Drug Repurposing Guidebook

Building Block E138

This document defines the content of the FACT SHEET to be created for each identified tool, incentives, initiative or practice (the Building Block) introduced by public bodies or used by developers to expedite drug repurposing in Rare Diseases (RDs).

ITEM	DESCRIPTION
Building Block (BB) Title	Innovative Licensing and Access Pathway (ILAP)
References	https://www.gov.uk/guidance/innovative-licensing-and-access-pathway
Description	The Innovative Licensing and Access Pathway (ILAP) is a unique initiative that connects the medicines regulator with health technology assessment bodies in the UK, creating a pathway that aims to deliver safe, effective, financially sustainable, and early patient access to innovative medicines. These medicines include new chemical entities, biological medicines, new indications and repurposed medicines. It comprises of an Innovation Passport designation, a Target Development Profile (TDP) and provides applicants with access to a toolkit to support all stages of the design, development and approvals process. ILAP offers an opportunity to align regulatory evaluation and access activities throughout the development pathway, integrating multi-stakeholder views to create medicines that are both regulatory and access ready.
Category	Regulatory and HTA engagement
Type of BB	Regulatory
Geographical scope	Europe
Availability	Available to developers of innovative medicines, including repurposing approaches

ITEM	DESCRIPTION
Scope of use	Provides opportunity for enhanced regulatory and other stakeholder input through the Target Development Profile and ILAP toolkit.
Stakeholders involved	UK Regulatory and HTA bodies, sponsors, patient groups through the ILAP patient and public reference group
Enablers/ Requirements	The first step in the ILAP is the Innovation Passport application. The Innovation Passport is the mandated entry point to the ILAP and is open to developers at the pre-clinical trial stage through to the mid-development programme point. For repurposing projects, the following criteria must be fulfilled. **Criteria 1: details of the condition, patient or public health area** • the condition is life-threatening or seriously debilitating and/or there is a significant patient or public health need **Criteria 2: the medicinal product fulfils one or more of a specific area (indicate which are applicable in your application).** b) medicines being developed in a clinically significant new indication for an approved medicine **Criteria 3: the medicinal product has the potential to offer benefits to patients** You must provide a summary of how patients are likely to benefit from the product or indication, including proposed improved efficacy or safety, contribution to patient care or quality of life, as compared to alternative therapeutic options. This should be based on evidence from the applicant with the product. The claims can be supported either by data from valid non-clinical models of the condition or if justified extrapolated from another relevant model. Depending on the stage of development of the product any available clinical data in a relevant population of patients can be provided. Applicants are strongly encouraged to include the views from patients or patient organisations around the benefits of a product in their evidence, if available.

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Output	Develop products that are both regulatory and access ready through the use of the ILAP toolkit, particularly novel methodology and real-world data collection
Best time to apply and time window	Early to mid-stage development programmes The pathway will allow entry very early, based on non-clinical data, where all the tools described below might be options, as well as catering for products with mid-development 'global' dossiers. However, to maximise the benefits, applicants are encouraged to apply early in the development of their products. Products that are 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.
Expert tips	Although ILAP is a UK initiative, the framework could produce data helpful in other jurisdictions. If you would like help with the Innovation Passport email innovationpassport@mhra.gov.uk For queries about the Target Development Profile email TDP@mhra.gov.uk