

ACTION PLAN FOR API EMISSION REDUCTIONS

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GLOSSARY

GLOSSARY

API	Active pharmaceutical ingredient
AWT	Advanced wastewater treatment
BPR	Biocidal Products Regulation
BSAP	Baltic Sea Action Plan
BSR Pharma	Baltic Sea Region Pharma Platform
CLP	Classification, Labelling, and Packaging of Substances and Mixtures
EIONET	European Environment Information and Observation Network
EUSBSR	European Union Strategy for the Baltic Sea Region
GDPR	General Data Protection Regulation
GWD	Groundwater Directive
HELCOM	Helsinki Commission
IED	Industrial Emissions Directive
IPCHEM	Information Platform for Chemical Monitoring
MSFD	Marine Strategy Framework Directive
NORMAN	Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances
PE	Population equivalent
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
UNESCO	United Nations Educational, Scientific and Cultural Organization
UWWTD	Urban Waste Water Treatment Directive
WFD	Water Framework Directive
WWTP	Wastewater treatment plant

EXECUTIVE SUMMARY

This report provides a political action plan to reduce emissions and loads of active pharmaceutical ingredients (APIs) into the Baltic Sea Region (BSR). The political action plan is based on the findings from the three-year Clear Waters from Pharmaceuticals (CWPharma) project funded by the EU's Interreg Baltic Sea Region Programme.

CWPharma investigated API loading into the Baltic Sea from six river basin districts in collaboration with seven countries in the BSR: Denmark, Estonia, Latvia, Germany, Finland, Sweden, and Poland. Advanced wastewater treatment (AWT) options for API reduction were tested at full- and pilot-scale. These results were combined with other API reduction measures, such as the improved collection and disposal of unused pharmaceuticals and increased sewer network coverage, and computationally modelled to visualize and assess the effects these reduction measures would have on API loading to the Baltic Sea. It is apparent that different types of measures are necessary to decrease the API load reaching the Baltic Sea.

This report summarizes the most important political recommendations derived from the CWPharma project, organized into three action groups for targeted implementation.

Awareness actions for avoiding API emissions to the environment

To decrease and ultimately avoid API discharges to the Baltic Sea, environmental awareness must be increased within the healthcare sector and amongst the general public. Therefore, all BSR countries should have a take-back system for all unused human and veterinary medicines from households. Residents, doctors, pharmacists, veterinarians and farmers should be educated on the negative effects of pharmaceuticals in the environment through national information campaigns, conducted at least annually during the next five years, after which

the viability of the information campaigns should be re-evaluated. These topics could be covered in the educational programs of the related professions. Large livestock farms, where unreasonable amounts of pharmaceutical waste are generated, as well as hospitals, medical clinics, elderly care homes and other healthcare institutions should be obliged by law to collect their pharmaceutical waste and send it directly to waste treatment facilities to avoid discharges to the Baltic Sea.

Technical measures for minimizing API emissions to the environment

Reducing API discharges can also be done at the wastewater treatment plant (WWTP) receiving excreted API and API metabolites via the municipal wastewater. This is partially accomplished through existing conventional wastewater treatment for some APIs, but minimizing the risks caused by more persistent and ecotoxic APIs through technical measures requires AWT technologies. However, numerous BSR countries are not yet compliant with the current EU Urban Waste Water Treatment Directive (UWWTD). Therefore, the first step to reducing APIs in WWTP discharge is for all BSR countries to be compliant with both the current UWWTD (before 2022) and the revised UWWTD when it is published. In parallel, WWTPs larger than 250 000 PE should be equipped with the appropriate AWT technology for removing APIs and other environmentally hazardous products no later than between 2025-2030. Smaller WWTPs (> 50 000 PE) should implement AWT no later than between 2035-2040. Additionally, in order to share technical information on API removal to speed up and improve implementation of WWTP and AWT upgrades, all BSR countries should be encouraged to establish a national knowledge platform. CWPharma reports provide guidance on the decision and implementation process for AWT at WWTPs.

