Baltic Marine Environment Protection Commission

Helsinki Commission
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HELCOM 38-2017

Document title	Establishing of a Correspondence Group on Pharmaceuticals
Code	4-5
Category	DEC
Agenda Item	4 - Matters arising from the subsidiary bodies
Submission date	24.1.2017
Submitted by	Executive Secretary
Reference	Outcome of PRESSURE 5-2016, Para 7.20 and Annex 3

Background

The Status report on pharmaceuticals in the Baltic Sea was agreed for publication in August 2016. The report, aimed at implementation of the MD2013 commitments, highlighted the significance of the issue for the region and identified the need of the common regional approach to tackle the problems as well as identified knowledge gaps. Taking into account the scope of the problems raised by the Report and the request by HOD 50-2016 to elaborate measures addressing reduction of input of pharmaceuticals into the environment, PRESSURE 5-2016 suggested to establish an intersessional correspondence group to facilitate further HELCOM activities in this field. PRESSURE 5-2016 suggested a 3-year working period and agreed on a draft Terms of Reference for the group.

The draft Terms of Reference was also considered by the State and Conservation group via correspondence and comments were provided by Denmark, Estonia, Germany and Finland. The ToR was updated taking into account suggestions by national experts.

The document contains the updated draft Terms of References for the HELCOM Correspondence Group on Pharmaceuticals (HELCOM CG PHARMA).

The existing HELCOM expert network on hazardous substances (2015-2018) includes in its ToR tasks to e.g. develop and operationalize indicators on hazardous substances (including on pharmaceuticals) as well as to provide expert input to consideration of pressures from hazardous substances and relevant measures and investigate possibility for a project e.g. in cooperation with the EUSBSR PA Hazards.

The expert network on hazardous substances has so far mainly focused on operationalization of core indicators for use in HOLAS II (neither of the two pharmaceutical indicators has reached the core indicator stage) and its ToR will be revisited once HOLAS II has been finalized. It is suggested that the ToR of this new correspondence group is amended to include a task to further develop the pharmaceuticals indicators (instead of within the expert network) and contribute to the State of the Baltic Sea report (HOLAS II). Further, the ToR could be revisited at the same time as the ToR of the expert network to ensure coordinated priorities and optimal arrangement of tasks within the both work strands (on hazardous substances and specifically on pharmaceuticals) as need might be. In the meantime, the chairs of both groups could be tasked to ensure information exchange to ensure no overlap in the work.

Action requested

The Meeting is invited to consider and approve the proposed draft Terms of Reference, and decide to revisit the ToR together with the ToR of the HELCOM expert network on hazardous substances in 2018.

Terms of Reference for the HELCOM Correspondence Group on Pharmaceuticals (HELCOM CG PHARMA)

Background

In the 2010 HELCOM Ministerial Declaration, the Contracting Parties of HELCOM agreed to 'further assess the environmentally negative impacts of pharmaceuticals and other substances that are not monitored regularly, with the aim as a first step to assess in a coordinated manner their occurrence in the Baltic Sea and evaluate their impacts on the Baltic biota' (HELCOM 2010). The commitment was followed up by the 2013 Ministerial Declaration, in which the Contracting Parties agreed 'to collect more information and assess the state of contamination with pharmaceuticals and their degradation products of the aquatic environment' (HELCOM 2013).

The EU directive 2013/39/EU considers the contamination of water with pharmaceutical residues as an emerging environmental concern (European Commission 2013). Diclofenac, 17-beta-estradiol (E2), 17-alpha-ethinylestradiol (EE2) and estrone (E1), a breakdown product of E2, and three macrolide antibiotics erythromycin, clarithromycin and azithromycin are included on the first 'watch list' under the EU Directive 2013/39/EU.

HOD 50-2016 approved the publication of the Status report on pharmaceuticals in the Baltic Sea region and noted that the Status report has to be followed by elaboration of measures addressing reduction of input of pharmaceuticals into the environment. PRESSURE 4-2016 had decided to establish an expert group to work further in order to suggest further actions on pharmaceuticals in the Baltic Sea region.

Objective

The HELCOM Correspondence Group on Pharmaceuticals (hereinafter - CG PHARMA):

- provide a scientific background for the regional environmental policy regarding pharmaceuticals in the environment;
- provide a scientific background of suggestions on the regional actions to minimise environmental impact by release of pharmaceutical substances
- serve, in cooperation with PA Hazards of EUSBSR, as a platform for regional dialog on the various environmental aspects of the use of pharmaceutical substances and treatment of the wastes and other matters containing pharmaceuticals in the Baltic Sea region.

