SIDLEY

Pharma Opportunities in Post-Brexit UK

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Since January 1, 2021, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) has affirmed its new role as an independent regulator through the implementation of various changes including the launch of new marketing authorization application (MAA) assessment routes designed to speed up patient access to innovative medicines (I). With this goal in mind and with a view of promoting international regulatory cooperation and alignment, the UK has also joined Switzerland and other international partners in becoming a member of Project Orbis and the Access Consortium initiatives (II). Under the new regime, the MHRA now wears two hats: (i) the Competent Health Authority in Great Britain and (ii) the Competent Authority for Northern Ireland, where EU legislation applies under the terms of the Northern Ireland Protocol.

I. New MHRA Assessment Routes

150 Day MAA Assessment

The MHRA provides for a new reduced timeframe for the assessment of "high quality" MAAs concerning new and existing active substances and biosimilar products. The assessment lasts 150 days (as opposed to 210 days in the standard procedure) which, according to MHRA guidance comprises a first phase of 80 days followed by a 60-day clock stop should more information or clarification be required before moving on to the second assessment phase.

Innovative Licensing and Access Pathway (ILAP)

ILAP is a new accelerated assessment procedure launched by the MHRA that enables companies with innovative or repurposed products to enter the UK market faster. Companies can integrate ILAP as soon as non-clinical data is obtained provided they apply for, and are granted, an Innovation Passport. The Innovation Passport will be granted if the following three criteria are met:

1. The condition is life-threatening or seriously debilitating or there is a significant patient or public health need;
2. the medicinal product fulfils one or more of the following specific areas: (a) innovative medicines (advanced therapy medicinal product, new chemical or biological entity, or novel drug device combination), (b) repurposed medicines (new indication), (c) medicines for rare diseases, or (d) development aligning with the objectives for UK public health priorities;
3. the medicinal product has the potential to offer benefits to patients.

Once an Innovation Passport has been granted, companies are able to access a specialised toolkit and a target development profile "roadmap" developed by a team of experts that

sets out how the applicant "can work with other UK stakeholders for coordinated and efficient evidence generation and evaluation and address commercial and managed access considerations." Such stakeholders include, among others, the National Institute for Health and Care Excellence and the National Health Service, which will provide applicants with input that can be of significant benefit. According to MHRA guidance, the ILAP procedure is not generally suited to products that are close to the end of their development programme unless they have one or more indications still under active investigation.

So far, ILAP has proven to be an attractive option for companies. Since its launch in January, at least 10 applications have been made to ILAP, and one Innovation Passport has been granted.

Rolling Review

The UK has launched its own version of the European Medicines Agency's Rolling Review procedure, used by the EU regulator to accelerate the assessment of medicines during public health emergencies, as the regulator reviews data as soon as it is generated by clinical studies.

The UK Rolling Review enables broader access to the procedure than the EU version as it is open to MAAs for new active substances and biosimilar products based on a full dossier whether or not there is a public health emergency. This procedure has already demonstrated its efficacy in the assessment of the COVID-19 vaccines.

New Conditional Marketing Authorization (MA) Scheme

Companies applying for an MA in Great Britain (only) for a new medicinal product that fulfils an unmet need, and are not yet in possession of complete clinical data, may benefit from the MHRA's new Conditional MA Scheme. For this scheme to apply, the MAA "*contains adequate evidence of safety and efficacy*" and fulfils the same criteria required for the EU equivalent scheme, which include the following:

- The benefit-risk balance of the medicine is positive;
- it is likely that the applicant will be able to provide comprehensive data post-authorization.
- the medicine fulfils an unmet medical need;
- the benefit of the medicine's immediate availability to patients is greater than the risk inherent in the fact that additional data are still required.

II. Project Orbis and Access Consortium Initiatives

Project Orbis

Project Orbis is a programme created by the U.S. Food and Drug Administration Oncology Center of Excellence charged with the approval of oncology product approvals. It involves

regulatory authorities of the U.S., Australia, Canada, Singapore, Switzerland, Brazil, and, since January 1, 2021, the UK.

In the UK, MAA submissions for Project Orbis must be national (Great Britain only) and satisfy the criteria required to obtain an Innovation Passport within ILAP detailed above. Where a U.S. parent company's application involves a UK affiliate, MHRA participation is contingent on agreement with that UK affiliate. The MHRA issued its first marketing authorization under Project Orbis on May 7, 2021.

Access Consortium

Access Consortium involves regulatory authorities from Australia, Canada, Singapore, Switzerland, and, since October 2020, the UK. The aim of the consortium is to "maximize international co-operation between partners in the consortium, reduce duplication, and increase each agency's capacity to ensure patients have timely access to high quality, safe and effective therapeutic products."

The Consortium organises two authorization pathways, the New Active Substance Work Sharing Initiative and the Access Generic Medicines Work Sharing Initiative.

Key Takeaways for Swiss Life Sciences Companies

- The UK caters to innovative life sciences companies by facilitating pathways for more rapid market entry.
- Companies using the UK's regulatory pathways have access to expert advice and support from various stakeholders at early stages of the product's development.
- The UK is cooperating with other regulatory authorities including Swissmedic by joining initiatives such as Project Orbis and the Access Consortium with the goal of enabling faster patient access to medicines across the involved countries.