The Post-Brexit UK Access Landscape:

Does Project Orbis Significantly Accelerate Patient Access for Oncology Drugs in the UK Versus Europe?

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Introduction

- Following Brexit, the MHRA has become the standalone regulator for medicines in the UK (except Northern Ireland)
- To ensure timely access to innovative oncology products, the UK joined Project Orbis, an FDA-led review programme
- Project Orbis provides a framework for concurrent submission and review of oncology products among international partners
- This research compares UK reimbursement outcomes for medicines approved through Project Orbis with EU4

Methods

- MHRA-approved products through Project Orbis were identified from https://www.gov.uk/guidance/guidance-on-project-orbis
- MHRA, EMA authorisations, and EU4 reimbursement assessments were extracted from their respective websites (20-Jan-2023)

Results

Overview of MHRA-approved products via Project Orbis

- 14 products have been authorised in Great Britain via Project Orbis
  - Only 9/14 (64%) were also authorised in Europe; 8/9 were approved by the MHRA before the EMA
- MHRA approval was, on average, 96.4 days earlier than EMA

Table 1: Regulatory statuses of MHRA-approved Project Orbis products

Product	Indication	MHRA approval	EC approval	Days from MHRA => EC
Tagrisso	EGFR M+ NSCLC	06-May-21	21-May-21	15
Trovdelvy	3L+ mTNBC	08-Sep-21	22-Nov-21	75
Lumykras	KRAS M+ NSCLC	08-Sep-21	06-Jan-22	120
Lorviqua	1L ALK+ NSCLC	23-Sep-21	27-Jan-22	126
Tepmetko	METex14 NSCLC	24-Sep-21	16-Feb-22	145
Rybrevant	EGFR M+ NSCLC	15-Nov-21	09-Dec-21	24
Tecentriq	PD-L1+ NSCLC	27-Jan-22	07-Jun-22	131
Exkivity	EGFR M+ NSCLC	17-Mar-22	Withdrawn	N/A
Jakavi	GvHD	23-Mar-22	29-Apr-22	37
Welireg	VHL-associated cancers	31-May-22	N/A	N/A
Kimmtrak	HLA-A*02:01 uveal MEL	07-Jun-22	01-Apr-22	-67
Rezurock	Chronic GVHD	07-Jul-22	N/A	N/A
Opdivo	PD-L1+ NSCLC	16-Aug-22	N/A	N/A
Nubeqa	mHSPC	22-Nov-22	N/A	N/A
Mean time from MHRA to EC approval (days):				**96.4**

Reimbursement of Project Orbis products in the UK compared to EU4

- Compared to most other European HTA bodies, therapies authorised under Project Orbis have tended to receive NICE and SMC assessments that are:
  - Faster
  - With more favourable outcomes, and
  - A greater number of therapies having been assessed

Table 2: HTA outcomes of MHRA-approved Project Orbis products and time from marketing authorisation (MHRA or EMA, whichever came first) to HTA publication

Product[a]						
Tagrisso	CDF (Optimized)	Restricted	ASMR IV	No added benefit	Class H[d]	Reimbursed
Trodelvy	Recommended	Recommended	ASMR III	Major	Class H[d]	Reimbursed
Lumykras	CDF (Rec'd)	Recommended	ASMR V	No added benefit	N/A	N/A
Lorviqua	N/A	Recommended	ASMR IV	No added benefit	N/A	N/A
Tepmetko	Recommended	Recommended[c]	N/A	No added benefit	N/A	N/A
Rybrevant	Not recommend	N/A	SMR insufficient	No added benefit	N/A	N/A
Tecentriq	CDF (Optimized)	Recommended	SMR insufficient	Non-quantifiable	Class H[d]	N/A
Exkivity	Recommended	Recommended	EMA marketing authorisation application withdrawn			
Jakavi	Non-submission	Not recommend	ASMR IV	N/A	N/A	N/A
Kimmtrak	N/A	N/A	N/A	Considerable	N/A	N/A
Time from MA to HTA (days):	**256[b]**	**209**	**271**	**248**	**313**	**342**

[a] Welireg, Rezurock, Opdivo, and Nubeqa have not yet been approved by the EC nor assessed by NICE/SMC

[b] In England, 5/14 (36%) products had national access agreements reached between NHSE and manufacturers prior to NICE guidance publication, further accelerating patient access by an average of 71 days

[c] Resubmission [d] Innovative status granted

Key: = Favourable; = Moderate; = Unfavourable

Conclusions

- MHRA approvals via Project Orbis were typically earlier than EMA's by an average of over 3 months
- Further, several have achieved favourable NICE and SMC outcomes, whereas the number of therapies assessed, outcomes and time to reimbursement are much less favourable in many EU4 countries (except Germany, where reimbursement is available from the date of marketing authorization independent of time to HTA)
- Project Orbis offers a route for expedited UK oncology access, but manufacturers need to ensure that they have a tailored pricing and market access strategy ready to fully take advantage of this

Abbreviations: ASMR: additional medical benefit, **CDF**: Cancer Drugs Fund, **EC**: European Commission, **EMA**: European Medicines Agency, **FDA**: Food and Drug Administration, **HTA**: Health Technology Assessment, **MA**: marketing authorisation, **MHRA**: Medicines and Healthcare products Regulatory Agency, **NHSE**: National Health Service England, **NICE**: National Institute for Health and Care Excellence, **N/A**: not available, **SMC:** Scottish Medicines Consortium, **SMR:** medical benefit

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