Survey | How do pharmaceutical manufacturers address the environmental impact of their production at both their own-operated facilities and those of third-party suppliers?

Context

Recognising that most Active Pharmaceutical Ingredients (APIs) are produced in emerging and developing countries, this survey aims to gather information about how pharmaceutical manufacturers manage manufacturing waste throughout their supply chains and identify best practices.

Pharmaceutical residues have been detected in surface water, sewage effluents, groundwater, drinking water, manure, soil, and other environmental matrices globally. There is scientific evidence that even low concentrations of pharmaceuticals have harmful effects on animal and plant life. Some of the effects of pharmaceuticals in the environment described in research are:

- Residues of diclofenac, an anti-inflammatory drug, can cause renal failure in vulture populations feeding on carcasses of cattle treated with the drug. As a consequence the vulture population in the Indian subcontinent declined by 80-99% between 2003-2004
- The contraceptive drug ethinylestradiol can impair reproduction in fish population
- The antibiotics enrofloxacin and ciprofloxacin have toxic effects and can inhibit the growth of aquatic species such as cyanobacterium and duckweed

Pharmaceutical residues can enter the environment during their production, consumption, and disposal. Many pharmaceutical companies have outsourced their API production outside Europe/US, mostly to China and India - the APIs produced there are sold on to markets worldwide. Pharmaceutical manufacturing is a source of pharmaceutical pollution that can be exacerbated by weak environmental legislation in countries that produce many of the APIs for pharmaceutical products globally.

The effects of pollution from pharmaceutical production are not only a local or national problem - numerous studies and documentaries point out that uncontrolled manufacturing discharges contribute to the spread of resistant bacteria from the environment to humans and animals with a global impact due to travel and trade.

The survey

This survey is being sent to the top 50 pharmaceutical companies worldwide (according to annual ranking published by Pharmaceutical Executive). The respondent companies that manufacture APIs in emerging and developing countries will be scored and ranked according to their responses, as well as any other publicly available information.

The resulting data and ranking will be presented in a report to be published by HCWH Europe in 2018 that will be widely disseminated and published online. HCWH Europe plans to repeat this type of evaluation periodically with the aim of benchmarking pharmaceutical companies' environmental practices across four key areas:

Policy and commitments (75 points):

- What are the company's environmental policies?
- How are these policies implemented?
- What are the company's future goals for reducing its environmental footprint?

Governance (25 points):

- Is there a department in the company in charge of reducing company's environmental footprint?
- How does the company incorporate environmental aspects into its sourcing policies?

Traceability (50 points):

- Is the list of suppliers, from manufacturing to raw material level, made publically available on the company's website?
- If yes, how much information is shared there?

Supplier assessment and remediation (50 points):

- How does the company verify that its suppliers' environmental policies are being implemented?
- What assessement procedures are in place?
- How does the company deal with problems found at suppliers'facilities?
- Are assessment findings reported or made publically available?

This survey was prepared by Health Care Without Harm (HCWH) Europe, a non-profit European membership organisation hospitals, healthcare systems, healthcare professionals, local authorities, research/academic institutions and environmental and health organisations. HCWH Europe brings the voice of healthcare professionals to the European policy debate about key issues, and educates the healthcare sector to understand the importance of its environmental footprint. HCWH Europe also works to encourage healthcare leaders and professionals to advocate for broader societal policies and changes.

The survey will take approximately **40-45 minutes to complete** - we hope that you will take the time to complete the survey with information from your company. Companies that choose not to respond will be listed as non-responsive in the resulting report, but will still be included in the ranking based on their publicly available information.
Deadline for submitting your response: 31 August 2018 - 23:59 CEST

1. ABOUT YOU	
1.1	Company name: ……..
1.2	Department name: ……
1.3	Company address: …… ……
1.4	Contact person name and title (please note that your name will not be made public and is meant for follow-up and clarification only): ……
1.5	Contact person email (please note that your email will not be made public and is meant for follow-up and clarification only): ……
1.6	Contact person phone number (please note that your phone number will not be made public and is meant for follow-up and clarification only): ……
Disclaimer: *I hereby confirm that I am authorised to complete this survey on behalf of ****Company name*** *and I understand that the data collected in the remainder of this survey will be aggregated and published by HCWH Europe without further notice (i.e. your responses will not be publicly linked to ****Company name****).* *Data related to individual companies will not be published or shared with third parties in any form for any purpose, but will be used internally to rank/score against other companies.*	
2. ABOUT YOUR COMPANY	
2.1	Your company is: ☐ An original drug developer ☐ A generics company
2.2.1	Your company produces: ☐ Medicinal products for human use ☐ Medicinal products for veterinary use ☐ Both
2.2.2	If 'both', what is the percentage breakdown between human and veterinary medicinal products that your company produces? ☐ Human medicinal products (%): …… ☐ Veterinary medicinal products (%): ……
2.3	Are your human and veterinary medicinal products both produced at the same manufacturing site(s)? ☐ Both are produced at the same manufacturing site(s) ☐ They are produced at different site(s)
3. ABOUT YOUR MANUFACTURING FACILITIES	
3.1	What % of pharmaceuticals you sell (in terms of volume) are produced in your own facilities? ……
3.2	What % of pharmaceuticals you sell (in terms of volume) are outsourced to suppliers? ……..
3.3	Does you company have manufacturing sites for active pharmaceutical ingredients

