not included."

The floor was then given to **Anders Finnson**, Senior Environmental Advisor at the Swedish Water & Wastewater Association, who highlighted the importance of source-controlled actions to prevent pharmaceutical discharges into the environment in line with the precautionary and polluter pays principles.

He supported the OECD recommendation that end-of-pipe measures should only be complementary to source-directed and use-orientated measures. Anders commented, *"an over-emphasis on upgrading wastewater treatment plants is not a sustainable, optimal use of limited resources."*

There are several projects related to end-of-pipe treatments in Sweden, but only as a complementary step, he explained. The Swedish Environmental Protection Agency has provided budget for pre-studies, pilot plants, and full-scale plants; there are 29 projects running in Swedish wastewater treatment plants.

The next speaker, **Emanuele Torri**, Medical Director at the Autonomous Province of Trento (Italy), is involved in the Anti-SUPER-Bugs Pre-Commercial Procurement project, coordinated by the Agència de Qualitat i Avaluació Sanitàries (AQuAS) in Spain. The project's objective is to promote the development of ICT solutions to detect the presence of resistant microorganisms.

Emanuele noted that *"the pre-commercial procurement (PCP) approach is not so common in Europe, but can be interesting from a procurer perspective as it offers an opportunity to identify practical needs at a very early stage and to launch a tender for companies to offer solutions."*

At the moment, the project is in the first phase of the PCP, which comprises prototype design. The call for proposals launched in 2018 yielded six proposals that will soon be evaluated; this will be followed by a development phase and a testing phase in hospitals.

He concluded that the business case is quite strong as the impact of AMR is well known in the healthcare system and many healthcare-acquired infections are creating problems. Procurement is very important to have an impact on the system and engage with companies to meet expectations.

The last speaker, **Sharon Pfleger**, Consultant in Pharmaceutical Public Health at NHS Highland (UK) (a HCWH Europe member), presented the One Health Breakthrough Partnership (OHBP), which aims to reduce environmental harm from pharmaceuticals in the Scottish Highlands. The OHBP was developed in 2017 following a workshop on emerging contaminants in the environment co-hosted by HCWH Europe and the Highlands and Islands Enterprise (HIE).

The One Health Breakthrough Partnership brings together four public sector organisations, six research institutes and universities, and the private sector. *"Our overall vision is to have a non-toxic Highland region, and the first issue that we are tackling is pharmaceuticals in the environment."*

The OHBP is working to 'green' NHS Highland's formulary (list of medicines) by including persistence, toxicity, and bioaccumulation information, reducing medicines use through a realistic approach to care, and calculating the reduced environmental impact of less environmentally damaging medicines.

The OHBP is also supporting several on-going PhD research projects currently investigating a variety of topics including blue-green prescribing, biodegradation of molecules, and use of new removal technology involving seaweed. The partnership has implemented a data-sharing agreement between three of the public agencies to combine prescribing data with environmental regulation and wastewater data.

Session 3: The healthcare sector as a hub for good practice

In the third session, three presentations on how the healthcare sector in Europe can address the issue of pharmaceuticals in the environment were presented.

The Mermiss project (DK): Environmentally friendly treatment of highly potent pharmaceuticals in hospital

First **Caroline Kragelund**, Scientific Coordinator at the Danish Technological Institute, presented the Mermiss project, which aimed to efficiently remove highly potent pharmaceuticals present in hospital wastewater in Denmark. The project ended in 2018; the final project report is available in English.

Caroline explained to participants that in Denmark, legislation requires hospitals to remove environmentally harmful pharmaceuticals from their wastewater in accordance with the polluter pays principle. The Mermiss project questioned the efficiency of treating wastewater at the hospital level rather than at the municipal level, as only 5% (approximately) of all medicines in Denmark are consumed in hospitals.

The project demonstrated that medicines could be removed at the municipal level by implementing very simple steps using biofilm technology. *"For Diclofenac, for instance, we saw remarkable removal rates, which haven't been seen before or recorded in literature,"* said Kragelund.

Caroline described how the project also showed that removing pharmaceuticals from wastewater at the municipal level has both a greater environmental impact and a lower cost per cubic metre when compared to the hospital level. She also highlighted that the cost of establishing a small wastewater treatment plant at the hospital level is relatively similar to modifying an existing conventional municipal wastewater treatment plant.

As a next step, Caroline described on-going work at the municipality level where biology is used to remove pharmaceuticals in three reactors – each measuring 5m^3 – the results of this new project will be scalable for a full-scale plant.

The MEDUWA project (DE/NL): Solutions to reduce or prevent the contamination of food, soil and water by medicines and AMR

Alfons Uijtewaal and **Margarita Amador**, Project Developers at Foundation Huize Aarde (a HCWH Europe member), presented the MEDicines Unwanted in WAter (MEDUWA) project. The project is a cross-border collaboration between 16 companies, eight

research institutes and universities, a regional water authority, and two NGOs seeking to lower emissions of pharmaceuticals and multi-resistant microorganisms in the environment.

