Assessing the Cost Burden of UWWTD Extended Producer Responsibility on Pharmaceuticals: Implications for the accessibility, availability and affordability of medicines

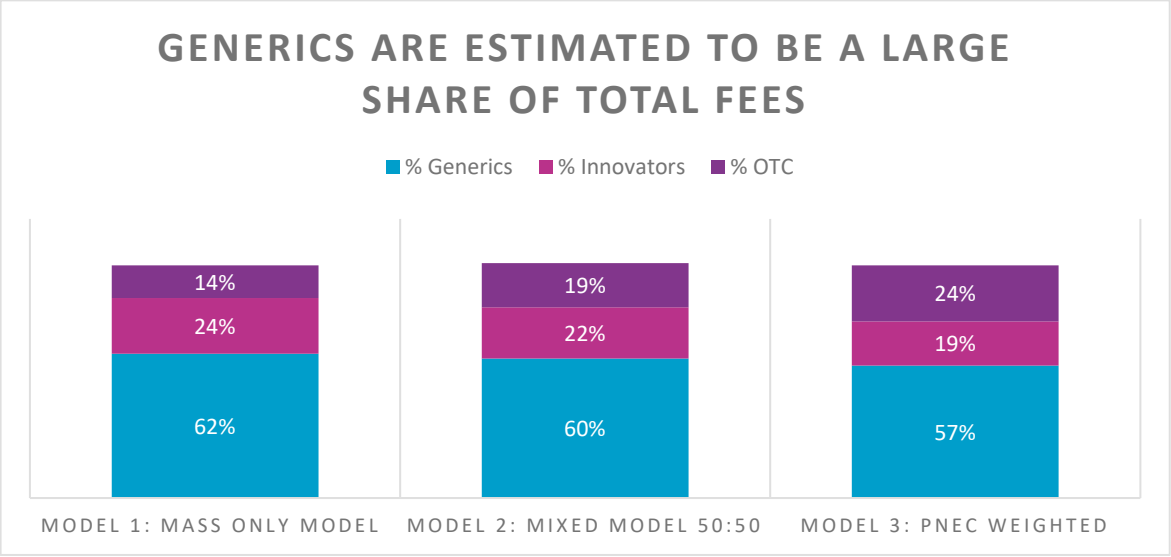
28 July 2025

Background

Medicines for Europe has conducted an analysis to assess the impact of the Urban Wastewater Treatment (UWWTD) Extended Producer Responsibility (EPR) scheme on the pharmaceutical sector based on modelling developed by IQVIA. Using IQVIA's MIDAS dataset, the model distributes the estimated €1.18 billion[1] annual cost of EPR scheme based on market volumes (Active Pharmaceutical Ingredient weight), a possible indicator for the hazardousness of substances (PNEC), and exemptions. Three models were developed to assess the cost allocation, considering both active substance weight and possible environmental hazardousness. To make the analysis practical, we have estimated the impact purely based 1) on API weight, 2) hazardousness weighted model (PNEC values) and 3) mix of the two (50% on weight and 50% on hazardousness-weighted). Further details on the methodology are provided at the end of this document.

EU-wide Impact - **Generic Medicines Bear a Disproportionate Burden**

Our analysis across all three models (mass only; 50/50 mixed model; hazardousness weighted) shows that **generic medicines will be disproportionately impacted by the EPR scheme, accounting for approximately 60% of the total EPR fees, despite accounting for only 19% of the pharmaceutical market value**[2]**.** Due to the low value of these medicines, this imbalance of the EPR fee burden will have a negative impact on the availability, accessibility and affordability of these essential medicines.



[1] European Commission Impact Assessment on the Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast), pages 57, 68, 146

[2] IQVIA report Value of generic medicines, March 2024.