	in Europe/US? ☐ Yes If 'Yes', please indicate where (country and city): ……. ☐ No
3.4	Does your company have manufacturing sites for active pharmaceutical ingredients in emerging and developing countries?: ☐ Yes If 'Yes', please indicate where (country and city): ……. ☐ No
3.5	Does your company have suppliers for active pharmaceutical ingredients who operate in emerging and developing countries?: ☐ Yes If 'Yes', please indicate where (country and city): ……. ☐ No
3.6	What percentage of the active pharmaceutical ingredients used by your company are produced: - In emerging and developing countries (%): …… - In Europe/US (%): ……
3.7	Is the list of suppliers, from manufacturing to raw material level, made publically available on the company's website? ☐ Yes If 'Yes', please provide the link: ……. ☐ No
4. ENVIRONMENTAL SUSTAINABILITY AT YOUR COMPANY	
4.1	Does your company have policies and/or guidelines regarding the management and processing of pollution generated during the pharmaceutical manufacturing process? ☐ Yes If 'Yes', how long they have been implemented? ……. If 'Yes', are they publicly available? ☐ Yes ☐ No If 'Yes', please provide a link: …….. ☐ No If 'No', does your company plan to produce policies/guidelines in the future? ☐ Yes ☐ No
4.2.1	Are all your sites ISO 14001 certified? ☐ Yes ☐ No
4.2.2	The ISO 14001 standard does not contain specific environmental performance criteria, but simply provides a framework for the "holistic" improvement of a

	company's environmental performance. Please therefore list all measures you take to demonstrate how you specifically address the environmental and public health impact of your manufacturing waste: …… …… ……
4.2.3	Do you apply the same level of environmental requirements to sites that are both ISO 14001 and non-ISO 4001 certified? ☐ Yes ☐ No
4.3	If you use suppliers for active pharmaceutical ingredients, do you require that your external suppliers have environmental policies in place? ☐ Yes ☐ No ☐ N/A
4.4	If your company has manufacturing sites in emerging and developing countries, have you set a specific goal to reduce pharmaceutical pollution at these sites? ☐ Yes If 'Yes', please describe this goal and the deadline set to achieve it: …….. ☐ No ☐ N/A
4.5	If your company has manufacturing sites in Europe/US and in emerging and developing countries, are the pharmaceutical pollution policies for these sites different in each region? ☐ Yes If 'Yes', please explain how and why these policies are different: …… …….. ☐ No ☐ N/A
4.6	Does your company have a Third Party Risk Management policy? ☐ Yes If 'Yes', please list all measures in place included within this Third Party Risk Management policy: …… …… ☐ No
4.7.1	How regularly do you undertake inspections to verify compliance with GMP of your own-operated manufacturing sites in emerging and developing countries? ☐ 1-2 times/year ☐ 3-5 times/year ☐ More than 5 times/year ☐ N/A ☐ Other

4.7.2	Since GMP does not cover site-specific environmental risks and hazards, do you have any particular tools in place to address the site-specific nature of those risks at your own-operated sites? Please list: .....
4.7.3	Are factory operators pre-notified of these inspections? ☐ Yes ☐ No ☐ N/A
4.7.4	Does the inspection team have a pre-defined brief to assess environmental impacts from manufacturing? ☐ Yes ☐ No If 'No', do you conduct separate inspections on environmental impacts? ☐ Yes ☐ No If No, how do you verify compliance with environmental legislation/your own policy requirements?: …… ……
4.8.1	How regularly do you undertake inspections to verify compliance with GMP of your third-party operated manufacturing sites in emerging and developing countries? ☐ 1-2 times/year ☐ 3-5 times/year ☐ More than 5 times/year ☐ N/A ☐ Other
4.8.2	Since GMP does not cover site-specific environmental risks and hazards, do your third-party suppliers' sites have any particular tools in place to address the site-specific nature of those risks? Please list: .....
4.8.3	Are factory operators pre-notified of these inspections? ☐ Yes ☐ No ☐ N/A
4.9	Before entering into a contractual arrangement with a third-party supplier, do you conduct due diligence on their environmental performance? ☐ Yes ☐ No ☐ N/A
4.10	Do you verify that your own-operated or third-party operated facilities have the legally required environmental permits or authorisations? ☐ Yes ☐ No ☐ N/A
4.11	Do all your own-operated or third-party operated facilities publicly report environmental monitoring data? ☐ Yes If 'Yes', please indicate where this information can be accessed:

