EU Public consultation on Supplementary Protection Certificates (SPC) and patent research exemptions for sectors whose products are subject to regulated market authorisations

Contribution by SIOP Europe (SIOPE)

4th Jan, 2018

***1. Which best describes you?**

☒ Health, incl. medicines (human and/or veterinary medicines)

Please specify

Paediatric Haematology Oncology

***1.1. If the health sector, are you a:**

☒ Health care professionals (e.g. doctors, associations of health care professionals)

Please specify

SIOPE - the European Society for Paediatric Oncology, represents all professionals working in the field of childhood cancers across Europe.

3. What do you think are the effects of SPC protection on investment in developing innovative medicines [/plant protection products] with added value for patients [/farmers and consumers]?

☐ 1 (Negative)

☒ 2

☐ 3 (Positive)

☐ Impossible to know

☐ We don't know

☐ No opinion

Answer 2

Please explain your answer (max. 2 000 characters, incl. spaces). 2000 character(s) maximum

SIOPE is contributing from the perspective of paediatric cancer, which is the leading cause of children's death by disease above one year of age in Europe and contributes substantially to morbidity in survivors.

The European landscape of paediatric medicine development has been overall improved by the Paediatric (Medicines) Regulation (PMR, EC 1901/2006). The PMR can be viewed as being "attached" to the SPC mechanism, as it combines obligations and rewards where the SPC by itself was not sufficient to incentivise the development of safe and effective medicines for children in Europe.

Even though the Paediatric Regulation fell short of addressing the unmet needs of children and adolescents with cancer (https://www.siope.eu/wp-content/uploads/2013/06/1.-Paediatric_Reg_Position_paper.pdf), SIOPE believes that an efficient patent protection system remains a necessary backbone of paediatric medicine development in Europe. It is important to appropriately incentivise pharmaceutical companies to run and complete paediatric research on their medicines. However, the current reward system stands to gain from targeted revision to improve the timely and science-driven development of paediatric medicines, in particular in the field of paediatric oncology.

SIOPE acknowledges that delaying the entry of generic medicines into the market is an important issue at a time when more effective but expensive anticancer drugs are marketed for the treatment of adult cancers. However, the principle of appropriately formulated SPC extension is essential in the paediatric field for ensuring that innovative medicines are developed for children with life-threatening disease across Europe.

11. In your experience, is SPC protection sufficient to encourage investment in certain types of innovations (e.g. antibiotics, medicines for the treatment of neglected diseases and orphan diseases)?

☐ Yes

☒ No

☐ Don't know/no opinion

Please explain your answer (max. 1 500 characters, incl. spaces). 1500 character(s) maximum

In the field of paediatric oncology medicine development, the SPC protection by itself is inefficient to encourage investment in innovation, as is the case in any rare and/or paediatric disease. The 6-month extension of the SPC as a reward for completed Paediatric Investigation Plans (PIPs) is an essential part of the Paediatric (Medicines) Regulation (PMR, EC 1901/2006). However, the obligation to have a PIP or a waiver approved at the time of filing for the adult indication is a much stronger driver of the PMR implementation.

There is a need to improve incentives for the development of paediatric medicines by means of:

- A European SPC title making the PMR rewards more attractive and easier to claim;
- Provisions for more effective, proportionate and flexible rewards for companies undertaking early and timely PIPs and for those researching therapies specifically for cancers which only occur in children.

16. Which language combination would you prefer for the publication of the unitary SPC?

☐ The notice of granting a SPC should be published in all official languages of the EU English, German and French would be sufficient (Commission working languages)

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☐ English only would be sufficient

☐ Other options, please explain: