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Practical Implementation of the Requirements of the SPC Waiver Regulation

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Regulation (EU) 2019/933, amending the Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (hereinafter referred to as the Regulation) was published in the Official Journal of the European Union on 11th June 2019 and thus came into effect on 1st July 2019. The amended Regulation establishes the so-called “*SPC waiver*”, that excludes certain acts, which would otherwise require the consent of the SPC holder, from protection conferred by the SPC, if the prescribed conditions are met. In order to avail from this waiver, the maker shall, *inter alia*, timely notify the Industrial property office(s) of the EU Member States in which such making is to take place (hereinafter referred to as the Offices), using the standardized form (Annex -Ia of the Regulation). To this end, the Regulation lays down several requirements on the Offices *vis-à-vis* the prescribed conditions for parties wishing to benefit from this waiver. Implementation of these requirements was the subject of my personal study. Said requirements may be summarized as follows:

- **Receipt of the SPC waiver notification** from the maker, using the standard form for notification (according to the amended Art. 5(2)(b) and Art. 5(6) of the Regulation);
- **Receipt of changes to the SPC waiver notification** from the maker, using the standard form for notification (according to the amended Art. 5(2)(c) and Art. 5(6) of the Regulation);
- **Publication of the information** listed in Art. 5(5) of the Regulation, **as soon as possible**, together **with the date of notification** of the information received (according to the amended Art. 11(4) of the Regulation);
- **Publication of any changes to the information notified** in accordance with point (c) of Art. 5(2) of the Regulation, **as soon as possible** (according to the amended Art. 11(4), second sentence of the Regulation);
- **Possibility to require payment of a fee**, for notification and changes to the notification as referred to in points (b) and (c) of Art. 5(2) of the Regulation (according to the amended Art. 12(2) of the Regulation), at a level which does not exceed the administrative cost of processing notifications and updates (according to the 14th recital, last sentence of the Regulation).

The aim of my study was to conduct a short research project regarding the practical implementation of the aforementioned requirements among all of the 27 Offices. The majority of the Offices provided some form of a response. It is worth mentioning that, at the time of conducting this study, **not a single Office reported that it had yet received such notification.**[1]

Further, due to the progressive application of the waiver under Art. 5(10) of the Regulation (the transitional period for the SPCs that were applied for before the date of entry into force of the Regulation, *i.e.* before the 1st of July 2019, but have not yet taken effect before that), several Offices are still in the process of preparing their measures in-line with the Regulation (as the Lithuanian and Latvian Office have replied). It is also probable, that the remaining Offices that have not provided their response in any way, have not set-up a final procedure as well.

Below is a table summarizing the approach each Office has taken, according to the information provided. There are some considerable differences among the Offices in their accepted means of filing, ways of publication of the notification and whether they require payment of a fee or not.

Some Offices seem to have taken an approach similar to any other application, *i.e.* standard way of filing according to the general rules (in paper form and/or on-line), publication in the official gazette (usually available on-line) and also possibly in the on-line register (this allows users to search in the notifications unlike the pdf gazette; however, some Offices have not implemented this option or others, such as the Danish Office, have not yet decided about this).

Others seem to have taken a different approach, *e.g.* submission by e-mail (the standardized [Posta Elettronica Certificata](#) procedure is to be followed in Italy; the Bulgarian Office will require subsequent provision of the original; and the Belgian Office does not exclude the use of e-mail, but does not encourage it for the security reasons) or publication in a separate table on the Office's website (which seems to provide the most comprehensive and quick overview for the users).

Surprisingly, some of the Offices have created their own specific form for submission of the notification, namely the German Office ([P2041/7.19 form](#)), the Spanish Office ([INIFAB form](#)) and the Slovakian Office ([special form](#)). The remaining majority of the Offices use the standardized form annexed to the Regulation as mentioned above.

As it is apparent, most Offices do not require payment of a fee at the moment (although this is still under consideration at the Spanish and the Netherlands Office and the Offices may also re-evaluate this, depending on the volume of notifications received, as stated by the Belgian Office). An amendment of the Law on Patents and Utility Models Registration is currently underway in Bulgaria, according to which a fee (the amount has not yet been specified) will be required for each submission of the notification.

Hence, a varied approach has been taken by the Offices in implementing the requirements of the Regulation. This may also, among other aspects, hinder the exploitation of the Regulation by the makers. As in most instances, no notifications have yet been received by the Offices and as several Offices are still in the process of preparing their measures in line with the Regulation, the way these requirements are implemented may change, sooner or later.

Lastly, let me please extend my sincere gratitude to my friends and fellow patent attorneys in the EU Member States for being helpful in contacting the Offices, during compilation of this study!

	Means of filing	Fee	Means for publication
AT	Paper form, on-line	–	Official Gazette; On-line Register
BE	Paper form, on-line, e-mail	–	Official Gazette; On-line Register
BG	Paper form, e-mail	Yes	Official Gazette; On-line Register
CZ	Paper form, on-line	–	Official Gazette; On-line Register

DE	Paper form, on-line	–	Official Gazette; On-line Register
DK	Paper form, e-mail	–	Official Gazette
EE	Paper form	–	Official Gazette
ES	Paper form, on-line	–	Official Gazette; On-line Register
FI	Paper form	100 EUR	Official Gazette; On-line Register
FR	On-line	27 EUR	Official Gazette; On-line Register
GR	Paper form, on-line (<i>soon</i>)	–	Official Gazette; On-line Register
HR	Paper form	–	Official Gazette; On-line Register (<i>planned</i>)
HU	Paper form, on-line	–	Official Gazette; On-line Register
IE	Paper form, e-mail	–	Official Gazette; On-line Register; Separate table
IT	Certified e-mail	–	Separate table
LT	<i>Not stated</i>	–	<i>Not stated</i>
LU	Paper form, e-mail	–	Official Gazette; On-line Register
LV	Paper form, on-line	40 EUR	Official Gazette
NL	Paper form, e-mail	–	Official Gazette; On-line Register
PL	Paper form, on-line	–	Official Gazette; On-line Register
PT	Paper form, on-line	–	Official Gazette; On-line Register
SE	Paper form	–	Official Gazette
SI	Paper form, e-mail	–	Separate table
SK	Paper form, on-line	–	Official Gazette

[1] However, this is not valid anymore, as at least the Slovenian Office, had already received a notification from Lek on the 20th of November 2020, see [here](#)).

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This entry was posted on Monday, January 4th, 2021 at 5:39 pm and is filed under [European Union, Legislation, SPC](#)

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