European Commission

ROADMAP			
TITLE OF THE INITIATIVE	Strategic approach to pharmaceuticals in the environment		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	DG ENV C1 AND B2	**DATE OF ROADMAP**	28/04/2017
LIKELY TYPE OF INITIATIVE	Commission Communication		
INDICATIVE PLANNING	*2018 first quarter*		
ADDITIONAL INFORMATION			

This Roadmap aims to inform stakeholders about the Commission's work in order to allow them to provide feedback and to participate effectively in future consultation activities. Stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have. The Roadmap is provided for information purposes only and its content may change. This Roadmap does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content.

A. Context, Problem definition and Subsidiarity Check

Context

Pollution of the environment by human and veterinary pharmaceutical substances is an emerging environmental problem[1,2,3]. Article 8c of Directive 2008/105/EC[4] (as amended by Directive 2013/39/EU[5]) requires the Commission to develop a strategic approach to the pollution of water by pharmaceutical substances, and.to follow this, where appropriate, with proposals for measures to be taken at Union and/or Member State level to address the possible environmental impacts of pharmaceutical substances, with a view to reducing their release into the aquatic environment. This requirement ties in with the Commission's commitment to follow up existing work under the pharmacovigilance legislation examining the scale of the problem of pharmaceuticals in the environment. The initiative is consistent with the vision set out in the 7th Environmental Action Programme[6] for a non-toxic environment. Various pieces of Union legislation are directly or indirectly relevant to the production, use or disposal of pharmaceuticals and their safety for the environment[7].

Problem the initiative aims to tackle

The manufacture, use and disposal of active pharmaceutical ingredients (APIs) leads in various ways to their release into the environment, and some APIs may pose a risk. In particular:

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[1] Communication on "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector" COM (2008) 666 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2008:0666:FIN

[2] Regulation (EU) No 1235/2010 OJ L 348, 31.12.2010, p. 1–16 and Directive 2010/84/EU OJ L 348, 31.12.2010, p. 74. (part of the so-called "pharmacovigilance legislation") http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R1235&qid=1493205869407&from=EN and http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010L0084&qid=1493205642429&from=EN, respectively

[3] COM (2011) 748 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2011:0748:FIN; Communication COM (2011) 748 on an Action plan against the rising threats from Antimicrobial Resistance: in which the Commission recognised that the pollution of the environment by antimicrobials is accelerating the emergence and spread of resistant microorganisms, and committing, under Action 8, to initiate multilateral cooperation on reduction of the environmental pollution by antimicrobial medicines particularly from production facilities

[4] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy. OJ L348, 24.12.2008, p.84. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0105&from=EN

[5] Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. OJ L 226, 24.8.2013, p.1. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:226:0001:0017:EN:PDF

[6] Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet'. OJ L354, 28.12.2013, p. 171) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D1386&from=EN

[7] http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm

- Some APIs can affect wildlife at concentrations at and below those found in the aquatic environment.
- Evidence that the presence of antibiotics in the environment may contribute to the development and spread of antibiotic-resistant strains of bacteria is beginning to grow[8].
- There is uncertainty about the presence of many APIs in the environment and about the levels that could harm the environment and/or human health via the environment, including, for antibiotics, their possible contribution to the development, maintenance and spread of antimicrobial resistance.
- Risk assessment approaches may need to be improved to consider the possibility of effects on humans of inadvertent chronic exposure to low levels of APIs in drinking water, also taking account of the potential for combined effects from multiple APIs, and of vulnerable sub-populations[9].

APIs generally need to be able to act at concentrations low enough to be tolerated by the whole organism, and to be stable and bioavailable. Ingested APIs are commonly excreted unchanged or in the form of metabolites which may have lower biological activity[10]. Most urban waste water treatment plants are not able to remove all of each API and manure from treated animals is usually spread on land. Concentrations of APIs reported for surface and groundwaters range from below ng/l to above µg/l[11]; some have the potential to bioaccumulate. According to figures from the pharmaceutical industry[12], the value of pharmaceutical sales, which can be used as an indicator of consumption[13] and thus environmental release, in the EU more than doubled between 1990 and 2000, and roughly doubled again in the following 12 years. About 3000 APIs are on the market. Environmental concentrations could increase as populations age and as online purchasing grows. The 2013 amendment of Directive 2008/105/EC established a Watch List monitoring mechanism under the Water Framework Directive[14], and six pharmaceuticals are in the first list[15], but this is relatively few.

