EU proposes wide-ranging changes to pharmaceutical exclusivities

Last week, the European Commission published a legislative proposal that could dramatically change the *status quo*, in particular with respect to how periods of exclusivity are awarded and calculated.

Existing regulatory exclusivities

Most innovative drugs authorised in the EU benefit from regulatory data and market protection periods. During the 8-year period of regulatory data protection (RDP), generic or biosimilar companies cannot reference the originator dossier in their marketing authorisation applications. Moreover, once approved, they are not allowed to place their generic or biosimilar drugs on the market until the end of the concurrent 10-year period of market protection. An additional year is granted when, with 8 years from the first authorisation, the drug is authorised for one or more additional new therapeutic indications that bring significant clinical benefit in comparison with existing therapies. The "8+2+1" periods compare favourable to corresponding regulatory exclusivity periods available outside of Europe.

In addition, innovator medicines for rare diseases can benefit from a 10-year period of orphan market exclusivity that runs concurrently with the 8+2 period. During the Orphan market exclusivity period, even makers of similar innovator drugs treating the same therapeutic indication are barred from filing for marketing authorisation, unless exceptional circumstances are present. The 10-year period can be extended by a 2-years when the results from a paediatric study are included on the label.

Changes to regulatory exclusivities

The Commission's proposal reduces **the baseline RDP period to 6 years** (Article 81(1) of the proposed directive) from the current 8 years.

To encourage launch of innovator drugs throughout the EU, the commission proposes to introduce **a 2-year RDP extension** if the drug is continuously supplied in a sufficient quantity to cover the needs of the patients in all Member States in which the marketing authorisation is valid. This must be achieved within 2 years of launch for larger companies and 3 years for SMEs, not-for-profit organisations and undertakings with less than five centralised marketing authorisations. To obtain the extension, the marketing authorisation holder must apply for a variation of the marketing authorisation. Moreover, each member state either must document that the drug has been continuously supplied or provide a waiver. It is unclear how the member states can be obliged to provide the necessary documentation and what would motivate a member state to waive the requirement to supply the medicine.

A further **6-month RDP extension** is available if the initial marketing organisation demonstrates the drug addresses an unmet medical need. An innovate drug that receives orphan designation will automatically meet this criterion. A further **6-month RDP extension** is available if the originator includes comparative clinical data in its application. The wording of the proposal and supplemental guidance suggests that an innovative medicine with improved efficacy over the standard of care could benefit from an additional year of RDP.

A further **1-year RDP extension** is available if the label is extended during the RDP period to include a new therapeutic indication that brings significant clinical benefit in comparison with existing therapies. This is similar to the current 1 year of additional market protection, but applies

to the RDP rather than the market protection period. The 1-year RDP extension may be available for extending the label to the paediatric population if the additional authorisation was for the adult population only. However, as before, marketing authorisation holders cannot simultaneously benefit from a 6-month paediatric extension of the term of SPCs covering the authorised drug.

The **2-year period of market protection** after expiry of the RDP remains the same. The proposal clarifies that this 2-year period is added to the combined period of data protection.

The proposal also introduces a new 4-year RDP for repurposed drugs. Only drugs that did not previously benefit from RDP or were first authorisation at least 25 years ago can obtain this protection.

The EU commission also proposes to introduce variable periods of 5, 9 and 10 years of orphan market exclusivity. Most orphan drugs may benefit for 9 years, but this period is reduced to 5 years for homeopathic medicines and increased to 10 years for orphan drugs that address a high unmet medical need. Indeed, the latter class of orphan drugs, or new active substances first authorised as orphan drugs, may benefit from a **1-year extension** of the period of orphan market exclusivity, if they are made available in all EU member states. A paediatric extension of the orphan market exclusivity period will no longer be available under the new proposal.

Conclusion

In summary, the proposed system may shorten the RDP and associated market protection periods significantly for companies that fail to continuously supply the whole EU market. The system may unintentionally favour large pharma companies that have an existing supply chain covering all member states. Drugs that address an unmet need and show an improvement over the standard of care could benefit from an additional year of data protection. Indeed, highly innovative drugs that are effective in multiple indications with a poor existing standard of care may benefit from up to 12 years of market protection, exceeding the current maximum of 11 years.

For more detailed advice in relation to any of the issues discussed above, or for advice relating to other matters regarding European practice, please do not hesitate to get in contact with your E+F representative or email us at elkfife@elkfife.com.