Note for the rapporteurs/shadow rapporteurs of the EU Pharmaceutical legislation: Impact of extending the duration of regulatory data protection in the new EU pharmaceutical legislation

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In the context of the new EU pharmaceutical legislation, this document provides an economic analysis of the extension of regulatory data protection periods proposed in the European Parliament, which have strong political support. These extension proposals derive from a misunderstanding about their concrete impact on the cost and access to medicines (see explanation below) due to the complex interplay between the EU pharmaceutical legislation and other patent and SPC laws.

The proposed extensions will have massive cost implications by extending the monopolies for blockbuster drugs well beyond the current legal framework. We have assessed that the overall cost of these prolonged exclusivities for healthcare budgets would range between **20 and 100 billion euros,** equivalent to the annual salary of hundreds of thousands of nurses or doctors. With this assessment, we urge the European Parliament to reconsider this important revision and to avoid introducing massive cost burdens on healthcare system.

Short summary of the cost impacts on pharmaceutical budgets:

	France	Germany	Spain	EU
13.5 years of regulatory data protection	**5.35 BN EUR**	**5 BN EUR**	**2.25 BN EUR**	**19.5 BN EUR**
18 years of regulatory data protection	**24 BN EUR**	**23 BN EUR**	**13.2 BN EUR**	**99.5 BN EUR**

Short summary of how these costs could impact in the healthcare system:

	EU	EU	France	France	Germany	Germany
The costs of 13.5 years of regulatory data could be allocated for ➡	550,000 nurses	235,000 specialised doctors	165,000 nurses	64,000 specialised doctors	114,000 nurses	34,000 specialised doctors
The costs of 18 years of regulatory data could be allocated for ➡	3,000,000 nurses	1,200,000 specialised doctors	740,000 nurses	286,000 specialised doctors	521,000 nurses	157,000 specialised doctors

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1. Purpose of this note: To facilitate a parliamentary position on the revision of the EU pharmaceutical legislation

The European pharmaceutical framework aims to balance incentivising innovation and safeguarding public health by making medicines affordable as soon as possible. Overall, the combination of intellectual property (IP) protection and regulatory measures in the EU should foster a competitive pharmaceutical market that promotes access to safe, effective, and affordable medicines for patients across the European Union. The European Parliament announced its intention to deliver its consensus position on the legislation before the 2024 elections reflecting its commitment to improving access to medicines. While supporting this ambition, we urge caution regarding the potential cost impact of some anticipated compromises to reach the necessary consensus.

We can see clearly that some proposals in the Parliament show a misunderstanding about how the pharmaceutical incentive system functions in practice as these proposals will, unknowingly to the proponents, extend effective monopolies for blockbuster drugs dramatically and thus increase costs for national healthcare systems everywhere in Europe.

In some ways, it is easy to create confusion about the impact of these proposals because the EU Pharmaceutical Legislation must be understood in conjunction with other legislations – notably patent and supplementary protection certificate (SPC) laws. Moreover, this type of analysis requires access to specialised information regarding patent expiries, pharmaceutical sales, and volume data[1] that the Parliament does not have. This note clarifies how these proposed amendments will interact with patent and SPC laws to provide a clear picture of the cost impact. Our objective is to facilitate the understanding of the impact by all political groups in the European Parliament so that MEPs (Member of the European Parliament) can take a conscious decision when voting on key proposals or compromises.

2. Understanding the dual track of pharmaceutical incentives (regulatory and patent/SPCs)

The EU affords two monopoly protection systems for originator medicines that run in parallel: patent (and SPC when applicable) protection and regulatory/market data protection. The interplay between SPC expiry and regulatory data/market protection is crucial because it determines when generic or biosimilar competition starts. *Once both the patent/SPC and regulatory data/market protection have expired*, other manufacturers can market generic or biosimilar versions of the medicine that lower prices for healthcare systems and patients through competition.

Under the current pharmaceutical legislation, the SPC protection is typically the last drug monopoly period to expire on the EU market (in 65% of cases).[2] The Commission proposal for the new legislation does not change this situation (except for scenarios where a transferable exclusivity voucher could be combined with other extensions). However, some parliamentary amendments to the new legislation, that have strong political support, extend the duration of the regulatory data protection period well beyond the SPC monopoly. This will have a massive cost impact on public pharmaceutical budgets as blockbuster drugs will benefit from longer monopolies on the EU market in the future.

[1] Even the European Commission does not have this data. For their legislative proposal, the Commission relied on data providers to make these calculations in their accompanying impact assessment.

