HPR54

A Review and Evaluation of the UK's Innovative Licensing and Access Pathway

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Objectives

To analyse the technologies approved under the Innovative Licensing and Access Pathway (ILAP) and identify any trends or advantages of the programme.

Methods

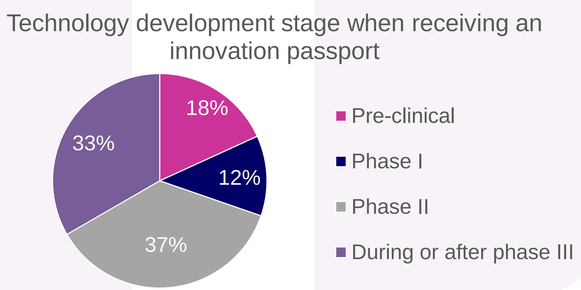
120 applications have been made since the ILAP programme was launched, with 71 passports awarded (1). Only 46% (n=33) of the awarded passports have had information about them made public; as a result, these technologies were further examined via a review of the literature and primary and secondary data.

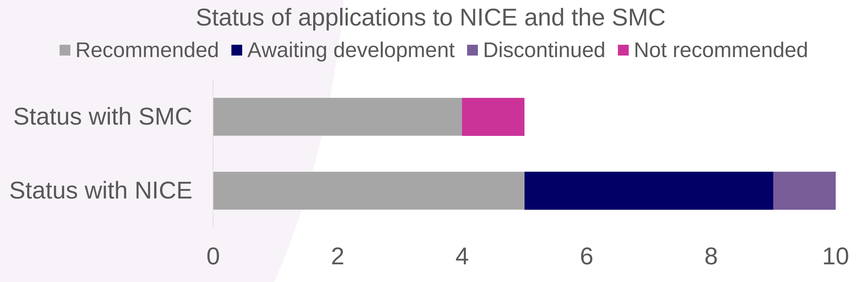
Results

Of the passports reviewed:

- 21% are advanced therapy medicinal products
- 30% had been positively certified as orphan drugs by the European Medicines Agency (EMA)
- 33% are oncology products.

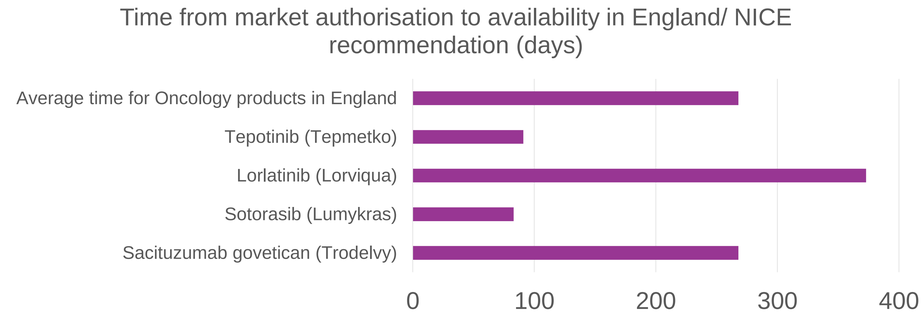
The majority (67%) of companies applied for the passport prior to Phase III clinical trials, with 18% of medicines in pre-clinical development, 12% at Phase I, and 36% at Phase II at the time of the passport being awarded.

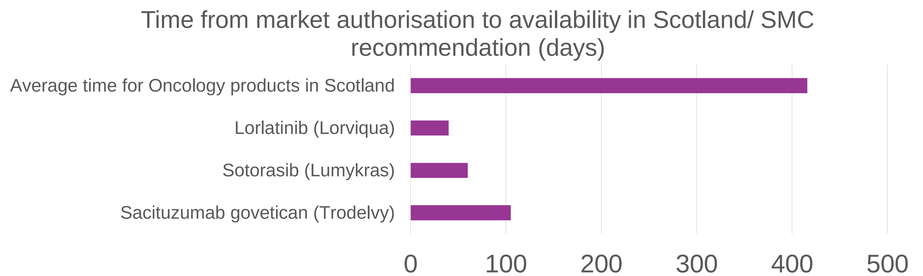




Ten technologies have been submitted to the National Institute of Health and Care Excellence (NICE) with varying statuses of being recommended, awaiting development or being discontinued. In comparison, only five technologies have been presented to the Scottish Medicines Consortium (SMC), with all but one of them being recommended.

All the recommended products to date are for oncology indications. The time from marketing authorisation (MA) to recommendation ranged from 40 to 1,834 days. With the exception of atezolizumab, which faced unique challenges in obtaining MA, the average time to recommendation for ILAP products in England is 65 days shorter than the average time for all oncology products. For Scotland it is 347 days shorter.





Conclusions

Although ILAP is a fairly new programme, it has shown popularity with 120 applications to date. This number is likely to continue to increase as awareness of the programme grows, and more details on the eligibility criteria and benefits of ILAP come to light.

Innovation passports cover a range of indications, and most are awarded during the early stages of product development. This is likely due to companies being able to maximise and access more benefits from the programme.

There has been a total of nine positive submissions in England and Scotland to date. The time taken from MA to a recommendation varies, but it is typically less than the average time for oncology drugs.

References: 1. https://www.gov.uk/guidance/innovative-licensing-and-access-pathway.

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