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HPR199

Impact of the Innovative Licensing and Access Pathway (ILAP) Designation on Regulatory and Health Technology Assessment (HTA) Outcomes

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BACKGROUND

- The Innovative Licensing and Access Pathway (ILAP) initiative by the Medicines and Healthcare products Regulatory Agency (MHRA) is designed to facilitate accelerated patient access to innovative medicines in the United Kingdom (UK).
- These medicines include new chemical and biological products, new indications, and repurposed medicines.
- ILAP comprises an Innovation Passport designation; entry criteria for the Innovation Passport are presented in Figure 1.[1]
  - Innovation Passport designation[1] is the first step in the process that triggers the MHRA and its partner agencies to create a target development profile to chart a roadmap for regulatory and development milestones (Figure 2).
  - The benefits of ILAP include a 150-day accelerated assessment, rolling review, and a continuous benefit-risk assessment.

Figure 1. Eligibility Criteria for an Innovation Passport

Criterion 1

The condition is life-threatening or seriously debilitating or there is significant patient or public health need

Criterion 2

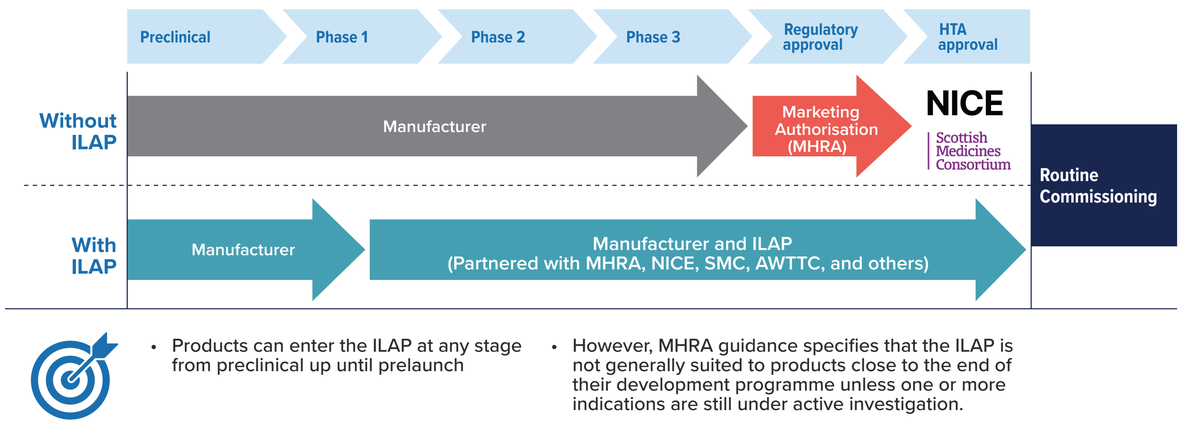
The medicinal product meets one or more of the following:

- Innovative medicine such as advanced therapy medicinal product 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 being developed for a rare disease and/or other special populations
- Development aligns with UK public health objectives

Criterion 3

The product may offer benefits to patients over existing treatment options

Figure 2. Overview of ILAP Process



- Products can enter the ILAP at any stage from preclinical up until prelaunch
- However, MHRA guidance specifies that the ILAP is not generally suited to products close to the end of their development programme unless one or more indications are still under active investigation.

AWTTC = All Wales Therapeutics and Toxicology Centre; HTA = health technology assessment; NICE = National Institute for Health and Care Excellence; SMC = Scottish Medicines Consortium.

OBJECTIVE

To evaluate the ILAP in the UK by reviewing publicly available information on products granted an Innovation Passport.

METHODS

- Public information on products granted an Innovation Passport under ILAP since its inception in January 2021 through 27 June 2024 was evaluated for:
  - Trends in therapeutic areas seeing the most innovation
  - Clinical development stage at the time of receiving an Innovation Passport
  - Influence of the pathway on licensing and HTA outcomes (NICE, SMC, and AWTTC)
  - Comparison of expedited status with other regulatory agencies (Food and Drug Administration [FDA] and European Medicines Agency [EMA])

RESULTS

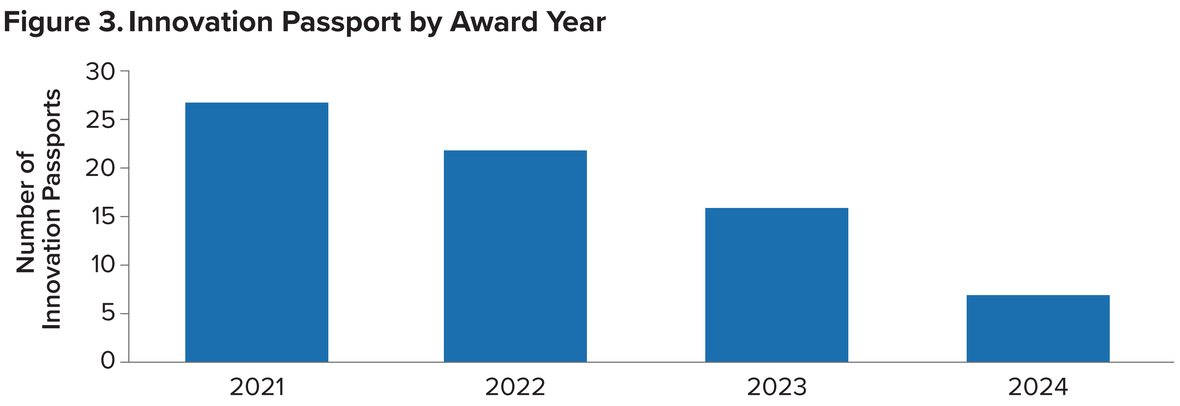
- Because information on ILAP awardees is exempt from disclosure due to its commercial sensitivity, there are no official publicly available resources to identify Innovation Passport awardees.
- Information on the MHRA website indicates half of applications have been granted an Innovation Passport.

