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**'I/A' ITEM NOTE**

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From: General Secretariat of the Council  
To: Permanent Representatives Committee/Council  
Subject: Draft DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE  
COUNCIL concerning urban wastewater treatment (recast) **(first reading)**  
- Adoption of the legislative act  
= Statements

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**Statement by Estonia**

We express serious concerns in relation to the Article 9 on applying the extended producer responsibility (EPR) to pharmaceuticals. While the EPR can be a useful source of funding to cover the costs of wastewater treatment from micropollutants (quaternary treatment), it should not be an obligatory or only solution for the Member States. When applying the EPR, Member States should be able to consider their specific national context regarding technical feasibility and economic viability of setting up the EPR, as well as wider socio-economic implications, in particular the availability and affordability of essential and critical medicinal products. Considering these aspects Member States should be able to decide to a greater extent on the use of alternative or additional funding sources to cover the costs of quaternary treatment and in justified cases be able to exempt certain product categories from the EPR.

Although we agree that the “polluter pays” principle is a necessary underlying concept of environmental protection, we are not convinced it is suitable for pharmaceutical sector in this Directive for the following reasons.

Firstly, **the clear added value of EPR in case of pharmaceuticals has not been confirmed by the feasibility study** (carried out as part of the Commission’s impact assessment), as the effect of EPR on behavioural change would be very limited. On one hand, EPR is unlikely to significantly incentivise the substitution of pharmaceutical active ingredients in short- to medium-term, considering their specific innovation cycles. On the other hand, patients do not have the option to decrease their consumption of a medically indicated medicinal product or switch to another product. In this respect, **ethical aspects are not sufficiently considered**, as additional costs will be borne by patients, putting a disproportionate and unfair burden on population groups in a vulnerable situation due to their health condition.

Secondly, we note with concern that the chosen approach of the EPR system will cause **unequal treatment between Member States**. Additional barriers to market entry and price increase of certain pharmaceuticals could significantly worsen the availability and choice of treatment, especially in the context of small markets, which are already faced with frequent market withdrawals due to economic reasons. Furthermore, in Member States without a substantial local pharmaceutical production, the costs will rather be transferred from the manufacturer to other downstream actors. This will not serve the initial aim of producer responsibility, as in these circumstances the costs of EPR will very likely be transferred to the health care budget and increase patients’ co-payments. Introducing mandatory EPR will thus have **negative socio-economic implications but also will intrude the Member States’ competence** in financing healthcare. Additionally, **economic feasibility and administrative burden** is not sufficiently considered, especially if the number of “producers” is relatively small. In smaller Member States with a lower consumption of pharmaceuticals, introducing EPR will lead to an unreasonable financial burden on a few actors on the market. Allowing to cover up to 20% of the quaternary treatment costs through national financing may not be sufficient to prevent negative impact on the availability and affordability of critical medicines.

Thirdly, we note that it remains unclear **who is the subject of the extended producer responsibility** in the case of pharmaceutical supply chain, which involves many actors who make the product available on the market. Consequently, due to parallel trade this may lead to **double taxation**.

Because of these reasons Estonia is not able to support the Directive of the European Parliament and of the Council concerning urban wastewater treatment and abstains from the vote.

### **Statement by France**

La France soutient la directive révisée sur les eaux résiduaires urbaines (UWWTD) et considère celle-ci comme un texte ambitieux, tenant compte des effets du changement climatique, permettant de renforcer la protection de la santé humaine et de l'environnement notamment contre les sources de contamination émergentes. La France soutient l'application du principe pollueur-payeur et le mécanisme de responsabilité élargie du producteur afin de financer la mise en place de systèmes de traitement quaternaire pour réduire la présence et les rejets de micropolluants dans les milieux aquatiques. C'est pourquoi la France confirme sa mobilisation pour atteindre les objectifs de la directive révisée.

