NOTE on Proposals to extend pharmaceutical intellectual property incentives in reaction to US tariffs

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Medicines for Europe is aware that EFPIA is proposing an extensive prolongation of pharmaceutical regulatory protections to counter the impact of US tariffs. This will not stop pharmaceutical companies from transferring their production to the US as some have already announced. This will bankrupt public health budgets which already struggle to finance the reimbursement of expensive drugs. The note provides some important facts for consideration.

1. **Europe has the longest pharmaceutical regulatory protection system in the world**, as highlighted in a Commission Impact Assessment (page 38):

Table 2 Basic regulatory protection periods for medicines globally[128]

Country	Protection	Duration
Canada	New Chemical Entity+ Market Protection	6+2 years
EU	New Chemical Entity+ Market Protection	8+2+1 years
Switzerland	New Chemical Entity	10 years
USA	New Chemical Entity (small molecule)	5 years
USA	Biosimilar Application Approval Exclusivity (biologic)	4+8 years
Israel	Market Protection	6 or 6.5 years
China	New Chemical Entity	6 years
Japan	New Chemical Entity	8 years

Compared to the US, Europe provides 8 years of regulatory and 15 years of patent and supplementary protection certificate (SPC) protections compared to 5 and 14 years in the US for equivalent protections.

CURRENT SYSTEM

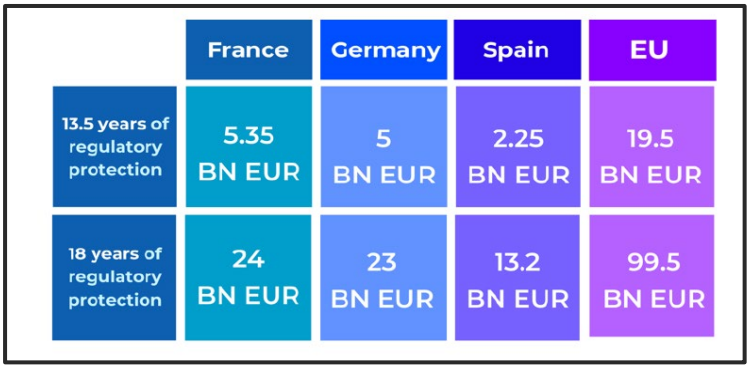
REGULATORY PROTECTIONS	EUROPE	UNITED STATES	DIFFERENCE IN YEARS
Small molecules	8DP+2MP+1MP = **11y**	5DP = **5y**	**+6y in EU**
Biological	8DP+2MP+1MP = **11y**	4DP+8MP = **12y**	**+1 in US**
Orphan medicines	10ME (equal to DP) = **10y**	7ME = **7y**	**+3 in EU**
		Total n. of years	**+8 in EU**

Despite these long EU protection periods that have been in force the last 30 years, R&D investments have grown much faster in the US (with shorter protection) and China (with very little protection) than in Europe. Lengthy **IP protections do not stimulate R&D investments in Europe**.

Extending regulatory protection from 11 years to 13/14 years would **dramatically increase costs for healthcare systems**, which cannot afford this. The same proposals were already rejected in the European Parliament and Council because they would cost between €20 and 100 billion annually, which is equivalent to the salary of hundreds of thousands of much needed nurses or doctors.

Simulation of the economic impact of extending regulatory data protection:

Europe is facing the risk of economic recession and needs to divert public spending to national defence. Under these circumstances, healthcare systems cannot afford €20-100 billion extra per year.



2. The Bolar Exemption is important for competition and for manufacturing in Europe

The **Bolar exemption** was enacted to allow the development and approval of generics and biosimilars for immediate competition at IP expiry. Multiple studies (including Commission studies) show that the lack of harmonisation of the Bolar have led to **(1) disinvestments in Active Pharmaceutical Ingredients (API)** development in Europe and **(2)** a misuse of the IP system to systematically and unduly **delay generic and biosimilar competition** (well documented by national competition authorities and courts), with severe delays for patient access to medicines and massive costs for healthcare budgets, as shown in the few examples below:

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**

For these very well documented reasons the Bolar exemption should be clarified and harmonised in the revised Pharmaceutical Directive.

MEDICINES FOR EUROPE POSITION

Medicines for Europe is ready to work with EFPIA on a balanced regulatory incentive system while stimulating investments in API production in Europe and access to medicines by harmonising the Bolar exemption. We support a united European response to US protectionism that is fact-based, fiscally sound and focuses on patient access to medicines and European strategic autonomy.