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The Path to Improved Wastewater Treatment of Pharmaceuticals

RECOMMENDATIONS

Related reports

These recommendations form part of a series of three publications.

The two other publications — an analysis and a background report — are not yet available in English. They can be accessed in Danish here:

ANALYSIS

The analysis summarises the key results and conclusions.



(In Danish)

**PHARMACEUTICALS IN THE
MARINE ENVIRONMENT**
*EXTENT, ENVIRONMENTAL
CONSEQUENCES AND THE PATH TO
IMPROVED WASTEWATER TREATMENT*

BACKGROUND REPORT

The background report contains the technical information employed in the analysis, including data and methodology.



(In Danish)

**PHARMACEUTICALS IN THE
MARINE ENVIRONMENT**
*BACKGROUND REPORT AND
METHODOLOGY*

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1. The path to improved wastewater treatment of pharmaceuticals

Medicines can treat disease and prolong human life, but the failure to remove these substances from wastewater has an impact on the marine environment. Some pharmaceutical substances are not absorbed by the body but are excreted into wastewater and discharged from there into the marine environment, where they can affect the behaviour, growth, endocrine systems and reproduction of marine organisms, among other things.

The revised Urban Wastewater Treatment Directive, adopted in November 2024, requires quaternary treatment to be fully implemented by 2045. This means that an increasing number of urban wastewater treatment plants will have to install advanced treatment processes capable of achieving an average removal of at least 80% for a selection of indicator substances, most of which are pharmaceuticals.

In this publication, the Ocean Institute puts forward 10 policy recommendations across four policy areas for how Denmark can reduce discharges of pharmaceuticals and other hazardous substances faster than the minimum deadlines of the Urban Wastewater Treatment Directive require. The recommendations are guided by an overarching principle: the interpretation and implementation of the Directive with the aim of ensuring as many treatment plants as possible meet the quaternary treatment requirements within the shortest possible timeframe.

Four considerations in particular call for ambitious and rapid implementation of the Urban Wastewater Treatment Directive:

1. **Substantial gains for the marine environment:** Rapid, prioritised implementation would appreciably reduce discharges of pharmaceuticals and other substances to the marine environment in the years leading up to 2045. The findings of the Ocean Institute's analysis *Pharmaceuticals in the marine environment* show considerable potential for reduced discharges of selected pharmaceuticals if quaternary treatment is brought forward.
2. **Quaternary treatment will be a requirement eventually:** Key stakeholdersⁱⁱⁱ expect that most treatment plants with a load above 10,000 p.e. will be covered by the requirement to introduce quaternary treatment before 2045. This follows both from the Directive's requirement to identify areas at risk and from the stricter conditions that the Water Framework Directive imposes in discharge permits. The latter will tighten further when the EU list of priority substances is extended to cover more pharmaceuticalsⁱⁱⁱ. For the individual treatment plant, the question is therefore not whether the requirement will have to be met, but when.
3. **Technological solutions are available:** Technologically mature treatment processes exist that can remove a considerably larger share of pharmaceuticals and other hazardous substances than treatment plants achieve today. These technologies, which include ozonation and activated carbon, are in operation at a number of treatment plants in Switzerland, Germany, the Netherlands and Sweden. In Denmark, only a few plants have begun installing these or equivalent treatment technologies.
4. **The implementation framework will be determined now:** The Directive must be transposed into Danish law by 2027 at the latest, and the political choices on pace and financing will therefore be made in the coming years. Starting now and drawing up a prioritised plan would also enable the factoring of investments into the ongoing adaptation and further development of the plants. The same applies to the extended producer responsibility scheme, which will cover at least 80% of the full costs of quaternary treatment and be in place by the end of 2028 at the latest.

About the Ocean Institute's work on the recommendations, and their scope

The recommendations build on the Ocean Institute's analysis *Pharmaceuticals in the Marine Environment: Extent, Environmental Consequences and the Path to Improved Wastewater Treatment*, together with interviews with a group of key stakeholders from Danish treatment plants, industry associations, consultancies, industrial companies and civil society, including some members of the Ocean Institute.

The recommendations focus on discharges of pharmaceuticals in urban wastewater. Discharges from urban wastewater treatment plants are the primary source of human pharmaceuticals in the aquatic environment in Denmark^{iv}. Treatment plants are a point source that is already regulated through discharge permits, and the technology to remove the substances exists and is in use in several European countries but is not widespread in Denmark.

At the same time, it is important to note that pharmaceuticals and other hazardous substances also reach the marine environment from other sources, including industry, aquaculture, agriculture and combined sewer overflows. These sources fall outside the scope of these recommendations, but all of them should feature prominently in the government's forthcoming action plan on hazardous substances in the marine environment.

Overview of recommendations	
Policy area:	Recommendations:
1. A prioritised national plan	1.1 Incorporate the implementation of quaternary treatment into the river basin management plans 1.2 Establish a national implementation programme and prioritise the list of areas at risk
2. Efficient and streamlined processing of permits	2.1 Streamline the requirements for discharge permits 2.2 Break down administrative barriers
3. Structural conditions for investment in improved wastewater treatment	3.1 Creating an enabling regulatory environment for investment in better wastewater treatment 3.2 Adopt an ambitious extended producer responsibility scheme
4. Systematic monitoring and knowledge sharing	4.1 Establish systematic monitoring of pharmaceuticals and other hazardous substances in the marine environment 4.2 Expand the monitoring of pharmaceuticals in the inflow and outflow of treatment plants 4.3 Consolidate and fund the knowledge base on the implementation of quaternary treatment 4.4 Establish a national screening tool for prospective risk assessment

2. Recommendations

Policy area 1: A prioritised national plan

Every year, many tonnes of pharmaceuticals are discharged into Danish fjords and coastal waters, where they can affect fish and other organisms even at low concentrations^v. Technologically mature treatment processes exist that can remove a considerably larger share of pharmaceuticals and other hazardous substances than treatment plants achieve today. In Denmark, only a few plants have begun installing these technologies.