Néanmoins, si la directive révisée permettra de créer des incitations afin que nos industriels investissent dans le développement de produits plus respectueux de l'environnement notamment en ce qui concerne les micropolluants, la France sera attentive dans sa mise en œuvre à l'importance d'éviter les effets de bord négatifs pour les industries pharmaceutique et cosmétique afin de ne pas perdre de vue l'objectif primordial du renforcement de l'autonomie stratégique et de la compétitivité mondiale de l'UE. Il est nécessaire que nos industries puissent maintenir leurs investissements et innovations (en particulier dans la production de produits plus responsables) dans nos territoires. S'agissant des médicaments, la mise en œuvre de la directive ne doit pas créer de risques d'accroissement de pénuries en favorisant les délocalisations, dans un contexte de prix régulés.

Enfin, la France invite la Commission à une préparation finement calibrée du futur acte délégué, concernant la définition de la liste des substances qui déterminera le champ des contributeurs à la REP et appelle à ce titre la Commission à ne pas faire peser une charge excessive sur certaines entreprises. La France recommande également de veiller à une mise en œuvre harmonisée entre les différents Etats membres afin de préserver le bon fonctionnement du marché intérieur.

Pour ces raisons, la France veillera à ce que toutes les informations nécessaires soient mises à disposition de la Commission et préconise la réalisation d'une étude d'impact complémentaire ciblée en vue de la préparation de l'acte délégué.

### **Statement by Cyprus**

The Republic of Cyprus shares the overall environmental objectives of the Urban Wastewater Treatment Directive, and thus supports the adoption of the Urban wastewater treatment Directive (recast).

However, the current Directive has been proven very difficult in its implementation, and therefore, Cyprus maintains legitimate concerns associated with the increased administrative burden, the significant financial costs, and the rather limited timeframe for Cyprus' compliance with the more ambitious requirements of the new Directive.

It is pertinent to recall that Cyprus has the following unique characteristics: the absence of rivers or lakes, the great depth of groundwater (in many cases more than 100 meters deep) and the fact that most of the treated wastewater is already used for agricultural irrigation. In fact, River Basin Management Plans of Cyprus confirm that in most cases no water bodies are negatively affected from wastewater discharges.

The challenges we are confronted with the implementation of the current Directive, despite our best efforts and genuine political commitment, are telling of how difficult it will be to implement the new Directive that significantly raised the ambition. In particular, thus far we were not able to comply with the requirements of the current Directive for 28 agglomerations out of a total of 57 agglomerations. The delays encountered are linked to the enormous economic costs, the heavy administrative burden, the discovery of archaeological findings during the works and the need for extensive government coordination and consultations with local authorities. Our revised National Implementation Programme (NIP-2020) submitted to the European Commission on 30 June 2022 and the latest revised National Implementation Programme (NIP-2022) submitted to the European Commission on 30 June 2024, set 2030 as the end date for full compliance with Directive 91/271/EEC.

The new threshold of agglomerations of 1 000 p.e., will render it very difficult for Cyprus to find the necessary resources to construct collecting systems and secondary treatment in 26 additional agglomerations. It should be noted that due to the size of our country, we have a very limited number of contractors that can execute the required systems.

Despite the serious implementation difficulties, Cyprus supports the adoption of the Urban wastewater treatment Directive (recast) because we understand its importance for protecting the environment and human health.

Cyprus is confident that these concerns will be given due consideration when the new Directive enters into force, including through safeguarding sufficient EU funding that will enable Member States in meeting the Directive's significant financial requirements.

### **Statement by Latvia**

Latvia supports the Directive concerning urban wastewater treatment, which aims to better protect the environment and human health. During the negotiations, Latvia has repeatedly expressed support for updating of the requirements on wastewater collection and treatment, as well as on the increasing sustainability and efficiency of the wastewater management sector.

However, it should be noted that the implementation of the Directive is associated with significant challenges.

In general, Latvia believes that the extended producer responsibility (EPR) system is an effective tool for implementing the polluter-pays principle. However, neither Latvia, nor other countries have previously established the EPR system in the field of wastewater management and have not applied the EPR system to pharmaceuticals. We share the concerns of other Member States regarding the application of the EPR systems to medicinal products for human use and possible impact on prices and accessibility of these products for the most vulnerable population. We are also concerned that these impacts have not been fully assessed during the Impact assessment, nor were the current shortages of medicinal products affecting many Member States properly considered. Therefore, we invite the Commission to continue evaluating these impacts also after the adoption, and act accordingly, if necessary.

We still believe that achieving energy neutrality will be very challenging, particularly for smaller urban wastewater treatment plants, for which not all renewable energy sources are technically and economically feasible.