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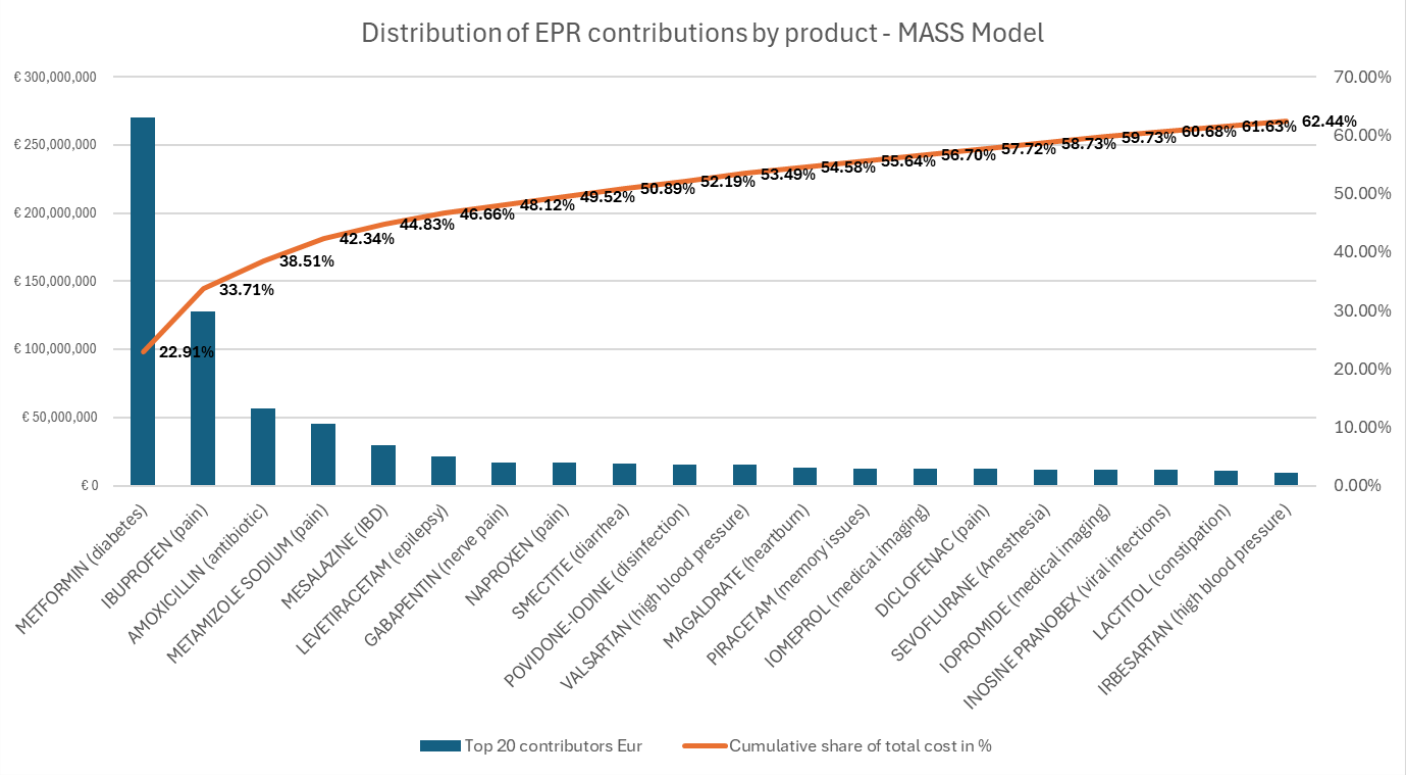
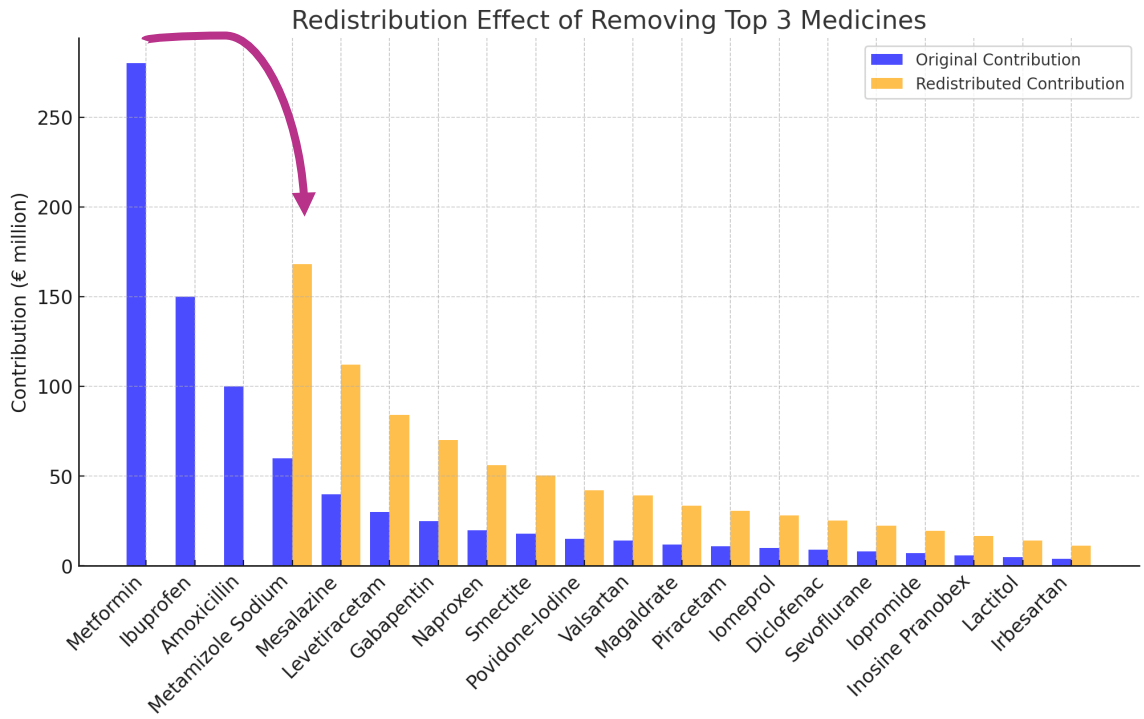
The cost burden is highly concentrated on a small number of medicines.

Regardless of the mass, mixed or hazardousness weighted model, the EPR fees will be concentrated on a small number of medicines and will render most of them economically unviable. In the first mass model, for example, **metformin, an essential medicine for diabetes, alone would account for 23% of the total fees. The top 10 medicines together represent 52.5%** of the total EPR fees (€617 million based on the lower Commission estimate of the costs). The next 10 medicines account for another **10.4%**. This means that just 20 medicines bear nearly two-thirds of the total cost, rendering many of these low cost medicines economically unviable.



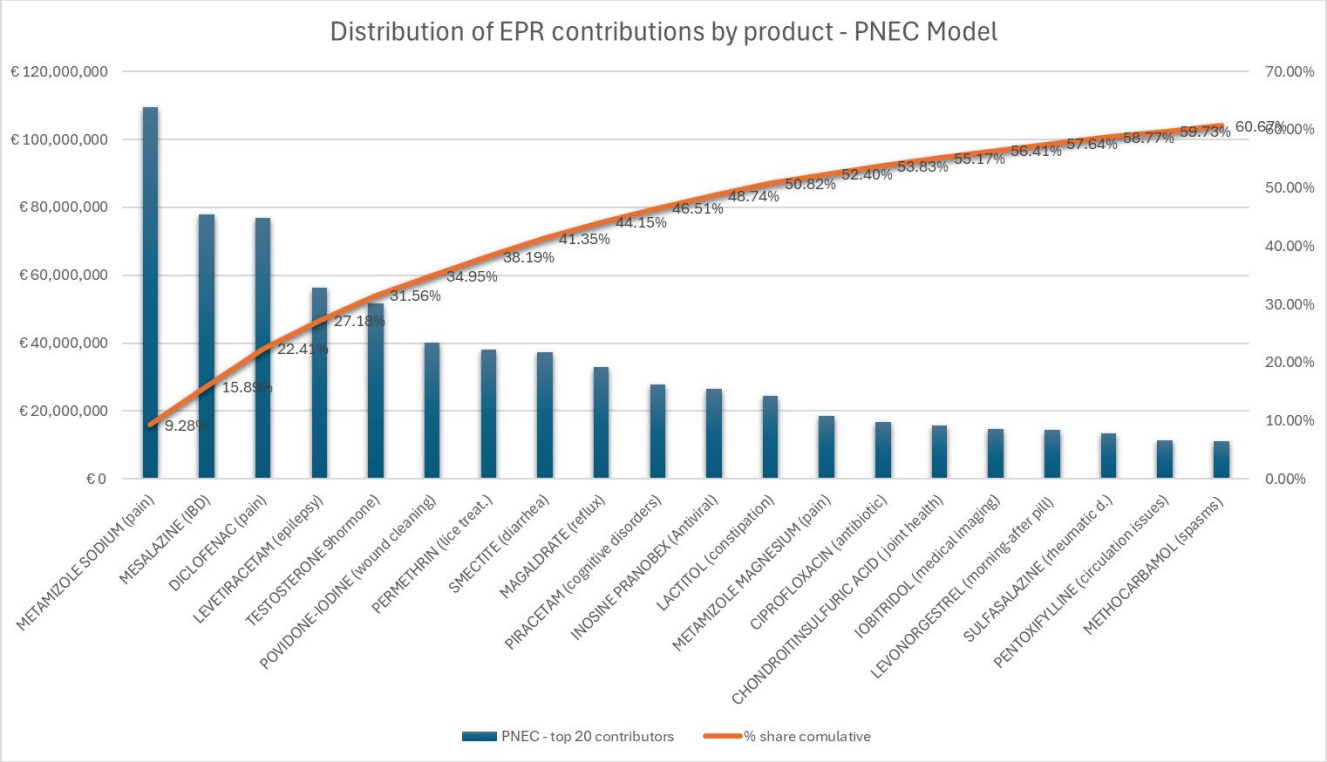
Vicious circle: The withdrawal of medicines due to the EPR fees will transfer the fees to other generic medicines, rendering them economically unviable.