	…… ☐ No
5. WASTE AND CONTAMINATION MANAGEMENT AT YOUR COMPANY	
5.1	Do you require certificates from your suppliers to ensure that appropriate wastewater treatment and waste handling measures are in place? ☐ Yes ☐ No ☐ N/A
5.2	Are you aware of any environmental incidents (i.e. illegal dumping of untreated effluent, improper waste management) at any of your own-operated or third-party operated facilities in the last three years? ☐ Yes If 'Yes', please list: …… If 'Yes', how have you addressed environmental incidents? (please list all procedures in place): …….. …… ☐ No
5.3	Do all your own-operated or third-party operated facilities have hazardous waste reduction programmes in place? ☐ Yes ☐ No
5.4	Have your supply facilities developed and implemented a hazardous substances management programme? ☐ Yes ☐ No
5.5	If your supply facilities use hazardous substances, is there a spill containment system? ☐ Yes ☐ No ☐ N/A
5.6	During inspections at your manufacturing sites, have you detected any soil or groundwater contamination with hazardous substances? ☐ Yes If 'Yes', how have you addressed them? (please list all procedures in place): …… …… ☐ No
5.7	Please list all the pollution control activities to tackle air emissions generated at your own-operated facilities: …… …… ……
5.8	Please list all pollution control activities to tackle air emissions generated at your

	suppliers' facilities: …… …… ……
5.9	In your own-operated sites, can you guarantee that at your own-operated sites all APIs contained in various waste-types are eliminated via the waste management processes in place? ☐ Yes ☐ No If 'No', do you have any procedures in place to reduce API concentrations in wastewater? ☐ Yes ☐ No If 'Yes', how do you verify compliance with environmental legislation/your own policy requirements?: …… ……
5.10	At your suppliers' facilities, can you guarantee that all APIs contained in the various types of waste are eliminated via the waste management processes in place? ☐ Yes ☐ No If 'No', do they have any procedures in place to reduce API concentrations in wastewater? ☐ Yes ☐ No If 'Yes', please list: …… ……
5.11	In order to determine the potential environmental impact of APIs, does your company monitor own-operated facilities and evaluate the discharge of wastewater to surface waters? ☐ Yes ☐ No
5.12	In order to determine the potential environmental impact of APIs, does your company monitor your suppliers' facilities and evaluate the discharge of wastewater to surface waters? ☐ Yes ☐ No
6. WASTE TREATMENT AT YOUR COMPANY	
6.1	Does your company make use of Common Effluent Treatment Plants? ☐ Yes If 'Yes', do they send pharmaceutical manufacturing effluent to these plants? ☐ Yes ☐ No If 'Yes,' has this effluent been pre-treated at source? ☐ Yes ☐ No ☐ No
6.2	Do your suppliers make use of Common Effluent Treatment Plants?

	☐ Yes If 'Yes', do they send pharmaceutical manufacturing effluent to these plants? ☐ Yes ☐ No If 'Yes,' has this effluent been pre-treated at source? ☐ Yes ☐ No ☐ No
6.3	Are there differences between the effluent discharges standards that need to be met when you treat your own waste and when you make use of Common Effluent Treatment Plants? Please list: .....
6.4	Does your company implement any specific off-site treatment for pharmaceutical manufacturing waste? ☐ Yes If 'Yes', please list and describe treatment processes here: …….. …… …… ☐ No
6.5	Do your suppliers implement any specific off-site treatment for pharmaceutical manufacturing waste? ☐ Yes If 'Yes', please list and describe treatment processes here: …… …… ☐ No ☐ N/A
6.6	Does your company produce antibiotics? ☐ Yes If 'Yes', in light of the considerable public health threat posed by antimicrobial resistance (AMR), please list any dedicated on-site treatment in place to process antibiotic manufacturing waste: …… …… ☐ No

Please use the box below to add any relevant information to your response – when referring to a specific question please include the question number.

- You can upload any supporting documents here:

Please let us know if you have any feedback on the survey itself:

Thank you for your interest in HCWH Europe's survey: *How do pharmaceutical manufacturers address the environmental impact of their production at both their own-operated facilities and those of third party suppliers?*

Please visit: http://saferpharma.org/addressing-environmental-impacts-pharmaceutical-manufacturing-survey to complete the survey online.

You will be notified when HCWH Europe's report of this survey is published.

Please contact our Research Assistant, Maja Milkowska, at maja.milkowska@hcwh.org should you have any questions.