

Expediting Psychedelics Approvals In The EU, UK, Australia

By **Kimberly Chew, Ana Dukic and Sabrina Ramkellawan** (February 6, 2024)

In recent years, a growing body of psychedelic clinical trials has emerged, concentrating on addressing pressing unmet needs in areas such as post-traumatic stress disorder, treatment-resistant depression, and substance use disorder, among others.

Lawyers with a focus on regulatory affairs may benefit from a comprehensive examination of the expedited submission processes for psychedelic compounds across different legal regions. This expertise is highly relevant for the intricate navigation of regulatory frameworks during essential phases of research and development.

Furthermore, legal practitioners who assist with the international expansion of their clients' operations must possess a thorough comparative understanding of various regulatory environments.

Presented herein is a succinct summary of the available routes for expedited examination, detailing the specific criteria and projected timelines involved. This is the second installment in a two-part article that addresses expedited pathways in different jurisdictions. This article covers the pathways available in the European Union, the U.K. and Australia.



Kimberly Chew



Ana Dukic



Sabrina Ramkellawan

Table 1: The Requirements for Expedited Regulatory Path

Regulatory Body/Country	Type of Submission/Process	Requirements
European Medicine Agency (EMA) — Europe	PRIME — Priority Medicines	<p>Target conditions with an unmet medical need – for which no treatment option exists, or where they can offer a major therapeutic advantage over existing treatments.</p> <p>To justify such potential, applicants must provide any available data showing a meaningful improvement of clinical outcomes, such as:</p> <ul style="list-style-type: none">• Affecting the prevention, onset and duration of a given condition.• Improving the morbidity or mortality of a disease.

Regulatory Body/Country	Type of Submission/Process	Requirements
MHRA/U.K.	ILAP (Innovative Licensing and Access Pathway)	<p>1. The condition is life-threatening or seriously debilitating and there is a significant patient or public health need.</p> <p>2. One or more of the criteria below:</p> <ul style="list-style-type: none"> • Innovative medicine such as an advanced therapy medicinal product (ATMP) or new chemical or biological entity or novel drug device combination. • Medicines being developed in a clinically significant new indication for an approved medicine. • Medicines for rare disease and/or other special populations such as neonates and children, elderly and pregnant women. • Development aligning with the objectives for U.K. public health priorities, such as the Chief Medical Officer, Department of Health and Social Care (DHSC) or Life Sciences Sector Deal (including those in Devolved Administrations, where appropriate).
TGA/Australia	Priority Review Pathway	Proposed primary indication is for the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition. The drug must also represent a major therapeutic advance in safety or efficacy relative to already approved treatments. In addition to new drugs, new indications are eligible for the fast-track pathways.

The European Union

U.S. attorneys whose clients are seeking to enter the European market should be aware that the European Medicine Agency, or EMA, provides a program known as PRIME, or priority medicines, which seeks to address conditions with unmet medical needs. These are conditions for which there is either no current treatment option or where a proposed treatment can offer a significant therapeutic advantage over existing treatment approaches.

In order to justify such potential, applicants are required to provide any available data illustrating a meaningful improvement in clinical outcomes. These improvements can be demonstrated through various means, such as having an impact on the prevention, onset and duration of a given condition, or by indicating a marked improvement in a disease's morbidity or mortality.

Such dedication to improved clinical outcomes ensures that the PRIME program stands at

the forefront of medical innovation and patient care.

All medicines must have marketing authorization in order to be put on the market legally in the European Economic Area. Drug developers submit clinical trial applications or medical authorization applications to the EMA.

Conditional marketing authorization represents a practical and expedited avenue for the approval of a medicine filling an unmet medical need. Notwithstanding early approval, it ensures that the medicine adheres to rigorous EU standards pertaining to safety, efficacy and quality while maintaining the generation of comprehensive data post-approval. Please see Table 2 for additional information.

This could be relevant in the context of the EMA if, for instance, data or studies from third parties are needed to support the application for priority medicines designation.

Table 2: Expedited Drug Approval Pathway

	European Union	United Kingdom	Australia
Type of regulatory submission and to which agency	CTA/MAA within one or more EMA states	CTA/MAA to MHRA	CTA/MAA to TGA
Type of application needed for the agency's expedited review program	Conditional Marketing Authorization <ul style="list-style-type: none"> • Priority Medicines (PRIME) 	Conditional Marketing Authorization <ul style="list-style-type: none"> • Innovative Licensing and Access Pathway (ILAP) 	Provisional approval based on early evidence data package <ul style="list-style-type: none"> • Priority review
Timing of when the regulatory agency reviews the application	Requested during exploratory clinical Development (at least two to three months before submitting the MAA)	Within four to six weeks after receipt of application form, meet with MHRA to discuss how eligibility criteria are fulfilled	Presubmission meeting three months prior to request
Overall timing	Designation in 40 days Accelerated Assessment: 150 days	Designation granted in eight to 10 weeks (four weeks after meeting), although currently not the case	220 working days from start of first assessment Priority review: 150 working days

The U.K.

For those attorneys who are assisting their clients enter the U.K. psychedelic market, the U.K.'s Medicines and Healthcare products Regulatory Agency, or MHRA, has established the Innovative Licensing and Access Pathway, or ILAP, to address conditions that are life-threatening or seriously debilitating where there is a significant patient or public health need.

