



**EFPIA and Health Care Without
Harm Europe (HCWH) - Joint Debate
on Pharmaceuticals in the
Environment (PIE)**

24 October 2014

Science 14 Atrium, 14b Rue de la Science,
1040 Brussels

Program

Moderator **Faraz Kermani** (Informa)

10.05 Welcome note from the organisers

Richard Bergström, European Federation of Pharmaceutical Industries and Associations, EFPIA, Director General
Anja Leetz, Health Care Without Harm Europe, HCWH Europe, Executive Director

10.15 Introduction by the EU Commission

Ariane Vander Stappen, DG Health and Consumers, DG SANCO
Helen Clayton, DG Environment, DG ENV

10.45 Panel I: Managing environmental criteria in R&D, manufacturing and supply chain

Dan Caldwell, European Federation of Pharmaceutical Industries and Associations, EFPIA
Joakim Larsson, University of Gothenburg
Ton Breure, Dutch National Institute for Public Health and the Environment, RIVM
Kia Salin, Swedish Medical Products Agency, MPA
Andreas Hartmann, European Generics medicines Association, EGA

12.00 NETWORKING LUNCH

13.00 Panel II: Use of Pharmaceuticals

Bengt Mattson, European Federation of Pharmaceutical Industries and Associations, EFPIA
Andre Herchuelz, The Standing Committee of European Doctors, CPME
Åke Wennmalm, Stockholm County Council
Nicole Adler, German Federal Environment Agency, UBA

14.00 NETWORKING COFFEE

14.30 Panel III: Disposal of Pharmaceuticals

John Chave, Pharmaceutical Group of the European Union, PGEU
Raquel Gomes da Silva, Valormed
Romain Journal, French National Pharmaceutical Industry Trade Organisation, LEEM
Anders Finnson, EurEau (Europe's drinking water and waste water service operators)
Issa Nafu, noPills project

15.45 Concluding remarks and recommendations

Moderator, EFPIA and HCWH

1. Key Discussion Points:

Panel I: Managing environmental criteria in R&D, manufacturing and supply chain

EFPIA raised awareness that the pharmaceutical industry (through EFPIA, AESGP and EGA) has developed an Eco-Pharmaco-Stewardship (EPS) proposal, which has the potential to offer solutions throughout a product's life cycle to address some of the issues highlighted in the BIO-IS report.

Legacy products for which Environmental Risk Assessment (ERA) have never been done are an important concern. EFPIA highlighted that an IMI project (iPIE) should provide tools/solutions to assist with prioritisation of legacy substances.

Some stakeholders (e.g. regulators, NGOs and academics) favour having the Environmental Risk Assessment (ERA) considered as part of the benefit risk assessment for Marketing Authorisation (MA), and for environmental aspects included in GMP. Industry stakeholders feel inclusion of the ERA, as part of the B/R assessment (approval limiting), is not in the best interest of patients, as long as the continuous monitoring of environmental impacts of products that enter the market takes place. Reference was made to extended ERA scheme proposed by the pharmaceutical industry.

Panel II: Use of Pharmaceuticals

There was willingness by all stakeholders to collaborate, in particular with regard to raising public awareness and educating physicians and other healthcare professionals. HCWH already works to inform medical professionals on practices that can reduce unnecessary emissions of pharmaceuticals. EFPIA was willing to provide financial support for the 'Do not flush it!' campaign and would search for collaboration partners from other stakeholders.

Member States are responsible under the Medicinal Products Directive for ensuring appropriate mechanism for collection of pharmaceuticals. However, not all Member States have implemented collection systems and many of the systems could operate more effectively. Based on different sources only around 20 Member States have a system in place. Some stakeholders felt that harmonisation may be an appropriate way forward; others felt there should be scope for Member States to determine what is appropriate for their particular circumstances.

The collection systems of France and Portugal were presented at the conference; both are supported by multiple stakeholders and funded partly also by the pharmaceutical industry. Germany, in contrast, utilizes the municipal solid waste collection system to collect unused medicines, resulting in appropriate destruction at no incremental cost.

The benefits of the Swedish FASS system (environmental classification of medicinal products) were discussed (www.fass.se). It appears that there is no experience of a patient not having received the correct treatment because of the Swedish environmental risk-rating scheme.

