Pharmaceuticals in the environment

Make ideas work!

Tuesday, 6th September 2016

Workshop report
08:30 - 09:00  Registration & coffee

09:00 - 09:10  Setting the scene
  - Anja LEETZ, Health Care Without Harm Europe

09:10 - 09:30  Opening words
  - Maria KRAUTZBERGER, German Federal Environment Agency, Germany
  - Peter KORYTAR, Slovakian Presidency of the Council of the EU, Slovakia

09:30 - 10:30  The European perspective - where are we now?
  Progress on a European strategic approach to pharmaceuticals in the environment
  - Helen CLAYTON, European Commission, DG Environment
  - Ariane VANDER STAPPEN, European Commission, DG Sante (TBC)
  Study to inform the development of the commission's strategic approach to PiEs
  - Sarah LOCKWOOD, BIO by Deloitte, France

10:30 - 10:45  Questions & answers

10:45 - 11:00  Coffee break

11:00 - 11:45  The scientific evidence - what do we know?
  Pharmaceuticals in the environment - global occurrences and perspectives
  - Tim AUS DER BEEK, IWW Water Centre, Germany
  Impacts of pharmaceuticals in the environment on human health and environmental organisms - a critical overview of the scientific evidence and knowledge gaps
  - Thomas BACKHAUS, University of Gothenburg, Sweden
  MistraPharma's recommendations for improving environmental risk assessment of pharmaceuticals
  - Marlene AGERSTAND, University of Stockholm, Sweden
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Anja Leetz, Executive Director of Health Care Without Harm (HCWH) Europe welcomed all of the speakers and participants and spoke about the goal of the workshop: to inform, discuss, and learn from one another to drive the European policy agenda on pharmaceuticals in the environment forward. Everyone invited - both speakers and participants - are experts in this field and have been invited in their capacity to contribute to this important debate. Sharing national experiences and the latest science is important to evaluate where we currently are, what is already happening in Europe and beyond, and how we move forward to develop an EU policy that ultimately protects the environment and human health.

Maria Krautzberger, of German Federal Environment Agency, opened the workshop and spoke about how important it is to continue the discussion and debate about pharmaceuticals in the environment and their effect on human and environmental health. After welcoming participants from a wide range of countries and backgrounds, Ms Krautzberger reiterated that pharmaceuticals are very active biological substances and highlighted how prevalent they are in the environment, with 150 pharmaceutical substances having been detected in the German environment alone. These substances may be causing serious damage to environmental and human health and are present in soil, sediments, surface water, and drinking water. As a result of this, antimicrobial resistance (AMR) is on the rise and is now becoming a serious problem worldwide.

“We need to guarantee safe drinking water for future generations” Ms Krautzberger went on to assert. She also highlighted that current measures need to be amended to better protect public health and the environment, and that there is a need for a holistic approach to implement these measures.

Speaking about research and data, Krautzberger insisted that increased data transparency is needed and that we need more information about the risk of pharmaceutical substances, particularly in veterinary medicine, where little research has been done. Existing research in this area was confined to antibiotics.

Ms Krautzberger finished by stating that there is no lack of ideas (as was evident by the turnout and panel for the workshop), but that the real challenge will be merging existing ideas to develop a strategy which can quickly be implemented.

Peter Korytar, from the Slovakian Presidency of the Council of the EU, was next to speak at the opening of the workshop. In his opening words, Mr Korytar stressed the importance of pharmaceuticals in our society, with the benefits they have for human health and the ability to prolong life and reduce harm. Although everybody is aware of the benefits of
pharmaceuticals, much less is known about the ‘darker’ side of pharmaceuticals.

Mr Korytar highlighted the improper use of pharmaceuticals in animals and improper disposal of unused human pharmaceuticals as two of the biggest risks that can cause adverse effects on the environment.

In terms of effects, the environmental and public health effects were outlined by Mr Korytar, who cited well known cases of the feminisation of fish close to effluent from pharmaceutical production factories, and warned of the potential reduction in availability of effective medicines due to AMR.