The revised Urban Wastewater Treatment Directive requires quaternary treatment to be phased in at treatment plants up to 2045. In practice, this means that an increasing number of wastewater treatment plants will have to treat for a range of selected indicator substances, mainly pharmaceuticals, with a removal efficiency of at least 80%. Quaternary treatment must be achieved at all plants above 150,000 p.e. and at smaller plants discharging into identified areas at risk¹. DANVA, the industry association for Danish drinking water and wastewater companies, among others, expects that most treatment plants above 10,000 p.e. will in time be covered by the requirement^{vi}.

Denmark has shown before that new treatment technologies can be rolled out quickly across treatment plants and make a real difference to the marine environment. In the 1980s, the inner Danish waters suffered recurrent oxygen depletion after decades of rising nutrient inputs. The 1987 Action Plan on the Aquatic Environment I (Vandmiljøplan I) set clear reduction targets for discharges from treatment plants of 6,600 tonnes of nitrogen and 1,200 tonnes of phosphorus. With substantial investment in upgrading the plants, the nitrogen and phosphorus targets were met within nine years, in 1996^{vii}. Between 1987 and 1999, nitrogen and phosphorus discharges from treatment plants fell by 72% and 87% respectively. Over the same period, phosphorus concentrations in Danish fjords declined, and partly as a result the average algal biomass measured was lower^{ix}.

Today, the same level of political prioritisation and the same clear objectives are needed to reduce discharges of pharmaceuticals and other hazardous substances from treatment plants. The river basin management plans set out objectives and measures for the aquatic environment, and wastewater measures have formed part of the programmes of measures since the first planning cycles. The most recent version of the river basin management plans, the 2021-2027 plans following the revisit, nevertheless contains no specific measures to reduce discharges of hazardous substances from treatment plants^{xi}.

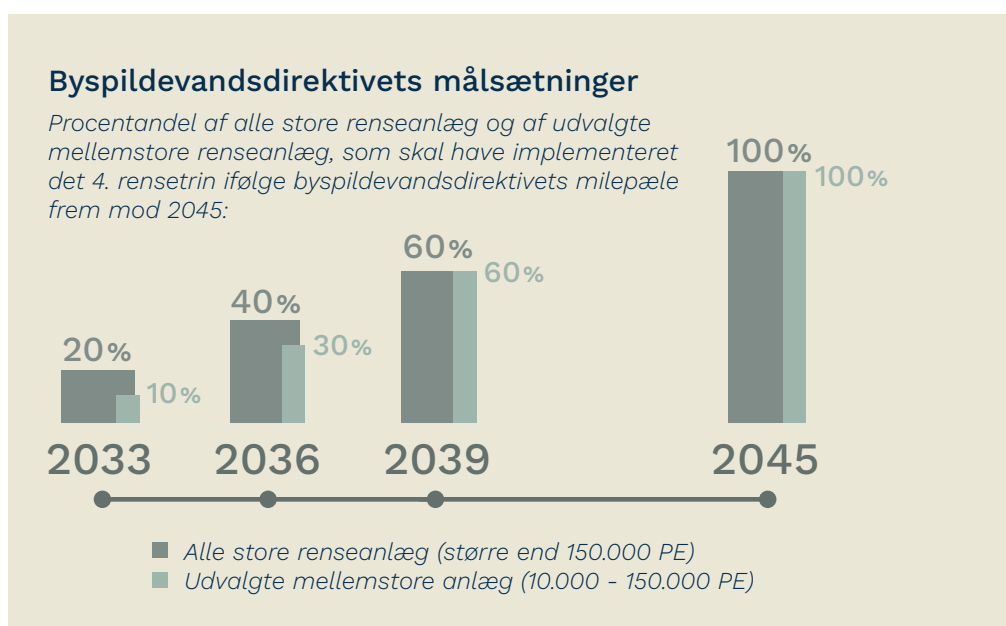
¹ The Directive's requirement for quaternary treatment (Article 8) operates with two thresholds, both of which must be met in stages up to 2045:

a) For treatment plants of 150,000 p.e. and above, the requirement attaches to the individual plant (Article 8(1)). All plants above 150,000 p.e. are covered.

b) For treatment plants between 10,000 p.e. and 150,000 p.e. the requirement attaches in principle to agglomerations in identified areas at risk (Article 8(4), cf. Article 2(4)). Work is under way among the authorities to clarify whether the catchment area of a treatment plant can be interpreted as an agglomeration, which would mean that all treatment plants above 10,000 p.e. discharging into identified areas at risk would be covered. These recommendations assume that the catchment area of a treatment plant can be interpreted as an agglomeration.

It must be ensured that the upgrading of treatment capacity is anchored politically, with clear objectives and a prioritised sequence, so that efforts are directed where they benefit the marine environment most and where the investment makes the greatest difference.