A few stakeholders (e.g. environmental regulators) supported the idea of a monograph system for substances in order to increase the availability of

information of substances. Industry stakeholders expressed their reservation as the monograph system refers to hazard-based and not risk-based approach.

Industry is keen to promote the better use of EPAR (European Public Assessment Report) and making ERA data available as some companies do voluntarily already at the moment. This would facilitate more data transparency as called by regulators, academics and NGOs. The need for a database was brought up, which would facilitate developing appropriate risk strategies for active pharmaceutical ingredients.

Panel III: Disposal of Pharmaceuticals

Source control and reduction of discharges, publication of data and companies responsibility was discussed and identified and advocated e.g. by some academics, regulators and NGOs.

Third party manufacturing was discussed, and different opinions emerged on the level of responsibility what companies have for their third party manufacturers.

Antibacterial resistance is an issue recognised by all. Academics suggested that it can occur due to chronic exposure to concentrations below current established limits.

The effect of mixtures is not well understood, and this uncertainty needs to be better researched.

There is a need to improve test methods for measuring environmental impact of substances.

There was a common understanding that separate collection of different wastewater streams from buildings would involve excessive pipework costs.

Some believe that there is a need for further stability studies aimed at extending current short shelf lives assigned to pharmaceuticals. Industry would in that case require measuring stability in real-life conditions, which is a challenge that has been discussed for years without resolution .

The public needs better education on the correct use of medication to prevent either under use, overuse or misuse.

General:

BIO-IS report will serve as a basis for developing an EU PIE Strategy.

PIE strategy for EU needs to be in place by September 2015. It will consist of identifying possible actions. The options need to be prioritised – impacts/costs/benefits calculated. There will be further public consultation. The Commission should propose by September 2017 measures to be taken at Union and/or MS level, where appropriate. The possible measures could range widely in nature.

All stakeholders need to be involved in addressing Pharmaceuticals in the Environment!

2. Discussion Notes

Opening Speakers

Richard Bergström (Director General, EFPIA)

Anja Leetz (Executive Director, HCWH)



Anja Leetz shared that HCWH is a global non-governmental group with over 500 members from hospitals, regions, local councils and unions, working on subjects such as pharmaceuticals, substances in medical products, procurement of goods to the health sector, etc. The European group has been active for 16 years. Anja stated that the main purpose of the workshop was to (i) listen to others (ii) network,

and (iii) reflecting and changing ones own practice, leading to long-term improvement for the environment and public health. HCWH Europe has been actively engaged on the subject for a number of years and promotes reduction of unnecessary use of medication, improved prescription practices, safe collection of unused medicine and awareness raising of impact of pharmaceuticals in the environment for general public, doctors and patients. The organisation is also involved in policy development at EU level and shares best practices among their 76 European members. The current challenge of pharmaceuticals in the environment is only to increase and needs addressing by all stakeholders.

Richard Bergström shared that 15 years ago there was a 'poison-free environmental initiative' in Sweden, which had the goal of no CMRs entering Swedish territory. This initiative had prompted discussion about safe use of pharmaceuticals and the need for industry to talk, educate and change. Richard admitted that he was biased towards the Swedish approach, which provides risk information about pharmaceuticals and allows patients to make a choice. Richard shared information about the collection/takeback scheme that operates in Sweden, which has been in place for >10 years. He showed one of the plastic bags that are given out by pharmacists supplying drugs to patients as an example and referred to the importance for many stakeholders acting together in terms of collection of unused medicines. Richard concluded, "Industry needs to better understand and shape our proprieties".



Introduction by the EU Commission:

Speakers:

Ariane Vander Stappen (DG SANCO) and **Helen Clayton** (DG ENV)

Helen Clayton spoke about the Water Framework Directive (WFD) and Watch List. She commented that, although it has been argued that pharmaceuticals are different from other chemicals because of their use, like other chemicals they in fact do end up in the environment. The WFD is aimed at ensuring good quality of ground and surface water. Helen stated that the intention of regulating substances under the WFD is not to present an obstacle, but to help ensure the safe use of chemicals including pharmaceuticals. She pointed out that DG SANCO has already shown concern by committing to address the issues of ecopharmacovigilance and antimicrobial resistance. The BIO-IS report will serve as a basis for developing the Commission strategic approach to PIE. The Commission September workshop had been structured around a life-cycle approach, and on-going work needs to consider all parts of the cycle, relevant sectors of the community and different areas of legislation.