If the top contributing medicines were excluded or withdrawn from the market due to their economic unviability—since they are mostly low-cost, widely used treatments—the total EPR cost would remain unchanged. Thus, the financial burden of the EPR scheme would shift to the next set of generic medicines, making them increasingly economically unviable. This redistribution could lead to multiple market distortions and reducing the availability of medicines for patients.



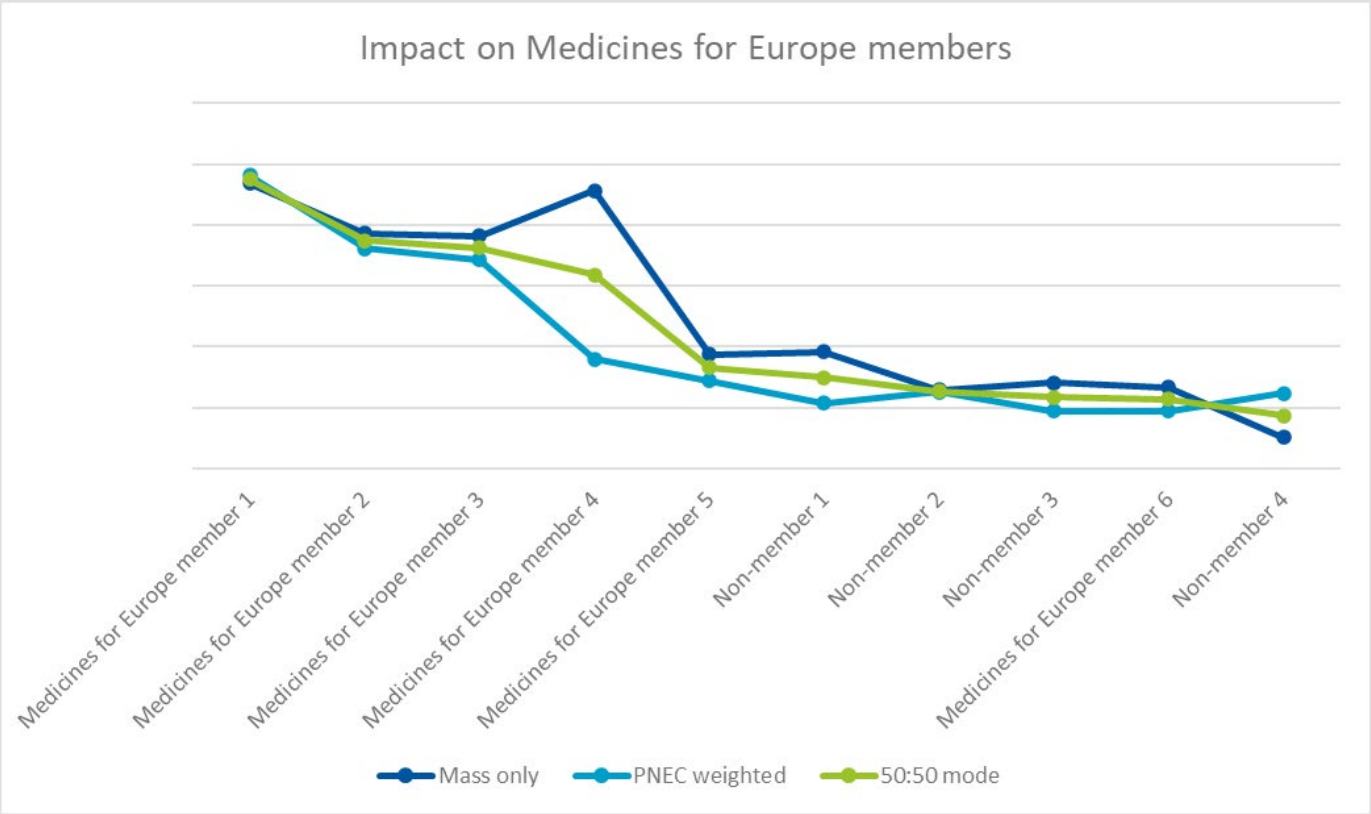
this graph is indicative

In the hazardousness weighted model, same trend can be observed. The first 10 medicines account for 46.51% of the total ERP fees and the next 10 account for another 14.16%, together just 20 medicines bear nearly two-thirds of the total cost, rendering many economically unviable.