Speaking from the EU regulatory perspective, Mr Korytar said that this was a relatively new topic in this regard, and spoke of the Commission’s acknowledgement of the problem and of the Commission’s obligation under Water Framework Directive to develop a strategic approach to deal with the problem of pharmaceuticals in the environment. He expressed his hope that this workshop would contribute to the quick development of this strategic approach.

### The European perspective – where are we now?

In her presentation, ‘Progress on a European strategic approach to pharmaceuticals in the environment’, Helen Clayton from DG Environment of the European Commission opened by saying that it didn’t please her or anyone else working on the issue in the Commission that they had not met the deadline of September 2015 for the development of a strategic approach to address the problem of pharmaceuticals in the environment.

Ms Clayton said that the roadmap was being finalised at the moment, and that a study was being carried out to guide the development of the strategic approach. Once the roadmap has been adopted by the Commission, there would be a public consultation of about 4 weeks.

Regarding the study currently being carried out, Ms Clayton stated that it will identify “what we know and what we don’t know” in terms of the problem. It is expected that the results of the study will help identify actions that could be taken in the shorter and longer term. Work will be done to assess the feasibility and cost of different options.

By the end of the year, the Commission expects to have the first set of monitoring data from the Watch List of substances (including for 6 pharmaceuticals – 3 antibiotics and 3 others) that need to be monitored in water in each EU Member State to confirm whether they pose a risk to or via the environment.

Ms Clayton reported on the on-going review of the priority substances list, and noted that the new monitoring data for the pharmaceuticals will need to be considered (once available).

Ms Clayton also spoke about other ways in which the problem of pharmaceuticals in the environment is being dealt with at the European level, including the Innovative Medicines Initiative (IMI) and the EU project SOLUTIONS.

‘Green Pharma’ was also highlighted as an opportunity for innovation and protecting the environment from pharmaceuticals. Ms Clayton said that pharmaceuticals need to be considered in the same way as other chemicals in terms of their potentially polluting
and mixture effects. Another point she raised was that we shouldn’t just focus on water treatment, but also on the source of pharmaceutical compounds.

Next, Sarah Lockwood from BIO by Deloitte highlighted that there were many options for moving forward in terms of tackling the problem of pharmaceuticals in the environment, and that they were examining the best policy options.

Ms Lockwood also spoke about the size of the pharmaceutical industry (with about 3,000 APIs on the market), particularly in Europe (which has the second largest market in the world) and about how there were many differences between the market for human and veterinary medicine. She also stated that despite progress achieved through the implementation of environmental risk assessment, there is still a lack of data and insufficient information about the environmental risk of the majority of pharmaceuticals.

In terms of environmental contamination from pharmaceuticals, Ms Lockwood said that fresh surface water was the most contaminated and (according to latest studies), no risk to human health from pharmaceuticals in drinking water to human health has been shown. She did, however, stress that more research was needed on this issue and that the long-term effects of pharmaceuticals in the environment could not yet be predicted with current knowledge. Ms Lockwood also mentioned that evidence about pharmaceuticals in ground water, manure, soil, and biota is scarce.

Ms Lockwood also spoke about how pharmaceutical pollution downstream of production facilities was increasingly recognised and that increased outsourcing of API production to developing countries meant that this was turning into a global issue.

She highlighted that the need for further knowledge about pharmaceuticals in the environment should not justify inaction and that current knowledge could already help to improve practices. She then spoke of the many options that could be implemented to tackle the problem along the entire life cycle of pharmaceuticals both now and in the near future, including measures to tackle inefficiencies in the way pharmaceuticals are currently managed.

In the last presentation from a European perspective, Axel Singhofen of the European Parliament opened by stating both his happiness and frustration at being at such an event. Mr Singhofen spoke about his appreciation that such a large group from diverse backgrounds were coming together to discuss this issue but also his frustration that we are still trying to address this issue in the absence of a strategic approach to pharmaceuticals in the environment.