Ariane Vander Stappen said that there was a need to dig further into difficult questions. There are differing views about whether current ERA's are appropriate or need to be improved, whether current testing is appropriate, whether a monograph system for APIs is the way forward and if yes, how to do this. What would be the difficulties? Would it be suitable for new and/or legacy substances? How would the system work? Could data from other users be taken into account? The pros and cons would need to be worked out. Ariane raised the issue of going beyond the BIO-IS Report in the actions needed in EU. A



large proportion of substances are made outside the EU, and so would GMP be appropriate to use as a vehicle? If not, why not, and what other methods are there that could be used (e.g. need for a manufacturing certificate/accreditation scheme)? Would classification of products encourage use of greener products? What risk would such a scheme pose to patient prescription? Would patients be deterred from taking the medicine if deemed an environmental hazard? If yes, how could this risk be overcome? How can over prescription and over consumption be avoided? What happens once medicines are returned to the pharmacies? Are takeback/collection schemes effective? What are the options?

Helen noted that the PIE strategy needs to be in place by September 2015. The options need to be prioritised based on estimates of impacts/costs/benefits; the full impact assessment would follow with any subsequent proposals for measures. There will be further public consultation.

Ariane pointed out that there are legislative and non-legislative options.

A question was asked as to whether the Commission would use the findings from the IMI project. Helen agreed that translation of science into policy is not always rapid, but the results of the IMI project had the potential to help prioritising a large number of substances that otherwise need to be looked at.

Ariane said that EMA could be requested to revise guidelines relating to ERA if a need is identified.

A question was asked as to how substances had been selected for the Watch List. Helen explained that the major factor was the predicted risk quotient. The purpose of the Watch List is to get more monitoring data to determine the actual risk. In the case of erythromycin, for example, a high-risk quotient had been predicted based on toxicity and estimated environmental exposure as well as limited monitoring. There was also a potential link to antibiotic resistance development, but that was not the reason for considering it for the Watch List.

Panel I: Managing environmental criteria in R&D, manufacturing and supply chain

Panel I focused on how the environmental criteria is and could be even better taken into account in R&D, manufacturing and supply chain.

Dan Caldwell (Johnson&Johnson, EFPIA) shared that industry is actively engaged and wants to be an active partner in addressing the issue of PIE. He shared information about the IMI project, pointing out that it is a 10 million Euros project aimed at eco-risk-prediction (ERP). He shared that there are 3 major pathways by which pharmaceuticals get into the environment (i) patient use/excretion (ii) improper disposal, and (iii) discharge from manufacturing. There is a need to avoid another Hyderabad type situation and responsible companies have programs to address external contract manufacturing organizations (CMO). IED limits manufacturing discharges, but most companies go beyond this and set in-house limits for their API's. They also expand in-house expectations to CMO's for effluent assessment. Dan gave an outline of Eco-Pharmaco-Stewardship and the main pillars covered: 1) extended ERA, 2) extending the science through IMI project and 3) emission control. The approach taken for the latter is based on best practices, benchmarking and a risk based approach.



Joakim Larsson (University of Gothenburg) stated that emissions from manufacturing can be much higher and often significant, with industrial discharges being up to one million times higher than concentrations found in patient's urine/faeces. He said that the

concentration levels can reach toxic levels. Pharmaceuticals are often highly toxic, potentially leading to antibiotic resistance with both local and global impact. Key challenges are (i) the large proportion of manufacturing outside the EU; (ii) environmental regulation very rarely covers the whole effluent toxicity/emissions; (iii) it is difficult to predict manufacturing emissions and measurements are needed; and (iv) there is little incentive to invest in upgrading WWT. A Swedish initiative is for the county hospitals to require environmental monitoring by the manufacturer. Companies compete to get tax subsidies. Joakim considered that environmental aspects should be included in GMP and that the Swedish are going to do this. He also thought that the ERA should be revised after MA if needed. Joakim considered it possible to include discharges in certain circumstances. He also thought that there should be transparency throughout the supply chain to ensure subcontractors manage waste properly.

