

Frequently Asked Questions: Brexit and SPCs

Supplementary Protection Certificates (SPCs)

What are SPCs?	<p>A Supplementary Protection Certificate (SPC) is a form of IP that comes into force at the end of your patent's life to extend the term of protection by up to 5 years for specific medicinal or plant protection active ingredient covered by the patent. A 6 month extension of the SPC term is possible via a paediatric extension. SPC legislation is derived from an EU Regulation, but SPCs are applied for and maintained on a country-by-country basis. Therefore, to obtain patent term extension in multiple countries in the EEA, you have to apply for an SPC in each country individually (even before Brexit).</p> <p>In order to apply for an SPC in the UK, you must be the proprietor of a EP(UK) or UK patent in force that covers the active ingredient for which a first marketing authorisation to place a product containing the active ingredient on the UK market as a medicinal or plant protection product has been granted.</p>
Will UK SPCs be affected by Brexit?	<p>Yes.</p> <p>The EU Regulation governing SPCs will no longer apply in the UK after the date Brexit becomes effective. This could be 31 January 2020, or a later date if a transitional period is agreed.</p> <p>Guidance notes from the UK government suggest that even in a No-Deal Brexit, current SPC legislation will be retained in UK law. There may be some changes to the law in addition – we will update you as and when we know more.</p>
Will applying for a UK SPC be affected by Brexit?	<p>Clarification is needed about the marketing authorisation the SPC can be based on.</p> <p>As SPCs are granted on a country-by-country basis, UK applications are lodged with the UK IPO. This will remain the case after Brexit.</p> <p>However, applying for marketing authorisations required for SPCs may change after Brexit.</p> <p>Currently, marketing authorisations to place a new medicinal or plant protection product on the market in the UK can be granted in one of two ways: either by a centralised procedure governed by the European Medicines Agency ("EMA") or from the UK Medicines & Healthcare products Regulatory Agency ("MHRA").</p>

	<p>After Brexit, it is possible (but not certain) that marketing authorisations for the UK will need to be obtained solely from the UK MHRA and that EMA centralised procedure marketing authorisations will not be valid in the UK.</p>
<p>What will happen to my marketing authorisation applications that are still pending at the time of Brexit?</p>	<p>Clarification is expected soon.</p> <p>We think it's likely that if your marketing authorisation application was lodged with the UK MHRA you won't need to do anything.</p> <p>Conversely, if you have applied for marketing authorisation via the centralised EMA procedure it is possible (but not certain) that you will have to reapply to the UK MHRA if your marketing authorisation application has not been granted before the effective date of Brexit.</p>
<p>What about UK SPC applications that are still pending at the time of Brexit? Do I have to reapply?</p>	<p>Clarification is expected soon.</p> <p>The present expectation is that EU SPC legislation will be put into UK law in the event of No Deal Brexit, and the UK Government has provided guidance suggesting that pending SPC applications will be processed as before (even for marketing authorisations granted under the EMA centralised procedure).</p>
<p>Will my granted UK SPC be affected by Brexit?</p>	<p>No.</p> <p>Even in the event of No-Deal Brexit, your granted UK SPC will continue to have effect in the UK after Brexit.</p>
<p>Will I have to do anything different to maintain my granted UK SPC after Brexit?</p>	<p>No.</p> <p>Renewal fees for the duration of the UK SPC are paid to the UKIPO before the SPC comes into force. Therefore you won't have to do anything else.</p>
<p>Will R&G still be able to help me with my SPC applications in the UK and abroad?</p>	<p>Yes!</p> <p>We will still be able to support you through the SPC application process in the UK (and elsewhere) before and after Brexit.</p>