Finally, we must keep in mind the enormous future costs required to ensure that wastewater management infrastructure meets the requirements of this directive. The implementation will demand substantial investments over the next 15-20 years, amounting to at least several billion euros in Latvia. These costs cannot be fully borne by the users of wastewater management services alone. We will continue to emphasize the need to ensure appropriate financial resources, including from the next Multiannual Financial Framework.

### **Statement by Lithuania**

Lithuania supports the recast of the Directive on Urban Wastewater Treatment, which aligns with the EU's goals for environmental protection and water quality. Lithuania supports the Directive's focus on improving wastewater treatment infrastructure and reducing pollution, both of which are critical for safeguarding our water resources.

However, Lithuania finds that the current level of ambition, particularly regarding the implementation timelines and resource allocation, is excessively high. This poses significant challenges, especially for Member States with diverse infrastructures and varying economic capacities. Lithuania must acknowledge that even the current Directive (91/271/EEC) has been challenging to fully implement, and many Member States, including Lithuania, are still working towards compliance. This makes the heightened ambition of the revised Directive even more difficult to achieve.

The extension of the scope, particularly the obligation to connect all agglomerations from 1 000 p.e., places a significant financial burden on Lithuania. Given its geographical and demographic situation, especially in smaller settlements where population decline due to migration is a reality, the installation of wastewater collection systems may have a negligible impact in reducing and preventing pollution. In these cases, the investment is not justified from an economic standpoint.

Lithuania also accepts the common goal to implement the principle of Extended Producer Responsibility (EPR) more effectively. However, Lithuania questions the rationale for applying the EPR principle exclusively to the pharmaceutical and cosmetics industries. Lithuania notes that the Directive's impact assessment on pharmaceutical industry, including the accessibility and pricing of medicinal products, has not been fully assessed, particularly in the context of current shortages of medicinal products and ongoing efforts to ensure autonomy of the EU's pharmaceutical industry. Lithuania strongly believes that the Directive should cover all sectors emitting micropollutants to ensure a comprehensive and fair application of the "polluter pays" principle. Lithuania is concerned about the feasibility and enforceability of these provisions and how they will affect not only its manufacturers in these sectors but also supplies of the important products from other member states. Concerning EPR, Lithuania would have preferred that the costs of quaternary treatment be shared more equitably through a stronger application of the "polluter pays" principle.

Finally, it is important to emphasise that the implementation of the new Directive will require considerable financial resources. Like many other Member States, Lithuania faces challenges with funding the necessary infrastructure upgrades and operational costs. The ambition of the Directive cannot be met without substantial financial support, and Lithuania stresses the need for dedicated EU funding to assist Member States in meeting the requirements of the Directive. Without this financial backing, the feasibility of implementing the Directive, especially in smaller Member States, is questionable.

### **Statement by Malta**

Malta has always acknowledged and supported the Commission's ambition to address the source of pollution in our waters and ultimately, achieve zero pollution in the European Union.

While, from an implementation perspective, Malta understands the rationale behind Extended Producer Responsibility (EPR) schemes and whilst acknowledging the benefits that such schemes bring, Malta remains of the opinion that having patients bear the ultimate financial burden is not acceptable. In this regard, Malta positively acknowledges the amendments introduced to the Directive to enable the necessary flexibilities to address the potential impacts of EPR schemes on the accessibility, availability and affordability of medicines at the national level, by enabling Member States to finance part of the costs of the quaternary treatment in case such impacts occur.

Having said this, Malta believes that ambition must not come at a disproportionate social cost. In line with the position adopted from the beginning of the negotiations in Council, Malta still has a major political concern on the application of the proposed extension of the EPR to cover all medicines in Annex III. Patients undergoing treatment have little to no control over the manner in which they receive such treatment, much less choice over the type of medication prescribed. The current text, whilst significantly increasing the flexibility through which EPR schemes can be developed in the respective Member States, still does not provide enough safeguards to ensure that the financial impact (even if marginal) on the pharmaceutical industry will not trickle down to patients.

Malta believes that price increase of certain pharmaceuticals would significantly worsen the availability and choice of treatment, particularly for a small market like Malta's market. This would ultimately make it even worse for patients, who are the most vulnerable.