Ton Breure (Dutch National Institute for Public Health and the Environment, RIVM) highlighted that there are research activities going on all over the supply chain including Waste Water Treatment (WWT) involving collection of excretion products – urine collection into holding tanks, solidifying and incineration. Stakeholders have been identified throughout the chain with decisions being made on how you can influence – R&D, production, registration etc. – to avoid discharges into the environment. There is a need to look at the decision making and identify key 'gates' to change decisions, for example registration – a point at which environmental information is badly used – and a need to use environmental criteria to determine if the product should be brought to market. When a compound is registered there should be a need to pay for take up in the insurance package. He thought that environmental aspects should be brought into GMP particularly outside the EU. What criteria can you use to avoid discharge/environmental damage?



In the Netherlands, pharmaceuticals have been found in low concentrations everywhere. It is not just the concentration of a substance that poses a problem but also the effect of mixtures; mixtures are not investigated. The risks of chronic exposure to unknown mixtures are not known.

Kia Salin (Swedish Medical Products Agency, MPA) stated that source control is paramount. She pointed out that different topic link – (i) improve testing methods, (ii) data collection and sharing, (iii) prioritization, (iv) negative impacts from emissions and consumption, and (v) minimum set of requirements for production with regard to emissions. Kia made the point that testing methods needed to be improved and information to be provided to the authorities in order to take adequate measures for protection.

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Andreas Hartmann (European Generics Medicines Association, EGA) shared that EFPIA, AESGP and EGA have developed Eco-Pharmaco-Stewardship proposal that should help address some of the issues. He stated that EGA acknowledges the issues and is committed to limiting the impact of PIE. He shared that many companies go beyond current regulatory requirements. Several have developed company standards



that aim to protect the environment in regions where there are no laws. Others have sophisticated programmes in place that often reach out to CMO's. It can be a challenge to influence CMO's. PSCI is aimed at managing supply chain issues via setting principles and standards, together with auditing. It has helped strengthen PiE as a priority: PiE is now in the top 10 of key priorities in the field of Environment, Health and Safety. Many companies have set safe levels < NOAEL. In the absence of a NOAEL a min. concentration limit is set (e.g. 10ng/L). When there is no apparent environmental risk, the loss minimisation can still be set at a determined percentage of the tonnage handled on site (e.g. 1%). Sandoz favours the use of internationally accredited CMO's (i.e. ISO14001, OHSAS 18001. There are efforts in place to train and audit CMOs. If performance requirements are not met this can lead to a termination of collaboration.

Andreas went on to talk about the option of including environmental aspects into GMP, saying that this was not the right place – the focus of GMP should be on patient and product safety. To include environmental aspects would dilute the current system and its' focus.

Key points from the Panel I Q&A session:

Joakim Larsson said that GMP should be used as a mechanism to help manage PIE. He thought it should work in parallel with other regulations. He also added that ERAs should be updated after MA if needed. He pointed out that transparency was an issue. There is a need to know where large companies are manufacturing their products and that they should be responsible for their production in places like India etc.

Dan Caldwell said that he thought the current ERA process is fit for purpose but that it could be 'tweaked'. He pointed out that J&J had been open with a lot of environmental data provided to IBM. He also pointed out that imposing EU criteria on other manufacturing companies in other regions is very difficult. J&J has a maturity ladder that they use with the purpose of bringing all of their CMOs to Level 4. If this can't be achieved they stop using this particular CMO.

Kia Salin shared that GMP could be used not to cover all of the environmental issues, but to help prioritise for a few APIs that are well defined – for example to ensure that discharges allow required limits. She supported use of GMP. She encouraged industry to come up with new solutions. One might be an external certified body, to whom industry provides data that show discharges are controlled, but it would need to be discussed how this can be applied outside the EU.

Ton Breure pointed out that the information that J&J had made open to IBM was limited to 4 compounds and that only 3 of these had standards set.

Comments were made that responsibility of CMO manufacturing is with the main company contracting the work if the process is theirs. However, if the contracted company uses the same process for a number of companies this is more difficult as they are separate legal entities.

In the case of off-patent pharmaceuticals, quality standards are already in place, but EHS is less standardised. Andreas Hartmann pointed out that performance standards can be set, but the company contracting out the work cannot be held responsible for the CMO's performance.

Joakim Larsson said that there is no paper that shows low levels of emissions from manufacturing. Some suggested that this is because this type of information does not make the news/gets published. Joakim went on to say that manufacturers have the moral responsibility over the production of their medicines.