Mr Singhofen spoke about recent changes to the EC internal structure and organisation, which now influence the whole legislative process, making it more complicated and slow.

Speaking of the delay to the development of the strategic approach (and highlighting other examples from chemicals legislation), Mr Singhofen said that we were in danger of “risk-assessing ourselves to death”, and that more affirmative action was needed.
Mr Singhofen added that more data was needed in terms of emissions from manufacturing and that although the European Parliament is clearly concerned, health and environmental protection is being downgraded by the delay of the strategic approach by the European Commission.

The scientific evidence – what do we know?

Opening the session about the scientific evidence relating to pharmaceuticals in the environment, Tim aus der Beek from the IWW Water Centre in Germany spoke about the fact that there is growing evidence showing that pharmaceuticals in the environment are present worldwide. He added, however, that there are gaps in data for Africa and Central Asia and that more research needs to be carried out in these regions.

Mr aus der Beek then highlighted some results from a recent study (conducted in conjunction with Adelphi), which highlighted a drastic increase in pharmaceuticals downstream of cities. The study shows that pharmaceuticals were detected in the environment in 71 countries around the world (covering each of the 5 UN regional groups).

In each UN regional group, approximately 38 different pharmaceuticals have been found in surface water, groundwater, drinking water, and tap water. Additionally, pharmaceuticals have been found in drinking/tap water in every UN regional group of countries. Less data is available in this case.

713 pharmaceuticals have been analysed, of which 142 are transformation products. 631 have been found above their detection limits in the environment, of which 127 are transformation products.

16 pharmaceuticals were found in surface water/groundwater/drinking/tap water in each of the 5 UN regional groups.

Mr aus der Beek also analysed the occurrence of pharmaceuticals in each regional group, which showed that in Asia, for example, more antibiotics have been found in the
environment whereas in Africa, more estrogens have been found. He also stated, however, that this could be due to the fact that research groups in these regions were more focused on finding data about these specific drugs.

Concluding his presentation, Mr Aus der Beek added that urban wastewater discharge is the dominant emission pathway, but that discharges from manufacturing, animal husbandry, and aquaculture are all important regionally.

Following Mr aus der Beek, Thomas Backhaus from the University of Gothenburg in Sweden presented more scientific evidence and knowledge gaps related to pharmaceuticals in the environment.

Mr Backhaus highlighted that pharmaceutical residues in the environment don’t directly impact human health, however, the development of AMR is a major cause for concern, even though it goes beyond pharmaceuticals in the environment.

Highlighting research carried out in different countries, Mr Backhaus spoke about the concentrations of pharmaceuticals found in the environment in The Netherlands, Portugal, Japan, and China, and the effects on the environment and wildlife in those countries.

He spoke about the impacts on human health and presented studies that support the idea that, until now, no effects on humans have been reported. Mr Backhaus, however, stated that one must take into account that there are no studies regarding the effects in vulnerable people, such as children - who respond to lower doses of pharmaceuticals.

He then presented some studies about the impacts on environmental organisms: the effects of oxazepam on fish behaviour, of clotrimazole on marine algae, chlortetracycline on natural lake bacterial communities and metformin on fish development and fecundity.

Concluding his presentation, Mr Backhaus said that concentrations of pharmaceuticals in surface water may approach levels of concern and that we are increasingly dependent on water purification technologies and this demands continuous monitoring. Unlike chemicals, when evaluating pharmaceuticals’ hazard and risk assessment, one must take into account that there are more categories of pharmaceuticals than chemicals, and that the pharmaceutical group must also be considered. Pharmaceuticals should also be grouped according to their therapeutic effect, which is an important parameter when carrying out these types of assessment.

