Medicines & Healthcare products Regulatory Agency

Innovative Licensing and Access Pathway (ILAP)

Joint MHRA, NICE & SMC initiative

Dan O'Connor – Medical Assessor – June 2021



CPRD NIBSC MHRA

The ILAP is delivered in partnership

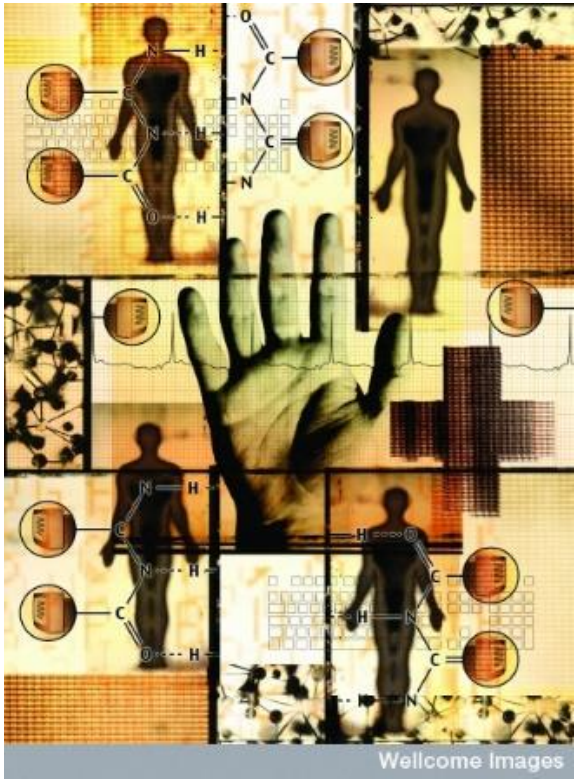
Medicines & Healthcare products Regulatory Agency

NICE National Institute for Health and Care Excellence

Healthcare Improvement Scotland | SMC

What is the ILAP?

- Opportunity to think and practice differently after EU exit
- The ambition of the ILAP is to deliver safe, early and financially sustainable patient access to innovative medicines
- Key aspect of the ILAP is the partnership between the MHRA, NICE and Scottish Medicines Consortium (SMC)
- The NHS in England and Scotland are closely engaged, along with the Accelerated Access Collaborative and other UK health system partners



The ambition at launch

Lord Bethell, Minister for Innovation

- The new pathway represents a totally new way of thinking and is a truly collaborative approach between the healthcare system, the pharmaceutical industry and patients

Dr June Raine, CBE (MHRA)

- Transforming the way innovative medicines reach patients in the UK is not a ‘nice to have’. It’s a ‘must do’. An imperative. And the time to do it is now

Prof Gillian Leng, CBE (NICE)

- Partnering with the MHRA and others to build this frictionless pathway to the timely availability of cost-effective medicines is one of the ways NICE is delivering benefits for patients, the NHS and life sciences industry

Healthcare Improvement Scotland

- The ILAP offers a genuine and significant opportunity to ensure new and innovative products reach patients across the UK, safely and quickly

Innovative Licensing and Access Pathway overview

- ILAP was launched 1st of January 2021
- **Innovation Passport:** A new medicine designation links to the development of a roadmap to patient access
- **Target Development Profile** (TDP): Creates a unique UK roadmap, utilising tools from a toolkit and providing a platform for sustained mutli-stakeholder collaboration

- **A toolkit**: tools are intended to drive efficiencies in the development programme, supporting data generation and evidence requirements
- **An integrated pathway**: Pulls together expertise from across the MHRA, NICE and SMC and partners in the wider healthcare system including the NHS in England and Scotland