A comment was made that India has in fact got some of the best (as well as worst) factories, and that general assumptions should not be made based on publication of the worst case scenarios. There needs to be a way to show a more balanced view of what is actually taking place.

Joakim responded to a question about the risks for direct effect on humans through drinking water is much less of an issue than direct effects in water-living organisms.

Helen Clayton repeated that the various options need to be looked at and a cost/benefit approach should be used to evaluate the options.

When asked about cost to industry of controlling manufacturing effluents, Dan Caldwell shared that it took approximately 100 million dollars to set up a production line in India. Where you have multiple facilities making product for different customers it is a lot more difficult. Analytical methods are costly to develop. He pointed out that the IMI project should provide solutions for prioritizing legacy compounds. Low effort may be as low as 10 million if you have good prioritization tools vs lab testing 3000 API's.

Helen Clayton pointed out that you can't measure anything if you don't have methods. She also raised that very little is known about mixtures, including the interaction of medicines with other chemicals.

Joakim Larsson said that there no sufficient effort to manage manufacturing discharges. There is no regulation to measure toxicity of an effluent. On line systems with test organisms can be used in manufacturing. EPA has methods that are fit for purpose.

A comment was made that a lot of work has been done on PiE, in particular in Sweden, and while good techniques have been developed, measurement data is missing.

Jason Snape, Astra Zeneca (AZ) shared that AZ sets emission limits, measures and sets expectations for compliance. They have a monitoring strategy to ensure compliance. All of this work is transparent and cited on their Corporate Social Responsibility website.

Panel II: Use of Pharmaceuticals

Panel II focused on how the environmental risk assessment might be better utilized in market authorisations, how regularly updated post-approval could include actual exposure estimations (revision of PEC or MEC) and new information on potential effects (revision of PNEC), how health care professionals' practices could be optimized, and how an environmental classification of pharmaceuticals can be used to reduce pharmaceutical emissions.

Bengt Mattson (Pfizer/LIF Sweden/EFPIA) shared details of the Eco-Pharmaco-Stewardship (EPS) initiative, developed by industry associations EFPIA, EGA and AESGP, which consists of 1) extended ERA, 2) extending scientific knowledge base through iPIE/IMI and 3) emission control scheme. The industry opinion on ERA is that this should not be part of the marketing authorisation decision, as the latter must focus on effectiveness and efficacy of the product to patients. Under EPS and the Extended Environmental Risk Assessment scheme (eERA), regular reviews of ERA would be undertaken, including the re-evaluation of PEC/PNEC and refinement of the PNEC, if needed. Regulation would be needed in regards to the inclusion of field studies and application of risk management measures (RMM) within EPS. Bengt highlighted that information campaigns are a vital way to ensure the correct use and disposal of pharmaceuticals. Other areas of potential RMMs that need discussion include dosing regimes, urine capture and WWTP (waste water treatment plant) upgrades if deemed necessary. Bengt also underlined that accountability lies with a wide range of stakeholders and an understanding of how compliance can be achieved while ensuring patient safety.



Andre Herchuelz (The Standing Committee of European Doctors, CPME) raised concerns that pharmaceuticals have a relatively short shelf life of between two and five years, which is too short in his opinion. He suggested more stability studies are needed to show that the materials can still be used after the current timelines. A Swedish delegation has developed position papers on the issue of a shelf life, which are expected to be released by the end of 2014.



Åke Wennmalm (formerly of Stockholm County Council) presented Sweden's classification system of pharmaceutical substances that has been in operation for nine years. The classification, which was originally hazard based, extended to include risk assessment when LIF, the trade association for the research-based pharmaceutical industry in Sweden, became collaborators and took ownership of the scheme. More information is available at www.fass.se. The importance of PiE in the Swedish system was explained: medical students receive training as part of their education; environment and quality are considered as part of procurement; information is provided to patients; a collection system has been implemented and annual measurements are taken in sewage treatment and drinking water. Åke Wennmalm supported the inclusion of environmental aspects under GMP. Stockholm and UBA are already coordinated on this and the Netherlands, France and Italy were said to be interested in expanding. He recognised that the Swedish environmental classification process has effectively raised awareness about PiE and prescription habits have changed. Sweden has continued to push the EU on this issue.