The final speaker in this session was Marlene Ågerstand from Stockholm University. Ms Ågerstand outlined ten recommendations from MistraPharma which are based on results from research into the issue of pharmaceuticals in the environment, reviews of available Environmental Risk Assessments (ERAs), and lessons learned from other regulatory frameworks such as REACH, the Plant Protection Product Regulation (PPP), and the
These ten policy recommendations are:
1. Require ERAs for products put on the market before 2006 (as older products are not safer than newer ones)
2. Add requirements to assess the risk for development of antibiotic resistance
3. Perform only one ERA per API
4. Refine the Tiered Approach (in order to have a greater focus on problematic APIs)
5. Perform mixture toxicity assessments on APIs with similar MoA
6. Mandate the use of all available ecotoxicity studies
7. Include environmental risks in the risk-benefit analysis
8. Require review of ERAs at regular intervals
9. Include data on emissions from production in ERAs
10. Increase transparency

National policies – what is being done?

The workshop continued with a discussion about national policies and what is being done at an individual country level to tackle the problems associated with pharmaceuticals in the environment.

Firstly, Sandra Mol from the Ministry for the Environment in The Netherlands outlined the Dutch approach to the problem. Ms Mol began by outlining that although they had been working on pharmaceuticals since 2007, there still isn’t a clear picture about the effects and problems associated with pharmaceuticals in the environment.

The Ministry, however, are working with all stakeholders to gain a common understanding of the problems that can occur at all stages of the life cycle of pharmaceuticals. Ms Mol highlighted that there should be more collaboration at the European level, in particular with DG Environment and DG Sante.

One of the Dutch pilot projects she outlined was that of the Ministry of the Environment, who are facilitating municipalities and pharmacists by providing guidelines for the collection of unused medicines. She also spoke about wastewater treatment, and how projects are being run at several hospitals, 5 of which are using the Pharmafilter system. Mol concluded that not everything can be done at a national level - for example the improvement of ERAs and the availability of data needs to be encouraged by legislation at an EU level.

Next, Maria Wallin of the Chemicals Division of the Swedish Ministry of Environment & Energy outlined their activities in the area. She said that there was a broad political consensus regarding these issues in Sweden and that eight milestone targets had been established regarding hazardous substances.

One of these milestone targets is aimed at tackling pharmaceuticals in the environment and there are four proposed measures to reach this target. These are:
1. Information on environmental impact of medicinal products should be made available
2. Environmental risk should be considered in risk-benefit to manage risk mitigation
3. There is a need for more appropriate and better environmental tests and a revision of the ERA guideline
4. Development of regulatory instruments in order to set minimum requirements for manufacturing conditions
Ms Wallin highlighted the need for an EU wide database to provide information on environmental assessments for pharmaceuticals in Europe and stated that cooperation between ministries and authorities of health and social affairs, industry, researchers, healthcare providers, and water management bodies is crucial.

She also spoke about the national Swedish Pharmaceutical strategy (2016-2018) that aims to ensure the sustainable use of pharmaceuticals. This strategy is chaired by the Swedish health ministry and includes projects related to containing environmental impacts of pharmaceuticals.

Finally, Ms Wallin also said that precautionary measures could and should be taken within EU regulations on human and veterinary medicinal products and in international agreements.

Local experiences - practical steps towards reduction

After the lunch break, the workshop continued with a session focused on local experiences of pharmaceuticals in the environment, as well as practical steps being taken at this level.

Thomas Ternes from the German Federal Institute of Hydrology opened the session with a presentation about the products of transformed pharmaceuticals, their formation and occurrence in the urban water cycle.

Mr Ternes spoke about the incomplete removal of pharmaceuticals in wastewater treatment plants and highlighted the formation of transformation products in these plants. He explained how these transformation products were frequently present in groundwater and drinking water.

He gave the example of acyclovir – which, in biological wastewater treatment, is transformed into Carboxy-Acyclovir and via ozonation this transformation product is further converted into COFA (a stable transformation product). This was shown to have occurred in lab-scale experiments as well in pilot scale experiments, which replicate the ozonation system in advanced wastewater treatment facilities.

Ternes also gave the example of carbamazepine and oxcarbazepine (antiepileptic drugs)
- the transformation products of which were found in wastewater post treatment.