Tasks (to be amended as necessary)

The CG PHARMA will

a. elaborate suggestions on prioritization of pharmaceutical substances against their impact on the environment with the view to include them into the HELCOM priority list;
b. facilitate HELCOM work on assessment of the environmental impact by pharmaceutical substances;
c. elaborate suggestions on regional needs in monitoring of pharmaceutical substances in the environment and thus provide input to the work of State & Conservation Group;
d. provide regional guidance on methods and technics for monitoring of the selected pharmaceutical substances in the aquatic environment, to assure compatibility and comparability of the data obtained through national monitoring programmes, and thus provide input to the work of State & Conservation Group;
e. guide collection of national data on selected regionally prioritized pharmaceutical substances (including agricultural usage and diffuse sources) to fill in gaps in regional knowledge on sources and pathways of pharmaceuticals into the environment;

Commented [A1]: DK It is important to recognize the member States national monitoring programs, so that guidance on methods and technics for monitoring is kept optional and kept in line with existing national monitoring programs.

Commented [A2]: DK The requirements for data reporting should be kept at a minimum to limit the burden on Member States. It is therefore important to consider a method which is practical and realistic. Collection of national data should therefore be based on a risk assessment that designate which pharmaceuticals are relevant and appropriate.

Commented [A3]: EE

f. [further develop HELCOM indicators on pharmaceuticals] and contribute to preparing the State of the Baltic Sea Report within the HOLAS II project by mid-2018;

~~f.~~g. elaborate suggestions on research needs to identify threats posed by pharmaceutical substances to the environment;

~~g.~~h. elaborate suggestions on regional recommendations and guidelines on upstream measures to prevent/minimise input of pharmaceutical substances into the environment e.g. promotion of take-back systems, handling medical waste, public awareness, etc.;

~~h.~~i. establish a dialog with relevant stakeholders, organize regional stakeholder meeting(s) and elaborate suggestions on environmental practices and technical solutions for waste water management to prevent/minimise input of pharmaceutical substances into the environment;

~~i.~~j. cooperate with regional and global projects in the sphere of the expert group expertise;

~~j.~~k. cooperate with international organizations and institutions acting in the field of the group expertise, in particular, PA Hazards/EUSBSR, EC, UNESCO, UNEP, SAICM, etc.;

~~k.~~l. follow up implementation of measures aimed at prevention/minimizing of impact by pharmaceutical substances on the environment;

Deliverables ~~**of the group shall be**~~ (among others)

a. priority list of pharmaceutical substances posing risk for the environment in the HELCOM area;
b. recommendations, guidelines and other regional documents regarding monitoring of pharmaceutical substances in the environment for consideration by State & Conservation Group;
c. overviews of the regional data, filling in informational gaps;
d. regional projects aimed at filling in gaps in knowledge on environmental effects of pharmaceutical substances;
e. suggestions for regional action ~~plans~~ to minimize environmental impact by pharmaceutical substances;
f. regular reports to HELCOM State and Conservation and Pressure Groups.

Working procedures and timeline

The work of the CG PHARMA will be based on the findings of the Pharmaceutical Report and should take up recommendations herein, such as filling the data gaps that have been identified in the report.

The CG PHARMA will report to Pressure Group and will assist other subsidiary bodies and projects of HELCOM with requested information.

The CG PHARMA will assure cooperation with HELCOM State&Conservation group regarding the issues related to the methodologies and technics used for monitoring of the pharmaceutical substances in the marine environment through involvement of the representatives of this HELCOM group and submission of the relevant materials to the group for consideration.

The CG PHARMA will coordinate activities related to elaboration of HELCOM core indicators on pharmaceutical substances through close cooperation with the HELCOM expert network on hazardous substances.

The CG PHARMA will involve experts of various specializations to provide relevant expertise to fulfil the task of the correspondence group.

The CG PHARMA group will meet as often as necessary and will utilise video-/teleconferencing as the major working method, though physical meetings are possible, if appropriate.

Commented [A4]: New proposal by the Secretariat

Commented [A5]: DE

Commented [A6]: DE

Commented [A7]: DK The development of a regional action plans is to our opinion pre-mature. We think that CG PHARMA in its first term should focus on evaluating on the current status report, define the extent of the problem and fill in knowledge gabs. Hereafter, it can be decided whether a proper action plan is needed

Commented [A8]: DK We agree that regional recommendations and guidelines regarding monitoring should be developed and delivered as input to the work of State & Conservation and the pressure Group.

Commented [A9]: DE

The Secretariat will provide administrative support during the meetings. The CG PHARMA group will focus on elaboration of proposals, documents and products, and will record the outcomes of the meetings in the form of short memos.

The CG PHARMA group will identify tasks that may require additional resources and may come up with proposals for projects.

The mandate of the CG PHARMA group will last for an initial period of 3 years which can be extended for further years.

Resources needed

The Contracting Parties are to nominate their representatives to the group, and the work will rely on expert participation and contribution of the Contracting Parties. Additional resources will be sought for through various projects.