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Implementation towards the achievement of the 2020 goal of sound chemicals management: emerging policy issues and other issues of concern: proposal on environmentally persistent pharmaceutical pollutants as a new emerging policy issue

Workshop documentation on pharmaceuticals in the environment: global occurrence, effects and options for action

Note by the secretariat

The secretariat has the honour to circulate documentation from a workshop, held in Geneva on 8 and 9 April 2014, entitled "Pharmaceuticals in the environment: global occurrence, effects and options for action". The workshop was initiated by the German Federal Environment Agency and the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety and organized by Adelphi Consult and IWW Water Centre, Germany.

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Annex

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

Umwelt Bundesamt

Supported IWW adelphi

Workshop Documentation

Pharmaceuticals in the Environment - Global occurrence, effects, and options for action

April 8th and 9th 2014, International Environment House II, Geneva, Switzerland

Chair´s conclusions

A two-day international workshop on "*Pharmaceuticals in the Environment – Global occurrence, effects, and options for action*" initiated by the German Federal Environment Agency (UBA) and the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) and organized by adelphi consult and IWW Water Centre, Germany, took place in Geneva, Switzerland, on April 8th and 9th 2014.

More than 70 representatives of governments, academia, industry, and non-governmental organisations from 24 countries engaged in the workshop to review the current state of knowledge on the global occurrence of pharmaceuticals in the environment and the adverse effects they can have on organisms and ecosystem health, and discuss potential cooperative actions.

Based on the recently enlarged scientific evidence presented, the participants concluded that pharmaceuticals occur globally in the environment, including developing, emerging, and industrialized countries. Case studies presented during the workshop demonstrated that pharmaceuticals can cause adverse effects on ecosystem health at concentrations measured in the environment. Pharmaceuticals have also been found in drinking water, albeit at concentrations generally well below minimum therapeutic doses for humans, suggesting appreciable adverse impacts on human health are unlikely according to current knowledge. The scarcity of systematic monitoring programmes presents one of the key challenges in assessing the potential health risks associated with trace concentrations of pharmaceuticals in the environment.

With regard to ecotoxicological effects on the environment (and as a precautionary measure to reduce pharmaceutical occurrence in drinking water), the participants discussed opportunities for cooperative action, especially if pharmaceuticals are nominated as an Emerging Policy Issue under the Strategic Approach to International Chemicals Management (SAICM). Representatives of the Ministry of Housing, Land Planning and Environment of Uruguay and the International Society of Doctors for the Environment (ISDE) informed participants on the nomination dossier they recently submitted jointly with Peru to propose "Environmentally persistent pharmaceutical pollutants" as an Emerging Policy Issue under SAICM. The SAICM secretariat invites comments on the nomination dossier by 11 July 2014, before a finalized nomination dossier is presented to the second meeting of the Open-ended Working Group (OEWG2) to be held in Geneva on 14-17 December 2014.

Participants called for appropriate action to reduce the entry of pharmaceuticals into the environment without compromising effectiveness, availability, or affordability of medical treatment, especially in countries in which access to health care is still limited. Participants concluded that SAICM would be an appropriate policy framework to address the issue pharmaceuticals in the environment on a global level. Cooperative action under SAICM could initiate the multi-sectoral multi-stakeholder approach needed to prevent, reduce, and manage pharmaceuticals entering the environment on a global scale, to use synergies in raising awareness and to guide prescription, application, and disposal patterns, as well as to strengthen capacities in developing countries and countries with economies in transition.

Welcome and Introduction

The participants were welcomed by the German Federal Environment Agency (UBA). The SAICM secretariat presented the SAICM programme as a global policy framework, aiming at, until 2020, chemicals being produced and used in ways that lead to the minimization of significant adverse effects on human health and the environment. An emerging policy issue under SAICM is considered by the Conference to be an issue involving any phase in the life cycle of chemicals and that has not yet been generally recognized, is insufficiently addressed or arises from the current level of scientific information and which may have significant adverse effects on human health or the environment. Current emerging policy issues under SAICM are Lead in Paint, Chemicals in Products, Hazardous substances within the life cycle of electrical and electronic products, Nanotechnology and Nanomaterials, and Endocrine-disrupting chemicals.

