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Open submission on supplementary protection certificates for medicinal products in the European Union

We are providing this submission to you regarding the supplementary protection certificate (SPC) mechanism for medicinal products and its impact on access to affordable medicines for patients. As requested under the Council Conclusions adopted in June 2016¹ (point 47), the European Commission is currently reviewing Regulation EC 469/2009 concerning the supplementary protection certificate for medicinal products.² As civil society organisations, we welcome the Commission's recognition of "the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems",³ and recommend a thorough review of the impact of the SPC mechanism on access to affordable medicines.

By prolonging the monopolies of originator pharmaceutical companies, SPCs lead to unaffordable medicines prices that prevail for longer periods of time – threatening the sustainability of national healthcare systems and delaying patients' access to lifesaving medical innovation. We recommend that the European Commission abolish this mechanism.

As civil society organisations working on access to medicines and public health, we have witnessed the detrimental impact of some intellectual property rules on access to affordable medicines. Over the past few decades, developing countries have faced increasing pressure to adopt intellectual property laws and policies that give pharmaceutical corporations additional monopoly rights that exceed international legal obligations. Granting extended terms of patent protection and additional periods of market exclusivity delays generic competition, a proven method to sustainably reduce medicine prices and improve access to medicines.⁴ These are not challenges for developing countries alone. In Europe, SPCs are having a similar effect on generic competition – disproportionately favouring commercial interests over public health needs.

The market prices pharmaceutical companies charge for new medicines have increased steeply over the past decade, and recent trends have compelled governments across the European Union to explore and apply alternative and new policies to cope with unsustainable medicines prices. Sofosbuvir, for instance, a breakthrough medicine to treat hepatitis C, was launched at prices that made it impossible for a number of European countries to finance its roll-out for all patients that could benefit. Countries such as Switzerland⁵ and the United Kingdom⁶ have rationed sofosbuvir due to its high price. Italy has exceptionally decided to allow hepatitis C patients to import a much cheaper generic version of sofosbuvir from Indian producers.⁷

Broad intellectual property rules facilitate so-called ‘evergreening’ strategies of pharmaceutical companies. Evergreening strategies are employed by pharmaceutical companies to extend market monopolies through a variety of means, including filing multiple patents on one medicine or pursuing prolonged patent terms. This allows companies to avoid generic competition and to charge higher prices to patients and governments. Furthermore, enhanced monopoly power for pharmaceutical companies does not improve innovation; in fact, it often encourages behaviours among pharmaceutical companies that undermine innovation and focus private investment in areas that do not address unmet needs. Introducing extended market monopolies can only deepen this challenge. A study from Australia on the impact of patent term extensions has demonstrated that elimination of patent term extensions could have saved the Australian government up to 241 million Australian dollars per year on public expenditure for pharmaceuticals.⁸

The introduction of SPCs was initially and partly justified in order to “to meet the innovative pharmaceutical concern that they were no longer given a fair opportunity to recover their Research and Development efforts and investments”.⁹ We disagree with this premise. First, studies demonstrate that the expansion of patent and market exclusivity protection on medicinal products worldwide has not addressed unmet medical and public health needs.¹⁰ Instead, the use of patents encourages pharmaceutical companies to prioritise research and development (R&D) that responds only to profitable markets rather than unmet medical needs.¹¹ Experiences in other countries have also shown that there is no evidence of increased investment, or visible incentive to innovate for novel pharmaceuticals after the introduction of extension of patent terms.¹²

