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Background

The decision on compilation of the Regional status report on pharmaceuticals in the Baltic Sea environment was taken by the meeting of the HELCOM Heads of Delegation (HOD 48-2015) pursuing the goals identified by the Declarations adopted by the Ministers of the HELCOM Contracting Parties in 2010 and 2013. The Declarations committed the Contracting Parties to collect information on pharmaceuticals and assess the status of contamination of the Baltic Sea marine environment by pharmaceuticals and their degradation products. The scope of the document and working plan of the status report elaboration were also approved by HOD 48-2015 (see *Annex 1*).

At the first stage, the HELCOM groups Pressure, State and Conservation and Agri were invited to report about the availability of data regarding occurrences of pharmaceutical substances in the marine environment as well as regarding their sources and pathways. The information on data availability was provided by Denmark, Finland, Germany, Poland, Russia and Sweden. All the reports, complemented by the published data, were compiled into a summary of data availability (see *Annex 2*).

Based on the collected information, reporting guidelines and templates were elaborated. The guidelines (contained in *Annex 3* and *Annex 4*) together with templates were circulated to HECLOM groups State and Conservation and Pressure in late August 2015. The Working Groups were invited to report the data by 25 September 2015. An overview of the reported data will be presented to the Meeting.

Action required

The Meeting is invited to:

- take note the information on progress in elaboration of the Status report on pharmaceuticals in the Baltic Sea, and
- provide feedback regarding further steps towards preparation of the document in due time according to the agreed working plan.

Annex 1.

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)?

Working plan

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

Annex 2

Analysis of the data availability for the regional status report on the pharmaceuticals in the Baltic Sea environment

*1. **National sources of data on concentrations of pharmaceutical substances in all the compartments of the environment.***

State and local environmental monitoring and screening programmes

Denmark

The Danish Centre for Environment and Energy (DCE), Aarhus University, collects data on pharmaceuticals in the environment under the National Monitoring and Assessment Programme for the Aquatic and Terrestrial Environment (NOVANA). The data on pharmaceuticals have been collected since 2011. http://dce.au.dk/en/monitoring/. The detailed information is available at the WEB pages in Danish language only.

Germany

Regular annual measurements of a range of pharmaceuticals (e.g. Carbamazepin, Oxezepam) in water Bundesamt für Seeschifffahrt und Hydrographie (BSH). The data are available at national level. Systematic monitoring of a range of pharmaceuticals in surface and coastal waters in Mecklenburg-Vorpommern (since 2008).

Sweden

In Sweden, at least, antibiotics are included in the national monitoring program since 2010. The highest concentrations have been reported for clindamycine, roxithromycin, erythromycin and clarithromycine (SEPA 2013a).
The Swedish EPA is responsible for the national monitoring programmes of contaminants, these programmes can include pharmaceuticals, if considered relevant. National monitoring also includes screening activities, where the occurrence of emerging substances such as pharmaceuticals are investigated.

Projects and screening studies

Finland

The following scientific studies has been carried out in Finland. The results are published.
Lahti M1, Brozinski JM, Segner H, Kronberg L, Oikari A. Bioavailability of pharmaceuticals in waters close to wastewater treatment plants: use of fish bile for exposure assessment. Environ Toxicol Chem. 2012 Aug;31(8):1831-7. doi: 10.1002/etc.1879. Epub 2012 Jun 1
Vieno, N. (2007) Occurrence of pharmaceuticals in Finnish sewage treatment plants, surface waters and their elimination in drinkin water processes. Doctoral thesis. Tampere University of Technology.
Vieno, N.M., Härkki, H., Tuhkanen, T. & Kronberg, L. (2007) Occurrence of pharmaceuticals in river wate rand their elimination in a pilot-scale drinking water treatment plant. Enviro. Sci. Techno. 41:5077–5084.
Muziasari WI, Managaki S, Pärnänen K, Karkman A, Lyra C, et al. (2014) Sulphonamide and Trimethoprim Resistance Genes Persist in Sediments at Baltic Sea Aquaculture Farms but Are Not Detected in the Surrounding Environment.

Poland

Contamination of the southern Baltic Sea waters by the residues of selected pharmaceuticals: Method development and field studies. The study carried out by the group of authors from Gdansk University and Institute of Oceanology, Polish Academy of Sciences in 2015 identified occurrence of thirteen pharmaceuticals in seawaters collected from southern Baltic Sea.