Distribution of EPR contributions by product - PNEC Model
€ 120,000,000
€ 100,000,000
€ 80,000,000
€ 60,000,000
€ 40,000,000
€ 20,000,000
€ 0
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
9.28%
15.89%
22.41%
27.18%
31.56%
34.95%
38.19%
41.35%
44.15%
46.51%
48.74%
50.82%
52.40%
53.83%
55.17%
56.41%
57.64%
58.77%
59.73%
60.67%
METAMIZOLE SODIUM (pain)
MESALAZINE (IBD)
DICLOFENAC (pain)
LEVETIRACETAM (epilepsy)
TESTOSTERONE 9hormone)
POVIDONE-IODINE (wound cleaning)
PERMETHRIN (lice treat.)
SMECTITE (diarrhea)
MAGALDRATE (reflux)
PIRACETAM (cognitive disorders)
INOSINE PRANOBEX (Antiviral)
LACTITOL (constipation)
METAMIZOLE MAGNESIUM (pain)
CIPROFLOXACIN (antibiotic)
CHONDROITINSULFURIC ACID (Joint health)
IOBITRIDOL (medical imaging)
LEVONORGESTREL (morning-after pill)
SULFASALAZINE (rheumatic d.)
PENTOXIFYLLINE (circulation issues)
METHOCARBAMOL (spasms)
PNEC - top 20 contributors
% share comulative

Medicines for Europe corporate members represent 6 out of the top 10 likely contributors to the EPR scheme[3]

As major providers of widely-used generic medicines, in all 3 models, Medicines for Europe direct corporate members would be allocated a significant share of the costs, which ranges from 33% in the PNEC-only model to 40% in the mass-model. This would translate into approximately 2/3 of the total costs allocated to the generic sector in the models, representing a significant proportion of the sector.



[3] Based on presentation from Richard Bergstrom at the Medicines for Europe Annual Conference 2025

Impact at the National level

1. The Netherlands

The assessment on the impact was done by Medicines for Europe/Bogin, using the IQVIA modelling and publicly available data from the healthcare institute, Zorginstituut Nederland / GIP database.

The **Extended Producer Responsibility (EPR) scheme** for the Netherlands is estimated to cost €64,77 million per year[4] according to the Commission Impact Assessment**. However, the Dutch government has projected a much higher EPR cost of at least €400 million per year**[5].

In 2023, the total reimbursement for generic medicines in the Netherlands amounted to **€889 million**, as reported by Zorginstituut Nederland. As the lion's share of the EPR fees will fall on high volume generic medicines, a €400 million per fee could destabilise the entire generic medicines market which accounts for 80% of prescriptions in the Netherlands.

Case study: Metformin

If applied based on mass, the EPR fees could exceed the total sales value of metformin which is used by close to 50% of diabetes patients. In the Netherlands, in 2023, **681,700 patients**[6] relied on metformin for diabetes treatment, out of approximately **1.2 million people**[7] **diagnosed with the condition**. In 2023, the **average cost per patient** in 2024 was **€21**[8], leading to a **total expenditure of €14,317,900**[9] in 2024. The EPR fees **could be as high as €125 million per year which is almost nine times the annual sales or reimbursement cost.** This is an impossible burden for manufacturers and for healthcare systems.

Product	total expenditure in 2023 (Zorginstituut Nederland / GIP)	EPR cost for the country		**contribution based on model 1: mass only model**	**% of total expenditure**
METFORMIN	**€ 14,317,900**	**EC ESTIMATE**	€ 64,774,361.00	€ 20,286,900.63	142%
diabetes, first line treatment		**Dutch government estimate**	**€ 400,000,000**	**€ 125,277,349**	**875%**

Comparative Analysis Across Therapeutic Areas

This issue extends beyond metformin and affects other critical medicines, such as anti-epileptics (like levetiracetam) and antibiotics (like amoxicillin). The impact of the EPR scheme varies depending on the model used, with some medicines bearing a heavier financial burden than others. For example, in a mass-based model, metformin faces the highest financial burden, while levetiracetam's burden is lower. However, the impact is reversed in other models, where levetiracetam faces the highest EPR fees and metformin faces lower fees. Either

[4] As per the European Commission's Impact assessment accompanying the Proposal for a revised Urban Wastewater Treatment Directive (20-10-2022), page 146

[5] As per Dutch governmental brief to the Dutch parliament, 12-12-2024, page 21

[6] **Zorginstituut Nederland / GIP**, the data was last updated on **26-06-2024**

[7] de Vries, F. M., Denig, P., Visser, S. T., Hak, E., & Postma, M. J. (2023). Use of hospital care among Dutch diabetes patients. *Diabetes, Obesity and Metabolism*, 25(1), 123-131. doi:10.1111/dom.15105

[8] **Zorginstituut Nederland / GIP**, the data was last updated on **26-06-2024**

[9] **Zorginstituut Nederland / GIP**, the data was last updated on **26-06-2024**

way, neither manufacturers, nor healthcare systems can afford these fees which exposes patients to near certain medicine shortages.