It is in this spirit that whilst continuing to believe that in the European Union's pursuit of a better-quality water, Malta affirms that this Directive should not jeopardise the accessibility, availability and affordability of vital products such as medicines which are a necessity and not a luxury.

### **Statement by Austria**

Österreich unterstützt die Ausrichtung der überarbeiteten kommunalen Abwasserrichtlinie (UWWTD) und sieht diese als wichtige Maßnahme für einen langfristigen und nachhaltigen Schutz der Wasserqualität. Daher stimmt Österreich auch für die Annahme der UWWTD. Gleichzeitig ist es wichtig, im Sinne der branchenspezifischen erweiterten Herstellerverantwortung (EPR), Anreize für die Verursacher zu schaffen und in die Entwicklung umweltfreundlicherer Produkte zu investieren. Österreich weist vor diesem Hintergrund auf die Bedenken der pharmazeutischen und kosmetischen Industrie hin, und würde sich für eine frühzeitige Evaluierung in Hinblick auf die erweiterte Herstellerverantwortung aussprechen.

Dies würde auch zur übergeordneten Zielsetzung hinsichtlich der Stärkung der strategischen Autonomie sowie der globalen Wettbewerbsfähigkeit der EU in sensiblen Sektoren beitragen und wichtige Investitionen, Innovationen und Produktion - beispielsweise im Arzneimittelbereich – in der EU halten.

## Statement by Poland

Polska dostrzega potrzebę nowelizacji obecnie obowiązującej dyrektywy dotyczącej oczyszczania ścieków komunalnych.

Polska popiera szerszą wizję Komisji Europejskiej w zakresie nowych regulacji. Ambicje zawarte w Europejskim Zielonym Ładzie i innych politykach europejskich powinny zostać uwzględnione w nowych przepisach dotyczących oczyszczania ścieków. Polski sektor wodno-kanalizacyjny angażuje się w wiele aktywności dotyczących: działań na rzecz klimatu, efektywności energetycznej, gospodarki o obiegu zamkniętym i ambicji „zero zanieczyszczeń”. Pomimo nowych bieżących działań, jednym z największych wyzwań jest nadal zapewnienie pełnej zgodności z istniejącą dyrektywą w sprawie ścieków komunalnych (91/271/EWG). Nadal potrzebne są ogromne inwestycje i wiele kosztownych działań dotyczących: rozbudowy sieci kanalizacyjnej, modernizacji oczyszczalni ścieków, kontroli systemów indywidualnych i odpowiedniego zarządzania.

Tekst kompromisowy dyrektywy dotyczącej oczyszczania ścieków komunalnych wskazuje na wysoki poziom ambicji. Nowa dyrektywa wymagać będzie zarówno długich terminów na wdrożenie (np. na realizację inwestycji), jak również wysokich nakładów finansowych oraz dużych wysiłków organizacyjnych. Ponadto ważne jest zapewnienie środków unijnych na nowe obowiązki wynikające z dyrektywy.

Polska wyraża zaniepokojenie zaostreniem wymogów i skróceniem terminów w porównaniu z osiągniętym kompromisem w ramach Podejścia ogólnego, przyjętego 16 października 2023 r.

Polska podtrzymuje swoje obawy dotyczące wykonalności przepisów umożliwiających skuteczne stosowanie rozszerzonej odpowiedzialności producenta (ROP), biorąc pod uwagę fakt, iż proponowana dyrektywa nie obejmuje wszystkich sektorów emitujących mikrozanieczyszczenia (lecz tylko dwa: kosmetyczny i farmaceutyczny), zapewniając realną realizację zasady „prawdziwie zanieczyszczający płaci”.

Ponadto, rozszerzenie dyrektywy na aglomeracje o RLM od 1 000 do 2 000 spowoduje konieczność realizacji ogromnych inwestycji i wysokie koszty operacyjne, które również będą miały wpływ na taryfy za odbiór ścieków.

Niemniej, Polska widząc potrzebę ochrony środowiska, popiera projekt dyrektywy. Jednakże, aby dyrektywa dotycząca oczyszczania ścieków komunalnych była wykonalna i skutecznie wdrażana, konieczne będzie zapewnienie znacznych środków unijnych.