Alfons and Margarita highlighted the knowledge gap around pharmaceutical pollution; so far, the general emphasis has been on the water route, they explained, but other routes, such as exposure through food, could be more or equally important. *"The environmental cycle of medicines and AMR creates problems for all sectors. Policies are needed to support responsible use of medicines."*

The MEDUWA project consists of eight work packages looking at pharmaceuticals across their life cycle, which have led to the development of 12 innovations including algae and herbal mixtures as an alternative to antibiotics and the development of biopharmaceuticals, which deals with producing and applying alkaline phosphatase (AP) as a natural inflammatory medicine.

According to Alfons and Margarita, green medicines are often portrayed as 'utopia' because industry wants stable molecules but approximately one third of all medicines are already biodegradable. They drew attention to Prof. Klaus Kümmerer's research at Leuphana University Lüneburg, which shows that the stability of a medicine can go hand in hand with biodegradability and improve therapeutic effects while reducing side effects.

Alfons and Margarita closed their presentation by calling for the promotion of cross-sectoral pilot projects that work throughout the life cycle of medicines, the development and testing of source-oriented solutions, including prevention, and the creation of incentives for start-ups and universities to research biodegradable medicines.

The PharmaSwap project (NL): Creating a marketplace for pharmacists to prevent pharmaceutical waste

The last presenter was **Jelmer Faber**, Hospital Pharmacist at BovenIJ Hospital, who co-founded the PharmaSwap project in the Netherlands, a marketplace for pharmacists to prevent and reduce pharmaceutical waste, based on the principle of the sharing economy.

In the Netherlands, pharmaceuticals represent 18% of the healthcare sector's total CO2 emissions, yet approximately 4,500 packs of generic medicine are destroyed per day – 1.6 million packages per year.

Jelmer showed that, according to researchers, at least 100 million medicines per year are destroyed in the Netherlands (40% of which can be prevented); he added that we do not know, however, the total wastage within the whole pharmaceutical supply chain, and it could be much higher.

PharmaSwap is a marketplace that helps to addresses pharmaceutical wastage at the pharmacy level. Pharmacists can list their unneeded medication that is close to its expiry date or search for the medication they need before purchasing new medicines. When available, both pharmacists agree on a price, thus also generating extra revenues for the seller and saving costs for purchaser, as well as reducing pharmaceutical waste.

In 2019, a pilot project was carried out with 20 pharmacists; 68 packages were sold on the platform saving approximately €54,000 in purchasing costs. Within five years, Jelmer hopes that all pharmacies in the Netherlands will be connected to the platform; *"we like to say: if you don't use it, share it".*

Closing session: The way forward – Working together towards effective solutions

Throughout the workshop, participants were asked to submit best practice and solutions that regulators, water industry, and pharmaceutical industry could implement to tackle pharmaceutical pollution. Their suggestions were discussed in this closing session with representatives from these three sectors after short introductory remarks.

Ines Rönnefahrt, Senior Scientist at the German Environment Agency (UBA), outlined the role of UBA in conducting Environmental Risk Assessments (ERAs) within the marketing authorisation process of human and veterinary medicinal products. She generally regretted the lack of availability of environmental data, particularly for legacy pharmaceuticals (authorised before the guidelines on ERAs came into force). *"There is a lack of data for many active substances. We have environmental data for less than 50% of substances that we can find in our rivers,"* she added.

Ines called for the creation of a publicly available database of environmental data for substance-based rather than product-based environmental risk assessments. She proposed implementing a 'monograph system' on active substances, a collection of environmental fate and effect data, as a base for every kind of risk assessment.

At the European level, Ines advocated for further linkage between different regulatory areas; she suggested using ERA data to set environmental quality standards within the Water Framework Directive's list of priority substances as an example. She closed by saying there must be a connection between authorisation of a medicinal product and risk mitigations in other regulatory areas.

Koen Laenen, Quality and Regulatory Affairs Manager at Medicines for Europe, highlighted existing initiatives from the pharmaceutical industry to address the environmental impact of pharmaceuticals.

Koen commented that the main pathway for pharmaceuticals to enter the environment is patient excretion, whilst manufacturing emissions only plays a minor role. Despite no existing requirements on pharmaceutical discharges, industry actors have been establishing voluntary discharge limits across the supply chain based on priority and sound scientific background with antibiotics as a top priority to fight AMR.

At the European level, Koen said the pharmaceutical industry has created an Inter-Association Task Force on Pharmaceuticals in the Environment with experts from the European Federation of Pharmaceutical Industries and Associations (EFPIA), Medicines for Europe, and the Association of the European Self-Medication Industry (AESGP).

This Task Force launched an Eco-Pharmaco-Stewardship (EPS) programme, which focuses on stewardship priorities where the pharmaceutical industry can effectively reduce the potential environmental risk that might result from their activities; the EPS is supported by three pillars:

1. Intelligence-led assessment of pharmaceuticals in the environment
2. Manufacturing effluent management
3. Extended Environmental Risk Assessments (eERA); the industry promotes a refined ERA process to ensure that it remains up-to-date and relevant throughout the whole life cycle of medicinal products

Koen also highlighted that information campaigns (such as the #MedsDisposal initiative), which target health professionals and the general public are a vital way to ensure the responsible use of medicines and the appropriate disposal of expired or unused pharmaceuticals.

