What does the new ILAP refresh mean for pharmaceutical development and patient access in the UK?

HPR238

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Overview

Objectives:

On 31st March 2025 the MHRA launched the refreshed Innovative Licensing and Access Pathway (ILAP) aimed at accelerating patient access to transformative new medicines. It is important that the life sciences sector understands how this will be achieved. This research aims to identify the key changes from the previous ILAP and explore the value that ILAP 2.0 could have for patient access.

What is ILAP and why was it created?

ILAP is a UK initiative to accelerate and streamline development and delivery of transformative new medicines, ensuring patient access is considered at every stage through a collaborative framework. ILAP was developed to address key challenges: to accelerate access, increase collaborative support and address unmet patient needs.

ILAP Stakeholders:

MHRA, NICE, SMC, AWTTC, NHSE

Supporting partners:

DHSC, HRA, NIHR, OLS, devolved administrations

What can ILAP support with?

1. Prioritised Access to Key Services
2. Clinical Development
3. Clinical Trial Delivery
4. Market Access
5. Health System Adoption

Methodology

All published information from the MHRA and NICE on ILAP was leveraged to compile updates on the key changes.

Functional experts within Takeda with prior experience of ILAP and responsibility for Clinical Science, Regulatory Affairs, Corporate Affairs, Medical Affairs, and Market Access were consulted to evaluate the impact of the changes on pharmaceutical development and patient access.

Three research questions were explored:

- What are the **changes** to ILAP?
- How does ILAP offer **value** for pharmaceutical development and patient access?
- What **considerations** are needed by pharmaceutical companies before using ILAP?

Q1: What are the changes to ILAP?

Method:

Desk research utilising publicly available materials published by the MHRA and NICE.

Results:

ILAP 2.0 was created to:

- Incorporate stakeholder feedback on the previous version of ILAP
- Enhance patient access to innovative therapies
- Improve efficiency and effectiveness of the pathway through the new quarterly cycle application process
- Increase transparency in healthcare processes
- Support real world evidence decision making
- Enable more streamlined communication and collaboration across stakeholders

What are the key changes to ILAP 2.0?

Entry Criteria
More focused to prioritise the most innovative medicines. The eligibility criteria is now more selective so that only products prior to confirmatory trials can enter ILAP.

Support for Developers
Enhanced package with early-stage collaboration with regulators and HTA bodies e.g. the prioritised scheduling pass which allows ILAP partners priority access to specific services.

Application Process
Now operates in quarterly cycles with defined windows for greater efficiency.

NHS Involvement
Direct NHS participation to aid timely adoption and service preparedness.

Sustainability & Impact
Refinements to ensure long-term effectiveness and avoid overly permissive entry criteria.

Q2: How does ILAP offer value for pharmaceutical development and patient access?

Method:

Assessing the value of each service offering through looking at the lens of a global pharmaceutical company by consulting functional experts within Takeda.

Results:

From the perspective of a global pharmaceutical company the services of the highest value are some of those associated with the prioritised scheduling pass and support achieving health system adoption.

	ILAP offering	Exclusive to ILAP	New to ILAP	What is this service?
High added value	MHRA Scientific Advice*	☒	☒	MHRA offer standalone meetings with them only, or joint meetings with NICE. The primary MHRA advice service is targeted scientific advice for individual products along with broader non product specific advice across the entire product lifecycle.
	MHRA pre submission meetings*	☒	☒	The MHRA offer a pre-submission service before applying for Marketing Authorisation. This aims to provide support for prospective applicants, whichever application route is chosen.
	Clinical Practice Research Datalink (CPRD) *	☒	☒	Prioritised access is granted to services from the CPRD (a UK RWE research service supporting studies using pseudonymised patient level data from a network of General Practices including 60 million patients).
	NICE Advice services*	☒	☒	Advisory service to help prepare for a NICE evaluation, or engagement with commissioners, supply chain or NHS payers.
	SMC prioritisation for evaluation & potential eligibility for interim acceptance*	☒	☒	Prioritisation of HTA appraisal evaluation and SMC can decide to accept some medicines on an interim basis meaning that the medicine can be accepted for use subject to ongoing evaluation and reassessment once further evidence is available.
	Health System Adoption	☑	☒	Offers support to engage with NHS partners across England, Scotland and Wales to inform system preparedness and operational planning.
Moderate added value	ILAP Joint Scientific Advice	☑	☑	Access to ILAP exclusive services enabling interactions with all relevant ILAP partners and patients as part of a system wide approach to the products lifecycle key points.
	ILAP Access Forum	☑	☒	Exclusive offering aiming to promote and optimise market access approaches to benefit patient access.
	NIHR Study Support Service*	☒	☑	Access across the Research Delivery Network (RDN) to support patient identification, clinical advice, research delivery advice, and discuss trial delivery issues.
	Active National Delivery	☒	☑	Access to support and advice from the NIHR RDN to provide guidance on study development and delivery to meet the evidential requirements for transit through regulatory and HTA processes.

*Services within the prioritised scheduling pass, enabling products to be prioritised in the ILAP partners' work schedule.

Q3: What considerations are needed by pharmaceutical companies before using ILAP?

Method:

Discussing and evaluating, with functional experts within Takeda, the potential impact of external environmental changes on the value of ILAP, and the key considerations before using it.

Results:

1. ILAP may be more beneficial for companies not bound by global clinical trial designs or lacking clinical development, regulatory, and access expertise. The services on offer lend themselves to companies whose clinical development is determined at a UK level.

2. Using ILAP demands collaboration from a wide cross functional team (Regulatory, Medical, Market Access, and Commercial plus representatives from Global, Regional and Local teams). Companies using it should plan resourcing accordingly.

Conclusion

The refreshed ILAP could add value to pharmaceutical development and patient access for products which have not yet reached confirmatory trials, especially those with a rare disease focus.

The ILAP service offerings provide a useful route for earlier engagement with regulators, HTA bodies and the NHS, however this pathway may be more beneficial for companies not bound by global clinical trails.

Key Remaining Questions?

- Will the abolition of NHSE impact ILAP? If so, how?
- Do the changes to ILAP drive the real-term improvements in effectiveness and efficiency that are sought?
- What are early experiences with the refreshed ILAP?
- How can patient access be accelerated and service preparedness be improved for innovation medicines that are in later stage development?

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Abbreviations: AWTTC: All Wales Therapeutics and Toxicology Centre; HRA: Health Research Authority; HTA: health technology assessment; ILAP: Innovative Licensing and Access Pathway; MHRA: Medicines and Healthcare products Regulatory Agency; NHS: National Health Service; NHSE: National Health Service England; NICE: National Institute for Health and Care Excellence; NIHR: National Institute for Health and Care Research; SMC: Scottish Medicines Consortium; UK: United Kingdom, DHSC: Department of Health and Social Care; OLS, Office for Life Science