Actions for improving knowledge on emissions, environmental concentrations and ecotoxicity of APIs

Pharmaceutical plants should be required to obtain environmental permits that mandate the plants to estimate their API emissions and impacts on WWTPs and surface waters. When necessary, environmental permit requirements for pharmaceutical plants should be further supplemented with industrial wastewater contract requirements.

APIs posing environmental risks should be included in regular environmental monitoring programmes managed by national or regional authorities to improve knowledge and management of risks. In case API concentrations in surface water bodies exceed PNEC values, operators of WWTPs and pharmaceutical plants should be additionally required to monitor their emissions. This will enable appropriate political actions to further reduce emissions, for instance via increasing wastewater treatment efficiency by advanced methods.

Finally, numerous actions can be taken to both broaden and deepen knowledge about APIs not analysed in prior and ongoing projects as well as their effects on the ecosystem. Future project funding should focus on a) the further development of analytical methods for API detection, especially for metabolites, hormones and antibiotics, prioritising those seldom analysed so far; b) more comprehensive screening and monitoring campaigns to produce a representative overview of API concentrations in the environment; and c) assessing the combined ecological risks of medications through more ecotoxicological data on single APIs and their metabolites, on mixture toxicity, on toxic effects for different trophic levels, and on chronic effects.

INTRODUCTION

Background

In 2017, numerous knowledge gaps on how emissions of active pharmaceutical ingredients (APIs) influence the Baltic Sea were identified by the United Nations Educational, Scientific and Cultural Organization (UNESCO) and Helsinki Commission (HELCOM) report on pharmaceuticals in the Baltic Sea [1]. Several of the identified knowledge gaps were addressed in the Clear Water from Pharmaceuticals (CWPharma) project, which included partners from Denmark, Estonia, Finland, Germany, Latvia, Poland, and Sweden. The CWPharma project screened a wide range of APIs within six river basin districts to understand and quantify the sources, emissions and environmental concentrations of APIs within the Baltic Sea region (BSR). Using empirical data from case study locations as well as literature, the overall API emissions and their impact on the environment in the BSR were assessed. Different kinds of emission reduction measures, including advanced wastewater treatment (AWT) and improved take-back and disposal of unused medicines, were evaluated. Outputs of the CWPharma project include the environmental screening of pharmaceuticals in the BSR [2], models of API loading into the Baltic Sea [3], guidelines for selecting AWT options [4-7], as well as recommendations for take-back and disposal of unused pharmaceuticals [8], for efficient dissemination of information on APIs [9], and for enhanced permitting of pharmaceutical plants [10], as well as scenarios for reducing API emissions [11].

The findings from the CWPharma project can serve as a blueprint for political actions worth considering in the process of adopting the 2021 Baltic Sea Action Plan (BSAP). Additionally, the CWPharma project can provide important input to the Baltic Sea Pharma platform (BSR Pharma^[1]) of the EU Strategy for the Baltic Sea Region (EUSBSR). BSR Pharma brings to-

gether projects and stakeholders from the BSR to share knowledge and support regional policy development related to pharmaceuticals in the environment.

To bridge the science-policy interface, some recommendations gathered from CWPharma project conclusions have been highlighted in this report, which is a policy-oriented action plan for API emission reduction in the BSR. This plan is directed at target groups responsible for drafting and approving legislation and implementing policies. In an effort to organize and potentially accelerate their implementation, the recommendations have been assigned to different levels of governance, including the European Union (EU) and affiliated institutions, national governments and administrations, and regional and local authorities. Focusing on the political recommendations and their applicability will, in turn, contribute to sustainable policies for reducing API emissions into the environment in the entire BSR.

In March 2019, the European Commission published the European Union Strategic Approach to Pharmaceuticals in the Environment (PiE) [12]. The approach outlines six action areas and several specific actions related to possible measures covering all stages of the pharmaceutical life cycle, from design and production to disposal and waste management. It emphasizes elements such as sharing good practices, cooperating on the international level, and improving understanding of risks. The recommendations and actions presented in this report answer the call issued by the EU Strategic Approach to PiE.