Innovation Passport (IP) designation

- Enables access to the pathway and future activities in the TDP:
    - Broad and inclusive definition of innovation
    - 3 criteria, all should be met for a positive opinion
    - Built-in flexibility, with multiple entry points along the pathway
    - Apply with non-clinical data or clinical trial evidence
    - Commercial or non-commercial applicant
    - New or repurposed medicines
- Non-clinical entry point provides ambition for long-term interactions, Applicants are encouraged to apply early
- Thinking about the patient from the start
- Encourages structured engagement between the MHRA, HTA and drug developer
    - Joint decision making between MHRA, NICE and SMC
- IP submitted for each separate medicinal product; a single IP can cover multiple indications for the same medicine

Innovation Passport – criteria 1

- **Criterion 1: Details of the condition or public health area**
  - The condition is life-threatening or seriously debilitating or
  - There is a significant patient or public health need

- Symptoms, life span and quality of life aspects and current treatment landscape

- Evidence is likely to be generated from information in the public domain and/or patient engagement activities

TAGS: United Kingdom | Review Pathway | Innovation

ASK THE ANALYST EMAIL

MHRA Explains Entry Criteria for UK's New Innovative Medicines Pathway

'Innovation Passport' Will Be Gateway To Targeted Development

30 Oct 2020 | NEWS

by Ian Schofield

@ScriplanS | ian.schofield@informa.com

Executive Summary

A new licensing route is to be introduced by the UK MHRA next year for products that meet specific criteria, such as treating life threatening conditions or rare diseases and where there is a significant patient need. At a webinar this week, an MHRA medical assessor looked at the requirements that products will have to meet to enter the new pathway.

Innovation Passport – criteria 2

- **Criterion 2: The medicine fulfils one or more of the following areas:**
  - Innovative medicine (ATMP, first in class or novel drug device combination)
  - Medicine is being developed in a clinically significant new indication
  - Medicine for rare disease and/or other special populations such as neonates and children, elderly and pregnant women
  - Development in line with objectives for public health priorities (Chief Medical Officer, DHSC or Life Sciences Sector Deal)

Innovation Passport – criteria 3

- **Criterion 3: Medicinal product has the potential to offer benefits to patients**

- Summary of how patients are likely to benefit, improved efficacy or safety, contribution to patient care or quality of life, as compared to alternative therapeutic options

- Applicants are strongly encouraged to include the views from patients or patient organisations around the benefits of a product in their evidence

First Do No Harm

The report of the Independent Medicines and Medical Devices Safety Review

Target Development Profile (TDP)

- TDP will define key regulatory and development features, identify potential pitfalls and create a road map for delivering early patient access, including tools from a toolkit

- The TDP will include how the company can work together with other UK stakeholders for coordinated and efficient evidence generation and evaluation

- The TDP step allows high-level consideration of a broad range of issues impacting product development, licensing and access allowing end to end planning

- Positive feedback from 4 companies and stakeholders in the TDP pilot run over the Autumn 2020

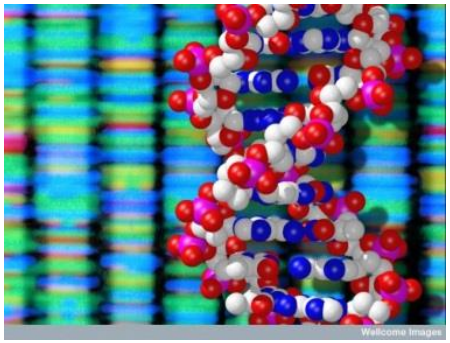
Target Development Profile (TDP)

- Applicant submits the TDP request form and populates the following:
  - Section 1: Kick-off meeting and stakeholders
  - Section 2: About the product development
  - Section 3: Future development and evidence generation
  - Section 4: Scientific advice
  - Section 5: Patient engagement
  - Section 6: Special populations
  - Section 7: Product life cycle
  - Section 8: Issues in the kick-off meeting

- The Applicant invited to meet the partner organisations and discuss the future components to the TDP roadmap
- Roadmap issued after the meeting with consolidated partner views
- Likely that multiple TDP meetings will be required over time