Denmark should use the latitude the Urban Wastewater Treatment Directive gives Member States for environmentally targeted implementation of quaternary treatment above the minimum requirements of the directive. Recital 3 of the Directive states that *“In line with Article 193 of the Treaty on the Functioning of the European Union (TFEU), Member States can go beyond the minimum requirements set out in this Directive. Member States could consider for instance applying deadlines or thresholds more stringent than those included in this Directive, reaching energy or climate neutrality more rapidly or imposing additional requirements for, or broadening the spectrum of the application of, their national extended producer responsibility systems”*^{xii}.



quality standards set for one or more pharmaceuticals are exceeded in 10 municipalities, that discharges of pharmaceuticals have adverse effects on the already pressured Danish marine environment, and that one treatment plant in ten above 10,000 p.e. discharges wastewater containing concentrations of pharmaceutical residues and other hazardous substances directly into marine protected areas. The same analysis also contains estimates of discharges of antidepressants, analgesics, antibiotics and oestrogens (including ethinylestradiol from contraceptives).

The role of the river basin management plans is to set the sequence and pace of an upgrade that has to be carried out in any event. Work is under way on a catalogue of measures for hazardous substances under VP4^{xiv}. Upgrading the treatment capacity of the plants should be a central element here. VP4 should also be used to set the priorities for upgrading treatment technologies at the plants (see recommendation 1.2).

Specific measures:

- The installation of treatment technologies that meet the requirements for quaternary treatment should be included as a specific measure in the catalogue of measures for hazardous substances in the forthcoming VP4 (2027-2033).
- The prioritised sequence from the implementation programme (see recommendation 1.2), should be incorporated into the programme of measures for the fourth planning cycle, stating the prioritisation mechanism and the timeframe.
- The recommended measures relating to extended monitoring of pharmaceuticals and other hazardous substances under Policy area 4 should also be incorporated into VP4. In addition, the setting of further relevant environmental quality standards should form part of this work (in conjunction with recommendation 4.1).

1.2 Establish a national implementation programme and prioritise the list of areas at risk

Background:

The Urban Wastewater Treatment Directive sets deadlines for the stepwise implementation of quaternary treatment at large treatment plants (150,000 p.e. and above). The Directive likewise requires quaternary treatment to be installed, between 2033 and 2045, at an increasing share of treatment plants between 10,000 p.e. and 150,000 p.e. that discharge into an area included on the national list of areas at risk from micropollutants.

The Directive's deadlines for the share of treatment plants in the two categories that must have implemented quaternary treatment are shown in the figure below². Faster implementation than shown below would spare the marine environment many tonnes of pharmaceuticals³.



Figure 1. Deadlines for the stepwise implementation of quaternary treatment in the Urban Wastewater Treatment Directive. Graphic: Ocean Institute, based on the Urban Wastewater Treatment Directive^{xv}.

The Directive must be transposed into Danish law by 31 July 2027 at the latest. By 1 January 2028, Denmark must submit a national implementation programme to the Commission which must, among other things, prioritise the necessary investments, taking into account the load expressed in p.e. and the scale of the environmental impact from urban wastewater discharges. The programme must be updated at least every six years.

Which plants will actually have to install quaternary treatment depends, however, on the list of areas where micropollutants pose a risk to the environment or human health, which Denmark must draw up by 31 December 2030. It would be prudent to bring that list forward so that it is available in time to feed into the implementation programme. The Ocean Institute also recommends that Denmark designate all marine areas as at risk from micropollutant discharge.

In early 2027, a representative analysis of the plants' discharges of hazardous substances, including pharmaceuticals, is also expected (the so-called "*fingerprint analysis*"). It is important that these results are used in setting priorities. A coherent national plan, a clear prioritisation mechanism and close monitoring of progress are necessary conditions for faster and more ambitious implementation.

² As set out in footnote 1, the treatment requirement for agglomerations above 10,000 p.e. that discharge into an area at risk is interpreted as equivalent to the catchment area of a treatment plant.

³ The Ocean Institute's analysis, *Pharmaceuticals in the marine environment: Extent, Environmental Consequences and the Path to Improved Wastewater Treatment*, estimates the potential for avoided discharges of selected substances if the rollout is accelerated.

Specific measures:

- The government should draw up a national implementation programme with a clear description of the plants covered, a prioritised sequence and an end date for each covered plant's implementation of quaternary treatment.
- The prioritisation of plants should take account of an overall weighting of, among other things:
 - The size and load of the plant expressed in p.e.: Within the group of plants between 10,000 p.e. and 150,000 p.e., larger plants should be prioritised ahead of smaller ones. (All plants above 150,000 p.e. should also be prioritised.)
 - The status of the local water body, including whether the plant discharges into a protected marine area: treatment plants discharging into a vulnerable aquatic environment and/or a protected area should be prioritised ahead of plants discharging into less sensitive receiving waters.
 - Particular sources in the catchment area: treatment plants with especially heavy catchment sources of pharmaceuticals and other hazardous substances should be prioritised ahead of treatment plants without comparable sources.
 - The plants' current treatment techniques and planned reinvestment, upgrades or other factors bearing on cost-effectiveness: plants with limited treatment for pharmaceuticals and other hazardous substances, and plants facing major rebuilding, reinvestment or upgrades, should be prioritised.
- The government should work to bring forward the designation under Article 8(2), so that the list of areas at risk is available as soon as possible and can feed into the implementation programme in 2028. The government should use the discretion within the directive to designate all marine areas in Denmark as risk areas from micropollutant discharge.
- The programme should ensure that quaternary treatment can be installed quickly as an environmental improvement measure, while setting a clear path for further reductions where quaternary treatment alone is not sufficient to achieve the environmental objectives.
- Requirements and timetables should as far as possible be linked to the programmes of measures in the river basin management plans, so that the reductions achieved at individual treatment plants form part of a coherent and documented plan for meeting the environmental objectives in the water body concerned (see also recommendations 2.1 and 4.1).