Subsidiarity check

Water and other environmental pollution is trans-boundary (e.g. roughly half of the river basin districts in the EU cross borders) justifying action at EU level. In its Communication on a Renewed Vision for the Pharmaceuticals Sector[16], the Commission identified the objective of making further progress towards a single and sustainable market in pharmaceuticals, and acknowledged the importance in this of addressing the potentially harmful impacts of pharmaceuticals on the European environment and public health. Again, this would justify the identification of policy options for follow-up at EU level; even as regards non-legislative measures, support for EU-level guidance or the EU-wide provision of information could be more efficient than action taken separately by individual Member States.

B. What does the initiative aim to achieve and how [max 25 lines]

The main objectives of the initiative will be to

- identify remaining **knowledge gaps** and uncertainties, and present possible solutions for filling them;

- explore how to address the **challenge to protect the environment** (and human health via the environment) **and** at the same time **safeguard access to effective and appropriate pharmaceutical treatments** for human patients and animals, considering *inter alia* the opportunities for innovation.

The strategic approach will aim to address pharmaceuticals in the environment generally, meaning largely but not only the water environment, in order to cover the requirements in the water and pharmacovigilance legislation, noting that the latter refers also to soils. It could include policy options relating to a number of different areas, given that emissions of pharmaceutical substances to the environment occur during their whole lifecycle, i.e. from production through consumption to disposal. Existing legislation already provides a fairly comprehensive framework, but it might be appropriate to consider its effectiveness in relation to this specific

[8] e.g. http://www.ema.europa.eu/docs/en_GB/document_library/Report/2015/01/WC500181485.pdf; http://cid.oxfordjournals.org/content/early/2013/06/21/cid.cit355.short

[9] http://apps.who.int/iris/bitstream/10665/44630/1/9789241502085_eng.pdf?ua=1

[10] See the case studies in the report at http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm for examples.

[11] http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm

[12] http://www.efpia.eu/uploads/Figures_2014_Final.pdf

[13] e.g. http://apps.who.int/medicinedocs/en/d/Js6160e/6.html#Js6160e.6; http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(14)70780-7/abstract

[14] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Communicty action in the field of water policy, OJ L327, 22.12.2000, p.1. http://eur-lex.europa.eu/resource.html?uri=cellar:5c835afb-2ec6-4577-bdf8-756d3d694eeb.0004.02/DOC_1&format=PDF

[15] Commission Implementing Decision (EU) 2015/495 of 20 March 2015 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council. OJ L78, 24.3.2015, p.40. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D0495&qid=1493124116873&from=EN

[16] Communication on "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector" COM (2008) 666 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2008:0666:FIN

issue.

The Commission will reflect on policy options already identified in a report[17] and on outputs from a Commission workshop held in September 2014 at which participants discussed a range of options from that report[18]. It will also consider possible additional options identified during the course of a supplementary study to support the development of the strategic approach. Finally, it will include feedback from a Commission public consultation.

Possible options include the stimulation of voluntary initiatives at EU or national level, as well as mandatory measures. In view of the need to take into account the outputs of the supplementary study, it is premature to identify the options that might be included in the strategic approach.

C. Better regulation

Consultation strategy

In the context of the study being undertaken to inform the development of the strategic approach, some targeted consultation of experts has already been carried out, and the **Commission will conduct a 12-week open public consultation** to involve as wide a range of relevant stakeholders as possible. The consultation is expected to be launched in the first half of 2017. Emails and web-based publicity are foreseen. The launch of the public consultation will be announced in the consultation planning document that can be found at http://ec.europa.eu/yourvoice/consultations/docs/planned-consultations_en.pdf

Impact assessment

No IA will be carried out for the strategic approach itself, as no specific policy proposals or commitments will be made and no significant impacts expected. However, the identification of potential options to be included in the strategic approach for possible follow-up (at EU, MS, organisation or individual level) will be informed by a preliminary analysis. Options subsequently followed up as proposals for measures will need to be further assessed if they might have significant impacts (full impact assessment where relevant). This is consistent with the two-step procedure outlined in Article 8c of Directive 2008/105/EC as amended by Directive 2013/39/EU, which states that at the second step, i.e. in proposing measures in the framework of the strategic approach, the Commission shall take *"into account public health needs and the cost-effectiveness of the measures proposed"*.

Evaluations and fitness checks

An external study was launched by the Commission in 2011 to analyse the scale of the problem of pharmaceuticals in the environment and to suggest solutions for improvement. The study report was published in 2014[19]; the outcomes of the workshop held to discuss that study report in September 2014 will also be used[20]. The information already available is being complemented by the new study mentioned above.

[17] http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm

[18] The report can be found at https://circabc.europa.eu/w/browse/5d532921-1e1f-48f5-b0e0-3057798423ca

[19] http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm

[20] The report can be found at https://circabc.europa.eu/w/browse/5d532921-1e1f-48f5-b0e0-3057798423ca