The recently submitted nomination dossier of pharmaceutical pollution in SAICM was presented by the International Society of Doctors for the Environment (ISDE). To refer to these chemicals ISDE suggest the term Environmentally Persistent Pharmaceutical Pollutants, EPPP. Pharmaceuticals are groups of synthetic chemicals specifically designed to act on living cells. Pharmaceutical chemicals entering the environment during their life-cycle, may persist and disseminate there presenting a special and unwanted risk of exposure. It was shown that in particular persistence and bioaccumulation of pharmaceuticals in the environment, their increasing use, and their potential effects on animals and humans can pose potential threads. Chemical residues of many pharmaceuticals are presently found in surface and drinking water and are detected in wildlife where they may accumulate. They may pose a threat of magnitude with significant adverse effects on the environment and human health with special impact on vulnerable human and biological populations creating a new and emerging environmental chemical safety problem. ISDE promotes this initiative of nominating EPPP, which are insufficiently addressed and not covered by other international or regional agreements or arrangements.

An introduction to exposure schemes, pathways as well as the environmental risk assessment of pharmaceuticals was presented by UBA. For new medicinal products, regulation is in place in Europe to assess their fate and effects in the environment. The environmental risk assessments and research projects have shown that some pharmaceuticals have ecotoxicological effects in the environment. For many widely used substances data on fate and effects is however not existent, yet.

Global relevance of pharmaceuticals in the environment

Reviewing more than 1000 international publications, a research project conducted by the IWW Water Centre, Germany, showed that pharmaceuticals occur globally in the environment, covering at least 71 countries in all five UN regional groups. Even though there is less data available for developing and emerging countries, similar patterns as in

industrialized countries are evident. Data indicate that in total 631 different pharmaceutical agents (or their metabolites and transformation products) have been detected in the environment, including antibiotics, analgesics, lipid-lowering drugs, estrogens, and many other therapeutic groups. For example, diclofenac, a non-steroidal inflammatory drug, has been detected in the environment of 50 different countries worldwide. Most pharmaceuticals have been detected in surface water and sewage effluent, but also in groundwater, tap water/drinking water, manure, soil, and other environmental matrices. In many countries, certain pharmaceuticals prevail at concentrations above Predicted No-Effect Concentrations (PNEC) in surface waters, suggesting adverse ecotoxicological effects on organisms at these locations. Urban wastewater discharge is the dominant emission pathway globally, while discharge from animal husbandry and aquaculture are important regionally. Point sources, such as production facilities and hospitals need specific attention.

The panel discussion dealt with the following questions and comments:

- The establishment of reliable PNEC-values are important to evaluate potential effects of pharmaceutical concentrations measured in the environment.
- There was concern about small-scale burning of expired drugs, e. g. in Africa. According to WHO, waste incineration at 800°C is sufficient for pharmaceutical waste disposal.
- Impact of often untreated sewage into the Mediterranean Sea from adjacent countries.
- Data on consumption patterns is very limited, especially in developing and emerging countries, precluding an assessment of pharmaceuticals used in high quantities and their occurrences in the environment.
- Funding of measuring campaigns remains a problem as well as knowledge transfer, such as laboratory equipment and analytic methods.
- The potential of conducting risk assessments with models.
- The scope of the EPI nomination (i.e. encompassing all active ingredients, not excipients).
- The definition of “persistence” in the term “EPPP” (i.e. persistence in the sense of continuous introduction into the environment rather than as defined in regulatory assessments of degradability and persistence, e.g. for PBT and POP).
- Consideration of the issue of disposal of pharmaceuticals in landfills, incinerations, and emissions (into water and air).
- Combined effects of pharmaceuticals with other chemicals (i.e. cocktail effect)

Regional Perspectives

Scientists from all five UN regions supported the global findings, but also emphasized regional differences.

For Africa, less data from monitoring campaigns are available than in other continents due to lack of funds and knowledge. However, existing studies point out high concentrations of hormones, e.g. due to high consumption of growth stimulants in cattle feedlots. Also, easy access on street markets in Africa to drugs available upon prescription only in other countries and inappropriate disposal contribute to their occurrence in the environment. Therapeutic groups which are used more often in Africa compared to other areas are antiretroviral and

antimalarial drugs. The use of anticancer drugs also increases. An issue of concern in Africa is the adequate disposal of drugs, also of donated, unused drugs.