Policy area 2: Efficient and streamlined processing of permits

The requirement for quaternary treatment will follow from the Urban Wastewater Treatment Directive and from the forthcoming Danish implementing legislation. The discharge permit is where the requirement is translated into specific conditions for the individual plant, and the issuing of reviewed discharge permits must therefore support the implementation of quaternary treatment in practice.

Several utilities have already begun work in connection with structural analyses and new construction in order to prepare their plants for future requirements. This is partly because of requirements under the Water Framework Directive, which in some cases may mean that installing advanced treatment technologies is a necessary condition for a treatment plant to obtain a new discharge permit.

Many Danish treatment plants currently discharge wastewater on the basis of older discharge permits that contain no specific requirements for pharmaceuticals and certain other hazardous substances. The revised Urban Wastewater Treatment Directive requires all discharge permits for treatment plants to be reviewed between 2027 and 2037. New knowledge about the occurrence and environmental impact of these substances may therefore mean that existing permits have to be reviewed and that new conditions are set for reducing the substances that contribute to the environmental objectives for the receiving water body not being met.

The processing of discharge permits is currently characterised by varying requirements and procedures, long processing times and the involvement of several different authorities. Policy measures are therefore needed to ensure that the review of discharge permits does not become a bottleneck for the implementation of quaternary treatment, and that administrative processing becomes more efficient and more consistent across municipalities.

Installing quaternary treatment will in itself reduce discharges of pharmaceuticals and other micropollutants and thereby reduce the impact on the aquatic environment. Such a reduction does not constitute deterioration within the framework of the Water Framework Directive. The difficulty arises instead when a permit is reviewed and a new discharge permit is issued, if the remaining discharge continues to contribute to the environmental objective set for the water body not being achievable.

Under section 8(3) of the statutory order *Indsatsbekendtgørelsen*, an authority in a water body where the environmental objective is not met may only take a decision on an impact if the decision can neither cause deterioration nor prevent the achievement of the environmental objective^{xvi}. This means that, when reviewing a permit, the authority must determine which reductions are necessary if the discharge is not to maintain or prolong a situation in which the environmental objective cannot be met.

Quaternary treatment should therefore be seen as a key measure for gradually bringing existing discharges in line with the environmental objectives of the Water Framework Directive. Where an upgrade alone is not sufficient to achieve those objectives, a clear national framework is needed for how requirements for further reductions, timetables and any supplementary measures are set, so as to ensure documented and sustained progress towards good chemical status for all water bodies.

2.1 Streamline the requirements for discharge permits

Background:

Differing interpretations of national requirements and varying administrative processes can result in an unpredictable framework and raise the cost of implementing better wastewater treatment. The first Danish treatment plants now installing quaternary treatment have their requirements set through the discharge permit as a consequence of the Water Framework Directive. This process can result in protracted administrative processing without changing the technical design of the plants, since the technologies used are essentially the same. DANVA has previously described the difficulties of an uncertain administrative basis for issuing new discharge permits in a consultation response on guidance concerning requirements for discharges of certain pollutants^{xvii}. Those difficulties remain.

The Urban Wastewater Treatment Directive does not itself set concentration requirements for quaternary treatment, but requires at least 80% removal measured on selected indicator substances. A common set of rules is needed, with a list of identified indicator substances and a consistent monitoring framework that provides clarity in relation to the requirements of both the Urban Wastewater Treatment Directive and the Water Framework Directive. The rules should also specify which environmental quality standards are relevant for the selected pharmaceuticals and other hazardous substances, and which treatment technologies are considered effective and well documented.

The Directive's requirement that all treatment plants must have renewed permits between 2027 and 2037 creates both an urgent need and an opportunity to secure ambitious treatment requirements for the benefit of the marine environment and a level playing field across municipal boundaries.

Specific measures:

- The Danish Environmental Protection Agency should draw up national guidance on requirements for discharge permits, giving municipalities a clearer and more operational administrative basis. The guidance should enter into force no later than the date by which the Directive must be transposed into Danish law. The guidance should create the greatest possible consistency in administration within the framework of current legislation, while still allowing local conditions to be taken into account, including inflow concentrations at the treatment plants and the environmental status of the receiving waters.
 - The guidance should be developed in cooperation with DANVA, Local Government Denmark (KL) and other relevant stakeholders, and should describe:
 - Which indicator substances are used when calculating the removal requirement, in accordance with Annex I to the Directive.
 - A national overview of effective and well-documented treatment techniques for meeting the requirements for quaternary treatment.
 - The guidance should specify what documentation is sufficient when a utility uses a technology from the national overview, so as to avoid unnecessary reassessment of solutions with documented treatment performance.
 - The guidance should be anchored in the forthcoming legislation implementing the Urban Wastewater Treatment Directive, so that it becomes a common administrative basis for municipalities' processing of discharge permits.
- The authorities should assess on an ongoing basis whether the guidance needs updating as new knowledge emerges about environmental effects and relevant technologies.