Nicole Adler (German Federal Environment Agency, UBA) explained that the market authorisation for veterinary medicines includes the ERA as part of the



decision-making process, but in the case of human pharmaceuticals it does not. The ERA can identify substances of concern and this regulation is needed to protect the environment. Currently post Market Authorisation (MA) studies are not binding and there is no ecopharmacovigilance in case of human medicines. An ERA for legacy products is not foreseen by the current Directives. Nicole also highlighted that data from the environmental risk assessments are not transparent or readily available.

Though industry sometimes publishes data and endpoints online or in publication to inform the public about environmental issues, this is voluntary and is not regulated by the law. An independent authority does not normally assess information provided by industry in the public domain.

As a result, there is a need for a database that includes valid ERA information and monitoring data. Nicole presented the position that the ERA should be part of MA, there should be a monograph approach, legacy products need to be captured and there needs to be control post MA. She also suggested that the ERA is part of the risk/benefit assessment for human medicines to strengthen the requirement to perform ERA studies and allow post-marketing control.

Key points from the Panel II Q&A session:

Richard Bergström (EFPIA) pointed out that stability tests are conducted under standard conditions but often pharmaceuticals are not stored under such conditions by consumers/patients. As a result, ways to emulate real-life storage conditions could be explored if the issue should be addressed.

An attendee raised the issue of lack of transparency in ERA data and queried how industry would provide more information on substances. Bengt Mattson stated that industry opposes the idea of a monograph system, as it would indicate hazard rather than risk. Nicole Adler countered, stating that substance or product approach should be the way forward, which can also be risk-based.

An attendee asked how patient benefit would be analysed if ERA were included in decision-making regarding MA. Nicole Adler stated that this would require assessment by an independent authority. Bengt Mattson supported the inclusion of a post-MA commitment involving a pharmacovigilance-like approach.

One attendee stated that the law should prioritise patients' needs and that the ERA should not prevent access to medicine. Another suggested that PiE is really more of a public health issue and pharmacies should be required to supply more information on the amounts of pharmaceuticals used, for instance information on the potential to reduce pharmaceutical use by still preventing a disease would be interesting.

Panel III: Disposal of Pharmaceuticals

Panel III examined the end of the life cycle of pharmaceuticals, including the Member State obligation, per article 127(b) of the Directive on medicinal products 2001/83/EC (as amended), to ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.

John Chave, (Pharmaceutical Group of the European Union, PGEU) pointed out that to his

knowledge only 17 Member States have implemented pharmaceutical collection system, and effectiveness varies from one Member State to another. John Chave supported more formal requirements on Member

States to implement the collection of pharmaceuticals, but didn't find that harmonization is the best path. John highlighted practices of some pharmaceutical collection systems in European Member States, but raised concerns about costs and disposal. An innovative idea from Norway that could address costs and patient participation would be to create a deposit scheme for return of unused pharmaceuticals. He also underlined the need to raise patient awareness of pharmaceutical collection systems, and confirmed that pharmacists are willing to be involved.



Raquel Gomes da Silva (Valormed) shared the experience of Valormed, the pharmaceutical collection system of Portugal. Valormed seeks to “close the lifecycle of pharmaceuticals” by using reverse logistics, involving industry, distributors and pharmacists in the responsible use, collection, and safe disposal of pharmaceuticals and packaging. Payment for each collection occurs using the circuit that is already in place for distribution, SIGREM, which is financed by pharmaceutical packagers who pay €0.00512 per packaging placed on the market. An estimated 98% of pharmacies in Portugal are involved, and last year 325 kg of waste was collected per pharmacy. Waste materials are sorted and classified with approximately 43% being recycled. Media campaigns, including television and radio spots, help raise public awareness.



Romain Journal (French National Pharmaceutical Industry Trade Association, LEEM) shared the experiences of Cyclamed, the pharmaceutical collection system of France initiated in 1993. Cyclamed, a non-profit organisation, which is funded by the pharmaceutical industry, involves all supply chain players in the collection and incineration of unused medicines and packaging. In the beginning the system was based on the voluntary participation of all the players. The obligation on pharmacies to collect unused medicines was introduced in 2007. The collection and disposal of unused medicines have been regulated by a Decree published in 2009. A strong involvement of each party is very important to enable the functioning of the collection system. In this context, Cyclamed and the pharmaceutical industry educate patients through various communication channels (TV, Internet, leaflets and posters). Approximately 14,700 tonnes of unused medicines were collected and incinerated in 2013 through Cyclamed. In a survey conducted in 2014, about 77% of the French said that they take back their unused medicines to.