For the Asian and the Pacific region, a comparative study between five countries (Japan, South Korea, China, Bangladesh, and Vietnam) indicated that several factors are influencing occurrences of pharmaceuticals. For example, high population density, as shown for several Asian megacities, can strongly increase environmental concentrations. Sanitary infrastructure, such as waste water treatment plants, has not been developed in the same extent, leading to increasing water pollution near megacities. Another important factor is the availability and price of a specific pharmaceutical agent in a country. It could be shown that low prices in general increase the probability of finding these pharmaceuticals in the environment. A strong correlation pattern between availability and occurrence in the environment has been demonstrated during the outbreak of the bird flu in Japan.

For Latin America and the Caribbean Islands, it was illustrated that systematic measurements of pharmaceuticals in the environment are limited; most data available has been published in Brazil. Even though laboratory equipment and knowledge is available in Brazil, high sample costs interfere with measuring campaigns. Therefore, it was proposed to use other available markers, such as caffeine, as a proxy for anthropogenic pollution in order to prioritize sampling sites and to reduce cost for analytics. Nevertheless, due to the lack of adequate wastewater treatment infrastructure, concentrations in surface waters are relatively high. Both pharmaceuticals and illicit drugs have been identified in drinking water in Brazil. However, some globally occurring pharmaceuticals, such as ibuprofen, are rarely to be detected in the Brazilian environment as pricing policies lower their distribution in the society. It was also discussed that due to climate change induced increasing number and intensity of droughts, river runoff will be reduced, resulting in an increase of pharmaceutical concentrations.

For the Eastern European regions, data availability on measured environmental concentrations of pharmaceuticals is increasing but unequally distributed. Few data sets for e.g. Ukraine, Belarus, and Russia exist, while more data is available for e.g. Hungary and Czech Republic. Similar to other regions, Eastern European wastewater infrastructure has been identified as one of the major factors influencing environmental concentrations. For Croatia it was shown that about 50 different pharmaceuticals are regularly being detected in wastewater, indicating large potentials in wastewater management and treatment. Also, a temporal pattern of different antibiotic groups in wastewater and streams is evident, as sulphonamides are more often detected in summer and macrolides in spring and winter. Illegal landfills and discharge from pharmaceuticals have been identified as additional contributors to pharmaceutical pollution in the Croatian environment. A summary on the current knowledge regarding the occurrence of pharmaceuticals in Russia was provided as hand-out. In Russia, measuring campaigns have only started recently, even though it ranks seventh on the global pharmaceutical market and consumption rates have tripled in the last decade. First results from seven reservoirs and three rivers in the Moscow area indicate high concentrations of several pharmaceutical agents.

For western countries, the strategies of the International Commission for the Protection of the Rhine (ICPR) were presented, which concluded that the highest concentrations in surface water bodies were found in water bodies presenting a high wastewater share, where adverse ecological or eco-toxicological effects cannot be excluded. For several sites environmental quality criteria were exceeded. At times, the precautionary values for drinking water production are exceeded in the lower course of the Rhine and in certain tributaries; wastewater from secondary effluent is the most important discharge pathway despite biological waste water treatment. Switzerland reported plans to upgrade about 100 out of

over 700 municipal wastewater treatment plants with advanced treatment processes in the next 25 years, resulting in an enhanced treatment of more than 50% of all wastewater being produced in Switzerland. The implementation concept targeted the largest WWTPs in order to reduce high loads, WWTPs at stretches of water with insufficient dilution, and WWTPs at stretches of water which are of significance for drinking water production. In that way, micropollutant load will be cut in half, at estimated total investment costs of about CHF 1.2 billion, which is considered a justifiable cost-benefit ratio. In parallel, additional action, such as measures at the source, will be identified and implemented.

