Document title	A regional status report on pharmaceuticals in the Baltic Sea
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Background

Pharmaceuticals are an important element of the modern society and their beneficial effects on human and veterinary health are widely acknowledged. However, their undesired occurrence and potential effects in the environment is of global emerging concern. Residues of various types of pharmaceuticals (hormones, pain killers, antibiotics, etc.) have been detected in several environmental compartments in different regions of the world, including the Baltic Sea.

The 2010 HELCOM Ministerial Declaration gives the HELCOM Contracting Parties a clear obligation 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'*. The commitment was followed up by the 2013 HELCOM Ministerial Declaration in which the Contracting Parties agreed to collect information on pharmaceuticals and assess the status of contamination of pharmaceuticals and their degradation products in the marine environment.

HELCOM has also agreed to develop a second holistic assessment of the ecosystem health of the Baltic Sea (2013 HELCOM Ministerial Declaration). A key requirement of the assessment is that it should follow-up progress towards Good Environmental Status (GES) in the Baltic Sea, as agreed in the HELCOM Baltic Sea Action Plan (BSAP) and required by the Marine Strategy Framework Directive (MSFD). The core indicators form the basis for HELCOM assessments. An indicator on diclofenac is currently under development to support the agreed assessments.

The EU directive 2013/39/EU considers the contamination of water and soil with pharmaceutical residues as an emerging environmental concern. It also includes diclofenac and some of the most common hormonal agents on the first watch list of the EU Priority Substances with the aim to gather monitoring data for the purpose of facilitating determination of appropriate measures to address the risk posed by those substances.

Policy Area Hazards of the EU Strategy for the Baltic Sea Region (EUSBSR) has decided to give pharmaceuticals in the Baltic environment increased attention in the years 2015-2017. The decision was based on the generally growing concern over potential environmental impacts of pharmaceutical substances, the current policy movements within HELCOM, the EU and internationally, and an expressed interest in more knowledge and coordinated action by several Baltic Sea countries. In addition, a specific objective related to decreased discharges of hazardous substances, including pharmaceuticals, in the Interreg Baltic Sea Region Programme 2014-2020 opens up possibilities for financial support to new projects within this area.

The aim of PA Hazards is to establish a platform for dialogue and knowledge exchange between stakeholders in the region. Two concrete activities are planned for 2015-2016: 1) Produce a status report on environmental concentrations of pharmaceuticals in the Baltic Sea environment, based on available data, and 2) Organize a

stakeholder conference to stimulate network building in the Baltic region and the development of good quality project applications to the Interreg programme.

Currently, there is no comprehensive overview of the status and pressures of pharmaceuticals in the environment in the Baltic Sea Region. Numerous data on environmental concentrations are available through e.g. national screening campaigns, projects and reports; however the data is scattered and needs to be compiled. Also, there are no systematic regional studies aimed at identifying sources and pathways in the Region of pharmaceuticals into the environment.

In order to develop a regional approach to the problem of contamination of the Baltic Sea environment by pharmaceuticals, HELCOM, represented by the Chairs of the HELCOM Pressure and State&Conservation groups and the Secretariat, PA Hazards coordinator and national experts from Germany and Sweden (see list of members of the drafting group in the attached document) met to discuss the possibility to launch a joint process aimed at a comprehensive assessment of input of pharmaceuticals to the Baltic Sea and the status of contamination of the Baltic Sea marine environment by these substances. The aim of the process is to develop a regional status report on pharmaceuticals in the Baltic Sea.

The outcome of the drafting group was submitted to Pressure and State&Conservation groups for consideration and further development. PRESSURE 2-2015 (6-8 May 2015) was of the opinion that it is an important initiative, supported the proposed steps and timeline for carrying out the work and took note of information by Finland, Lithuania and Sweden on the sources and pathways of pharmaceuticals (cf. Agenda Item 4.2 of the Outcome). STATE&CONSERVATION 2-2015 (11-15 May 2015) welcomed the proposed activity, agreed to provide information on national data availability and sources and to report national data on concentrations and effects of pharmaceuticals and took note of information by Sweden on the sources and pathways of pharmaceuticals (cf. paragraph 4MA.16-4MA.19 of the Outcome).

The attached document contains the objective, scope, deliverables and provisional timetable of the assessment.

Action required

The Meeting is invited to

- take note of the initiative to prepare the regional assessment regarding pharmaceuticals,
- express views regarding possible contribution of agriculture to contamination of the aquatic environment by pharmaceuticals,
- inform about availability of national data on using pharmaceuticals in agriculture and their possible pathways to the environment.

Scope and timetable for preparation of a "Regional status report on pharmaceuticals in the Baltic Sea"

The objective of the process is to develop the "Status report on pharmaceuticals in the Baltic Sea" integrating information on production and consumption of the pharmaceuticals in the region, their pathways to the Baltic Sea environment, concentration in all the compartments of the environment and effects. The report will also identify knowledge gaps and possible measures to fill them.

The assessment will be based on compiling existing information available through publications at national and regional level. The assessment will not include any new sampling or analytical procedures.