Methodological Framework

This report converts the numerous findings of the CWPharma project into politically relevant recommendations. Although the BSR countries, HELCOM and the EU are all unique political entities, due to the nature of transnationality within the EU, translating research findings into political recommendations re-

¹ A regional cooperation platform to reduce pharmaceuticals in the Baltic Sea – Swedish Environmental Protection Agency (swedishepa.se)

quires an understanding of how political decisions are aggregated from ideas and concepts into political authoritative decisions, which are then implemented at different levels of society.

The political systems of the nations around the Baltic Sea can be understood by two concepts derived from classical political theory. The first is the concept of the “political arenas,” which make authoritative decisions for a given, typically geographical, area. Each “arena” consists of an administrative organisation servicing, in the parts of the Baltic Sea region belonging to the EU, a publicly elected body. An example of this is the organization of the EU, which includes a Parliament, a Council of Ministers, a Commission, and other political elements. Other examples include EU member states which have governments and parliaments, federal states, regions and local authorities. Both examples include an elected body or council and an administrative arm which implements the decisions, which can be agencies or similar actors within the specific national legal context.

The second concept is the theory of transnationality [13], where traditional actors, such as governments and governmental organisations, interact with transnational actors, such as multinational companies, non-governmental international, national, and commercial actors, and other non-state national entities. This concept highlights the movement of (in)tangible influence across state boundaries, which can affect the course of international and national events and policy making. The formation of policies in the political arenas affecting the Baltic Sea region cannot be understood as a solely national political situation. Decisions are made through networks of interactions between transnational, national and intergovernmental actors. Some of the major relevant effects of transnationalism include: 1) attitude change; 2) international pluralism – linking of national interest groups in transnational structures, 3) increases in constraints on states through dependence and

interdependence; 4) increased ability of certain governments to influence others; and 5) emergence of autonomous actors who may deliberately oppose/impinge on state policies e.g. on environmental issues [13].

Therefore, this report links each political recommendation to the four levels of political decision making capable of creating authoritative decisions and influencing change: the EU, the national, the regional (e.g. federal states in Germany and regions in Sweden), and the local (e.g. municipality) levels. It is important to also consider that directives and regulations are applied at the EU level, made into law at the national level, but implemented and enforced at the regional and/or local levels. Furthermore, the role of transnational and non-governmental organisations and interest groups relevant for APIs and the Baltic Sea are

POLITICAL RECOMMENDATIONS FOR REDUCING API EMISSIONS TO THE BALTIC SEA

The current report presents the political recommendations for reducing the API emissions to the Baltic Sea. The political recommendations are based on reports produced within the work packages 2 [2, 3], 3 [4-7], and 4 [8-10] and the 5.1 [11] and 5.2 [14] activities. It is therefore worth noting that the political recommendations and actions described here are condensed from a number of more technical and specific conclusions described in greater detail in other CWPharma reports, which readers should refer to for more information.

Actions for avoiding API discharges to the environment

Recommendation #1: All countries should have a take-back system for all unused human and veterinary medicines from households. It should be anonymous, free of charge, easy to access, and provide dedicated collection points accessible to all residents. This particularly applies to countries which do not have uniform systems already in place, such as the non-uniform take-back schemes in Germany. Additionally, the collection mechanism for unused household pharmaceuticals functions poorly in Latvia, Lithuania and Poland [8]. Although not an EU member country, the absence of a take-back system in Russia should also be addressed [8]. [More detailed information can be found in the CWPharma Activity 4.1 report \[8\].](#)

Application level:

[national](#) [regional](#) [local](#)

Recommendation #2: In all countries, national information campaigns should be conducted at least annually during the next five years to increase awareness about the negative effects of pharmaceuticals in the environment amongst residents, doctors, pharmacists, veterinarians and farmers. The viability of these information campaigns should be re-evaluated after the first five years. For the public and farmers, communicating informa-

tion about the proper disposal of unused medicines and highlighting the harmful environmental impacts of incorrect disposal of human and animal medicines should be arranged and suited to the target audience. Pharmacists or veterinarians should verbally instruct their customers about proper pharmaceutical usage, disposal, and collection points when providing the medicines. Billboards or other print (brochures), television, and online media (smartphone applications, videos) could be used to disperse reminders about proper disposal of pharmaceuticals. [More detailed information can be found in the CWPharma Activity 4.1 \[8\] and 4.2 \[9\] reports.](#)

