Press Release

Parliament's balanced stand on Unitary SPC regulation rewards innovation via an efficient Unitary SPC system that protects against access to medicines delays

Brussels, 28 February 2024

The position adopted today by the European Parliament on the proposals for the Unitary Supplementary Protection Certificate (SPC) and SPC Regulation recast, led by MEP Tiemo Wolken, is a significant milestone for innovation and access to medicines across Europe in this important legislative process.

The Unitary SPC will significantly expand the geographical coverage of this IP right that extends the exclusivity (monopoly) of medicines up to 5 years beyond the life of the patent. This "unitary protection" will now cover countries where these drugs are not normally launched or launched very late. The legislation is therefore highly impactful for access to medicines. For this reason, safeguards are essential to prevent misuse of the system.

The transparency and quality of examination procedures for the grant of Unitary or national SPCs are key principles embedded in the text adopted in plenary by the European Parliament. The Parliament rightly identifies the necessary safeguards for the scrutiny of applications before the granting of an SPC. This pre-grant opposition mechanism will prevent invalid (non-innovative) SPCs from being enforced and ultimately invalidated in Court, delaying access to generic and biosimilar medicines, as experienced recently for HIV and other multiple essential medicines.

Moreover, the transparency of SPC expiry dates in the register should not be misused to implement unlawful and anti-competitive patent linkage strategies to delay generic and biosimilar medicines in Member States. The explicit ban of the unlawful patent linkage introduced by the European Parliament will ensure that competition to blockbuster drugs will not be delayed beyond SPC expiry, as is the case today where, on average, competition begins more than 5 months late. Patent linkage has been declared unlawful by the European Commission in the Pharmaceutical Sector Inquiry Report of 2009.

Commenting on the report, Adrian van den Hoven, Director General of Medicines for Europe said "*The position of the Parliament goes in the right direction and rightfully bans patent linkage. The pre-grant opposition will ensure a timely grant of SPCs for innovative drugs (a maximum 14 months or 12 with an expedited procedure) and prevent monopoly extensions for those drugs that do not have a legal right to an SPC because they are not innovative. The ban of patent linkage will serve access to medicines by preventing pricing and reimbursement or tender procedure delays for generic and biosimilar medicines at SPC expiry. Medicines for Europe will engage*

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constructively with the EU institutions to ensure the most efficient, quality, and fair SPC system possible for the future."

ANNEX*:*

A few recent examples of undue generic medicines delays due to patent linkage. More information on patent linkage, here. On the Unitary SPC, here.

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**

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe, and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.