Is the UK's ILAP process delivering its intended benefits? A review of access to Orbis-designated oncology products within the UK

HPR31

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Background & objectives

- The UK's Innovative Licensing Access Pathway (ILAP) provides manufacturers the opportunity to engage early with UK stakeholders with the ambition to improve patient access to innovative medicines.
- ILAP was launched on 1 January 2021 and a total of 164 ILAP applications were received by January 2023, of which 65% were awarded the Innovation passports.
- Little is known about the benefits as there is no publicly available documentation on the products accepted into ILAP, although ORBIS-designated oncology products are publicly listed and must also qualify for ILAP.
- Time to decision and availability of HTAs by NICE and SMC for Orbis-designated products were reviewed to assess if they receive the benefits of the ILAP scheme.

Methods

- A search of an international database of extracted HTAs (HTA Accelerator) was conducted in October 2023 to identify NICE and SMC HTAs of products that received Orbis-designation.
- Data extractions included the evidence under assessment, agency critique, outcome, and time to recommendation.

Results

- As of March 2023, 16 products accepted into Project Orbis have been granted a GB marketing authorisation or have had their existing authorisation extended to include a new indication (**Table 1**).
- The majority (n=9; 56%) were indicated for non-small cell lung cancer (NSCLC).
- From NICE, 50% received positive recommendations (+/- restrictions), 25% were negative, 13% did not submit, with remainder ongoing.
- From SMC, 63% received positive recommendations (+/-restrictions), 7% were negative, 13% did not submit, with remainder ongoing.
- In two instances, SMC and NICE appraisal decisions outcomes were divergent.
- Mean and median time to decision was 78 and 113 days longer for NICE compared to SMC, respectively [NICE: 322 or 275 days; SMC: 244 or 162 days] (**Table 2**).
- Mean time to availability was 250 days in England vs 264 days in Scotland, which compared to the 2021 EFPIA Patient WAIT survey for oncology products, was slightly longer for NICE (250 vs 241) but faster for SMC (264 vs 374) (**Table 2**). Same holds for the median.

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Product	MHRA	NICE				SMC				Time to decision NICE vs SMC (days)
	Grant date	Decision date	Decision	Time to decision (days)	Time to availability (days)	Decision date	Decision	Time to decision (days)	Time to availability (days)	
Tagrisso® (osimertinib) Line extension	06 May 2021	19 January 2022	Positive w. restrictions	258.00	258.00	08 October 2021	Positive w. restrictions	155	155	103.00
Trodelvy® (sacituzumab govetican)	08 September 2021	17 August 2022	Positive recommendation	343.00	343.00	04 February 2022	Positive recommendation	149	149	194.00
Lorviqua® (lorlatinib) Line extension	23 September 2021	26 April 2023	Negative recommendation	580.00	N/A	04 February 2022	Positive recommendation	134	134	446.00
Lumykras® (sotorasib)	08 September 2021	30 March 2022	Positive w. restrictions	203.00	203.00	04 February 2022	Positive w. restrictions	149	149	54.00
Rybrevant® (amivantamab)	15 November 2021	14 December 2022	Negative recommendation	394.00	N/A	No application	N/A	N/A	N/A	N/A
Tepmetko® (tepotinib)	24 September 2021	18 May 2022	Positive recommendation	236.00	236.00	09 December 2022	Positive recommendation*	441	441	-205.00
Tecentriq® (atezolizumab) Line extension	27 January 2022	28 September 2022	Positive w. restrictions	244.00	244.00	08 July 2022	Positive recommendation	162	162	82.00
Jakavi® (ruxolitinib) Line extension	23 March 2022	No application	N/A	N/A	N/A	06 May 2022	Negative recommendation	44	N/A	N/A
Exkivity® (mobocertinib)	17 March 2022	04 January 2023	Positive recommendation	293.00	293.00	09 December 2022	Positive recommendation	267	267	26.00
Welireg® (belzutifan)	31 May 2022	Ongoing	N/A	N/A	N/A	09 October 2023	Positive recommendation	496	496	N/A
Kimmtrak® (tebentafusp)	07 June 2022	15 August 2023	Negative recommendation – appeal ongoing	434.00	N/A	Ongoing	N/A	N/A	N/A	N/A
Rezurock® (belumosudil)	07 July 2022	4 October 2023	(Draft) Negative recommendation	454.00	N/A	10 July 2023	Positive w. reassessment after 3 years	368	368	86.00
Opdivo® (nivolumab) Line extension	16 August 2022	22 March 2023	Positive recommendation	218.00	218.00	Ongoing	Publication due 11 December 2023	N/A	N/A	N/A
Nubeqa® (darolutamide) Line extension	22 November 2022	21 June 2023	Positive recommendation	211.00	211.00	9 October 2023	Positive recommendation	321	321	-110.00
Imfinzi® (durvalumab) Line extension	25 January 2023	Ongoing	N/A	N/A	N/A	Ongoing	Publication due date 13 November 2023	N/A	N/A	N/A
Tabrecta® (capmatinib)	27 March 2023	No application	N/A	N/A	N/A	No application	N/A	N/A	N/A	N/A

Conclusions

- Timelines for HTA approval for products in Project Orbis are slightly longer in England and faster in Scotland versus all oncology products reviewed in the 2022 EFPIA W.A.I.T. indicator survey covering HTAs conducted from 2018 to 2021.
- Regulator and HTA decisions are not always aligned as indicated by negative HTA decisions. More oncology drugs are available in Scotland than in England.
- Recent Orbis approvals in 2022/2023 show a trend for quicker time to decision and availability by NICE compared to 2021 approvals, representing the first year of ILAP. Data for SMC show a longer time to decision and availability in more recent years; however, data for SMC remain immature. Such findings suggest that earlier products accepted into the scheme were likely further along in their clinical development plan and may have been less likely to receive the benefits of an early engagement scheme such as ILAP.
- Project ORBIS products are not necessarily representative of ILAP more generally, but other information is currently not available. More transparency on non-Orbis products would help medicine developers to assess the benefits of participation in ILAP.

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All Orbis products with MHRA granted since 2021						
HTA body	Time to decision			Time to availability		
	Mean	Median	Range	Mean	Median	Range
Reference: EFPIA-England**	Not available	Not available	Not available	241.00	182.00	Not available
Reference: EFPIA-Scotland**	Not available	Not available	Not available	374.00	317.00	Not available
NICE	322.33	275.50	203-580	250.75	240.00	203-343
SMC	244.18	162.00	44-496	264.20	214.50	134-496
Orbis products with MHRA grant in 2021						
HTA body	Time to decision			Time to availability		
	Mean	Median	Range	Mean	Median	Range
NICE	336	301	203-580	260	247	343-203
SMC	206	149	134-441	206	149	134-441
Orbis products with MHRA grant in 2022 and 2023						
HTA body	Time to decision			Time to availability		
	Mean	Median	Range	Mean	Median	Range
NICE	309	269	211-454	242	231	211-293
SMC	276	294	44-496	323	321	162-496

Abbreviations. UK: United Kingdom; ILAP: Innovative Licensing Access Pathway; NICE: National Institute for Health and Care Excellence; SMC: Scottish Medicines Consortium; HTA: Health technology assessment; NSCLC: Non-small cell lung cancer; EFPIA: European Federation of Pharmaceutical Industries and Associations; N/A Not applicable.

* Prior negative recommendation 06/05/22

****IQVIA. EFPIA Patients W.A.I.T. Indicator 2022 Survey. April 2023. Pages 22-23.**