Looking at the broader dataset:

- **Levetiracetam, a common epilepsy treatment, faces costs between 119% and 322% of its total expenditure, depending on the calculation model.**
- **Amoxicillin, a first-line antibiotic, experiences costs ranging from 40% to 369% of its annual expenditure.**

Regardless of the model—mass-based, PNEC (predicted no-effect concentration), or a hybrid approach—the EPR scheme disproportionately impacts low-cost, high-volume medicines. This will undermine supply continuity and lead to increased costs for public healthcare budgets or for patients in the form of co-payments.

The table below compares the total expenditure on certain medicines in the Netherlands in 2023, as reported by the public health institute, with the modelled contribution to the EPR scheme. The first row shows the modelled contributions based on the European Commissions' assessment of the quaternary treatment cost. These figures are compared to the actual expenditure for the medicine (in %).

In the first model, which uses mass calculations, the estimated total cost for metformin is €20.28 million. This is 142% of the actual expenditure on the medicine, meaning it exceeds the total health insurance spending on this medicine.

The second row shows modelled contributions based on Dutch government assessment that the upgrade to the quaternary treatment would cost at least €400 million. For metformin, the projected total cost according to the first model is €125.27 million, in the second model, the total cost is €62.64 million and in the third model, the total cost is €3,291.

In some cases, the projected costs are much higher than the actual expenditure, showing the impossibility of implementing the directive without harming the availability of medicines used by millions of patients.

PRODUCT	TOTAL EXPENDITURE IN 2023 (ZORGINSTITUUT NEDERLAND / GIP)	EPR COST FOR THE COUNTRY		MODEL 1: MASS ONLY	% OF TOTAL EXPENDITURE	MODEL 2: MASS & PNEC WEIGHTED 50:50	% OF TOTAL EXPENDITURE	MODEL 3: PNEC ONLY	% OF TOTAL EXPENDITURE
METFORMIN	**€ 14,317,900**	**EC ESTIMATE**	€ 64,774,361.00	**€ 20,286,901**	**142%**	**€ 10,143,717**	**71%**	**€ 533**	**0%**
diabetes, first line treatment		**Dutch government estimate**	€ 400,000,000	**€ 125,277,349**	**875%**	**€ 62,640,321**	**437%**	**€ 3,291**	**0.02%**
LEVETIRACETAM	**€ 8,027,800**	**EC ESTIMATE**	€ 64,774,361.00	**€ 1,544,918.36**	**19%**	**€ 2,863,160.04**	**36%**	**€ 4,181,402**	**52%**
Treatment of epilepsy		**Dutch government estimate**	€ 400,000,000	**€ 9,540,308**	**119%**	**€ 17,680,823**	**220%**	**€ 25,821,338**	**322%**
AMOXICILIN	**€ 3,552,700**	**EC ESTIMATE**	€ 64,774,361.00	**€ 2,120,362.62**	**60%**	**€ 1,174,958.74**	**33%**	**€ 229,554.86**	**6%**
Critical Antibiotic		**Dutch government estimate**	€ 400,000,000	**€ 13,093,839**	**369%**	**€ 7,255,702.53**	**204%**	**€ 1,417,566**	**40%**

2. Germany

The assessment was conducted by Medicines for Europe/Progenerika, using the IQVIA model and publicly available data. The analysis focused exclusively on retail data and excluded over-the-counter (OTC) medicines, as well as hospital data. The source of the data is INSIGHT Health GKV-Abrechnungsdaten (NVI-KT). The list price of the manufacturer (Herstellerabgabepreis HAP) or the selling price of the pharmaceutical entrepreneur (Abgabepreis des pharm. Unternehmers ApU) was used in the analysis. The ApU excludes wholesaler, pharmacy, and tax costs.

For Germany, Commission estimated the cost of the quaternary treatment to be € 238.50 million per year. The German environment agency estimated that the total estimated annual cost for upgrading all WWTPs with a load of more than 10,000 PE ranges between €885 million and €1,025 million per year, while for those with a load exceeding 100,000 PE, the range is between €305 million and €318 million per year.[10]

The impact of the EPR fees will be significant across different critical therapeutic areas, including **pain management (metamizole), epilepsy (levetiracetam), antibiotics (amoxicillin), and diabetes (metformin)**.