The conclusion was that, in both examples, transformation products found in the environment can have a higher toxicity than the API itself.

Mr Ternes concluded by saying that due to their enhanced polarities, metabolites and transformation products of pharmaceuticals are present in surface water, ground water and drinking water, sometimes in considerable concentrations. He also said that transformation does not always mean that detoxification occurs, as there are examples where transformation products are more toxic and abundant than the parent compounds.

Following this, Jaroslav Slobodník from the Environmental Institute of Koš in the Slovak Republic spoke about the risk assessment of pharmaceuticals in the Danube River Basin.

Mr Slobodník outlined the project – a transnational network established to monitor the Danube River Basin, which carries out surveys every 6 years. The project spans 14 countries in the EU and in 2013, monitoring was carried out at 68 sites.

At these sites, 7,767 compounds were identified, many of which were pharmaceuticals or their transformational compounds. Mr Slobodník highlighted that more pharmaceuticals were found in Romania and Bulgaria than anywhere else, which was probably as a result of wastewater treatment plants there not operating properly.

He said that the benzodiazepines oxazepam and clobazam were found in high frequencies in the Danube River Basin (85% for oxazepam and 31% for clobazam).

Mr Slobodník also explained that they used the NORMAN approach to evaluate the data and when monitoring data were missing they employed the NORMAN Exposure Index.

Three pharmaceutical substances were found to be within the top 20 measured chemicals in the Danube River.

Mr Slobodník concluded by saying, however, that although pharmaceuticals were omnipresent in the Danube River Basin, they were not among the top toxic pollutants and that more in-depth emission studies were needed. He stated that antibiotic resistance should be taken seriously and that careful monitoring is needed before any outbreak occurs.

Pauline Göthberg from the Sustainable Procurement section of the Swedish County Councils and Regions then spoke about the sustainable procurement of pharmaceuticals, giving examples from Sweden.

Ms Göthberg highlighted the significant purchasing power of governments and regions,
stating that they can use this power to encourage more environmentally friendly products. In Sweden, County Councils make up 21% of the market for pharmaceuticals, with pharmacies accounting for the other 79%.

She then outlined the five steps that should be taken in terms of sustainable procurement:

1. Code of conducts established for suppliers
2. Contract clauses put in place
3. Desktop follow-up
4. Audits of suppliers and sub-suppliers
5. Corrective action plans

Ms Göthberg stated that this was not just a European problem, and that by importing pharmaceuticals and pharmaceutical ingredients, we were simply exporting the problem elsewhere. In particular, she highlighted the case of India, where over 80% of wells are contaminated and there are also problems in terms of human-rights violations.

As procurers are often not allowed to inspect the premises of sub-contractors, there is a lack of transparency, which needs to be tackled by internal capacity building at national and regional levels in Europe. She concluded that public procurement can be extremely useful in reducing pharmaceuticals in the environment.

The final speaker of the session was Thomas Møller, Environmental Coordinator at the Aarhus University Hospital in Denmark, who outlined the environmentally effective treatment and mapping of toxic wastewater in hospital wastewater.

Mr Møller began by outlining some of the different technologies being used to treat water, such as MBR technology, which is currently being operated in Herlev Hospital in Denmark, and MBBR (Moving Bed BioReactor) technology which has been tested at Aarhus University Hospital in 2015 and is now being tested in the MERMISS project in Herneing Vand.

This testing will allow for the mapping of the removal of pharmaceuticals from wastewater and also the calculation of treatment costs. In particular, mapping the environmental benefit of removing pharmaceuticals from wastewater is highly relevant as the process is quite expensive.

Mr Møller presented the results of one such mapping project - which was carried out at Aarhus University Hospital - which found that there was a significant (110%) increase in the
total environmental impact from drugs used at the hospital from 2011-2015. This contrasted with a less significant (60%) increase in the environmental impact from hospitalised patients over the same period.

He also said that when calculating the environmental impact of the drugs distributed by AUH between ambulant and hospital patients, the values are much higher in the ambulant area and are increasing.