Sweden
Results from the Swedish screening 2006 were published in 2007 by the Swedish Environmental Research Institute. The study was assigned by the Swedish Environmental Protection Agency and included measurements of pharmaceuticals concentrations in surface water, sediments, sewage water, storm water and biota.
The other screening campaigns assigned by EPA during the last 20 year were:
Occurrence of additional WFD priority substances in Sweden (diclofenac, 17β-estradiol, 17α-estradiol) 2012-2014 SWECO Environment AB.
Medicines. 2010-11 Medicines. IVL Svenska Miljöinstitutet
Anti-inflammatory and analgesic drugs. 2007-2008. IVL Svenska Miljöinstitutet
Veterinary medicines in agricultural area. 2006-2007. WSP Environmental.
Pharmaceuticals. 2006-2007. IVL Svenska Miljöinstitutet
Antibiotics. Anti-inflammatory substances and Hormones. 2005-2006. IVL Svenska Miljöinstitutet
Antibiotics. 2002-2003. Umeå Universite
All the reports are available in Swedish.

2. National sources of data on consumption/use of pharmaceuticals e.g. (specify per different of activity; e.g. human use, agriculture, veterinary)

Human health

Denmark
Information on drag consumption in Denmark is provided by the medstat.dk (http://medstat.dk) which is the database of statistics on the total sales of medicines in Denmark 1996-2013. Information is based on the data reported to the Register of Medicinal Product Statistics. It is mandatory to report the sale of medicines, and therefore, the data cover all sales in Denmark. The information is available in Danish and English.

Finland
National drug consumption database is run by Finnish Medicines Agency (http://www.fimea.fi/frontpage). Annual statistic reports on pharmaceuticals consumption based on the wholesalers reporting are available at the WEB site in Finnish and English.

Germany
National data on annual human pharmaceutical consumption are collected in the WidO database. The database operator is the Research Institute of the German Health Insurance AOK. An annual report on medicinal consumption has been published since 1980. All reports are in German and are sold via the bookselling trade. The data are aggregated on a national scale, a break down on regional scale is not possible.

Estonia, Latvia and Lithuania
Statistical data regarding consumption of medicines in the countries are collected and processed by the Estonian State Agency of Medicines (SAM), Latvian State Agency of Medicines (SAM) and Lithuanian State Medicines Control Agency (SMCA) respectively. In accordance with the national legal framework all the wholesalers are reporting the data on sold medicines to the authorities monthly in Latvia and Lithuania and quarterly in Estonia. The reported data in general contain information on medicinal product identification code, trade name, price per package, number of packages sold and consumer group to which the product was sold. The data regarding sales of medicines to the final recipient (pharmacies, healthcare institutions, private practices) are used for calculating medicines consumption statistics. The data have been collecting and analysing the data since 1994 in Estonia,

2001 in Latvia and 2009 in Lithuania. Annual statistic reports are available at the WEB sites of the competent agencies www.ravimiamet.ee, www.zva.gov.lv, www.vvkt.lt.

Poland
National Health Fund database
The Department of Parallel Import and Registry of Medicines is responsible for monitoring the consumption of medicinal products in Poland based on reports submitted by pharmaceutical wholesalers. http://urpl.gov.pl/pl-rejestr-i-import-rownolegly, http://urpl.gov.pl/pl-rejestr-i-monitorowanie-konsumpcji.

Sweden
Swedish eHealth Agency (http://www.ehalsomyndigheten.se/) is responsible for Sweden's national drug statistics. The authority compiles, processes and publish statistics on pharmaceutical sales in Sweden. The database contains reported information on Pharmaceutical expenditure in SEK, DDD, gender, indication for use as free-text is stated on the prescription, dose in free-text, prescriber information (nurse, doctor, veterinarian), date of shipment to caregiver, reimbursement status. The consumption statistics is available since 2000 in Swedish.

Veterinary

Denmark
The Danish Veterinary and Food Administration collects information about the distribution and use of prescription veterinary pharmaceuticals in the official register VetStat. All administration of drugs for use in animal production is reported on a monthly basis. The VetStat database which run since 2000 gathers information on prescribing veterinarian, receiving herd, product name, amount of product, animal species, age group and diagnostic group. Based on this information, various estimates of the Danish antimicrobial usage for production animals are regularly presented.