[2] Impact assessment report: Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, link

3. What will be the cost of extending regulatory protections beyond the patent/SPC?

We have analysed the cost impact of extending regulatory data and market exclusivities beyond the patent/SPC as foreseen in some amendments. We focus on 2 such proposals:

a.) One proposal would extend regulatory exclusivities to **13.5 years** (compared to the 11 in the existing legislation): 9 years basic Data Exclusivity (DE) + 1 year Data Exclusivity for meeting Unmet Medical Need + 0.5 DE for comparative trials + 1year DE for new indications + 2 years market exclusivity (ME). This does not include a potential Transferable Exclusivity Voucher of 1 year of DE.

b.) Another proposal would expand regulatory exclusivities to a cumulative period of **18 years** (compared to the 11 in the existing legislation) : 8 years RDP baseline + 1 year DE for launch in all markets (EC proposal) + 1 year DE for UMN + 1 year DE comparative trials + 1year DE for new indication + 1 year DE clinical trials in all MS + 1 year DE respect of environmental guidelines + 1 year DE public-private partnership + 1 year DE API produced in Europe + 2 years ME. This does not include a potential Transferable Exclusivity Voucher of 1 year of DE.

To estimate the impact of these extensions, we have looked at the 15 best-selling drugs [3]. We have compared the SPC expiry date for those top selling medicines with the two proposals described above assuming that the full exclusivity period would be granted. We make this assumption because the extended monopolies are so profitable that we would expect originator companies to make all necessary efforts to fulfil the criteria.

Data regulatory protection would be prolonged in both proposals, extending the effective monopoly period for the 15 analysed drugs. In the case of prolonging regulatory exclusivities to 13,5 years, 7 out of 15 drugs would have longer protection period overall, and in the case of prolonging it to 18 years, the monopoly period would extend for all the drugs on the list. This would represent a dramatic change to the EU market as the effective monopoly period for these blockbuster drugs would last well beyond projected SPC expiry as shown in the table below.

Product	Molecule	Therapeutic area	Extension of the protection, if 13.5 years of protection were granted (in years)	Extension of the protection, if 18 years of protection were granted (in years)
Keytruda	Pembrolizumab	Oncology	0.55	5.04
Eliquis	Apixaban	Anticoagulation	*SPC protection longer*	3.01
Darzalex	Daratumumab	Oncology-Haematology	*SPC protection longer*	3.16
Xarelto	Rivaroxaban	Anticoagulation	*SPC protection longer*	2.50
Opdivo	Nivolumab	Oncology	1.47	5.97
Stelara	Ustekinumab	Autoimmune	*SPC protection longer*	3.00
Imbruvica	Ibrutinib	Oncology-Haematology	*SPC protection longer*	3.00

[3] According to IQVIA MIDAS database, based on data for whole EU (Europe, All Country excluding: BELARUS, BOSNIA, KAZAKHSTAN, NORWAY, RUSSIA, SERBIA, SWITZERLAND, TURKEY, UK), based on List prices, accessed on 05/12/2023

Eylea	Aflibercept	Ophthalmology	0.99	5.50
Xtandi	Enzalutamide	Oncology	*SPC protection longer*	2.84
Trikafta	Elexacaftor/ Tezacaftor/ Ivacaftor	Cystic fibrosis (Orphan)	4.00	8.00
Ocrevus	Ocrelizumab	Neurology (Multiple sclerosis)	2.56	7.07
Ozempic	Semaglutide	Diabetes	0.36	4.87
Vyndaquel	Tafamidis	Amyloidosis (Orphan)	*SPC protection longer*	3.01
Ibrance	Palbociclib	Oncology	2.33	6.84
Biktarvy	Bictegravir	HIV	*SPC protection longer*	2.99

4. What will be the cost impact for healthcare in Europe?

When the monopoly for a pharmaceutical product is extended, it prevents generic or biosimilar manufacturers from bringing competition to the market, delaying access as well as savings. We have estimated what these extensions would entail for healthcare systems.[4] Although, this assessment is limited to 15 drugs, we consider this to be a reasonable proxy for the impact of the two proposed extensions because of possible differences between list and net prices in our data source. We have not been able to calculate the impact that these costs would have on delays for access to medicines, but we can safely assume that this would be the case.

For every year of prolongation of monopolies, the budget impact is estimated as the difference between the pharmaceutical expenditure in 2022, that is before the entry of the off-patent competition on the market, and expected expenditure after the competition enters the market. The basic assumption is that the prices of medicines would decrease by 70% in case of generic competition and 50% in case of biosimilar competition. For each year of delayed competition, **the cost would be 22 billion euros**. See table below:

Product	Molecule	Cost of delay of competition for 1 year in EUR (list price)
KEYTRUDA	**PEMBROLIZUMAB**	3,046,990,512.00
ELIQUIS	**APIXABAN**	2,246,525,043.70
DARZALEX	**DARATUMUMAB**	1,282,672,748.00
XARELTO	**RIVAROXABAN**	1,762,753,209.00

[4] For this calculation, we have used IQVIA MIDAS database, sales figures for the year 2022 for the 15 best selling drugs in EU mention above. The database includes listed prices and the volumes of medicines sold in the EU. In assessing the cost for healthcare, we have calculated how much the delay in the generic/biosimilar competition would cost. We acknowledge that IQVIA data is based on list prices and therefore does not include discounts. Additionally, different countries and healthcare systems may have varying pricing structures and regulations, leading to disparities in list prices across different countries. However, this assessment is limited to 15 drugs and therefore also underestimates the full impact of the proposals. Therefore, we consider this to be a reasonable proxy for the cost impact.