Anders Finnson (Europe's drinking water and waste water service operators, EurEau)

proposed that coherent actions to address PiE need to be taken at all levels, with a focus on source control, in line with the polluter pays and precautionary principles. He explained that wastewater treatment is moving toward an energy-neutral and circular economy, and that extra treatment is not sustainable due to increased energy costs, increased CO2 emissions, and increased resources. The increased wastewater treatment can only eliminate between 80-90% of the pharmaceutical products, and would result in increased consumer costs of between 18-100 euros per person per year, depending on the technology. Source control should focus on pharmaceutical design, authorization, marketing, hospital hot spots, health professional and household practices, and ultimately water treatment.



Issa Nafo (noPills project) presented two projects of the noPills project, a European cooperation project that seeks to reduce the pollution in waters from pharmaceutical residues.



The first project, conducted in Germany, examines ways to change behaviours of physicians, pharmacists and users in a town of 50,000 inhabitants. Current estimates find 25% of users are putting pharmaceuticals down the toilet. 40 physicians are at least sometimes cooperating to provide "four golden rules" to patients, including children, about the proper disposal of pharmaceuticals. The project seeks to measure the efficiency

of steps taken by tracking behavioural changes. The second project, conducted in Luxembourg and Germany, examined the practice of capturing urine from patients after treatment with contrast agents in hospitals. Patients' urine was collected, mixed with materials to solidify, and incinerate. After removal, waste water is measured to see if there is a load reduction. The urine separation practice was supported by the hospital staff and some patients.

Key points from the Panel III Q&A session:

One attendee raised the question of who the polluter would be under the polluter pays concept. If a car emits CO2 is the manufacturer the polluter? A comment was made that a fee could be added to the cost of pharmaceuticals to pay for waste collection/treatment of the user-polluter. It was agreed that all are involved and that there is a need for a clearer and stronger obligation to support collection systems.

An attendee asked for a costs comparison between urine separation and wastewater upgrades. Andreas Finnson shared that upgrades are expensive, providing the example rebuilding the waste water pipe system in Sweden cost 1,25 billion Euros/year.

Another attendee raised the point that due to different waste practices among Member states (i.e. landfill or incineration of household waste), collection of pharmaceuticals through pharmacies may not be necessary.

It was agreed by all that public awareness needs to be raised by brief messages such as 'Don't flush it!'

Concluding remarks and recommendations

Richard Bergstrom (EFPIA) pointed out that with regard to global aspects there are other important issues to consider. Approximately 25% of pharmaceuticals used in Africa are counterfeit and many parts of the world do not have health care systems in place. He pointed out that although regulations can serve to nudge industry along, a lot can be done without laws. Industry have shared their initiatives regarding EPS, which includes eERA, IMI and emission control. J&J have shared information about PNECS. We have heard about the Swedish system. There is a need for transparency in the supply chain. There is a lack of knowledge about supply that needs to be addressed, but without compromising/undermining competition. Something needs to be done about those countries where we see bad examples – perhaps the formation of a task force with industry representatives – need to talk to these countries. Industry is sceptical about the inclusion of environmental aspects in GMP. We need to be thoughtful about what we do globally. There may be resistance to having the EU dictating on HSE issues that are currently not in there – there could be push back. He went on to say that there is a lot of 'low hanging fruits' that could and should be addressed, including raising awareness. With current technology this should be easier than in the past, as well as less expensive. As an example of the use of technology in communicating information, he shared information about current efforts to replace patient leaflets with electronic information, thereby saving acres of forest. Richard added that EFPIA would be willing to provide financial support to the 'Don't flush it!' campaign.

Anja Leetz (HCWH) said that she heard willingness from industry to improve the control of discharges and be more transparent about it. She thought the GMP discussion is worth looking into further and that there is a need for marketing control after ERA. She ended by saying that raising patient/public awareness should involve all partners. The EU policy process will continue and she urged stakeholders to get involved to achieve reduction of pharmaceuticals in the environment.