Some of the tools being developed in the Toolkit

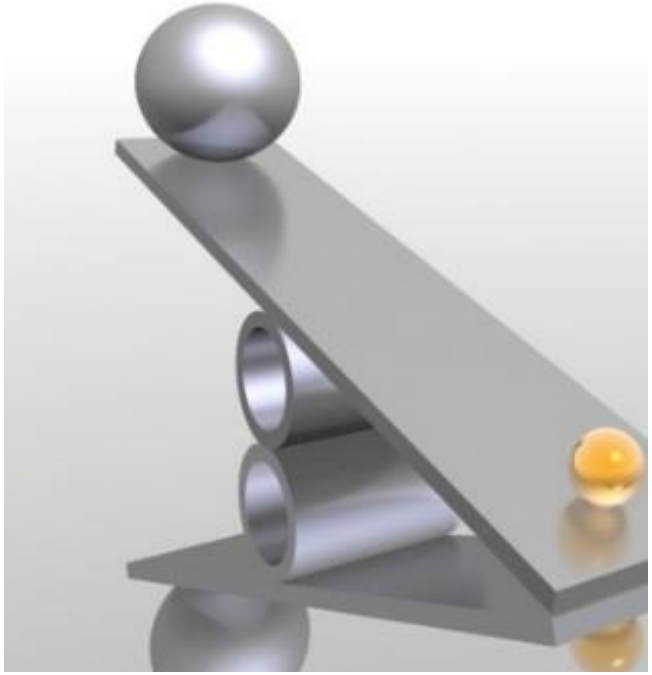
- Adaptive inspections
- Centre accreditation
- Novel CT methodology & design support
- Common medicine & device trial design
- Coordinated approvals process for co-developed medicines & IVDs
- CPRD assisted recruitment in clinical trials
- Rapid Clinical Trial Dossier pre-assessment service
- Certifications



- CPRD control groups
- Enhanced patient engagement
- Continuous benefit-risk assessments that integrate real word evidence
- New licensing procedures:
  - Rolling review
  - Accelerated timetables for marketing authorisation, flexibilities
  - International options
    - FDA Orbis
    - ACCESS

Some measures of success

- Number of applications over time
  - Approval rate
- Timing for the conversion of the TDP roadmaps to a licence and access
- Determine the attractiveness and speed of the pathway compared to other jurisdictions
- Demonstrate enhanced patient engagement and influence



ILAP activity

- 34 applications for the Innovation Passport:

➢ First Innovation Passport approval was in a rare disease

➢ Good representation of large and small industry, university spinout

➢ Common (e.g. cancers, community acquired pneumonia, chronic wounds, diabetes) and rare diseases

➢ Of the first 25 IP applications, 8 expressed interest in Project Orbis

➢ Project Orbis is an international collaboration with the FDA for oncology products

Press release

First Innovation Passport awarded to help support development and access to cutting-edge medicines

The Innovative Licensing and Access Pathway (ILAP) aims to reduce the time to market for innovative medicines

From: Medicines and Healthcare products Regulatory Agency
Published: 26 February 2021

MHRA

A promising treatment for a cancer-causing rare disease will be the first to pass a significant milestone under a new UK approval process designed to bring medicines more rapidly to patients.

Belzutifan, a treatment developed by MSD (UK) for adults with von Hippel Lindau disease (a rare genetic disorder that causes cancer) has been awarded the first 'Innovation Passport' by the Medicines and Healthcare products Regulatory Agency, National Institute for Health and Care Excellence and the Scottish Medicines Consortium (SMC).

Innovative Licensing and Access Pathway (ILAP)

- ILAP offers an ambitious route to medicines approval and access

➢ Innovative products require innovative approaches

✓ Better system alignment between MHRA, NICE and SMC and earlier engagement with companies

✓ Use of innovative methods and tools that accelerate availability of robust data

✓ Development of a specific TDP roadmap tailored to the needs of each innovative product

Thank you

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https://www.gov.uk/guidance/innovative-licensing-and-access-pathway

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