Recommendation addresses the following action areas of the EU Strategic Approach to PiE [12]: “Increase awareness and promote prudent use of pharmaceuticals” and “Reduce wastage and improve the management of waste”

Application level:

[national](#) [regional](#) [local](#)

Recommendation #3: Large farms, hospitals, medical clinics, elderly care homes and other healthcare institutions should be obliged by law to collect their pharmaceutical waste and send it directly to waste treatment facilities. The recommendation does not concern farms generated relatively small amounts of pharmaceutical waste (usually small sized farms). Pharmaceutical waste from small farms should be returned to veterinarians making check-up visits to the farms or to the same collection points used for unused household medicines. Other healthcare institutions include facilities providing housing services, retirement homes, assisted-living facilities, private clinics or other operators providing domiciliary care. Such collection systems are already in place in hospitals in Estonia, Denmark, Finland, Germany, Latvia, Poland and Sweden, as well as other health care institutions at least in Finland, Poland and Sweden, but there is still room for improvement. It

should be noted that information on Lithuania and Russia is lacking. [More detailed information can be found in the CWPharma Activity 4.1 report \[8\].](#)

Recommendation addresses the following action area of the EU Strategic Approach to PiE [12]: “Reduce wastage and improve the management of waste”

Application level:

[national](#) [regional](#) [local](#)

Actions for reducing wastewater treatment plant API discharges to the Baltic Sea

Recommendation #4: All countries should be obliged to ensure that wastewaters emitted to the Baltic Sea directly or indirectly through rivers and/or streams from WWTPs targeted in the existing Urban Waste Water Treatment Directive (UWWTD) meet the standards of both the current UWWTD (before 2022) and the revised UWWTD when it is published. Enforcing the polluter-pays principle in certain member states requires stronger national environmental governance and regulations. This applies to Latvia, Lithuania, and Poland, which as of 2016 were not yet fully compliant with the UWWTD [15]. Costs of upgrades and/or infrastructure will be different in each BSR member state, due to differences in energy costs, quantity of upgrades required, and other considerations explained in the CW-Pharma 5.1 report [11]. Additionally, the EU, individual member states, and other bilateral collaborations (e.g. HELCOM) should continue cooperating closely with Russia on addressing discharges to the Baltic Sea.

Recommendation addresses the following action area of the EU Strategic Approach to PiE [12]: “Reduce wastage and improve the management of waste”

Application level:

[EU](#) [national](#) [regional](#) [local](#)

Recommendation #5: All countries should be obliged to ensure that all wastewaters emitted to the Baltic Sea directly or indirectly through rivers and/or streams from WWTPs larger than 250 000 population equivalents (PE) are treated with an appropriate AWT technology removing APIs and other environmentally hazardous substances no later than between 2025–2030. The EU should establish a common standard to limit API concentrations in WWTP effluents for the BSR, based on the experience with the Swiss micropollutant standard^{[2][3]}. A dedicated funding scheme should be set up to support this recommendation, either at the EU, the BSR, or the national level.

Recommendation addresses the following action area of the EU Strategic Approach to PiE [12]: “Reduce wastage and improve the management of waste”

Application level:

[EU](#) [national](#) [regional](#) [local](#)

Recommendation #6: All countries should be obliged to ensure that all wastewater emitted to the Baltic Sea directly or indirectly from WWTPs larger than 50 000 PE are treated with an appropriate AWT technology removing APIs and other environmentally hazardous products no later than between 2035–2040. The same proposed EU standard to limit API concentrations in WWTP effluents mentioned above, as well as the funding scheme, would also be applicable here.

Recommendation addresses the following action area of the EU Strategic Approach to PiE [12]: “Reduce wastage and improve the management of waste”

Application level:

[EU](#) [national](#) [regional](#) [local](#)

2 [Microsoft PowerPoint - COST_Water2020_AJoss_15Apr2015.pptx](#)

3 [1_Presentation_Micropollutants_Switzerland_Christa_McArdell.pdf \(stowa.nl\)](#)

Recommendation #7: All countries should be obliged to establish a national knowledge platform to share technical information on API removal to speed up and improve implementation of WWTP and AWT upgrades. A knowledge platform or a competence centre for API removal in cooperation with national water associations would 1) compile national knowledge, 2) offer trainings, 3) facilitate inter-utility exchange and 4) translate relevant documents from other countries into the national language and link to other national platforms. This should be coordinated at the national level in cooperation with BSR Pharma.