Second, evidence suggests that, in practice, drug prices do not reflect R&D costs – whether claimed or estimated.¹³ Reported figures consistently indicate that prices charged by pharmaceutical companies globally significantly exceed the actual cost of R&D.¹⁴ In fact, pharmaceutical companies have too much opportunity and power to both recover their investments and earn outsized returns for new pharmaceutical products. Recent academic studies illustrate that companies are increasingly allocating revenues from high drug prices to share buybacks and dividends that boost executive and shareholder compensation. This indicates that most companies are earning returns that both accommodate their prior and future R&D investments and also enable them to pay executives and shareholders excessive compensation.¹⁵ In many cases, annual expenditure on share buybacks and dividend payments exceed companies’ R&D investments.¹⁶ From 2006 to 2015, Gilead Sciences, the patent holder for sofosbuvir and many antiretrovirals for HIV, spent US\$27 billion on share

buybacks and dividends, and only US\$17 billion on R&D.¹⁷ Over the same 10-year period, 18 large pharmaceutical companies collectively spent US\$516 billion on buybacks and dividends, and only US\$465 billion on R&D.¹⁸

SPCs prolong market monopolies and associated high prices of medicines in Europe

Prolonged exclusivity through SPCs has consistently delayed the availability of generic and biosimilar medicines in Europe, upsetting the balance between the commercial interests of pharmaceutical companies and the public interest of patients across European countries. For example, as shown in Table 1, generic versions of some key antiretroviral medicines for the treatment of HIV/AIDS have been widely used in other countries for the past 10 years; however, they remain unavailable in Europe – even after the expiration of primary patents – due solely to the extension of exclusivity through SPCs.

Table 1: Generic versions of key antiretroviral medicines for treatment of HIV/AIDS unavailable in Europe due to SPCs

Medicine	European patent expires	SPC extension	Generics available in global market since
abacavir/lamivudine	Mar 2016	Dec 2019	2006
atazanavir	Apr 2017	Apr 2019	2008
raltegravir	Oct 2022	Jan 2023	2015

More importantly, extending monopolies after the expiration of patent terms has enabled pharmaceutical companies to continue to charge excessive prices of lifesaving medicines across Europe, even as affordable and equivalent generic and biosimilar versions of new medicines are launched outside of the European Union. The lack of SPCs in these other countries means that generic competition can be initiated. Earlier generic competition is all the more critical, since price reductions due to generic competition often take a few years to take hold.

Table 2 (below) demonstrates the specific impact that SPCs have had on the price of medicines used to treat HIV and AIDS, cancer, and hepatitis C by comparing the prices of such products in 10 European countries with the prices of the same products in India. For example, due to an additional monopoly granted by SPCs, there was a 10-year delay for European countries to import or produce generic versions of imatinib mesylate, a medicine used to treat leukaemia. Even the lowest current generic price of imatinib mesylate in the 10 European countries is up to three times more expensive than the equivalent generic price in India, where generic competition began much earlier.

Table 2: Impact of SPCs on the price of medicines for the treatment of HIV/AIDS, cancer, and hepatitis C

Medicine *	European patent expires	SPC extension (France)	Generic/ biosimilar available in global market since	Prices (€) in European countries [†]										Prices (€) in India for generics/ biosimilars [†]
				^I The Netherlands	^{II} Belgium	^{III} Luxembourg	^{IV} U.K.	^V Portugal	^{VI} Denmark	^{VII} Hungary	^{VIII} Norway	^{IX} France	^{IX} Germany	
trastuzumab powder for injection From Roche	Jun 2012	Jul 2014	2013 (India)	590	556	1582	456	--	762	561	688	499 ^x	826	169 ^{XI} From Mylan, Biocon
sofosbuvir From Gilead	Mar 2028	Jan 2029	2014 (India)	14487	14487	13667	13060	15181	19731	--	16698	9567 ^{xii}	16809	210 From Gilead 91 From generic suppliers ^{xiii}
tenofovir/emtricitabine (TDF/FTC) From Gilead	Jul 2017	Feb 2020	2007 (India)	535	527	512	398	--	1113	481	604	347 ^{xiv}	820	4 – 5 ^{xv} From Hetero, Strides, Cipla, Aurobindo, Macleods
imatinib mesylate From Novartis or its generic company, Sandoz	Mar 2013	Dec 2016	2003 (India)	2584	984	956	2180	2354	2909	2146	2843	1843 ⁺ ^{xvi}	3408	25 From Natco ^{xvii} 36 From Cipla ^{xviii}
From generic suppliers [§]			→	2241	984	955	--	2354	80	839	--	987	3057	

* Product details: trastuzumab powder for injection - 150mg in vial, one vial; sofosbuvir - 400mg tablet, bottle of 28 tablets; tenofovir/emtricitabine (TDF/FTC) - 300/200mg tablet, bottle of 30 tablets; imatinib mesylate - 400mg tablet, bottle of 30 tablets.