Success rate of Innovation Passport applications (25 March 2024)

- **Total applications received (cumulative): 229**
- **Granted Innovation Passports: 115**

- There has been a noticeable decline in the number of products awarded the Innovation Passport since its peak in 2021 (Figure 3).

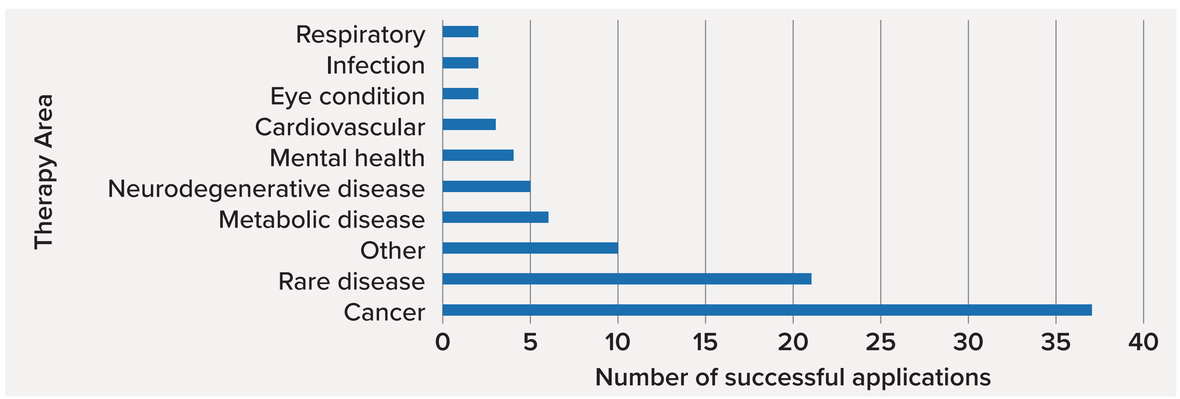
Figure 3. Innovation Passport by Award Year



Which Key Areas Are Seeing the Most Innovation Through ILAP Designations?

- Oncology (39%) accounted for most of the applications that were awarded Innovation Passports, followed by rare (22%), metabolic (6%), and neurodegenerative (5%) diseases (Figure 4).

Figure 4. Innovation Passport by Therapy Area



Note: "Other" therapy areas include allergy, antihypertensive, antimicrobial, autoimmune disease, degenerative joint disease, hearing loss, kidney disease, multisystem progressive disorder, substance use disorder, and systemic disorder.

At What Stage in Clinical Development Is an Innovation Passport Typically Awarded?

- As highlighted in Figure 2, ILAP applicants can enter the process during any of the following development stages:
  - Early stage: Preclinical stage, when first-in-human studies are not yet initiated
  - Mid stage: Phase 1 and/or nonconfirmatory phase 2 ongoing or conducted, pre-phase 3, early clinical data available
  - Late stage: Confirmatory trial ongoing/completed; significant clinical data available
  - Very late stage: Imminent submission of marketing authorisation application (MAA)
- Available information indicates that most products are at early-mid stage when they receive an Innovation Passport rather than late stage (Figure 5).

Figure 5. Development Stage of Products Currently Holding an Innovation Passport

Source: MHRA.[2]

Does the Innovation Passport Designation Influence Licensing and HTA Processes?

- Data were available for 90 ILAP applications. Of these:
  - 13 ILAP applications were recommended by NICE (Figure 6).
  - 28 also had FDA Fast Track designation.
  - Although the limited sample size and lack of information on their clinical development stage at entry restricts definitive conclusions, the available data suggest a potential trend: ILAP awardees may experience expedited authorisation approval processes (Figure 7).

Figure 6. NICE Appraisal Results for ILAP Awardees

Figure 7. Regulatory and HTA Approval Timescales for ILAP Awardees

CONCLUSIONS

- Information related to the identification of Innovation Passport awardees, the clinical development stage at the time of ILAP application, and the evaluation and outcome of ILAP applications is limited and inconsistent.
- Further clarity on information about the products awarded would be more useful for future applicants to evaluate their chance of success.

REFERENCES

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2. Medicines and Healthcare products Regulatory Agency (MHRA) information request (reference; FOI2024/00241; 28 June 2024).

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