Estonia
Since 2001 the Bureau of Drug Statistics of the Estonian State Agency of Medicines (SAM) is also collecting data from veterinary pharmacies which are obliged to submit the reports 4 times a year. According to the data received from veterinary pharmacies it is possible to put together records characterising retail sale of veterinary medicines in Estonia http://www.ravimiamet.ee/en/statistics-veterinary-medicines.
The data on use of the medical products in veterinary are also available in Latvia and Lithuania. Baltic Statistics on Medicines 2010-2012, Tartu, 2013. ISBN 978-9949-33-396-7.

Germany
The Federal Office of Consumer Protection and Food Safety (BVL) registers sales data of veterinary pharmaceuticals (antibiotics), a rough estimation on regional scale is possible.
http://www.bvl.bund.de/DE/08_PresseInfothek/01_FuerJournalisten/01_Presse_und_Hintergrundinformationen/05_Tierarzneimittel/2014/2014_08_01_pi_Abgabemengen_korrigiert_29_08_2014.html

Sweden
Medicinal use in food production, including fish farming, is monitored by the Board of Agriculture. Annual use is reported as part of the board´s feed control work.

3. National sources of data on pathways of pharmaceuticals into the environment such as concentration of the compounds in waste water, sludge, manure etc.
Projects and screening studies

Finland

Vieno, N. 2014. Harmful substances of municipal waste water treatment plants [Haitalliset aineet jätevedenpuhdistamoilla -hankkeen loppuraportti]. VVY:n monistesarja 34. 273 p. in Finnish. Finnish Water Utilities Association.
http://www.vvy.fi/julkaisut_ansiomerkit/monistesarja/34_haitalliset_aineet_jatevedenpuhdistamoilla_pdf.4051.news
The report contains the information on concentrations of medical substances in effluents of municipal wastewater and emissions. During sampling campaign executed in the period 2013-14 the concentration of 2 hormones and 3 other pharmaceuticals were measures in influents and effluents of 14 municipal waste water treatment plants. An assessment of releases of medical substances into the aquatic environment via municipal waste water effluent was done.
Kasurinen, V., Munne, P., Mehtonen, J., Türkmen, A., Seppälä, T., Mannio, J., Verta, M., Äystö, L. 2014. Organic contaminants in sewage sludge [Orgaaniset haitta-aineet puhdistamolietteissä]. 69 p. in Finnish. Finnish Environment Institute. Suomen ympäristökeskuksen raportteja 6/2014.
http://hdl.handle.net/10138/43224
The overview of contaminants (e.g. pharmaceuticals) in sludge of municipal wastewater treatment plants is given in the publication.

Germany

The data on concentration of hazardous substances and, in particular, pharmaceuticals in waste water are available from different data bases at different national institutions and can probably be delivered for the STATUS Report. In particular, the following information on the effluents from treatment plants situated in the Baltic Sea catchment area can be obtained:
Schleswig-Holstein - data from effluent waters of 5 WWTP in Schleswig-Holstein (catchment area of the Baltic Sea) (2013),
Mecklenburg-Vorpommern - data from effluent water from 11 WWTP in Mecklenburg-Vorpommern (2013)

Russia

A screening campaign on identifying sources and flow patterns of pharmaceuticals in St. Petersburg to the Baltic Sea was carried out in the frame of HELCOM BASE project. The report containing data on concentration of pharmaceuticals in the effluents from SPb waste water treatment plant is available at the HELCOM website.

Sweden

The Swedish EPA has monitored substances in sludge and outgoing water from 9 UWWTPs yearly since 2004. The monitored substances include some antibiotics and NSAIDs. In addition estrogenic and androgenic activity of the outgoing water is assessed.
The detailed report - Pharmaceutical residues and other emerging substances in the effluent of sewage treatment plants - has been recently published in 2015. The report contains a review of concentrations, quantification, behavior and removal options.
The National Veterinary Institute makes annual assessments of the extent of antibiotic resistance in the (terrestrial) environment.

Annex 3

Guidelines for reporting data on concentrations and effects of pharmaceutical compounds in the Baltic Sea environment

INTRODUCTION

At HELCOM PRESSURE 2-2015 (outcome item 4.4) and STATE&CONSERVATION 2-2015 (outcome item 4MA.17) the joint initiative by the HELCOM Secretariat and Policy Area Hazards of the EUSBSR to prepare a status report on pharmaceuticals in the Baltic Sea environment was supported and the tentative working plan was agreed. The report aims to integrate information on production and consumption of pharmaceuticals in the region, their pathways to the Baltic Sea environment, as well as observed concentrations and effects. 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.