More detailed information can be found in the CWPharma Activity 5.1 report [11].

Recommendation addresses the following action area of the EU Strategic Approach to PiE [12]: “Reduce wastage and improve the management of waste”

Application level:

EU national

Recommendation #8: When deciding on AWT options for specific WWTPs, the carbon footprint of the options must be considered on a country-by-country basis. Implementation and operation of AWT can have a significant impact on the carbon footprint of the associated WWTPs. The carbon footprint of an ozonation plant is highly sensitive to the national energy mix, whereas activated carbon is often purchased from the global market and, thus less dependent on national boundary conditions. Nevertheless, the choice of the most suitable AWT technology should not be based on the carbon footprint alone but should also consider costs and other WWTP specific boundary conditions.

More detailed information can be found in the CWPharma Activity 5.1 [11] and 3.4 [7] reports.

Recommendation addresses the following action area of the EU Strategic Approach to PiE

[12]: “Reduce wastage and improve the management of waste”

Application level:

national regional

Actions for improving knowledge on emissions, environmental concentrations and ecotoxicity of APIs

Recommendation #9: Environmental permits should require pharmaceutical plants to estimate their API emissions and impacts on WWTPs and surface waters. Legally enforceable emission limit values on API concentrations and biotesting in pharmaceutical industry wastewater should be set if impacts on WWTPs or surface waters are estimated to occur. Pharmaceutical plants should be aware of their API emissions and impacts on WWTPs and surface waters. Whether discharges meet threshold limits should then be controlled and enforced at the regional and local levels.

More detailed information can be found in the CWPharma 4.3 report [10].

Recommendation addresses the following action areas of the EU Strategic Approach to PiE [12]: “Support the development of pharmaceuticals intrinsically less harmful for the environment and promote greener manufacturing” and “Improve environmental risk assessment and its review”

Application level:

EU national

Recommendation #10: When necessary, environmental permit requirements for pharmaceutical plants should be further supplemented with industrial wastewater contract requirements. The pharmaceutical plant must first get initial approval from the authorities and water utilities to discharge industrial wastewater to the public sewer system. Although it is possible to draw up a contract

with an industrial facility without an environmental permit, the permit itself ensures better control over the actions of the industrial facility and helps to enforce best available techniques (BAT) on the premises and better API emission mitigation.

More detailed information can be found in the CWPharma Activity 4.3 report [10].

Recommendation addresses the following action area of the EU Strategic Approach to PiE [12]: “Support the development of pharmaceuticals intrinsically less harmful for the environment and promote greener manufacturing”

Application level:

regional local

Recommendation #11: APIs posing environmental risks should be included in regular environmental monitoring programmes managed by national and regional authorities to improve knowledge and management of risk and enable appropriate political actions. Broad screening campaigns of APIs should be performed regularly, preferably once every third year, and arranged and overseen by the appropriate authorities. The screening campaigns should focus on API concentrations in surface waters downstream of WWTPs and animal farms, as well as in sediments where API accumulation is expected, such as in lakes and Baltic Sea estuaries. In case API concentrations in surface water bodies exceed PNEC values, operators of WWTP and pharmaceutical plants should be additionally required to monitor their emissions and their impact on surface waters. Monitoring should focus on APIs and metabolites that pose environmental risks. The list of these APIs should be kept up-to-date with the newest information about environmental concentrations and risks and also reflect what is on the current Surface Water Watch List.

More detailed information can be found in the CWPharma Activity 2.1 & 2.2 report [2].

