The UK regulatory landscape: Gateways leading to new beginnings

Dr Thomas Lönngren, Strategic Advisor, NDA Group

The UK's withdrawal from the EU was an historic event. In January 1973, the UK joined the European Economic Community and was rapidly involved in the development of further EU legislation, such as the 1975 Directives which established the first pan-European licensing.[1] After being integrated in the European regulatory network for decades, benefitting from work-sharing, common legislation guideline procedures, and scientific standards, the UK will now perform all this on its own.

"This process does not happen in an instant," Thomas Lönngren, Strategic Advisor at NDA Group comments. "It will take a long time to build a new fully flexible independent regulatory system, with all its complexity and resourcing issues. It is a huge task for the MHRA to undertake."

An essential part of the new legislative framework that the UK government has put in place is to ensure that leaving the EU does not cause disruption to the supply of pharmaceuticals. And so far, it seems to have worked without any interruptions.

"From my perspective", Lönngren continues, "the UK has put a very interesting new regulatory system in place. It is well balanced, maintaining basic regulatory principles and scientific guidelines coming from the EU, while implementing a new regulatory standard."

There are some major differences in EU procedures and the UK has focused on shorter timelines and greater involvement of health technology assessment (HTA) bodies to ensure that new medicines are available faster. Through the 'Reliance route' for EU centrally authorised products, the UK will mutually recognise decisions to approve medicines receiving EMA approval. The national assessment time will be reduced from 210 days to 150 days, and the rolling review – demonstrated by the MHRA's rapid approval of the first COVID-19 vaccine – offers continuous regulatory input and feedback to enhance efficiency. Moving away from the close connection with the EU, the MHRA is also embracing new global partnerships to have common procedures and collaborations (for example, Project Orbis, Access Consortium) for the approval of, and access to, innovative medicine.

When leaving the EU and establishing itself as the UK's standalone drug regulatory agency, the MHRA announced the implementation

of the new Innovative Licensing and Access Pathway (ILAP). ILAP is part of the UK's plan to attract life science development in the post-Brexit era and aims to ease the process between clinical trials and patient access to new medications. Through closer collaboration and planning between the MHRA and other stakeholders including NICE and the Scottish Medicines Consortium (SMC).

The MHRA and NICE will work together to advise companies on their clinical trial design, with the aim of ensuring that optimal data is generated for regulatory approval and to show value from a health technology perspective. In this sense, ILAP represents a new way of thinking and a collaborative approach between the healthcare system, the pharmaceutical industry, and patients. Providing the common goal of getting first-class medicine to patients who need them as quickly as possible.

Medicinal products developed through the ILAP pathway will have an enhanced focus on patient involvement.[2] Direct and constructive patient interactions throughout the product lifecycle result in outcomes that successfully meet the requirements of both patients and developers.

"This is a new process and, of course, a huge step forward. If patients could access medicine directly after approval, consequently not having to wait for an additional assessment of the regulatory decision made by HTA and payers," Lönngren explained. "It is still too early to draw any conclusions regarding ILAP, but it is going to be very interesting to see if other regulatory authorities around the world will follow, over time."

The new system includes the novel 'Innovation Passport', which is a new medicine designation acting as a gateway, and will be awarded to innovative products such as advanced therapy medicinal products (ATMPs), medicines for rare diseases, and repurposed medicines, submitted to ILAP. ILAP offers pharmaceutical companies the opportunity to engage in dialogue with all stakeholders already at a pre-clinical stage, rather than after Phase III trials, having invested substantial time and money pursuing this route.

In addition, ILAP will offer companies a rolling review as per the COVID-19 vaccine, which will speed up the approval process further.

Drug developers can access the pathway as soon as they have non-clinical data on a new chemical entity, biological medicine, new indication, or repurposed molecule. Although the route also permits entry once a candidate is closer to market, products heading towards the end of their development programme are generally not suitable for the ILAP, unless there are one or more indications still under active investigation.[2] The MHRA is encouraging companies to apply early in development to maximise the benefits.

"During the upcoming months we will see a substantial amount of regulatory change and complexity in the UK which might be challenging for business to navigate," Lönngren says. "However, there are clear prospects for a beneficial change when developing products within the new UK system. The increase of flexibility and engagement is something good; good for patients and for the overall development of the regulation."

For questions regarding the new regulatory landscape in the UK, contact: asktheexpert@ndareg.com

To learn more, download our webinar: UK Regulatory Landscape post-Brexit

References

1. *Visit: www.fpm.org.uk/journals/the-place-of-the-uk-in-eu-medicines-regulation-past-present-and-future/*
2. *Visit: www.gov.uk/guidance/innovative-licensing-and-access-pathway*