The collection of data was agreed to be done in two steps. In the first step, Contracting Parties were invited to report on sources of data in each country. Reported national sources were compiled and analyzed by the Secretariat in July-August 2015. In this second step, **Contracting Parties are invited to** compile and report actual data.

Requested data are grouped into 3 categories:

1. Consumption and use of human and veterinary medical substances
2. Sources and pathways
3. Environmental concentrations and effects

The current document provides guidance for reporting data on **concentrations and effects** of pharmaceuticals in the Baltic Sea marine environment. The data should be reported using this guideline and provided templates (Excel sheets).

Each country should provide a **contact person** if clarification of the data is needed.

Concentrations and effects

Acquired information[1] on sources of data concerning concentrations and effects of pharmaceuticals in the Baltic environment indicates a significant number of available data. Sources include national monitoring, screening data, and scientific and commissioned studies. Many data have been published in national reports (in national languages) and some are available in national databases.

Contracting Parties are invited to compile and report available national data on **concentrations and effects** of pharmaceuticals in the Baltic marine environment. Data from scientific and commissioned studies relevant for each country should be included.

Requested data include available data on concentrations and effects of pharmaceuticals in the **Baltic Sea**:

a. Water (costal, open sea and transitional)
b. Sediment
c. Biota (concentrations and effects, specifically Baltic biota, not general)

Reporting format

Data are requested to be reported in one of two ways, depending on their accessibility.

[1] Collected from HELCOM Contracting Parties and from web searches

1) **Publically available data in English**
   All data that are publically available in the English language should be carefully listed. The list SHALL include:

- Title
- Type of data (e.g. monitoring data, scientific publication)
- Full reference (including e.g. author, year, report series, journal)
- Web link to full report, data base, publication or other. NOTE that the link should be functioning and be a direct link to the actual data/publication.
- If the source is a data base, please provide instructions of how to extract data and any necessary software requirements

Example:

Title: Results from the Swedish screening 2006. Sub-report 4: Pharmaceuticals.
Type of data: National screening
Full reference: Results from the Swedish screening 2006. Sub-report 4: Pharmaceuticals. Woldegiorgis, A., Green, J., Remberger, M., Kaj, L., Brorström-Lundén, E., Dye, C. and Schlaback, M. IVL report B1751. IVL Swedish Environmental Institute.
Web link: http://www3.ivl.se/rapporter/pdf/B1751.pdf
Additional information: All data in the report can be downloaded to Excel via this data base http://dvss.ivl.se/DataView1.aspx?unders_id=42 (in Swedish)

Title: Contamination of the southern Baltic Sea waters by the residues of selected pharmaceuticals: Method development and field studies
Type of data: Scientific publication
Full reference: Borecka, M., Siedlewicz, G., Halinski, L., Sikora, K., Pazdro, K., Stepnowski, P. and Bialk-Bielinska, A. (2015). Marine Pollution Bulletin 94(1-2):62-71.
Web link: http://www.sciencedirect.com/science/article/pii/S0025326X1500140X
Additional information: Access to Elsevier journals is needed to view the full article.

2) **All other data**
   If data are only available in the national language or otherwise inaccessible, the data SHALL be reported using the provided Excel templates.

   In addition, all data SHALL be provided with:

- A full reference, including web link if available
- An English summary and/or explanatory text

Example (in addition to filled-in Excel template):

Full reference: Zusammenstellung von Monitoringdaten zu Umweltkonzentrationen von Arzneimitteln
Bergmann et al. (2011). UBA 66/2011.
Web link: www.uba.de/uba-info-medien/4188.html
English summary: *In a comprehensive literature review we compiled an inventory of German and European monitoring data on the occurrence and behavior of pharmaceuticals in the environment. Environmental concentrations measured in various field campaigns and results of ecotoxicological and physico-chemical investigations were integrated in three databases. The analysis of these databases was used to identify priority pharmaceuticals and to suggest strategies for further monitoring.*

Templates

Templates that should be used for reporting data on concentrations in national language/inaccessible are **"Template_pharma_sea.xlsx"** and **"Template_pharma_biota.xlsx**". The templates contain drop-down lists and explanatory comments to the fields of the tables.