The panel discussion dealt with the following questions and comments:

- In Sweden, about 1500 different active ingredients are being used. Pharmaceuticals can have ecotoxicological effects at very low doses and the effects of mixtures are still unknown. As pharmaceuticals are found all over the globe, Sweden does consider them an emerging issue to be addressed under SAICM.
- For Africa it was discussed that many countries cannot afford upgrading the wastewater treatment infrastructure. Additionally, public and political interest in this type of environmental pollution is currently not on the forefront. Therefore, source control can play a particular role in order to lower concentrations in the environment in Africa. With time, additional sewage treatment will also become available. In addition, pharmaceutical production is increasing. There was a call to cooperate on assessing the impact of production facilities rather than relying on single national governments. It was noted that antibiotics are assumed to belong to the most used pharmaceutical agents, whereas measurements in the environment so far focussed on hormones.
- To reduce monitoring costs, it was suggested to use tracer substances of proven indicative reliability (e.g. caffeine in the presented study) to identify surface water stretches strongly affected by urban waste water discharge.
- The issue of fake drugs was raised.
- The issue of financing the costly upgrade of WWTPs was discussed. In Switzerland, the “polluter pays principle” is applied. Political consensus is paramount for the upgrade of specific sewage treatment plants.
- It was discussed that, while dealing with uncertainties, the precautionary principle must be applied in order to protect drinking water resources.
- ISDE suggested that a prioritization of pharmaceuticals is necessary to identify compounds of concern. In Sweden, focus is on antibiotics, endocrine disruptors, and highly produced compounds.
- The issue of different protection goals (ecosystem/ drinking water resources) was discussed.

Ecotoxicological Effects of Pharmaceuticals in the Environment

The session highlighted three prominent examples of ecotoxicological effects caused by pharmaceuticals in the environment, including (1) a near extinction of the vulture population on the Indian subcontinent caused by feeding on the carcasses of cattle treated with the anti-inflammatory drug diclofenac, (2) feminized male fish in lake experiments caused by the synthetic estrogen ethinylestradiol used in birth control pills, (3) effects of veterinary use of the parasticide ivermectin on dung decay, dung insect populations, and aquatic invertebrates.

For the Indian subcontinent, it was shown that the excessive use of veterinary diclofenac led to a dramatic decline of vultures in several regions between 1996 and 2007. Diclofenac was mainly given to cattle for pain relief prior to their death. As the meat of cattle is not being eaten by humans in India, vultures would feast on them and take up all remaining diclofenac residues. Indian vultures have proven to react very sensitively to even low doses of diclofenac, as confirmed by laboratory experiments, resulting in lethal gout in liver and tissue.

The adverse effects of ethinylestradiol on fish were experimentally proven in whole lake studies in Eastern Canada, in which ethinylestradiol was diluted to yield a concentration of 5 ng/L – a concentration detected downstream of waste water treatment plants in several water bodies worldwide. As a result, Vitellogenin concentration, which is an indicator for estrogen impacts in male fish, increased up to 9000 times in male fish species, such as fathead minnows. Although two years after the experiment was stopped, the reproduction of some fish species still remained near extinction rates. Additionally, other animal species were indirectly affected by the experiment. Top predators, such as trouts, which feed on fathead minnows, had less prey available and therefore, their population declined as well. On the other hand, populations of macro invertebrates, such as zooplankton and insects, strongly increased as they themselves serve as prey for the now missing fathead minnows. Four years after the experiment was stopped fathead minnow populations came back to pre-experiment levels, while other fish species recovered less well.

The parasticide ivermectin is used to remove parasites from livestock, but also from pet animals and humans. Studies from four countries for ten different insect species, which fed on dung from livestock with different dosages of ivermectin, show strong effects, such as developmental delay and reduction. Contaminated dung from grazing animals affects diversity and function of dung organism communities. Ivermectin is also highly toxic to aquatic invertebrates. To date, risk mitigation measures are not able to completely mitigate the risk. Due to partly higher parasite pressure, the use of ivermectin in other regions such as Australia or South America is at least as high as in Europe. Less knowledge is available on dung fauna ecology and fate of parasiticides.