2.2 Break down administrative barriers

Background:

Implementing quaternary treatment may involve a range of different authorities, including municipal environmental departments, the Danish Environmental Protection Agency, the Danish Coastal Authority, the Danish Agency for Green Land Use and Aquatic Environment, the Ministry of the Environment and the Ministry of Nature and Animal Welfare. Multiple administrative processes can delay projects even when they are politically prioritised. A better overall picture is needed of the difficulties treatment plants encounter on the way to upgrading treatment technology or building new plants.

Experience from the implementation of the Green Tripartite Agreement shows that dedicated units with a clear mandate can be one way of addressing barriers of this kind. The former Ministry for the Green Tripartite set up a unit with responsibility for breaking down barriers to the implementation of the agreement. A similar approach could usefully be applied to the implementation of quaternary treatment at Danish treatment plants.

Specific measures:

- A national task force should be set up under the Danish Environmental Protection Agency, with the participation of relevant authorities, stakeholders and the sector, drawing on the way the Green Tripartite was organised. The task force should have a mandate to:
 - Identify and address cross-cutting barriers to the implementation of quaternary treatment, support coordination between authorities and recommend adjustments to rules, guidance and administrative procedures on an ongoing basis where these cause unnecessary delay.
 - Develop proposals for more efficient administrative processing, including the possibility of processing several permits together where the plants belong to the same utility or discharge into the same water body.
 - Assess the overall capacity of municipalities in relation to the coming volume of reviews and recommend measures to remedy any shortfall in capacity.
 - Report annually with specific proposals for changes to rules and procedures, for the first time no later than one year after it is set up.
- A single point of entry should be created at the Danish Environmental Protection Agency where utilities, municipalities and other stakeholders can report specific barriers to the implementation of quaternary treatment. Reports are handled by the task force and feed into the annual reporting.
 - Cross-cutting conflicts between authorities that cannot be resolved administratively should be escalated to the political level for rapid clarification.

Policy area 3: Structural conditions for investment in improved wastewater treatment

Installing quaternary treatment at treatment plants across Denmark requires substantial investment. For DANVA, Envidan has compiled estimates of the investment and operating costs of installing quaternary treatment at all treatment plants above 10,000 p.e. at between DKK 630 million and DKK 703 million a year over a 30-year period (approximately EUR 84 million to EUR 94 million per year)^{xviii}.

Whether treatment plants are able to invest proactively in better treatment depends on two things in particular: the ongoing review of the water companies' structural conditions and the design of extended producer responsibility (EPR) for quaternary treatment. Decisive political choices on both the future structural conditions and extended producer responsibility will have to be made in the near future.

The water sector is expected to undergo major changes in the coming years, including through a forthcoming reform of the future economic regulation of the water sector initiated in 2024^{xix}. Since the regulatory conditions of treatment plants is crucial for their ability to plan and finance major capital investment, it is essential that the substantial investment needed for quaternary treatment is actively built into this ongoing review: the new regulatory model should give utilities the investment certainty they need to deliver an ambitious response to the requirements of the Urban Wastewater Treatment Directive and the Water Framework Directive, among others.

At the same time, the Urban Wastewater Treatment Directive introduces a requirement for extended producer responsibility (EPR) for pharmaceutical and cosmetics producers, who will have to contribute to financing at least 80% of the full costs of complying with the Directive's requirements for quaternary treatment. The Directive lays down minimum requirements but allows individual Member States to go further. Setting out clear principles for this scheme early on in the process, together with ambitious Danish implementation, will help create the long-term conditions needed to reduce the discharge of chemicals into the Danish marine environment.

3.1 Creating an enabling regulatory environment for investment in better wastewater treatment

Background:

The economic regulatory model for the water sector was not been designed to support the large, long-term investments that utilities face over the coming decades as a result of climate change and stricter environmental requirements, among other things. Investments are needed in order to meet the binding requirements for quaternary treatment in the Urban Wastewater Treatment Directive and to comply with the Water Framework Directive, among others. Treatment plants need certainty that the costs of complying with future requirements can be financed, even when the investment is made well before the requirement becomes legally binding. Without that certainty, there is an incentive to postpone investment.

The Urban Wastewater Treatment Directive assumes that investment in the wastewater sector is planned coherently and for the long term. By 1 January 2028, Member States must draw up a national implementation programme describing, among other things, the state of implementation, the expected investment needs and the financing of the requirements of the Directive.

All treatment plants with a load of at least 150,000 p.e. will be covered progressively up to 2045, whereas for plants and agglomerations between 10,000 and 150,000 p.e. it will not be determined until the end of 2030 at the latest which areas are at risk from micropollutants. That designation will therefore be a key basis for the subsequent prioritisation and updating of the investment programme for quaternary treatment.

The ongoing review of the water sector's economic frameworks^{xx} by the Water Regulation Committee under the Ministry of Climate, Energy and Utilities opens an opportunity to build the coming investment needs explicitly into the model and to ensure that treatment plants have the regulatory conditions they need for long-term planning.

Specific measures:

- The water companies' future economic frameworks should be designed with quaternary treatment explicitly anchored in them. This should ensure that investment in advanced treatment can be accommodated within the utility's economic framework and provide certainty that the costs of complying with future requirements can be financed, even when the investment is made well before the requirement becomes legally binding.
- The national implementation of the Urban Wastewater Treatment Directive in Danish law, including extended producer responsibility, should be planned and coordinated with the reform of water sector legislation, so that the new framework supports the task facing treatment plants. Specifically, the national implementation programme under the Urban Wastewater Treatment Directive (recommendation 1.2) should be drawn up in conjunction with the reform of water sector regulation, so that investment planning and the economic frameworks rest on the same assumptions.