Explanatory supplementary information can be provided in text, such as:

- Geographical, hydrological description of the site including presence of possible sources of contaminants and distance from them (e.g. outlets of WWTPs, landfills, agriculture or aquaculture etc).
- Sampling and analytical methods.
- Summary including evaluation of representativeness of the obtained analytical data, trends obtained during the monitoring period, annual and seasonal variations of concentrations and observed transformation of the monitored substances in the aquatic environment.

Data on **effects** of pharmaceuticals in Baltic biota, should be reported by providing an English summary of the study with all necessary information. If additional information is needed, we may enquire this specifically.

Expected outcome of data collection and timeline

The collection of data on concentrations and effects of pharmaceuticals in the Baltic environment is aimed at providing an overview of both the availability of data and presence in the environment. Based on this information, a status report will be produced. The compilation will be done by PA Hazards. A similar collection of data was done for the Nordic countries and published by the Nordic Council of Ministers in 2012; "PPCP[2] monitoring in the Nordic countries – Status Report". The status report on concentrations and effects will provide input to a full environmental assessment of the presence of pharmaceuticals in the Baltic Sea made by HELCOM and presented at the HELCOM 37-2016.

[2] PPCP = Pharmaceuticals and Personal Care Products. Link to report.

Annex 4

Guidelines for reporting data on sources and pathways of pharmaceutical compounds into the Baltic Sea environment

INTRODUCTION

At HELCOM PRESSURE 2-2015 (outcome item 4.4) and STATE&CONSERVATION 2-2015 (outcome item 4MA.17) the joint initiative by the HELCOM Secretariat and Policy Area Hazards of the EUSBSR to prepare a status report on pharmaceuticals in the Baltic Sea environment was supported and the tentative working plan was agreed. The report aims to integrate information on production and consumption of pharmaceuticals in the region, their pathways to the Baltic Sea environment, as well as observed concentrations and effects. 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.

The collection of data was agreed to be done in two steps. In the first step, Contracting Parties were invited to report on sources of data in each country. Reported national sources were compiled and analyzed by the Secretariat in July-August 2015[3]. In this second step, **Contracting Parties are invited to** compile and report actual data.

Requested data are grouped into 3 categories:

1. Consumption and use of human and veterinary medical substances
2. Sources and pathways
3. Environmental concentrations and effects

The current document provides guidance for reporting data **on sources and pathways** of pharmaceuticals into the Baltic Sea marine environment. The data should be reported using this guideline and provided templates (Excel sheets).

Each country should provide a **contact person** if clarification of the data is needed.

Consumption and use of human and veterinary medical substances

The statistical data regarding consumption of pharmaceuticals in most of the Baltic Sea countries are available for the period since 2010. In accordance with the national legal framework in most of the countries all the wholesalers are reporting the data on sold medicines to the competent authorities. The reported data in general contain information on medicinal product identification code, trade name, price per package, number of packages sold and consumer group to which the product was sold. These data are used for calculating annual statistics of pharmaceuticals consumption.

Only Germany and Russia are exemptions from the common practices in the Baltic Sea The statistics on medical products consumption is mainly compiled at the federal level in both countries and hardly available at the regional one. In this cases the assessment can be made using data on federal statistics together with demographic data on the particular regions which are located in the Baltic Sea catchment.

The data on pharmaceuticals, mainly antibiotics and hormones, consumption in veterinary can be also provided by the competent national authorities in most of the countries. In case when the data are unavailable, the consumption can be assessed using an average rate of pharmaceuticals application in animal and poultry husbandry and livestock intensity.

Contracting parties are invited to provide national annual statistical reports on consumption and use of pharmaceutical substances in the medicine and veterinary for the last available year. The information will be

[3] Analysis of the data availability for the regional status report on the pharmaceuticals in the Baltic Sea environment

used for compilation of the overview of the most common pharmaceutical products in the Baltic Sea catchment area which can potentially be found in the aquatic environment.

Sources and pathways

The data reported by contracting parties in the first step of data collection and published reports outlined 4 potential sources of releasing pharmaceuticals into the environment. They are: pharmaceutical industry, waste water treatment plants, agricultural enterprises and aquaculture and medical wastes.