Recommendation addresses the following action area of the EU Strategic Approach to PiE [12]: “Expand environmental monitoring”

Application level:

national regional local

Recommendation #12: Future research funding should focus on a) further development of analytical methods for API detection, especially for metabolites, hormones, and other antibiotics, prioritising APIs seldom analysed so far; b) more comprehensive screening and monitoring campaigns to produce a representative overview of API concentrations in the environment; and c) assessments of combined ecological risks through more ecotoxicological data on single APIs and their metabolites, on mixture toxicity, on toxic effects for different trophic levels, and on chronic effects. The analytical methods should be developed to allow measurement of more APIs and their metabolites, allowing agencies to make comprehensive estimates of environmental levels and risks. Ecotoxicological studies should be performed on single APIs and their metabolites, and on mixture toxicity. The effects of APIs should be evaluated on different trophic levels and on different matrices, e.g. freshwater, coastal and marine waters, sediment and soil. Also, knowledge of chronic effects from long-term exposure to APIs should be improved. Further studies should be performed on the environmental levels and risks of antibiotics, including the spread of antibiotic resistance genes. More detailed information can be found in the CWPharma Activity 2.1 & 2.2 report [2].

Recommendation addresses the following action areas of the EU Strategic Approach to PiE [12]: “Improve environmental risk assessment and its review” and “Expand environmental monitoring”

Application level:

EU national

TRANSNATIONAL ACTORS

When implementing policies targeted at a specific audience, considering how the policy will affect relevant economic, social, and legislative actors is also worthwhile. Actors with different levels of interaction with governments, including environmental and chemical legislative and regulatory agencies, national water associations, funding agencies, research institutes and intergovernmental bodies such as HELCOM, are imperative to consider when drafting or considering new legislation. Ultimately, the policies proposed in this document must consider the individual needs and focuses of interest groups in each member state. Although not all BSR countries are addressed in the following section, their involvement is also critical when drafting policy reform.

Environmental regulatory agencies and other environmental administrations

As the legislative structures of CWPharma project countries vary, implementing the political recommendations will also depend on the organization of the national, regional, and local legislative bodies. Fortunately, all CWPharma project countries have an environmental administration which is responsible for some, if not all, of the following: proposing and adopting legislative acts; overseeing the implementation of laws governing the environment and water; water management; and implementation of monitoring programmes and environmental risk assessments.

Although environmental policies are generally proposed on the national level in all CWPharma countries, administration of laws differs widely [16]. In some countries, such as Germany, the national and regional governments can work together to propose legislation: the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety proposes legislation at the national level, while the environmental ministries of the federal states can also propose legislation in explicitly defined areas, such

as nature and water protection [17]. In other countries, municipalities have authority over water supply and sanitation, requiring creative coordination: the 290 municipalities in Sweden [18], the recent reduction of autonomous municipalities from 213 to 79 in Estonia [19], or the regional enforcement of legislation prior to the implementation of the 2017 Water Law in Poland [20] are examples of country-specific situations which must be appropriately considered when drafting new laws and national regulations.

As of data from 2016, not all CWPharma project countries were compliant with the UWWTD, which particularly applies to Latvia, Lithuania, and Poland [15]. For these countries, API emissions could potentially be simultaneously addressed during WWTP upgrades. Additionally, Lithuania still needs to transpose the Environmental Impact Assessment Directive into law, as well as streamline environmental assessment procedures [15].

National water networks and associations

In all CWPharma countries, national water associations are stakeholders who should be involved in the process of drafting political decisions. These bodies are non-governmental and can include not only operators and utilities, but also researchers and other interested parties. As they can assist in the development and dissemination of national knowledge platforms, their opinion and interests should be considered when coordinating national, regional, and local legislation aimed at achieving the political recommendations.

Funding agencies

Banks and other financial bodies are extremely relevant stakeholders when infrastructure upgrades are needed, and should also be approached as a stakeholder and a provider. Financing instruments can play a major role in determining whether recommendations are

even considered, let alone achieved. Countries rely on a variety of financing mechanisms for operation and maintenance of water and sanitation infrastructure [16], including domestic funding such as public expenditures or household expenditures (Germany, Poland, Lithuania [21] [20] [22]), tariffs (Denmark, [23]), drinking water or wastewater fees (Finland, Sweden [24] [18]), or a combination of both domestic and EU funding (Estonia, Lithuania, Latvia [25] [22] [26]).