3.2 Adopt an ambitious extended producer responsibility scheme

Background:

The Urban Wastewater Treatment Directive requires EPR to be established for quaternary treatment, ensuring that the costs of removing pharmaceuticals and other micropollutants covered by the Directive are borne by the producers who place the products on the market. In practice, EPR for quaternary treatment will mean that the manufacturers, importers and distributors of human medicinal products and cosmetics covered by the scheme must finance at least 80% of the full costs (both installation and operation) of complying with the Directive's requirements for quaternary treatment (subject to certain exemptions), together with the costs of data collection and verification.

The Directive leaves the detailed design of the EPR scheme to the Member States. The scheme must be in force by 31 December 2028, while the Directive must be transposed into Danish law by 31 July 2027.

Denmark should design the producer responsibility scheme so that it is ambitious, administratively simple and supports a favourable environment for investments in improved treatment of wastewater. The rollout of extended producer responsibility is already under way: in early 2027, the “*fingerprint analysis*” mentioned above is expected, a representative analysis of the plants’ discharges of hazardous substances, including pharmaceuticals, which is to underpin the data basis for allocating the costs.

Specific measures:

- The framework for producer responsibility, including the calculation model, the contribution structure and verification and supervision, should be set out in the implementing legislation, so that the scheme can be put into operation as early as possible and aligned with the reform of the utilities' long-term structural conditions, see recommendation 3.1.
- The Directive's requirement that contributions be set according to quantity and hazardousness should be implemented so that the scheme encourages reductions at source. That means the scheme should allow producers to document a reduced environmental impact and thereby qualify for a reduction in their contribution. Equally, the scheme should be designed so that contributions from manufacturers, importers and distributors of medicinal products with a high potential environmental impact are higher.
- In line with the polluter pays principle, the EPR scheme should over time be extended to other relevant sectors in addition to the pharmaceutical and cosmetics industries, if it can be documented that producers in those sectors place products on the market that lead to discharges of relevant micropollutants. The possible addition of other sectors to the EPR scheme should not, however, stand in the way of a rapid rollout within the Directive's clear framework and deadlines.

Policy area 4: Systematic monitoring and knowledge sharing

Effective action against pharmaceuticals in the marine environment requires knowledge of what is discharged and of the status of the receiving waters. Pharmaceuticals do not form part of the monitoring of Danish marine areas, and most existing knowledge comes from streams and from isolated research projects. The Ocean Institute's analysis shows exceedances of environmental quality standards for one or more pharmaceuticals in streams in 10 municipalities^{xxi}.

Under the Urban Wastewater Treatment Directive, Denmark must identify and assess the risks that wastewater discharges pose to, among other things, the status of the marine environment by the end of 2027. Increased monitoring of pharmaceuticals in the marine environment will strengthen the basis for that assessment and the relevant policy responses.

The Directive also requires Denmark, by the end of 2030 at the latest, to designate the areas where discharges of micropollutants, including certain pharmaceuticals, from treatment plants pose a risk. That designation determines which plants below 150,000 p.e. are covered by the Directive's requirement for quaternary treatment. The requirement in the Urban Wastewater Treatment Directive therefore presupposes a data basis that does not exist today. Compliance with the Water Framework Directive may also lead to requirements for advanced treatment.

Greater knowledge of the chemical pollution of the marine environment already creates an obligation to act. The statutory order *Spildevandsbekendtgørelsen* requires a discharge permit to be renewed where “new information of significance emerges regarding the harmful effects of the pollution, or where the harmful effects of the pollution could not otherwise have been foreseen when the permit was issued”^{xxii}. Better monitoring of discharges and of the chemical status of the marine environment is therefore already a lever for promoting better treatment.

4.1 Establish systematic monitoring of pharmaceuticals and other hazardous substances in the marine environment

Background:

Pharmaceuticals are not part of the marine component of the national monitoring programme, NOVANA. Most existing knowledge about pharmaceuticals in the aquatic and marine environment comes from streams, from scattered research projects and from individual measurements taken in connection with the review of discharge permits. The Ocean Institute's analysis shows that even the sparse monitoring of streams reveals exceedances of environmental quality standards for pharmaceuticals in 10 municipalities. For Danish coastal waters there is no data basis for occurrence, concentration and effects. There is therefore a considerable need to extend this monitoring to the marine environment.

Improved data is a precondition for both the 2027 risk assessment and the 2030 designation of areas at risk, both of which follow from the Urban Wastewater Treatment Directive. The designation is the mechanism that determines which plants between 10,000 and 150,000 p.e. are covered by the requirement for quaternary treatment. Inadequate data will in practice mean uncertainty about which plants are covered. Greater knowledge of the status of the marine environment also makes it possible to prioritise effectively which plants are upgraded first, see recommendation 1.2.

Specific measures:

- The NOVANA monitoring programme should be extended to include systematic monitoring of pharmaceuticals and other hazardous substances in coastal water bodies. The purpose of the extended monitoring is to make it possible to track developments in water, sediment and biota and to adjust efforts as they go. The list of substances should be set nationally and adjusted on an ongoing basis, taking as its starting point the Directive's indicator substances and the substances covered by environmental quality standards, and revised as the list of priority substances is expanded (see recommendations 1.2 and 2.1).