Pharmaceutical industry with potential emissions into atmosphere and releases into water bodies is not considered as a significant source with the exception of accidental releases.[4] Nevertheless, industrial zones with high density of the pharmaceutical industries can be considered as hot spots with potential risk of releases of pharmaceutical substances to the environment. That is why contracting parties are invited to provide information on pharmaceuticals production in the countries in recent years, if relevant publications are available, or provide a link to the recent publication in English. The information will be used as a background data for the status report.

Releases of pharmaceuticals from agriculture and aquaculture are rather poorly assessed. Just a few studies were reported where the concentrations of pharmaceutical residues in manure or other waste products originated from the agricultural enterprises or aquaculture facilities were investigated. Any available information on concentration of pharmaceuticals in the wastes of agricultural production or aquaculture would serve as a background for the assessment of contribution by agriculture and aquaculture to the total input of pharmaceutical residues into the Baltic Sea environment. The template **Template_pharma_sources.xlsx** can be used for reporting.

Medical waste management is considered to be one of the possible pathways of pharmaceutical substances into the environment. Medical waste includes unused medicinal products (human or veterinary) and contaminated materials (e.g. packaging) and liquids generated during manufacturing and administration. Medical waste stream poses a significant challenge for waste storage, collection, and disposal. In order to assess possible permeation of the medical substances to the environment through the waste management system the following information should be provided:

- Overview of the national legislation regarding medical waste management.
- Existing practices of medical waste collection, handling and utilizing.
- Evaluation of the share of the total amount of unused pharmaceuticals which are involved into the take-back schemes.
- Prioritization of the pharmaceutical substances which should be carefully collected in order to prevent their release into the environment.

Waste water and its treatment products

The data on concentrations observed in influent water, effluent water and sewage sludge is to be reported using the template **Template_pharma_sources.xlsx**.

The following explanatory supplementary information on observation points should be provided in a text format:

- Available information on consumption of pharmaceuticals and their potential release to the sewage system connected to the monitored waste water treatment facility.
- Capacity of the WWTP, technologies for the waste water treatment and removal of pharmaceutical residues applied at the monitored waste water treatment plant.

[4] Study on the environmental risks of medicinal products. Executive Agency for Health and Consumers 12 December 2013

- Evaluation of the efficiency of pharmaceutical removal from sewage water and distribution of them between liquid and solid phases.

Pathways of pharmaceutical substances into the marine environment.
The data on measured concentrations of medical substances in river, groundwater and rain water as well as in soils and fresh water biota are to be reported. The template **Template_pharma_pathways.xlsx** has to be used for reporting the data on concentration of pharmaceuticals in river, ground and rain water while the templates **Template_pharma_soil.xlsx** and **Template_pharma_biota.xlsx** should be used for reporting data on concentration observed in soil and fresh water biota respectively.

The following explanatory supplementary information on observation points should be provided in a text format:

- Geographical, hydrological description of the observation site including presence of possible sources of contaminants and distance from them (e.g. outlets of WWTPs, landfills, agriculture or aquaculture etc.)
- Description of the land use; the use of water body or water area
- Sampling and analytical methods
- Summary including evaluation of representativeness of the obtained analytical data, trends obtained during the monitoring period, annual and seasonal variations of concentrations.

REPORTING FORMAT
Data are requested to be reported in one of two ways, depending on their accessibility.

1) Publically available data in English
All data that are publically available in the English language should be carefully listed. The list SHALL include:

- Title
- Type of data (e.g. monitoring data, scientific publication)
- Full reference (including e.g. author, year, report series, journal)
- Web link to full report, data base, publication or other. NOTE that the link should be functioning and be a direct link to the actual data/publication.
- If the source is a data base, please provide instructions of how to extract data and any necessary software requirements

2) All other data
If data are only available in the national language or otherwise inaccessible, the data should be reported using the provided Excel templates.
In case when measured values are not available, aggregated data can be reported using corresponding fields of the same templates such as sampling period, sampling frequency, number of averaged measurements as well as mean, minimum and maximum values.

In addition, all data SHOULD be provided with:

- A full reference, including web link if available
- An English summary and/or explanatory text containing information outlined in the corresponding sections of the Guideline.

Expected outcome of data collection and timeline
The collection of data on sources and pathways of pharmaceuticals into the Baltic Sea environment is aimed at providing an overview of both the availability of data and the environmental pressure. Based on this information, a status report will be produced.

All data collected on consumption, use, sources, pathways, concentrations and effects will provide information to a full environmental assessment of the presence of pharmaceuticals in the Baltic Sea, and presented at the HELCOM 37-2016.