These figures are alarming:

- Metamizole (used for severe pain) will face extremely high EPR costs under the Germany environmental agency estimate, exceeding annual sales by 381% under the PNEC model. For Metformin (a first-line diabetes treatment) EPR costs reach 445% of total expenditure under the mass model.
- Levetiracetam (epilepsy treatment) and Amoxicillin (a critical antibiotic) also show significant cost burdens. The e**ssential antibiotic, amoxicillin, would** face costs of up to 116% of total expenditure under the mass-based model, rendering this critical medicine unviable on the German market.
- The data shows that depending on the chosen EPR calculation model, the financial burden shifts between different essential and critical medicines.
- Low-cost, high-volume medicines (such as Metformin and Amoxicillin) face disproportionate financial risks, which would undermine medicine availability and patient access.

[10] Moving forward: The European Commission's Proposal for a Recast Urban Wastewater Treatment Directive With these cost functions, the additional costs for upgrading all WWTP with a load of more than 10 000 PE are **€1 025 million/a and €885 million/a respectively.** Upgrading all WWTP that have a load of more than 100 000 PE leads to €305 million/a and €318 million/a

Product	Germany total expenditure per year (Manufacturer's price)	EPR cost for Germany (TOTAL)		Model 1: mass only	% of total expenditure (sales)	Model 2: mixed model 50:50	% of total expenditure (sales)	Model 3: PNEC only	% of total expenditure (sales)
METAMIZOLE		**EC estimate**	€ 238,477,441	€ 29,960,073	**35%**	€ 53,087,917	**62%**	€ 76,215,760	**89%**
Severe pain (e.g., colic, tumour pain), non-responsive high fever	€ 85,893,104	**Germany environmental agency estimate**	€ 1,025,000,000	**€ 128,771,405**	**150%**	**€ 228,177,199**	**266%**	**€ 327,582,993**	**381%**
METFORMIN		**EC estimate**	€ 238,477,441	€ 51,623,986	**104%**	€ 25,812,631	**52%**	€ 1,275	0%
diabetes, first line treatment	€ 49,830,848	**Germany environmental agency estimate**	€ 1,025,000,000	**€ 221,885,080**	**445%**	**€ 110,945,280**	**223%**	**€ 5,480**	**0%**
LEVETIRACETAM		**EC estimate**	€ 238,477,441	€ 6,199,866	**13%**	€ 10,985,887	**24%**	€ 15,771,907	**34%**
Treatment of epilepsy	€ 46,420,314	**Germany environmental agency estimate**	€ 1,025,000,000	**€ 26,647,647**	**57%**	**€ 47,218,444**	**102%**	**€ 67,789,241**	**146%**
AMOXICILIN		**EC estimate**	€ 238,477,441	€ 6,525,560	**27%**	€ 3,594,789	**15%**	€ 664,018	**3%**
Critical Antibiotic	€ 24,158,472	**Germany environmental agency estimate**	€ 1,025,000,000	**€ 28,047,512**	**116%**	**€ 15,450,763**	**64%**	**€ 2,854,015**	**12%**

Annex: Modelling methodology

Medicines for Europe, based on modelling developed by IQVIA, has conducted an analysis to assess the impact of the EPR scheme on the pharmaceutical sector. The model is built on IQVIA's MIDAS dataset, widely regarded as the gold standard for market intelligence, with volume measured in kilograms of active substance where possible.

1. Annual cost for Waste Water Treatment

This analysis **applies the cost of the EPR scheme to cover quaternary treatment of urban waste water (**baseline is the European Commission estimate of **€1.18 billion** per year across for the EU/EEA. At the time of the analysis, there was no certainty on how costs might be shared between the pharmaceutical and cosmetics industries, potential co-financing, or the final EU-level expense. Moreover, the Commission has already indicated that the **€**1.18 billion estimate was based pre-Covid-19 data which may need to be adjusted for inflation (+30%). To assess the accuracy of the initial estimate, we compared it with emerging national projections, where available:

- **The Netherlands:** The Dutch government estimates costs of at least **€400 million**, which is **six times higher** than the Commission's estimate for the Netherlands.
- **Germany:** The German Environment Agency projects costs of **€1 billion**, **4.3 times higher** than the initial Commission assessment for Germany.

These figures suggest that the actual financial burden may be significantly greater than initially estimated by the Commission.