- The programme should be organised so that it can feed directly into the risk assessment due by the end of 2027 and the designation of areas at risk due by the end of 2030.
- Data from the extended NOVANA programme should be reported to a central national and publicly accessible database, for example the Danish Environment Portal, allowing comparison across receiving waters and supporting the ability of national and municipal authorities to prioritise.
- The data should also feed into reporting under the Water Framework Directive and be used as part of a broader effort to address the chemical pollution of the Danish marine environment, see recommendation 1.1 and the government's forthcoming action plan on hazardous substances in the marine environment.

4.2 Expand the monitoring of pharmaceuticals in the inflow and outflow of treatment plants

Background:

Treatment plants are the primary point source of human pharmaceuticals in the marine environment^{xxiii4}. At present, treatment plants are not systematically obliged to measure and report pharmaceuticals in their discharges. That will change with the Urban Wastewater Treatment Directive, which requires treatment plants (see footnote 1) with a catchment area corresponding to a load of between 10,000 p.e. and 150,000 p.e. to take at least one sample every two years in both the inflow and the outflow for a range of pollutants, which over time will include more pharmaceuticals^{xxiv}. For plants above 150,000 p.e. the requirement is two samples a year. The requirement takes effect on 31 July 2027, and the data must feed into a national data set from the end of 2028.^{xxv}

Work is also already under way to install treatment technologies that make compliance with quaternary treatment possible. Alongside this, work is being done to establish the data basis for extended producer responsibility, which is expected to be available in 2027, see recommendation 3.2. In addition, the research project GALADRIEL (2026-2030), led by the University of Copenhagen, will map hazardous substances in wastewater and link them to the treatment methods that remove them most effectively^{xxvi}. This experience, spanning laboratory trials, studies at treatment plants and practical experience from the plants themselves, should be used to guide the process ahead (see recommendation 4.3).

The minimum requirements of the Urban Wastewater Treatment Directive need to be supplemented with more frequent measurements at all larger plants in order to make national prioritisation of the implementation of quaternary treatment possible (see recommendation 1.2). It is also essential that the national requirements determine which substances are to be measured, so as to ensure streamlined and comparable data across plants, see recommendation 2.1.

Specific measures:

- The measurement frequency should be set above the Directive's minimum, so that developments can be followed at the plants that have not yet installed quaternary treatment.
- A single national list of relevant pollutants in urban wastewater should be drawn up, in which pharmaceuticals appear alongside other hazardous substances. The list should be established as part of the national guidance, see recommendation 2.1, so that it is applied consistently across municipalities. It should also be possible to add further substances where this is relevant for a particular catchment area.
- Measurement and reporting should be set as requirements in the discharge permits, see Policy area 2, and should cover both the inflow and the outflow, so that the removal efficiency can be documented and the data can feed into the basis for producer responsibility.

⁴⁴ Pharmaceuticals also reach the aquatic environment by other routes, including from agriculture. Given the scope set out above, these sources lie outside the remit of these recommendations.

- The data should be reported to a central national and publicly accessible database, for example the Danish Environment Portal, allowing comparison across plants and receiving waters and supporting the ability of national and municipal authorities to prioritise. The data should also be used to support recommendation 4.4 on a national screening tool to strengthen the risk assessment of pharmaceuticals in the aquatic environment.

4.3 Consolidate and fund the knowledge base on the implementation of quaternary treatment

Background:

Danish treatment plants face a substantial task in the coming years, in which technology choices, investment decisions and authority processing all have to be handled within a short space of time. Knowledge about advanced treatment is already being built up in the water sector's innovation environments, at the first plants now installing quaternary treatment, and at a knowledge centre for data on hazardous substances in treatment plant outflows that the sector itself has established.

This knowledge building is currently fragmented, and there is a risk that experience will be collected using different methods and will therefore not be comparable across plants. At the same time, the body of experience, both in Denmark and abroad, comes primarily from large plants. For medium-sized plants below 150,000 p.e. and closer to 10,000 p.e., operating economics, space requirements and climate footprint are far less tested.

Meeting these challenges requires, among other things, systematic collection of knowledge from the first plants now implementing quaternary treatment and its transfer to the authorities that must set requirements and create a prioritised national plan, see Policy areas 1 and 2. A coherent approach to knowledge building, with lasting funding and a clear institutional home, can support knowledge sharing going forward.

The challenge is not Denmark's alone. All Member States must install quaternary treatment within the same framework. A few Member States have plants in operation or under construction, while most are still at the planning stage. There is an opportunity for Denmark to actively seek out and share knowledge among European countries, particularly the other Baltic Sea and North Sea countries with which Denmark shares a marine environment.

Specific measures:

- The recently established knowledge centre for data on hazardous substances in treatment plant outflows, currently hosted by the consultancy Envidan, should be appropriated state funding and a clear institutional anchor ensuring access for all relevant actors, for example by being housed within the Danish Environmental Protection Agency or an industry association.
- Data collection for the knowledge centre should be organised so that it can feed directly into the national data set Denmark must establish under the Urban Wastewater Treatment Directive, see recommendation 4.2.
- A targeted development track should also be launched for treatment solutions for smaller plants, focusing on treatment efficiency, operating economics, climate footprint and similar factors.
- Experience and data built up by the knowledge centre should systematically feed into the national guidance and the task force, see recommendations 2.1 and 2.2.
- The knowledge centre should also gather and disseminate knowledge about effective routes to quaternary treatment in the EU. It should draw on the Member States that already have experience of quaternary treatment and on countries facing similar challenges, with the aim of promoting more ambitious implementation of the Urban Wastewater Treatment Directive across the EU. A joint initiative can strengthen knowledge sharing, create common interpretations and accelerate investment in technologies that reduce discharges of pharmaceuticals and other hazardous substances to the marine environment.