[†] Prices rounded to nearest whole euro. The prices indicated are the prices publicly available online as indicated in the references. The prices may not necessarily account for discounts or deals made between governments, pharmacies or hospitals and individual companies.

[‡] Three generic products have been approved in France but not marketed.

[§] The Netherlands, Belgium and Denmark: Accord Healthcare; Luxembourg: Eurogenerics; Portugal: Pharmoz; Hungary: Teva; France: multiple suppliers^{xix}

^I <https://www.medicijnkosten.nl>

^{II} <http://ondpanon.riziv.fgov.be/SSPWebApplicationPublic/nl/Public/ProductSearch>

^{III} <http://www.cns.public.lu/en/legislations/textes-coordonnes/liste-med-comm.html>

^{IV} British National Formulary 73rd Edition

^V <http://www.infarmed.pt/web/infarmed/servicos-on-line/pesquisa-do-medicamento>

^{VI} <http://www.medicinpriser.dk>

^{VII} http://neak.gov.hu/felso_menu/szakmai_oldalok/gyogyszer_segedeszkoz_gyogyfurdo_tamogatasi/egeszsegugyi_vallalkozasoknak/gyartok_forgalomba_hozok/dipc.html

^{VIII} <https://www.legemiddelsok.no>

^{IX} <https://www.medicinpriser.dk>

^X http://www.roche.fr/pharma/traitements-medicaux-innovants/nos_produits/herceptin.html

^{XI} https://www.msfacecess.org/sites/default/files/ACCES_report_FTPL_ENG_2016.pdf

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^{XIII} Forthcoming 2017 MSF Access Campaign publication on the diagnosis and treatment of hepatitis C

^{XIV} <http://medicprix.sante.gouv.fr/medicprix/detailPresentation.do?parameter=afficherPresDetail&idPresentation=49800>

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^{XVII} <http://www.cips.org.in/documents/2015/March/Half-day/Srinivasan.pdf> (public sector prices)

^{XVIII} <http://www.cips.org.in/documents/2015/March/Half-day/Srinivasan.pdf> (public sector prices)

^{XIX} <http://www.lepharmacien.fr/produitafine/medicament/substance/909?page=1>

SPCs are a new means for pharmaceutical companies to pursue ‘evergreening’ of market monopolies

The broad and ambiguous scope of SPCs enables and reinforces ‘evergreening’ strategies that most pharmaceutical companies seek to actively implement. First, multiple SPCs can be issued for the same product. This contradicts the purported goal of awarding one SPC for a product. In fact, SPCs for the same product can be granted to multiple companies if each company has a patent on the product.

In the case of trastuzumab, a medicine used to treat breast cancer, two SPCs had already been issued for two different companies: PDI Biopharma Inc. and Cetus Corporation – which did not perform the research leading to the authorisation of trastuzumab – before Roche, the originator company for trastuzumab, successfully secured a third SPC. This is partly because under case law of the Court of Justice of the European Union (CJEU)¹⁹, more than one SPC can be granted on the same product if the product is covered by multiple patents by different patent holders. This practice unnecessarily multiplied and expanded intellectual property rights of trastuzumab. While there are several biosimilar applications for trastuzumab under review by the European Medicines Agency, today Roche remains the only supplier of the product in European countries.²⁰ In fact, in association with this expanded monopoly, the average prices of trastuzumab in the 10 European countries we studied range from €456.29 to €1582.25 per vial (150mg). As shown in Table 2, biosimilar versions have been available in India since 2013 and are now available for €169.28 per vial (150mg).

