Prime Ministers
EU 27 Member States
c/c
Ministers of Health
EU 27 Member States

Ministers of Industry
EU 27 Member States

Ministers of Environment
EU 27 Member States

Brussels, 27 May 2025

OPEN LETTER: EUROPE MUST ACT NOW TO PROTECT PATIENTS ACCESS AND MEDICINES SUPPLY

From the Covid-19 pandemic to the war in Ukraine when we ramped up production and secured the supply of medicines — recent crises have underlined the need for a united European response to safeguard patients and strengthen critical medicines manufacturing and jobs in Europe. **Medicines for Europe, the European Association representing 70% of dispensed medicines in Europe,** proposes a Pharmaceutical Action Plan, calling on Member States and the Commission to:

1. Accelerate the adoption of the pharmaceutical legislation for access to medicines.

The threat of U.S. tariffs cannot justify extending Europe's intellectual property (IP) protection, which is already the most generous in the world. Any IP extensions would strain public health budgets and fail to prevent production shifts abroad, as already announced by several originator companies. EU countries spent €20 billion on just 5 top medicines in 2024; how much more should be expended in these very expensive medicines?[1].We call on all Member States to:

- **Maintain current regulatory exclusivities at 11 years**: any extension would cost healthcare systems billions without any clear benefit for society. Our simulation, based on the originator extension claims (13 to 18 years), for only 15 molecules shows that the costs for healthcare budgets would be between €20billion and €100billion [2] (fig. 1).
- **Enable competition from day one after IP expiry: an extended clarified "Bolar clause" must allow generics and biosimilars to enter the market immediately after IP expiry. As stated in the Commission sector Inquiry, the EU must stop unlawful anticompetitive delays due to illegal link of regulatory and IP procedures, including notifications that will make ineffective the Bolar clause.** These delays severely harm patients, create additionally economic burdens on healthcare systems and lead to litigations. Documented multiple cases show the significant patient access delays and lost savings across Member States. For example, a medicine for diabetes (Janumet) has been delayed by almost 7 months in Italy costing nearly extra 10€million to the healthcare system (the patent holder got a 14€million fine), while a medicines to treat sever pain (tapendatadol) has been delayed by 917 days in Germany costing approximately additional 185€ million (fig. 2).

The European Commission and Member States shall not be misled by on-patent medicines producers claiming that extension of exclusivities will increase R&D in Europe – it will only increase the costs for health payers.

[1] Slide deck enclosed with this letter – slide n.5
[2] Impact of extending the duration of regulatory data protection in the new EU pharmaceutical legislation.

2. Urgently amend legislation that harms industry competitiveness and equitable patient access.
Our industry supports the Green Deal by investing in water efficiency and lower emissions—and will continue to do so. However, the technical pharmaceutical regulation must take prevalence over non-sector-specific laws to avoid conflicting rules that threaten patient access to medicine. The **Urban Wastewater Treatment Directive** is a clear example that imposes a massive levy on medicines consumption and, if implemented, will cause a **tsunami of shortages** of diabetes, epilepsy, cardiovascular, antibiotic and hospital medicines. Medicine prices would have to increase dramatically for patients. For example, **in the Netherlands alone, the cost of diabetes medicine metformin is expected to increase by up to 900%, and the antibiotic amoxicillin up to 400%**[3]. **Medicines should urgently be exempted from this levy.**

2. Boost production of critical medicines
Europe must have critical medicine manufacturing as a strategic priority; the **Critical Medicines Act** should support:

- Mandatory above pricing criteria and multi-winner tenders to prevent shortages.
- **€4billion of EU funding and reform state aid** to support 150 strategic production projects and align the sector with green and digital goals.
- **Inclusion of health security in future trade agreements**.

Medicines for Europe is ready to work together with the European Union and National Governments to build a stronger, more resilient generic and biosimilar pharmaceutical sector that delivers for equitable patient access to medicines.

Your sincerely,
Medicines for Europe Executive Committee (signatures below)

Economic impact of extension of regulatory protection beyond 11 years on only 15 blockbuster molecules

medicines for europe	EU	GERMANY	FRANCE	SPAIN	POLAND	CZECH REPUBLIC
13.5 years of total regulatory protection	19.5 BN EUR	5 BN EUR	5.35 BN EUR	2.25 BN EUR	552.8 MN EUR	141.6 MN EUR
18 years of total regulatory protection	99.5 BN EUR	23 BN EUR	24 BN EUR	13.2 BN EUR	3.8 BN EUR	1 BN EUR

Molecule	Treatment	Country	Originator approval	SPC Expiry	Generic Entry	Delay	Cost of Delay Lost Savings
Oxycodone/ Naloxone	severe pain	Germany		29/3/2017	15/11/2017	231 days	**€ 51,6 Mln**
Ezetimibe/ simvastatin	high cholesterol	Italy	18/11/2004	16/10/2017	9/3/2018	144 days	**€ 15,4 Mln**
Ezetimibe/ simvastatin	high cholesterol	Germany	18/11/2004	17/4/2018	15/5/2018	28 days	**€ 11,3 Mln**
Lenalidomide	multiple myeloma, cancer	Hungary	14/06/2007	19/6/2022	1/6/2023	347 days	**€ 1.9 Mln**
Pirfenidone	idiopathic pulmonary fibrosis	Germany	27/02/2011	27/2/2021	15/11/2022	626 days	**€ 32,1 Mln**
Tapentadol	severe pain	Germany	19/08/2010	07/12/2020	15/1/2023	917 days	**€ 184,6 Mln**
Dasatinib	chronic myeloid leukemia	Poland	20/11/2006	22/5/2022	01/01/2023	224 days	**€ 4,5 Mln**
					Total:	**2,517**	**€ 301,4 Mln**

[3] MEMO on Urban Wastewater Treatment Directive and Rambroll study on Micropollutants on Urban Wastewater.

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