At the global level, Koen outlined the work carried out by the AMR Industry Alliance and the Pharmaceutical Supply Chain Initiative (PSCI). He called on the European Commission to look at existing industry initiatives to address pharmaceutical emission management when designing regulation around pharmaceuticals in the environment. *"We also call for an ERA database to further improve the overall accessibility and transparency of environmental data,"* he said.

The last speaker of the day, **Carla Chiaretti**, Head of Policy at EurEau, provided insight from the drinking water and wastewater service operators, who are looking at the issue both from a public health perspective (through the supply of drinking water) and an environmental perspective (through the Urban Waste Water Treatment Directive and the Water Framework Directive).

According to Carla, extra treatment at the wastewater treatment plant-level is not the 'silver bullet' to solve the issue of pharmaceutical pollution because it cannot completely remove pharmaceuticals, leads to more energy consumption, and incurs additional costs. *"It doesn't make sense from an environmental and economical point of view just to favour extra treatment,"* she said.

Carla highlighted EurEau's briefing note Treating micropollutants at wastewater treatment plants that shows the possibilities and limits of extra treatment, featuring case studies from Denmark, Finland, Switzerland, Sweden, and The Netherlands.

Switzerland is a particularly interesting case as the country is currently upgrading 100 of its 800 wastewater treatment plants to treat micropollutants, including pharmaceuticals – once complete this will mean that 50% of wastewater would receive extra treatment. Carla added that these upgrades are only possible due to a €15 tax for all Swiss citizens (whether their wastewater was treated or not) and she does not think that this could be applied to other EU countries due to affordability issues and energy consumption requirements.

To conclude the workshop, the event moderator **Jean-Yves Stenuick**, Pharmaceuticals Policy & Projects Officer at Health Care With-

out Harm (HCWH) Europe, asked the expert opinion of the three panellists on the following ideas suggested by participants during the day.

Ines was not convinced that environmental labelling would be an effective measure to reduce pharmaceutical pollution and would rather that doctors and pharmacists provide environmental information to patients.

Koen said that patient information leaflets already contain disposal information and, due to current legislation, the pharmaceutical industry is not allowed to include additional information on the outside of packages.

Carla considered that environmental information on medicinal products in an app format for consumers would be a good idea.

Ines said that different regulatory areas needed to be better connected; we need risk mitigation measures along the whole life cycle of medicinal products. She added that the authorisation process of medicinal product could not solve alone the problem.

Koen said that the industry would welcome discussions with all stakeholders along the distribution chain of pharmaceuticals from manufacturers to end consumers.

Carla stressed the importance of strengthened collaboration across sectors to tackle the issue of pharmaceutical pollution. She said that EurEau had recently joined an intersectoral initiative that brings together both environmental and health communities.

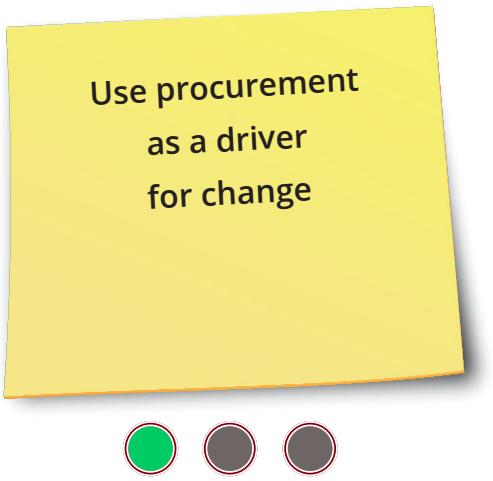
Ines said that a database for ERA data open to all stakeholders would be a huge step forward; she called for quality checks and validated data both transparent and easily accessible.

Koen said that there was a lot of environmental data already available, but that it lacked transparency; he welcomed the idea to create a database with all existing environmental and safety data to help identify knowledge gaps.

Carla said the water industry would also welcome this kind of database, she would be interested to also have access to information on transformation products and metabolites, she added.

Both Ines and Carla agreed that there was a need for legislative actions to accompany voluntary measures to tackle the issue and regretted that the EU Strategic Approach heavily relied on voluntary actions.

Koen added that the pharmaceutical industry was aware that legally binding measures were coming, but called on regulators to look at industry-driven solutions to turn them in a legally binding context.



Ines regretted that only a few countries were using procurement as a lever, as it could have a huge effect on curbing pharmaceuti al pollution.

Koen said that procurement was the way to go – it would allow companies who are making the necessary investments to be rewarded.

Carla agreed that procurement was an effective tool to drive change and called on countries to share best practice.

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Health Care Without Harm (HCWH) Europe is the European arm of a global not for profit NGO whose mission is to transform healthcare worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. HCWH's vision is that healthcare mobilises its ethical, economical, and political influence to create an ecologically sustainable, equitable, and healthy world.

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