The panel discussion dealt with the following questions and comments:

- The ban of veterinary diclofenac in India, Pakistan, and Nepal did not lead to a full recovery of the vulture populations in India. Cattle were treated with diclofenac intended for human use instead. Even though the well documented effect of diclofenac on specific vulture species received global attention, Spain released diclofenac for veterinary purposes shortly after the Indian ban. It needs to be mentioned that this is the only European vulture population, which in addition is strongly related to and as vulnerable as the affected Indian vulture species, whereas exposure pathways differ between India and Spain. Other vulture species, for example in North America, are not as sensitive to diclofenac. Generally, ecotoxicological effects of diclofenac on other bird and mammal species have been detected, however with less drastic effects.
- It was proposed to establish “good agricultural practice rules” for the use of parasiticides.
- European regulations are currently not available to mitigate the effects of any of three pharmaceuticals described above (ethinylestradiol, diclofenac, ivermectin).

- It was discussed if it was more appropriate to regulate all estrogens as a group rather than discussing standards for single compounds.

Stakeholder Perspectives

The World Health Organization (WHO) promotes the access, safety and quality of medicines, including WHO Model List of Essential Medicines, the WHO Pharmacovigilance Programme, and the Prequalification programme and Quality and Safety of Medicines. Antimicrobial resistance is seen as a global public health issue that is impacted by both human and non-human antimicrobial usage. The continuing emergence, development, and spread of pathogenic organisms that are resistant to antimicrobials are a cause of increasing concern. In order to minimize effects of pharmaceuticals on the environment, WHO provides guidelines on the safe disposal of pharmaceuticals, environmental safeguards for public health programmes, and is active in the UN Informal Interagency Task Team on Sustainable Procurement in the Health Sector (see below). In a technical report on pharmaceuticals occurrence in drinking water, WHO concluded that pharmaceuticals are rarely detected in treated drinking water, largely at concentrations several orders of magnitude below the minimum therapeutic doses. The substantial margins of safety for individual compounds suggest that appreciable adverse impacts on human health are very unlikely at current levels of exposure in drinking water. However, the scarcity of systematic monitoring programmes or comprehensive, systematic studies on the occurrence of pharmaceuticals in drinking-water, and limited occurrence data present the key challenges in assessing the potential health risks associated with trace concentrations of pharmaceuticals in drinking-water. Additional open questions are seen regarding the environmental impact of waste water in the manufacturing of medicines, the disposal of unused and expired medicines, the environmental impact of active ingredients or metabolites excreted after use, the exposure assessment and health impact assessment, as well as lifecycle analysis of greenhouse gas emissions and carbon footprint.

From the perspective of EUREAU, the European umbrella foundation for national drinking and waste water associations, pharmaceutical residues in water raise expenses for and complicate drinking water production and wastewater treatment. EU Member States shall take measures necessary to ensure that water intended for human consumption is free from any substances in concentrations that constitute a potential danger to human health and thus emphasising the relevance of the precautionary principle in water policies. Therefore, EUREAU supports current investigations by the European Commission to develop measures for pharmaceutical pollution of water by 2017. EUREAU has identified nine levels to holistically tackle pollution by pharmaceuticals: green pharmacy, (post)authorization, marketing, hospitals, healthcare professionals, households, wastewater treatment, and drinking water production. They concluded that pharmaceuticals are present in all WWTP effluent, in surface water, ground water and in our drinking water resources. Source control measures should be developed, and a holistic strategy is necessary to tackle pharmaceutical substances in water.

From the perspective of Healthcare Without Harm Europe (HCWH), a non-governmental organization, several options for mitigation of pharmaceutical concentrations and effects in the environment were provided. For example, new pharmaceutical products need an environmental risk assessment (ERA) in order to reach the market. However, most pharmaceuticals currently used and found in water bodies were released to the market before that rule applied. Therefore, HCWH demands ERA also for these pharmaceuticals. Additionally, HCWH asked for more research and development of pharmaceuticals that are better absorbed by the human and animal body. This could also be addressed by higher

investments in development and research in green pharmacy. Also, some pharmaceutical plants have shown to highly pollute local water bodies, especially in developing and emerging countries where regulations often are weak. Therefore, HCWH calls for the inclusion of environmental emission rules into the Global Manufacturing Practice (GMP). The option to monitor concentrations of pharmaceuticals in the environment should exist globally.