In his conclusion, Mr Møller said that it was time to think and reflect before more capital is invested. As the removal of pharmaceuticals from wastewater is relatively expensive, we should carefully consider where technology is implemented. He finished the session by saying that a common international list of all toxic pharmaceuticals is very much needed, and that this is something that AUH have been advocating for.

The way forward and possible solutions

The workshop concluded with a panel discussion about the way forward and possible solutions to pharmaceuticals in the environment.

During the discussion, Ruth Stringer, International Science and Policy Coordinator with Health Care Without Harm stated that we know that antibiotics are over-prescribed and that the extended producer responsibility concept (already used in other sectors) should be extended to the pharmaceutical industry also. She also argued that the pharmaceutical industry should be made responsible for the taking-back of unused pharmaceuticals.

Speaking of wastewater treatment, Ms Stringer said that this issue need to be higher on the agenda of aid agencies and that facilities in developing countries are primitive or do not exist.

Helen Clayton from DG Environment at the European Commission stated that the promotion of a healthier lifestyle amongst the public might reduce the need for pharmaceuticals in the first place.

Sandra Mol, from the Ministry of the Environment in The Netherlands said that there were regional differences when it comes to tackling the problems associated with pharmaceuticals in the environment and that we need to work on all levels to solve these.

Continuing on this theme, Axel Singhofen from the European Parliament said that it was
time to take a look at the broader picture when it comes to pharmaceuticals. He stated that we were up against tough opponents, as the pharmaceutical industry is one of the most prolific and brutal in terms of marketing, lobbying, and withholding data. He concluded by saying that the pharmaceutical industry often thinks that they are untouchable as they provide us with life-saving drugs but that we shouldn’t grant them this untouchable status.

In her concluding remarks, Sarah Lockwood from BIO by Deloitte highlighted that two things were crucial in terms of talking the problem of pharmaceuticals in the environment – transparency and raising awareness – and that medical practitioners have a key role to play in this regard.

Thomas Backhaus of the University of Gothenburg elaborated on this by highlighting the need for data transparency and a better quality of data. He said that REACH was a poor example of this in practice and that we need to look at the regulation of biocides and pesticides and treat pharmaceuticals the same way, particularly when it comes to the principle of substitution.

On this issue, Ruth Stringer said that REACH was an example of everything that is wrong with environmental legislation and that we should avoid making the same mistakes with pharmaceutical legislation.

Bringing the final session of the day to a close, Anette Küster from the German Environment Agency said that many little steps need to be taken to tackle the problem of pharmaceuticals in the environment and that it is very important to have an EU strategy to enable all stakeholders to identify their own role in reducing the entry of pharmaceuticals into the environment.

The Pharmaceuticals in the Environment: Make ideas work! workshop took place in Brussels on 6th September 2016. Over 60 participants from 8 different countries took part and heard from 16 speakers on the day.
Questionnaire

In addition to Q&A sessions with all our speakers and a closing panel session, participants were also able to offer their opinions on the issue of pharmaceuticals in the environment through a short questionnaire.

100% of those who participated in the questionnaire agreed that veterinary medicinal products should be included in an EU strategy and a majority of respondents (90%) believe that the long-awaited EU strategy should be followed by a legislative proposal for a sustainable use of pharmaceuticals.

Questionnaire respondents were also asked their thoughts on effective measures to address the issue of pharmaceuticals in the environment. The three most popular measures (accounting for nearly 70% of the answers) relate to awareness, production, and mitigating pharmaceuticals in the environment. The top suggestions were: wastewater treatment, public awareness, and stronger legislation/mandatory environmental considerations. The remaining suggested measures relate to other stages of the pharmaceutical life-cycle such as healthcare professionals/patients: reducing use of pharmaceuticals, or water agencies and research groups: further collaboration on collection of data, and governments. Other approaches to industry were also mentioned i.e. incentivising greener production.
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The Health Care Without Harm team

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