The issuance of multiple SPCs for the same product can also be used by a single company to expand its monopoly. Specifically, companies link their strategy for patenting minor changes to old medicines (such as combinations of existing medicines, derivatives of old medicines or changes in dosing formulations) as closely as possible to their strategy for applying for an additional SPC or SPCs on those minor changes. SPCs granted on these derivative features of medicines or insignificant modifications of old formulations extend and reinforce companies’ ‘evergreening’ strategies and extend their market monopolies through secondary patenting.

According to the current regulations, both “*combination of active ingredients*”²¹ and “*derivatives (salts and esters) of the substance*”²² could be subject to SPC protection, even where the active ingredient(s) or substance(s) themselves have already been the subject of an SPC. Yet patent applications on combinations or derivatives lack merit – and are often challenged – because such minor modifications often do not meet basic patentability criteria, namely providing an inventive advance compared to existing technologies.

For example, generic companies challenged the validity of Gilead Sciences’ SPC for the combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC), used for the treatment of HIV. Their argument centred on the fact that Gilead Sciences’ patent²³ essentially only relates to one of the two compounds (TDF). The British High Court of Justice made explicit in its decision²⁴ that the purported ‘inventive advance’ of the combination was not shown in the patent and that no SPC should be granted.²⁵ In parallel, Gilead Sciences has attempted to protect this combination by a later patent²⁶ which was revoked by the European

Patent Office. Gilead's application for an SPC on this combination has also been challenged and rejected in Sweden, Greece and the Netherlands.²⁷

Finally, SPCs are often sought in combination with other 'incentives' that also provide market exclusivities if applicants meet certain obligations. This includes, for example, an additional exclusivity period of six months for paediatric formulations (that is, in addition to a patent term or SPC),²⁸ and/or 10 years of data exclusivity for orphan drug products (with two additional years beyond the decade-long term if such product is for, or includes, a paediatric indication).²⁹ These additional periods of exclusivity allow companies to select amongst and design the optimal (i.e. the longest) monopoly – and therefore aid and abet 'evergreening' strategies when there are no appropriate safeguards in place. Novartis has used or attempted to use multiple exclusivities to expand its monopoly on its cancer drug imatinib, in particular orphan drug exclusivity, and the paediatric SPC extension described above.*

The impact of the sole use of an SPC or the combined use of SPCs with other non-patent exclusivity mechanisms needs to be reviewed closely during the current review of Regulation EC 469/2009 in order to safeguard public health and access to medicines.

SPCs misinterpret the reality of the time span between regulatory process and patent filing

One of the major justifications for introducing the SPC mechanism has been that “the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research”³⁰ and this could “lead to a lack of protection which penalises pharmaceutical research”.³¹ This assertion is fundamentally flawed. In particular, it increases medicine prices for governments and patients by expanding monopolies for life saving medicines via the SPC mechanism if and when regulatory agencies take the requisite time to protect public safety and public health by carefully assessing the safety, efficacy and quality of medicines. Furthermore, the above justification ignores the role companies themselves often play in prolonging the duration of review – for example, by failing to provide quality data or failing to respond to queries regarding dossiers in a timely manner. Any delay in regulatory approval due to a lack of capacity or resources within a drug regulatory agency should be mitigated by empowering regulatory agencies and expanding their resources, rather than providing additional market exclusivity to drug companies that have already benefited sufficiently.