The perspective of the innovative pharmaceutical production industry was provided by the European Federation of Pharmaceutical Industries and Associations (EFPIA). EFPIA is aware of pharmaceutical concentrations being found in water bodies. Therefore, EFPIA has initiated the Eco-Pharmaco-Stewardship, a life cycle based approach. EFPIA proposed three ways to approach pharmaceuticals in the environment. First, more data needs to be gathered and ERA methodologies as well as options for risk management need to be further developed. Second, a scientific eco-risk knowledge database for new and existing pharmaceuticals will be developed, in cooperation with research institutes. Third, a revised best practice approach for effluent control from pharmaceutical plants will be developed. EFPIA strongly advocated regulating pharmaceuticals under medical, not environmental legislation, because they feel that this is in the best interest of patients.

From the perspective of a national government, the Swedish Environment Ministry reported on pharmaceuticals in the environment with respect to their target of a non-toxic environment by 2020. The Milestone target for environmental consideration in EU pharmaceutical legislation and internationally includes 1) the amendment of EU legislation on medicinal products with raised requirements for companies to carry out environmental tests, 2) the creation of a database containing information on assessments of environmental risks, 3) the factoring in of environmental risks in use into the assessment of benefits and risks of medicinal products according to clear criteria, 4) minimum requirements for production conditions for all products sold on the European market (e.g. in the legislation on Good Manufacturing Practice).

The panel discussion dealt with the following questions and comments:

- Most of the stakeholders provide plans and strategies for action in order to reduce environmental impacts on the environment. However, without harmonization, coordinated development of strategies, measures, and action are not possible and will lead to a multitude of sectoral approaches. The participants of the discussion could not agree on how and by whom such coordination should be hosted; especially, as the geographical scale of the problem calls for a global solution.
- Participants called for capacity building in developing countries including Africa. Regional centres could focus on local monitoring campaigns focusing on regional perspectives. Collaboration between countries is needed.
- Participants raised concerns that online shopping of pharmaceuticals contributes to pharmaceuticals not adequately administered and disposed, since take-back systems are not in place.
- Participants called for proactive activities of both the innovative and generic industry, e.g. collaboration between generic companies and production sites outside Europe.
- With regard to drinking water, there was concern about potential effects on vulnerable populations which may not be adequately covered by current knowledge.

Options for action

As one of the proponents of the nomination dossier of "Environmentally persistent pharmaceutical pollutants" (EPPP) as an Emerging Policy Issue under SAICM, the Ministry of Housing, Land Planning and Environment of Uruguay called for improving the understanding among policy makers and other stakeholders of the risks posed by EPPP to human health and the environment, and the promotion of measures to reduce these risks. Some of the proposed cooperative actions are:

- Provide up-to-date information and scientific advice to policy decision makers and others responsible for chemicals risk management.
- Request International Programme on Chemical Safety (IPCS) to produce a document on the "state of the science".
- Provide information on prevention tools for the manufacturing of pharmaceuticals, like chemical substitution or modification of processes (Cleaner Production Management).
- Raise awareness and facilitate information exchange and networking.
- Provide international support activities to build capacities in developing countries and countries with economies in transition.
- Create an international network of scientists, risk managers, and others that are particularly concerned with EPPP issues to facilitate information exchange, discussion forums, and mutual support in research and advice on translation of research results into control actions.

Lessons learnt from implementing cooperative actions on Endocrine Disrupting Chemicals (EDCs) were provided by the United Nations Environment Programme (UNEP), which are an emerging policy issue under SAICM since 2012. Since several of the more than 800 known EDCs are pharmaceuticals (e.g. hormones), synergies need to be promoted. Another chemical group which is already included in SAICM are nanomaterials, which were presented by the United Nations Institute for Training and Research (UNITAR). Here, pilot projects have been started in Nigeria, Thailand, Uruguay, Armenia, Vietnam, and Jordan in order to deal with pollutant release and classification and labelling of chemicals containing nanomaterials.

The United Nations Development Programme (UNDP) presented the Joint UN Programme of Green Procurement in the Health Sector intended to establish health sector procurement policies and practices that promote and protect health and do not adversely affect the environment or human health and well-being. The programme develops evidence based standards on what constitutes "green" procurement in the health sector, supports UN procurement officers, suppliers, and health actors to be able to operationalize green procurement practices. The activities also involve greenhouse gas accounting for pharmaceutical products and medical devices. It was pointed out that environmental impacts could also be reduced by promoting pharmaceuticals with low ecotoxicological risks, similar to the classification system of Stockholm County Council. However, this option only is valid if similar agents are available and the specific needs of a patient have to be considered as well.