Access to this pathway is given under certain established criteria. It encompasses innovative medicines, such as advanced therapy medicinal products, new chemical or biological

entities, or novel drug-device combinations. The pathway also includes provisions for medicines being developed for clinically significant new indications for approved medicines. Particular focus is placed on rare diseases and other special populations, such as neonates and children, the elderly, and pregnant women.

The ILAP also aligns with the development objectives for U.K. public health priorities as outlined by the chief medical officer, Department of Health and Social Care, and the Life Sciences Sector Deal, incorporating those in devolved administrations where appropriate. The ILAP serves to expedite the development and subsequent approval of vital medicinal therapies, fulfilling a vital role in the U.K.'s healthcare system.

Upon submission of the ILAP or conditional marketing authorization application form, a period of four to six weeks is generally allocated before the sponsor convenes with the MHRA to deliberate on the fulfillment of eligibility criteria. If found eligible, the designation is typically granted in a time span of eight to 10 weeks — four weeks after the meeting. However, this timeline is not currently being followed.

Attorneys can assist sponsors in obtaining an ILAP designation from the U.K.'s MHRA in several ways based on the analogous pathways in the U.S.

First, sponsors should draft and submit applications for expedited designations. This includes ensuring that the application meets all necessary requirements and effectively presents the drug's potential benefits.

Sponsors must demonstrate the drug's safety, purity and potency. They could also use the publicly available information regarding the U.S. Food and Drug Administration's previous determination that the reference product is safe, pure and potent.

Second, sponsors must consider strategy for clinical trials and research necessary for approval. This is crucial in expedited pathways where the drug may not be entirely new or simply a generic version of a branded drug. Sponsors should consider devising efficient pathways for generating additional evidence needed about safety and efficacy.

This might include more frequent meetings with the regulatory agency to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval. They can also communicate with the agency about such things as the design of the proposed clinical trials and use of biomarkers.

Australia

U.S. attorneys representing sponsors of psychedelic trials looking to enter the Australian market should be aware that the Therapeutic Goods Administration, or TGA, has outlined a priority review pathway for expedited approval of medicinal drugs catering to serious needs.

The primary indication proposed must be for the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition. Furthermore, the drug should represent a major therapeutic advance in terms of safety or efficacy when compared to already approved treatments.

Not only does this pathway apply to novel drugs, but also extends to new indications for existing treatments, thus fostering a fast-track route to crucial advancements in patient care. By establishing such a pathway, the TGA aids in the swift introduction of pivotal therapeutic medicines to the market, ultimately benefiting patient health and well-being.

Obtaining provisional approval relies on the strength of the early evidence data package. The data packages form the basis of preliminary evaluation, serving as an initial endorsement that signifies promise in the therapeutic effect of a medicinal drug. Prior to the request for such provisional approval, a presubmission meeting is typically scheduled three months in advance.

This preemptive strategy facilitates an open dialogue and allows all involved parties to clarify any potential ambiguities, ultimately streamlining the path toward provisional approval based on the early evidence data package.

Sponsors should develop a legal strategy for their submission, emphasizing the therapeutic goods' significance in treating serious or life-threatening conditions.

Comprehensive documentation will help ensure that the submission highlights the goods' potential benefits and aligns with the TGA's criteria. Strategic planning can help ensure that the submission is made in a timely manner considering the urgency associated with priority review, and identifies and addresses potential legal risks.

Conclusion

The dynamic sector of psychedelic clinical research is intensifying its efforts to meet critical healthcare gaps in fields that include, but are not limited to, PTSD, treatment-resistant depression and substance abuse disorders.

For conditions categorized as especially pressing, streamlined regulatory pathways are frequently utilized to accelerate the development of these innovative treatments. It is imperative for stakeholders to grasp the nuances of these rapid regulatory submission tracks that vary by jurisdiction.

Within numerous legal frameworks, there exists a spectrum of expedited review mechanisms, each characterized by distinct stipulations and associated timelines.

The EU, through the EMA, has the PRIME program and conditional marketing authorization, dedicated to addressing conditions with unmet medical needs and maintaining rigorous EU standards. In the U.K., the MHRA executes the ILAP, focusing on combating life-threatening or seriously debilitating conditions, supported by specific criteria.

Similarly, Australia's TGA employs a priority review pathway centered on the treatment, prevention and diagnosis of serious conditions. The system also supports the process for obtaining provisional approval based on an early evidence data package. Together, these routes are instrumental in expediting the commercialization process for medications, medical devices and therapeutic treatments, thereby facilitating rapid access for patients requiring them.

For legal practitioners operating at the intersection of regulatory compliance and psychedelic research, familiarity with the expedited pathways available in various territories is indispensable to navigate the research and development stages effectively, facilitating a seamless advancement of psychedelic treatments from the research environment to the consumer.

Moreover, this expertise is foundational for broadening international operations, safeguarding intellectual property rights and meticulously evaluating investment ventures.

Kimberly Chew is senior counsel and co-leader of the firm's psychedelic and emerging therapies practice group at Husch Blackwell LLP.

Ana Dukic is a scientific and regulatory compliance consultant at AxialBridge.

Sabrina Ramkellawan is the chief operations officer and co-founder at AxialBridge.

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