OPDIVO	**NIVOLUMAB**	1,141,058,420.50
STELARA	**USTEKINUMAB**	1,031,860,999.00
IMBRUVICA	**IBRUTINIB**	1,297,636,568.20
EYLEA	**AFLIBERCEPT**	1,185,354,292.50
XTANDI	**ENZALUTAMIDE**	1,100,691,445.70
TRIKAFTA	**ELEXACAFTOR, IVACAFTOR, TEZACAFTOR**	2,943,150,623.70
OCREVUS	**OCRELIZUMAB**	607,641,573.00
OZEMPIC	**SEMAGLUTIDE**	882,022,020.60
VYNDAQEL	**TAFAMIDIS**	830,187,232.00
IBRANCE	**PALBOCICLIB**	587,034,486.50
BIKTARVY	**BICTEGRAVIR, EMTRICITABINE, TENOFOVIR ALAFENAMIDE**	2,342,910,717.00
	TOTAL	**22,288,489,891.40**

We have also assessed the total **or cumulative cost of the prolonged exclusivity**:

- ➔ In case of 13.5 years of regulatory data protection: **19.5 BN EUR**
- ➔ In case of 18 years of regulatory data protection: **99.5 BN EUR**

To contextualise these costs, the annual pharmaceutical budget of the EU27 is estimated at **175.44 bn EUR.**[5]

To provide some **country examples**:

For **France**, additional costs would amount to:

- ➔ In case of 13.5 years of regulatory data protection: 5.35 BN EUR
- ➔ In case of 18 years of regulatory data protection: 24 BN EUR

To contextualise these costs, the total annual pharmaceutical budget of France is estimated at **31.71 bn EUR.**[2]

For **Germany**, additional costs would amount to:

- ➔ In case of 13.5 years of regulatory data protection: 5 BN EUR
- ➔ In case of 18 years of regulatory data protection: 23 BN EUR

To contextualise these costs, the total annual pharmaceutical budget of Germany is estimated at **42.57 bn EUR.**[2]

For **Spain**, additional costs would amount to:

[5] **IGES report**: Reimbursement & Pricing of Pharmaceuticals in Europe 22/23; Source: based on BPI e.v. Pharmadaten 2021, p.38-40

- ➔ In case of 13.5 years of regulatory data protection: 2.25 BN EUR
- ➔ In case of 18 years of regulatory data protection: 13.2 BN EUR

To contextualise these costs, the total annual pharmaceutical budget of Spain is estimated at **22.02 bn EUR.**[2]

5. How will healthcare systems pay for these massive costs?

This data shows the **massive cost impact of extending regulatory/market exclusivities for EU pharmaceutical budgets**. There is no pathway to adjust public health budgets to absorb these costs. Therefore, we must assume that Member States would be required to use funds from other healthcare budget lines to pay for these monopoly extensions. We have thus calculated the number of nurses and doctors, which are in shortage in many Member States, to provide a picture of the potential impact. If we were to estimate how many **nurses** could be hired with that additional amount that would need to be allocated to the drugs budget due to these extensions (based on an average salary across the EU of 35.3k annually, OECD Health Statistics 2022):

- ➔ In case of 13.5 years of regulatory data protection: 550,000 nurses
- ➔ In case of 18 years of regulatory data protection: 3,000,000 nurses

- For **France** (based on an average salary of 32.4k annually, OECD Health Statistics 2022):
  - ➔ In case of 13.5 years of regulatory data protection: 165,000 nurses
  - ➔ In case of 18 years of regulatory data protection: 740,000 nurses

- For Germany (based on an average salary of 44k annually, OECD Health Statistics 2022):
  - ➔ In case of 13.5 years of regulatory data protection: 114,000 nurses
  - ➔ In case of 18 years of regulatory data protection: ca. 521,000 nurses

In **number of specialist doctors** (based on an average salary across the EU of 83k annually, OECD Health Statistics 2020):

- ➔ In case of 13.5 years of regulatory data protection: 235,000 specialists
- ➔ In case of 18 years of regulatory data protection: 1,200,000 specialists

- For **France** (based on an average salary of 84k annually, OECD Health Statistics 2020):
  - ➔ In case of 13.5 years of regulatory data protection: 64,000 specialists
  - ➔ In case of 18 years of regulatory data protection: 286,000 specialists

- For **Germany** (based on an average salary of 146k annually, OECD Health Statistics 2020):
  - ➔ In case of 13.5 years of regulatory data protection: 34,000 specialists
  - ➔ In case of 18 years of regulatory data protection: ca. 157,000 specialists

Considering the massive impact of extending effective drug monopolies, we urge the European Parliament to reconsider this important revision and to avoid accidentally introducing massive cost burdens on healthcare systems.