Industry Experience with ILAP

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The Innovative Licensing and Access Pathway (ILAP)

New UK MHRA scheme	• implemented 1st Jan.2021 (post-BREXIT)
Aims to accelerate time to market	• Innovative medicines and/or unmet medical need
Enables multiple entry points	• depending on the stage of development of the product, the data available…
Enhanced regulatory and other stakeholders input	• NICE, SMC, NHS England,…

The Innovative Licensing and Access Pathway (ILAP)

Target Development profile (TDP)	• roadmap defining key regulatory, development features
Enable faster MAA Accelerated assessment	• 150 day procedure, rolling review, …
Enable MAA Int'l collaborative review	• FDA coordinated Project Orbis
Innovation Passport designation	• prior requirement for ILAP inclusion

Innovation Passport for ILAP

Gateway to entry into the ILAP pathway

Eligibility, 3 criteria must be met

- Life-threatening/seriously debilitating condition and/or significant patient or public health need
- Innovative Medicine or medicine for a clinically significant new indication or medicine for rare disease/special population (children, elderly, pregnant women…), aligned to public health priorities of the Chief Medical Officer
- The medicinal product has the potential to offer benefits to patients

Innovation Passport for ILAP

- Application for assessment
- Applicant invited to MHRA meeting
- Assessment completed within 4 weeks
- Option to progress TDP

Practical aspects ILAP Pathway

- MHRA interaction
- MAA Application
- HTA agencies
- First year applications

Practical aspects ILAP Pathway

- Introduction
- MHRA interaction
- MA Application
- HTA agencies
- First year applications

Practical aspects ILAP Pathway

Introduction

- BREXIT timelines ruled scheme initiation 1st January 2021
- The ILAP guidance available in Dec. 2020
- MHRA was flexible and available to guide applicants on the scheme
- Engaging MHRA at earlier stage

Practical aspects ILAP Pathway

MHRA interaction

- Opportunity for additional interaction and discussion
- Identification of pitfalls, weak spots, expectation
- Opportunity to provide clarification
- Opportunity (assessors) to get familiarity with product, preliminary data ahead of filing

Practical aspects ILAP Pathway

MAA application

- Earlier interactions enable a more robust application
- Rolling review
- Accelerated -150-day- assessment
- ILAP required for Int'l collaborative assessment, i.e. Project Orbis
- Positive benefits ILAP pathaway

Practical aspects ILAP Pathway

HTA agencies

- SMC additional process for ILAP designated medicines, interim reimbursement
- NICE process unchanged
- Overall benefits from HTA process have been less significant than those on MAA evaluation

ILAP Pathway

First year in place, January to end December 2021:

- Total applications received: 71
- Number of Innovation Passports awarded: 41 (85%*)
- Number of Innovation Passports not awarded:7(15%*)
- Applications in process: 22

*% over assessed applications

Thank You

Innovation Passport

- Global regulatory status
- Pharmaceutical development status, Quality/Non-clinical/Clinical development
- Innovation Passport Criterion 1
  - life-threatening or seriously debilitating condition &/or unmet medical need
- Innovation Passport Criterion 2
  - Innovative medicine / clinically significant new indication/Medicine for rare disease/special population
- Innovation Passport Criterion 3
  - The medicinal product has the potential to offer benefits to the patients

ILAP pathway – practical aspects

MAA assessment

- ILAP guidance available Dec. 2021