Starting with summarizing the key concerns raised within the course of the two-day workshop, IWW Water Centre provided an overview of potential options for action to initiate a discussion on possible cooperative action under SAICM. They concluded that cooperative

action is needed to address global occurrences of pharmaceuticals in aquatic environments, especially to initiate the multi-sectoral multi-stakeholder approach needed to prevent, reduce, and manage pharmaceuticals entering the environment, to use synergies to raise awareness and guide prescription, application, and disposal patterns, and strengthen capacities in developing countries and countries with economies in transition. They proposed cooperative activities to be considered for inclusion into a global plan of action, following the categories of objectives of the overarching policy issues of SAICM: knowledge and information, capacity building and technical cooperation, risk reduction, illegal international traffic and governance.

Global awareness raising, up-to-date information, and scientific advice to decision-makers and stakeholders were considered most important options for action, with particular attention to needs of developing countries and countries with economies in transition. Additionally, information about pharmaceutical consumption, as well as knowledge about environmental behaviour, fate, and effects should be disseminated. Labelling schemes can be developed and implemented for environmentally friendly pharmaceuticals. Another applicable option for action includes capacity building and technical cooperation to allow for monitoring programmes in developing and emerging countries. Concerning risk reduction, several pathways can help to lower pharmaceutical concentrations in the environment. First, rely on prescription schemes for potentially harmful drugs and avoid unnecessary large package sizes. Second, reduce prophylactic use of human and veterinary drugs. Third, establish and promote collection and disposal schemes for unused pharmaceuticals. Fourth, promote sustainable production and pollution prevention in the pharmaceutical industry. Fifth, promote innovation and development of environmentally sound pharmaceuticals without compromising effectiveness and affordability. Sixth, increase population´s access to sewage connection and biological sewage treatment for sanitation and human health reasons. Finally, also governance aspects need to be considered in order to promote industry participation and responsibility, to adopt policy instruments to guide prescription and usage patterns, to assess and fill gaps in existing policies, legal and institutional framework, and to derive, implement, and enforce environmental quality standards.

The panel discussion dealt with the following questions and comments:

- ISDE presented the Swedish classification system of pharmaceuticals and called for global actions addressing relatively cost effective measures first.
- Participants raised concerns that pharmaceuticals will be continued to be measured in anthropogenically effected water bodies since detection limits are constantly dropping and trace concentrations in the pg/L range can be detected. Therefore, the focus should be set on enhanced ERA in order to prioritize pharmaceutical agents and their corresponding threshold levels.
- Some participants asked for rethinking the scope of the nomination dossier of EPPP to focus on the manufacturing of pharmaceuticals.
- Some participants raised questions how funding of monitoring and research activities could be promoted in developing and emerging countries.
- Concerns were raised with respect to the occurrence of pharmaceuticals in drinking water, which are, based on the current state of knowledge, below minimum therapeutic doses. However, there is concern that the continuous exposure to pharmaceuticals in drinking water may impact vulnerable groups.

- Some participants called for strengthening the dialog between governmental bodies in charge of health and with environmental issues, both nationally and internationally.

The way ahead

The German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) summarized in the concluding remarks that, based on the presented evidence, pharmaceuticals in the environment are indeed a global problem, potentially causing adverse ecotoxicological effects on organisms and ecosystems. Cooperative action in a multi-stakeholder and multi-sectoral context is needed to balance the benefits of pharmaceuticals for the society with the burden and costs of their entry into the environment. During the workshop, it was shown that EPPP is meeting important criteria for nomination as an Emerging Policy Issue under SAICM. If EPPP is successfully nominated, the voluntary framework of SAICM would be an appropriate policy framework to address the issue of pharmaceuticals in the environment on a global level in terms of information and knowledge, risk reduction, governance, technical cooperation, and illegal trafficking.

The workshop encouraged to submit comments, for constructively strengthening and focusing the nomination dossier, to the SAICM secretariat by 11 July 2014 on www.saicm.org. Comments will be considered in the finalized nomination dossier which will be presented at the second meeting of the Open-ended Working Group to be held in Geneva on 14-17 December 2014.