2. The split of the cost of Waste Water Treatment based on:

- Volumes released on the market: Weight of Active Pharmaceutical Ingredients, based on consumption of medicines across Europe is built on IQVIA data on consumption based on MIDAS dataset, that is seen as a gold standard of market intelligence in the sector[11] in the industry when it comes to data on release on the market. The volume measure used from the dataset was 'Kilograms' which is originally a molecule weight measure but has been converted to the 'active substance' weight where possible using MIDAS reference data sheets and known methodologies.

- Hazardousness of substances: As the legislation does not specify the hazardousness indicator, the Predicted No-Effect Concentration (PNEC) data, referenced in the UWWTD EPR feasibility study, was considered for the modelling. Various sources were used to determine PNEC information for products used in Europe and covered by the IQVIA database. Sources include the FASS.se dataset, ECHA dataset, academic sources, and company-

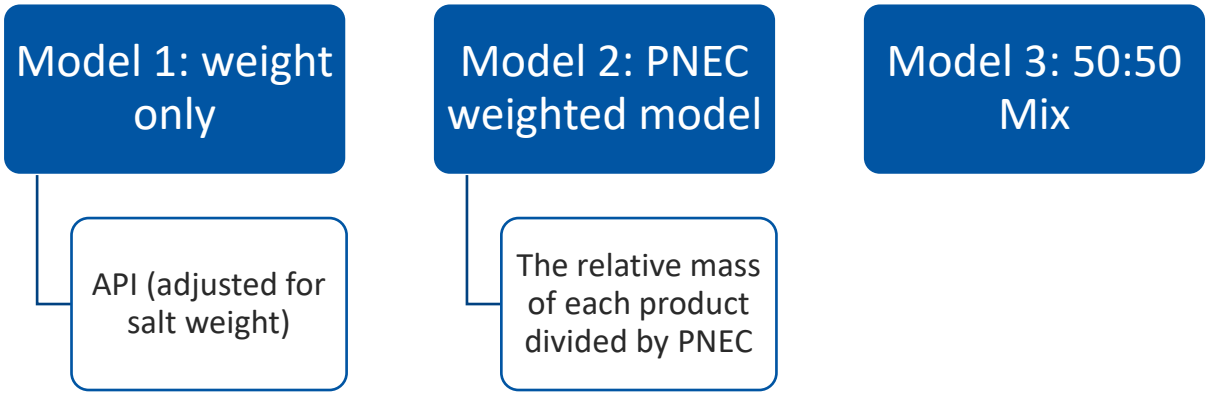
[11] *MIDAS allows cross country analysis Notes on methodology – supplementary document for Medicines for Europe* ***UWWTD dataset and modelling support, December 2024***
of sales and prescription drug volume share across 93 countries via 157 audits covering 10k+ molecules and 1.6Mn + products. Coverage varies between countries, and hospital data is not present in Greece, Luxembourg, or Estonia. Data on member states of relevant to the UWWTD that are not available are Malta and Cyprus.

submitted information[12]. Some gaps in the availability of PNEC data exist, especially for older medicines authorised before 2006. Environmental Risk Assessments (ERA) became mandatory at this time[13].

- Exemptions of substances: Exemptions are applied as Companies with <1 tonne of sales in their portfolio are removed and their volume removed from the totals and exemptions based on assumed biodegradability.

3. Based on this methodology, three models were developed:

1. **Mass-only model** – Allocates costs based on the relative mass of each molecule and sales data.
2. **PNEC-weighted model** – Adjusts mass data by dividing each product's weight by its PNEC value.
3. **Mixed model (50:50)** – Combines both approaches.



4. Limitations

This analysis provides an initial framework for cost allocation under the EPR scheme, but several key uncertainties could significantly impact the final financial burden on the pharmaceutical sector:

- **Unclear Cost Factors:** The EPR fees will depend on factors that are not yet defined, such as cost-sharing between industries, national implementation choices, and potential co-financing mechanisms.
- **Data Gaps on Hazardousness and Exemptions:** More analysis is needed to establish clear criteria for hazardousness and biodegradability exemptions, as current data is incomplete.

[12] In cases of uncertainty, where company data is provided it has been used above public data sources (e.g. instead of FASS or academic studies); where multiple values exist the lowest has been taken to simulate a '*worst case*' calculation but this rare.

[13] Where unknown, the default value has been chosen to be 0.01ug/L as per the EMA's preference for a conservative PNEC value.

- **Market Dynamics:** The model is based on 2023 data, but costs will be influenced by future changes, including patent expirations, generic competition, and shifts in medicine consumption patterns.

Despite these limitations, the analysis convincingly shows that the EPR scheme will seriously undermine the availability, accessibility and affordability of critical and essential medicines.