### **Statement by Romania**

Romania expresses its support for the final compromise text of the proposal for a Directive of the European Parliament and of the Council concerning Urban Wastewater Treatment (recast). While we endorse the proposal's overarching goal of aligning urban wastewater treatment with the latest scientific developments and the objectives of the Zero Pollution Action Plan, we would like to highlight that certain requirements will be challenging and costly to implement.

We emphasise that the successful execution of the Directive will require significant investments over an extended period, which will impact the availability and affordability of wastewater management services, mostly in rural areas. This is particularly crucial given that substantial work remains to fully implement the current Directive (91/271/EEC). We appreciate that the new Directive acknowledges the unique challenges faced by Member States that joined the Union more recently, including Romania.

The implementation and enforcement of the Directive will require funding from diverse sources, including substantial financial support from national and European Union funds. Additionally, broadening the scope to include agglomerations with populations between 1 000 and 2 000 will demand considerable investments and lead to higher operational costs. We wish to highlight a specific national concern: due to declining population trends, the lowered threshold increases the likelihood that some agglomerations may soon fall below this limit, which could compromise cost efficiency and drive up unnecessary expenses.

Romania also has reservations regarding the impact of the extended producer responsibility (EPR) provisions, particularly as they pertain to pharmaceuticals. From the intensive discussions we have had with the industry the implementation of EPR will lead to extremely high costs which will affect the availability and affordability of medicines, particularly generic ones. Such a situation could lead to a health crisis for our population. From the outset, we have underlined the necessity of implementing the EPR at the EU level to ensure equitable treatment among Member States. Therefore, we urge the Commission to facilitate discussions aimed at achieving a uniform implementation of the EPR across all Member States, ensuring that it does not impose undue burdens on populations in need of medicines.

### **Statement by Slovenia**

Slovenia supports and commits to the objectives of the Directive concerning urban wastewater treatment (recast) that will contribute to the reduction of emissions of substances into water as well as to the reduction of greenhouse gas emissions, to efficient use of energy and to the promotion of a circular economy by encouraging the reuse of treated wastewater and sludge and nutrient processing.

Slovenia welcomes the agreed extension of the deadlines for the implementation of the new or enhanced requirements of the directive. However, Slovenia believes that some of the objectives are very ambitious and some technically and economically very demanding measures will be needed to achieve them. Therefore, Slovenia urges the Commission to ensure sufficient EU funds to support the efforts of Member States.

Slovenia welcomes the ambitions in providing appropriate infrastructure for the collection and treatment of urban wastewater, as well as lowering of the threshold for agglomerations' size falling under the scope of this directive. At the same time Slovenia welcomes the provisions that allow for some flexibility according to specific national or local, especially geographic circumstances, or other specific local conditions. However, Slovenia is of the opinion that even more flexibility would be needed regarding the use of individual systems for the collection and treatment of urban wastewater. We emphasise our specific concern regarding the vague requirement to achieve the same level of environmental and human health and environmental protection that has to be achieved by individual systems, as well as regarding the uniform threshold of 2 % for the use of individual systems at national level that does not take into account the variety of circumstances at EU, national, or local levels.

Slovenia supports the enhanced implementation of the “polluter pays” principle. Nevertheless, Slovenia recalls concerns that the requirements on the extended producer responsibility are not sufficiently clear. In this respect Slovenia welcomes the obligation of the Commission to provide an exchange of information and is looking forward to exchanging experience and good practices.

Slovenia also points out that the implementation of the new obligation for the quaternary treatment and the achievement of the objectives in this regard will be a significant challenge at national level. Same goes for the ambitions on achieving energy neutrality of this sector. Slovenia believes that the contribution of this sector to the achievement of climate goals is necessary, and from this point of view supports the efforts to improve energy efficiency within the sector. However, Slovenia would like to recall its concerns as regards the feasibility of achieving energy neutrality within the sector at national level.

In addition, Slovenia recalls its concerns regarding the ambitious requirements for information collection and management of that information.

Despite serious concerns related to the ambitious objectives mentioned above, Slovenia nevertheless recognises the revised directive as an important step towards an enhanced protection of environment and human health, and thus votes for the adoption of this Directive.