Acknowledging that achievement of the objective requires collection of numerous volume of highly variable data and taking into account uncertainty of data availability, the meeting suggested two tasks which serve achievement of the objective and relevant to the HELCOM subsidiary bodies. The tasks also take into account specific aims of the PA Hazard in the joint activity.

The scope of the assessment of input of pharmaceutical substances to the Baltic Sea and the status of contamination of the Baltic Sea marine environment by these substances.

1. Assessment of the state of contamination of the Baltic Sea environment by pharmaceutical substances including:
    - Measured concentrations of pharmaceuticals in Baltic coastal and offshore areas, primarily in biota, water and sediment. The concentrations should be compared to effect limits when available.
    - Environmental effects of pharmaceuticals in the Baltic Sea conditions (or measured/observed effects of pharmaceuticals on Baltic biota)

2. Assessment of the Pressure on the Baltic Sea environment including:
    - Consumption/use of pharmaceuticals in the countries: human, agriculture, aquaculture, veterinary.
    - Information on production of pharmaceuticals in the HELCOM area – to map potential hot spots for releases of pharmaceuticals.
    - Pathways - point source of input of pharmaceuticals e.g. sewage treatment plant outlets, riverine loads [likely only available through screening studies]; concentration of pharmaceuticals in sewage sludge; concentration of pharmaceuticals in manure/sludge and sewage water from animal farming
    - Waste as possible sources of pharmaceuticals input to the environment (depending on existing waste management practises)?

Data collection will be based on the streamlined HELCOM structure and involve the HELCOM groups in the process and follow a step-wise approach.

1st step - scope availability and source of data (no data collection). Sources of relevant data with restricted access (e.g. commercial data, data which require anonymising etc.) should be identified.

- National sources of data on concentrations of pharmaceutical substances in all the compartments of the environment e.g. (specify programme, project, reference to data source etc.)
    - state and local environmental monitoring and screening programmes
    - regulated monitoring e.g. sewage treatment plants, industry
    - projects/screening studies
        - scientific studies
        - commissioned studies
- National sources of data on consumption/use of pharmaceuticals e.g. (specify per different of activity; e.g. human use, agriculture, veterinary)
    - authorities (environmental, health care s, veterinary, agricultural etc.)
    - professional associations
    - projects/studies
- National sources of data on pathways of pharmaceuticals into the environment such as concentration of the compounds in waste water, sludge, manure etc.
    - authorities
    - professional associations
    - projects/studies
- What is the accessibility to existing data e.g.:
    - open access - data base
    - reports
    - restricted
- Contact persons [likely a number of contact person in different authorities/institutions]

2nd step – a template for data collection will be prepared based on the results from the 1st step. The data will be collected in several categories:

a. available data on pharmaceutical concentrations in the Baltic environment, coastal and open water (water, biota, sediment)
b. available data on effects on Baltic biota
c. available data on sources including information on production and consumption of pharmaceuticals and pathways – concentration of these substances in waste water, sludge, manure etc.

The metadata, such as coordinates for concentration data, analytical methods, detection limits, data quality, etc., appropriate for the different categories will be collected.

Provisional outline

BACKGROUND (a review)

Legislation, environmental effects specified for the Baltic Sea region

MAJOR PART BASED ON THE COMPILED DATA

REGIONAL CONSUPTION AND PRODUCTION

- Evaluation of compiled data
- Data analysis, methods, visualising
- Conclusions

PATHWAYS

- Evaluation of compiled data
  - Data analysis, methods, visualising
  - Conclusions on the major pathways of pharmaceutical substance into the Baltic Sea environment

BALTIC SEA STATUS ASSESSMENT

- Evaluation of compiled data (concentrations and effects)
  - Data analysis, methods, visualising
  - Conclusions on the major threats for the Baltic Sea environment in terms of pharmaceutical substances.

OUTCOME

- Data gaps
- Possible measures

Provisional timetable

Date	Activity
May 2015	• Information about process at Pressure and State&Conservation meetings; ask for information about data availability and data sources from CPs • Information about process to PA Hazards steering group
June 2015	• Collect information about data availability and data sources from CPs • Develop and send out template for collecting data on concentrations and effects
July 2015	• Assess availability of data for sources, consumption, use and production • Develop and send out template for collecting data on Pressures - sources and pathways
August 2015	• Collect data on concentrations and effects • Start compilation of data on concentrations and effects
September 2015	• Collect data on Pressures - sources and pathways
October 2015	• Report on concentrations and effects ready • Discussion on progress in data compilation at Pressure Group meeting
November 2015	• Presentation of the report on concentrations and effects at State&Conservation meeting • Workshop/Stakeholder conference (PA Hazard - HELCOM) back-to-back with State&Conservation meeting
December 2015 – February 2016	• Compilation of Final report

Information and dissemination

All relevant stakeholders, including DG Environment, other relevant bodies within EU and/or actors connected with EUSBSR and HELCOM, will be informed about the cooperation. PA Hazard and HELCOM Secretariat will jointly plan for and share relevant information about the process. Resources and updates will be made available at the relevant website.

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