Financial instruments established by the EU and associated inter-governmental bodies which member states can access for upgrading WWTPs to comply with the UWWTD could possibly also require the reduction of API emissions. Member states in the BSR region which apply for EU transfers, loans, and/or public expenditures could also potentially be required to assess, and if applicable, mitigate, their API emissions in addition to complying with all the mandates of the UWWTD which have not yet been attained.

Research coordination and digitalization

Better integration of existing EU legislation, such as chemical regulatory frameworks (i.e., Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the Biocidal Products Regulation (BPR)) into environmental assessment and protection frameworks (i.e., Water Framework Directive (WFD), Groundwater Directive (GWD), UWWTD, Marine Strategy Framework Directive (MSFD)) will facilitate more coordinated, scientifically based legislation to protect water bodies and the environment. This was previously proposed in prior work [27], but is worth repeating in light of the upcoming revisions of numerous directives. Better interplay between regulatory frameworks and directives would reduce the emissions of harmful chemicals to the environment.

Countries could improve transparency on the state of the environment and efforts made to improve it by making better use of digital platforms [15]. Since the level of trust in the public administration, ease of business and the well-being of society are correlated with the quality of national public services [28], countries with digitally-savvy governments, such as Finland and Estonia, could serve as examples of transparency for other member states. This can encourage member states with existing infrastructure for implementing such transparency, such as Germany, to reconsider or update their policies, within the constraints of the General Data Protection Regulation (GDPR) and other legislation. Additionally, the establishment of a national knowledge platform depends upon member states establishing or providing sufficient digital infrastructure.

HELCOM and other non-state entities

Transnational agreements such as HELCOM and similar treaties are not binding unless they are made into national law, and can serve as an additional critical stakeholder when discussing political recommendations. Although several goals of HELCOM's Baltic Sea Action Plan have not been met by 2020, the impetus for doing so is still high and requires more focused cooperation and coordination, as well as support for member states along the path to achieving the target goal.

CONCLUSIONS

The actions taken until now by the EU and the Baltic Sea region countries to prevent the progressive deterioration of the Baltic Sea ecosystem have not met the goals and ecological objectives of Baltic Sea Action Plan [29]. The wide variety of pharmaceuticals found in wastewater, freshwater and marine environments in the Baltic Sea region indicate a need to further reduce emissions of pharmaceuticals into the environment [1, 2].

It is apparent that different types of measures are required to minimize the pharmaceutical load entering the Baltic Sea. AWT measures and other measures related to increased awareness about the negative environmental effects of pharmaceuticals and improved waste management of unused pharmaceuticals are examples of measures that need to be implemented.

This is in line with the Organisation for Economic Co-operation and Development (OECD) policy paper on pharmaceuticals, which states that no single policy instrument is capable of managing all sources of pharmaceutical pollution [30]. On the other hand, over-emphasizing AWT is not an optimal use of limited resources [30]. Therefore, an efficient abatement strategy combines policy options at various stages of the pharmaceutical life cycle, using source-directed, use-oriented and end-of-pipe measures.

The 12 political actions presented in this report are relevant not only for coastal regions, but also for inland areas connected to the Baltic Sea. Arguing that dilution decreases the need for actions is short-sighted, since regardless of the dilution factors in individual water bodies, the same mass of ecologically harmful and potentially persistent APIs can accumulate in the ecosystem. For example, low dilution in streams and rivers should be addressed through national emission reduction efforts to avoid high local concentrations.

It is important to note that by recommending increased research efforts to improve knowledge about APIs in the Baltic Sea region, this

report is not suggesting that currently available information on APIs is insufficient for political action. The results of CWPharma and other projects focused on the Baltic Sea Region provide ample scientific results for the need to take pragmatic political actions now.

There is an urgent need for coherent political actions to protect the Baltic Sea environment and its catchment areas, which are surrounded by 9 nations. In this respect, the EU and HELCOM should participate in creating or perhaps enforcing concerted actions for all countries in the Baltic Sea region.

The 12 actions described in this report are economically, technically, and practically feasible to implement within a short time span. For all actions, the relevant political actors, whether at the EU-, national-, regional-, or local-level, have been identified. In this way, all levels of political actors have been called upon to fulfil their collective responsibility for securing the good environmental status of the Baltic Sea ecosystem in the future.

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