4.4 Establish a national screening tool for prospective risk assessment

Background:

The Urban Wastewater Treatment Directive requires both measurement of inflow and outflow and a specific assessment of the health and environmental consequences of discharges. Under the Directive, Denmark must identify and assess the risks posed by wastewater discharges by the end of 2027. By the end of 2030, areas must be designated where discharges of pharmaceuticals and other hazardous substances covered by the Directive from treatment plants pose a risk.

Stronger monitoring of pharmaceuticals and other hazardous substances in the marine environment and of discharges from treatment plants is a good first step and makes retrospective action possible, which can be used to prioritise areas where pharmaceuticals and other hazardous substances already pose a health and environmental problem. It will take several years to build up sufficient data, since measurement data are not available for every substance and every water body. That is one reason why a screening tool is needed that can support prospective risk assessment and thereby provide a basis for assessing risks for substances and areas where measurement data are not yet available.

The screening tool can draw on sales of medicinal products, linked to knowledge of how large a share of a substance are excreted, degraded or removed at a conventional treatment plant. This should be supplemented with data on the persistence and toxicity of the substances. The screening tool can thereby give a picture of which substances are potentially discharged, in what quantities and with what environmental significance. This allows the authorities to follow trends and adjust monitoring accordingly.

A further advantage of the tool is that it can assess the metabolites and other transformation products of the active pharmaceutical ingredients. When a medicinal product is taken, it is rarely excreted unchanged: a large proportion is converted in the body into metabolites, and the substances are transformed further at the treatment plant. Because the tool already builds on knowledge of how substances are metabolised, altered and removed, it could be extended to estimate which transformation products are formed, and in what quantities. In that way it can give a more accurate picture of the environmental consequences of the discharge.

Specific measures:

- A national screening tool should be established, for example hosted by the Danish Environmental Protection Agency, estimating which pharmaceuticals are potentially discharged into the aquatic environment, in what quantities and with what environmental risk. The tool should be built as a mass balance and risk model that follows substances from sales through excretion and treatment to potential discharge, and links the result to the environmental properties of the substances. See Appendix 1 for a detailed proposal for the design of the tool.
 - The results should be used to prioritise which substances are to be measured, see recommendation 4.2, and in which water bodies monitoring should be intensified, see recommendation 4.1. Measurement data should conversely be used to validate and adjust the model's assumptions on an ongoing basis.
 - The results should feed into the basis for the risk assessment due by the end of 2027, the designation of areas at risk due by the end of 2030 and the prioritisation of which plants are upgraded first, see recommendation 1.2.

Appendix 1. Proposal for a national screening tool to strengthen the risk assessment of pharmaceuticals in the aquatic environment

A national screening tool can give the authorities a consistent and better basis for assessing which pharmaceuticals are potentially discharged into the Danish aquatic and marine environment, in what quantities and with what environmental risk.

The screening tool should be built as a simple mass balance and risk model that follows pharmaceuticals from sales to potential discharge. The model should combine information on the quantity of active substance sold with knowledge of how large a share is actually used, how large a share is excreted from the body after intake, how much reaches the treatment plants and how much is expected to be removed at a conventional treatment plant. The model should also take account of the fact that pharmaceuticals are not discharged solely as the original active substance. For several substances, metabolites and other transformation products may also be environmentally relevant. The screening tool should therefore include, as far as possible, knowledge of relevant metabolites and other transformation products and of the fate of substances in treatment plants and the aquatic environment.

The screening should also be linked to the physico-chemical properties and environmental risk of the substances. This includes knowledge of persistence, mobility, bioaccumulation, toxicity, endocrine-disrupting effects and known or expected effects on aquatic organisms. In that way, the tool can point not only to the substances discharged in the largest quantities, but also to those where even small discharges may pose a particular environmental risk.

The screening tool should therefore contain at least the following model steps:

- 1. Sales and use**
Annual sales are calculated in kilograms of active substance per pharmaceutical and adjusted for the share expected to be used.
- 2. Excretion from the body**
The quantity used is combined with knowledge of how large a share of the substance is excreted unchanged or as relevant metabolites .
- 3. Treatment at treatment plants**
The expected load reaching treatment plants is compared with knowledge of the removal efficiency for each substance at conventional treatment plants and, where relevant, at plants with advanced treatment.
- 4. Potential discharge**
An estimate is calculated of the quantity of active substance and relevant metabolites and other transformation products potentially discharged into the aquatic environment.
- 5. Environmental risk and prioritisation**
The calculated discharge is compared with knowledge of the substance's transport in the aquatic environment, persistence, toxicity, environmental quality standards, expected effects and the sensitivity of the receiving water bodies.

The screening tool should be used on an ongoing basis to follow developments in the sales of pharmaceuticals in Denmark. This will make it possible to identify new trends, new substances of concern and new medicinal products introduced onto the Danish market. It will give the authorities a more targeted basis for prioritising which substances should be monitored, and in which water bodies monitoring may need to be intensified. The screening tool will at the same time be a cost-effective instrument for ongoing risk assessment, because it can point to the substances and areas where the risk is expected to be greatest. It can also support the assessment of particularly vulnerable receiving waters and contribute to prioritising which treatment plants should be covered first when quaternary treatment is implemented.

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The Path to Improved Wastewater Treatment of Pharmaceuticals: Recommendations

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TÆNKE
TANKEN

Hav