

# The Post-Brexit UK Access Landscape:

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

Kenny Jae Kim, Katherine Leong, Stephanie Kennedy, Richard Macaulay; Global Pricing, Market Access and Analytics, PRECISIONadvisors

For further information, contact Richard.Macaulay@precisionvh.com or visit us on <https://www.precisionadvisors.com>

### 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)

### 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



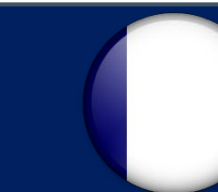



Product	Indication	MHRA approval	EC approval	Days from MHRA => EC
Tagrisso	EGFR M+ NSCLC	06-May-21	21-May-21	15
Trovdelvy	3L+ mTNBC	08-Sep-21	22-Nov-21	75
Lumykras	KRAS M+ NSCLC	08-Sep-21	06-Jan-22	120
Lorviqua	1L ALK+ NSCLC	23-Sep-21	27-Jan-22	126
Tepmetko	METex14 NSCLC	24-Sep-21	16-Feb-22	145
Rybrevant	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Exkivity	EGFR M+ NSCLC	17-Mar-22	Withdrawn	N/A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

### Results

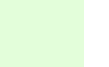


### Reimbursement of Project Orbis products in the UK compared to EU4

- 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 <sup>a</sup>						
Tagrisso	CDF (Optimized)	Restricted	ASMR IV	No added benefit	Class H <sup>d</sup>	Reimbursed
Trovdelvy	Recommended	Recommended	ASMR III	Major	Class H <sup>d</sup>	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 <sup>c</sup>	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 <sup>d</sup>	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 <sup>b</sup>	209	271	248	313	342

<sup>a</sup> Welireg, Rezurock, Opdivo, and Nubeqa have not yet been approved by the EC nor assessed by NICE/SMC  
<sup>b</sup> 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  
<sup>c</sup> Resubmission <sup>d</sup> 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