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The EU Pharma Package – Key Issues for the Pharma Industry

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The EU is currently working on revision of its main pieces of sector-specific regulation for medicinal products, following adoption of a package of measures by the European Commission in 2023 (the pharma package).

Revision of the current legislation has been steered by issues that have arisen in recent years, including concerns with antimicrobial resistance and supply chain security, tested to the extreme during the COVID-19 pandemic, where patient access to medicines was a particular concern.

Background and Need To Develop Current Rules

The main pieces of EU pharmaceutical legislation for humans have been in place for over 20 years and include EU Directive 2001/83 (the Directive) and Regulation 726/94 (the Regulation).

In broad terms, in relation to human medicines, the Directive covers most substantive controls on medicines, including definitions and scope, the need and process for authorisations for products and relevant activities; product information, classification, advertising and supply chain control; and pharmacovigilance. The Regulation covers operation of the European Medicines Agency, EU centralised procedures and arrangements for centralised committees, such as that dealing with pharmacovigilance.

The pharma package aims to revise and replace this legislation alongside other measures that all aim to enhance availability and equitable access to safe, effective and affordable medicines, provide an innovation friendly framework and reduce administrative burden. Security of supply of medicines and incentivising product development are also key aims.

Where Are We Now and What Are the Important Issues for Industry

The process for updating the legislation in the pharma package takes time and involves EU institutions and EU members states. Currently, proposals for the revision have been agreed with the EU Council of Ministers (made up of representatives of EU member states) and the Council of Ministers is to begin negotiations with the European Parliament and EU Commission with a view to reaching agreement on the pharma package legislation with the aim that the new legislation is in place over the next couple of years. We focus below on some of the most relevant areas for concern for the pharma sector.

Competitor Product Authorisations and Data and Market Exclusivity

One of the main areas of concern for industry has always been the ability to develop, market and protect products from innovators, and how and when competitors may enter these markets as periods of exclusivity expire. These rules naturally impact on the sources of supply of medicines, and how and when multisource markets develop. This relates to the willingness to develop new products, as well as the security of supply that multisource markets give, as evidenced during the COVID-19 pandemic.

The current rules on data and market exclusivity are contained in Article 10 of the Directive and follow the 8+2+1 rule, where there is eight years' data exclusivity plus two years' market exclusivity, that can be extended by a further year where one or more new therapeutic indications are added and bring significant clinical benefit in comparison to existing therapies.

It is noted that under current rules, the review of an Article 10 marketing authorisation application can begin after eight years, but the product cannot be marketed as a competitor to the innovator until at least 10 years has passed from initial marketing of the innovator's product.

The position adopted by the EU Council in ongoing negotiations is to alter this position to continue to provide eight years' data exclusivity but reduce market exclusivity from two years to one year. In effect, this reduces the 8+2 to 8+1. This market exclusivity would be increased further by a proposal to allow the possibility of an extension of two years to market protection (from nine to 10 years) where certain predefined conditions are met. The latter includes meeting an unmet medical need.

The initial proposal from the EU Commission was to reduce the current 8+2 period to 6+2 years, and so the EU Council's position appears as a compromise that will aim to enhance product availability and security of supply, while recognising that the original pharma package proposal reduced the reward available to innovators where significant R&D investments are made.

The proposed change to innovator product protection is probably viewed as the most significant area for concern by both the innovator, and generic and biosimilar sectors, where early market entry by competitors provides significant losses or rewards.

Exclusions From Patent Infringement for Studies and Trials is To Expand

Article 10 of the current Directive also provides an exemption from patent or supplementary protection certificate (SPC) infringement where necessary studies or trials and consequential practical requirements are conducted with a view to abridged applications under Article 10. These measures, akin to the Bolar exemption in the US, have been implemented in EU member states under national patent law and, as such, there is some scope for minor variation between these when implemented.

However, the pharma package is to include a proposal, agreed by the EU Council, that the exemption be extended to include submissions for procurement tenders as well as regulatory approvals. This is designed to allow earlier market access in the context of pricing approval and health technology assessment procedures that may cause delays under current rules. This would then support earlier market entry by competitor products to the original innovator product market.

New Obligation To Ensure Sufficient Supply of Medicines

The current EU legislation provides limited obligations on marketing authorisation holders (MAH) and distributors to ensure appropriate and continued supplies of products, within the limits of their responsibilities. MAHs also have obligations around notifications of supply cessation, permanent and temporary. The existing provisions are fairly vague, and enforcement of these was seen as problematic.

The pharma package proposal aims to strengthen these types of control on the supply of medicines by providing a new obligation that MAHs ensure sufficient supply of medicines within individual EU member states. It is unclear exactly how this measure will be promulgated or enforced, but it will provide an extra element of uncertainty for those aiming to market products and in considering where they choose to do so, given the global markets in which medicines are manufactured and supplied.

Other Measures Agreed by the EU Council and Beyond

In a measure aimed at encouraging the development of new antimicrobials, the EU's Council of Ministers has proposed the introduction of transferrable exclusivity vouchers that might be used from five years into a regulatory data protection period and to be subject to a revenue cap of €490 million in annual EU sales of the relevant product in the preceding four years.

This will aim to compensate what is seen as a lack of incentive to industry to develop antimicrobials, where return on investment can be low, especially where such products have low patient populations and are not usually destined for blockbuster status.

Additionally, while the factors mentioned above highlight changes to the main EU controls on medicinal products, it is noted that the EU is also looking at changes that aim to enhance laws on medicines used in rare diseases (also known as orphan medicinal products) and patent term extension (known as SPCs in the EU), and a broad overview of these proposals is also important to understand.

The changes raised above are complex and wide-ranging, and it is strongly recommended that participants in the sector monitor and evaluate how these might impact on their business going forward.

We are able to advise and assist in this; the main contacts for questions on this are Adrian Spooner and Peter Sellar.

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