Companies normally start filing patent applications from the earliest stages of product development, which also lengthens the duration of time between patent filing and completion of the regulatory process. Some patent applications have been filed so early that a tangible

* Imatinib initially received orphan drug designation, entitling 10 years of data exclusivity. Novartis asked for it to be removed just prior to patent expiration, and instead obtained an SPC for a six-month paediatric formulation, thereby securing a longer period of monopoly upon patent term expiration.

compound for pharmaceutical use will not even have been identified.* This behaviour creates unjustifiable ‘patent thickets’, as many such patent applications are abstract and overly broad, and may not fulfil the patentability criteria that warrant a patent. In this context, companies themselves are to blame for lengthening the duration of delay between the initial patent filing and the actual initiation and completion of the regulatory process. Providing additional market exclusivity rewards to companies for abusing the patent system through these early, speculative filings is the wrong approach. Instead, policy makers should take measures to safeguard against broad patent filings, including introducing stricter patentability criteria and examination practices and allowing companies to capture only a twenty-year monopoly from the initial patent filing. Introducing SPCs is the wrong solution.

SPCs are in direct conflict with policies for accelerating access to medicines and lack flexibilities for responding to public health needs

The SPC mechanism undermines the availability of affordable medicines across Europe since it directly conflicts with mechanisms designed to accelerate the introduction of generic and biosimilar medicines. Under current European Union regulations, there is no linkage between patent status and the regulatory approval process for medicines as patent linkage unlawfully restricts competition.³² In addition, Directive No. 2004/27/EC introduced the Bolar exemption,³³ an important public health safeguard during the regulatory authorisation process whereby generic drug applications for regulatory approval can be reviewed and approved prior to the expiration of a patent term in order to facilitate the introduction of affordable alternatives to patented medicines as soon as the patent expires. While these policies aim to accelerate generic and biosimilar entry and thereby reduce medicine prices, SPCs delay the entry of generic and biosimilar alternatives, which is associated with higher prices for new medicines that prevail for longer periods of time.

Furthermore, mechanisms to oppose the granting of SPCs should be bolstered. Third-party observations should be allowed during the examination procedure for SPC applications and an opposition procedure, opened to anyone, should be made available after an SPC is granted.

Conclusion

SPCs extend monopoly protection for new medicines, undermining access to affordable medicines while adding to the already tremendous revenues of originator companies that are not fully re-invested in R&D that meets unmet public health needs.

As organisations working on public health and access to medicines, we have long argued that broad intellectual property rules facilitate ‘evergreening’ strategies of pharmaceutical companies, and have a tremendous negative impact on access to affordable medicines in the countries where we work around the world, and those IP rules often not only lead to higher

* For instance, patent applications written in the so-called Markush claim are often filed at early stage of drug development. Those applications represent only broad and abstract chemical structure and can lead to millions of possible compounds.

medicine prices for longer periods of time, but also curtail R&D that would lead to innovation to meet unmet public health needs.

Today, as the European Union grapples with the challenges of high medicine prices, measures such as the SPC, which extends monopoly protection, often through industry's use of evergreening strategies, are measures which the EU can no longer afford to grant drug companies. Given the spiralling costs of medicines in the European Union, it is important that the European Commission reconsider measures that increase monopoly protection in Europe, given the social and financial costs for the European Union.

Recommendations

Abolish the SPC mechanism: The European Commission should abolish the SPC mechanism from its current legislation, regulations and practices. Provisions related to patent term extension under the European Patent Convention and other bilateral trade agreements to which European Union is a party should be reviewed and suspended in light of ensuring access to affordable medicines.

Stop encouraging SPCs and similar mechanisms, such as patent term extension through free trade agreements: The European Commission must stop pushing for TRIPS-plus provisions in its negotiations of trade agreements with other countries and should remove any previously negotiated provisions in free trade agreements that bind other countries, and the European Commission, to the use of SPC and similar mechanism such as patent term extension.

In the event SPCs remain:

Bolster opposition procedures: Mechanisms to oppose the granting of SPCs should be bolstered. Third-party observations should be allowed during the examination procedure for SPC applications and an opposition procedure, opened to anyone, should be made available after an SPC is granted.

Improve transparency of market exclusivity status: The European Commission should create an easily searchable public database for consumers, procurement agencies, civil society organisations and governments to identify SPCs that have been awarded and the delays to generic competition that such SPCs will cause.

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