Update on the Windsor Framework and its Relevance to SPCs and Paediatric Extensions in the UK

The EU and the UK formally adopted the Windsor Framework (WF) on 24 March 2023. Subsequently, the UK government has issued some additional guidance[1] on the application of the "Medicines" measures in the WF. These measures will replace the corresponding elements of the Northern Ireland Protocol (NIP) and so will change the regulation of medicines in Northern Ireland. In particular, upon implementation, the UK's Medicines and Healthcare products Regulatory Authority (MHRA) will have sole responsibility for the regulation of medicines throughout the UK and the EU's European Medicines Agency (EMA) will cease to have any role.

As we discussed in our previous report on the WF (available here), this must necessarily impact SPCs in the UK. It will additionally impact requests for paediatric extension of SPCs, since these are also currently dependent on procedures governed by both the EMA and the MHRA, specifically the assessment of compliance with agreed Paediatric Investigation Plans (PIPs).

The most important part of the new guidance is the confirmation that the WF measures will commence from **1 January 2025** (the WF date). This means that medicines authorised from this date will receive a single UK-wide marketing authorisation (MA) from the MHRA, covering both Great Britain (GB) and Northern Ireland (NI). Assessment of PIPs and issuance of compliance statements will also be the sole competence of the MHRA and will be UK-wide.

This replaces the current dual regulatory arrangement under the NIP. In order to cover the whole territory of the UK under the NIP, a new drug generally requires one MA for GB issued by the MHRA and another MA for NI issued by the EMA. Similarly, paediatric extensions require one request based on a compliance statement for GB issued by the MHRA and another based on a compliance statement for NI issued by the EMA. The new guidance also confirms that the NIP arrangement will apply up to and including 31 December 2024.

Unfortunately, the guidance is silent as to how the transition from one regime to another will be managed, particularly with respect to SPCs and paediatric extension requests that have been filed under the NIP. It is hoped that in due course the UK government will issue an equivalent of their earlier document, "SPCs and the Northern Ireland Protocol[2]", which helped to explain the similar transition that took place at the end of the transition period following the UK's formal exit from the EU. That is on 31 December 2020 (the Brexit implementation date, BI date). More guidance on the transition to the WF would be particularly welcome, because we think the situation is more complicated than the previous transition to the NIP. This is because there are now multiple different categories of SPC / paediatric extension that are affected in different ways, and so the transition to the WF is likely to require more careful explanation and implementation. We discuss some of the different categories below.

Pre-Brexit SPCs / paediatric extensions - filed up to BI date (31 Dec 2020)

The previous transition required a change for SPCs / paediatric extensions that existed at the BI date from a single, UK-wide regulatory regime under the EMA, to a dual regulatory regime under the EMA and MHRA, which was nonetheless (automatically) UK-wide by operation of the "conversion" process. What is now required is for such "previously converted" (pre-Brexit) UK-wide SPCs / paediatric extensions to "re-converted" to the new, single, UK-wide regulatory regime under the MHRA. We think this should be relatively straightforward to explain and implement.

WF SPCs / paediatric extensions - filed on / after WF date (1 Jan 2025)

Any SPC application or paediatric extension request filed after the WF date will necessarily fall under the new, single, UK-wide regulatory regime under the MHRA. That is, a MA issued by the MHRA will be required to file the SPC application, and a compliance statement issued by the MHRA will be required to file the extension request. Again, we think this is relatively straightforward to explain and implement.

The changes may though disadvantage applicants who would have been ready to file SPCs / paediatric extensions shortly after the WF date based on EMA elements, but will subsequently to wait for completion of MHRA elements, which typically come later. In extreme circumstances, applicants who could at least have obtained coverage for NI before the WF date may subsequently be time-barred from obtaining SPC / paediatric extension coverage for any of the UK. This could apply if the required MHRA elements only become available after the relevant final deadlines linked to the terms of the underlying rights have expired[3].

NIP SPCs / paediatric extensions - filed between BI date and WF date

Where the most complexity may arise is for any SPC application or paediatric extension request initiated under the dual regulatory regime of the NIP – in the window between the BI date and the WF date.

We do not anticipate a problem for NIP SPCs / paediatric extensions for which the collective effect is already UK-wide, that is where both the EMA elements for NI and the MHRA elements for GB are already in place at the WF date. It should be relatively straightforward for such dual regulatory UK- wide SPCs / paediatric extensions to be switched to the single, UK-wide

regulatory regime under the MHRA.

We also do not anticipate a problem for NIP SPCs / paediatric extensions for which the MHRA elements for GB are already in place at the WF date. We envisage that a simple territorial "expansion" of the existing MHRA elements would result in such GB-only SPCs / paediatric extensions becoming UK-wide in the new, single, UK-wide regulatory regime under the MHRA.

A problem may though arise for NIP SPCs / paediatric extensions for which only the EMA elements for NI are in place at the WF date. In many such cases, it may be possible simply to wait for the corresponding MHRA elements to become available. Provision could then be made for the MHRA elements effectively to be "merged" with the existing EMA elements for NI-only SPCs / paediatric extensions, such that the resulting UK-wide effect is still provided by simple application of the new, single, UK-wide regulatory regime under the MHRA. This would be somewhat similar to the process under the NIP for SPCs / paediatric extensions covering only part of the UK, whereby the "missing" MA or compliance statement can be added later to expand the territorial scope.

However, this raises the question of what happens if the required MHRA elements will only become available after established final deadlines for such additions have expired? These final deadlines here are similar to those in the previous section for filing SPC applications / paediatric extension requests, being linked to the terms of the underlying rights[4]. The transitional arrangements for the WF may therefore need to include special provisions to permit late addition of the MHRA elements, or otherwise include also some form of "adoption/conversion/expansion" of the EMA elements into the new, single, UK-wide regulatory regime under the MHRA.

Conclusions

The (relatively) brief period during which the NIP was in force may nonetheless have consequences for SPCs / paediatric extensions in the UK which extend beyond the entry into force of its successor, the WF. The transition from the dual regulatory regime of the NIP to the new UK-wide regulatory regime of the WF is more complicated than the previous Brexit transition to the NIP. The implications for applicants will therefore require careful explanation and management and we look forward to further guidance from the UK government and its responsible institutions (the MHRA, the UKIPO). No matter when or whether such guidance is issued, the SPC team at J A Kemp LLP will be ready to assist you with any questions regarding SPCs or paediatric extension requests in the UK. Please feel free to contact any of the team or your usual J A Kemp contact with any questions.

Footnotes

1. Windsor Framework medicines announcement. https://www.gov.uk/government/news/windsor-framework-medicines-announcement
2. SPCs and the Northern Ireland Protocol. https://www.gov.uk/guidance/spcs-and-the-northern-ireland-protocol
3. This does not refer to the procedural deadlines for filing SPC applications / extension requests, but rather than final deadlines that apply based on the underlying rights. The final deadline to file an SPC application is prior to expiry of the underlying basic patent. The final deadline to file a paediatric extension requests is 2 years before expiry of the underlying SPC.
4. The deadline to add a "missing" MA to expand the territorial scope of a NIP SPC is the date of entry into force of the SPC, i.e. the patent expiry date. The deadline to add a "missing" compliance statement to expand the territorial scope of a NIP paediatric extension is 2 years before the expiry of the SPC.

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