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8 things you need to know NOW about UK market access in 2021…

Following the end of the Brexit transition period, this year has the potential to be game changing in shaping the UK's healthcare landscape, with numerous regulatory, HTA, and commercial initiatives

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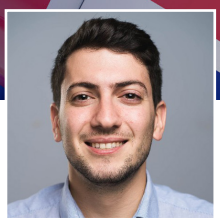

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1. MHRA's New Licensing Pathway

Post-Brexit, the UK will see the MHRA assuming a greater role as the country's sole medicines regulatory body. The recent early approvals of COVID-19 vaccines demonstrate the agency's willingness to be at the forefront of innovation, expediting access to life-saving treatments. In December 2020, the UK government announced the new Innovative Licensing and Access Pathway (ILAP), which enables faster access for medicines that meet the criteria for the scheme. Such criteria include that the condition is life threatening or severely debilitating and that there is a significant patient or public health need. From January 2021, ILAP will harness the expertise of NICE, SMC, and NHSE&I, providing a single integrated platform for sustained collaborative working between the MHRA, partners, and manufacturers. *Published January 2021;* **see here**.

2.NICE Methods Review

In the past 20 years, NICE's HTAs have played a key role in supporting access for medicines, providing a reference point for agencies across the globe. But with health technologies rapidly advancing so does the need to update evaluation methods. To ensure it stays ahead of the curve, NICE launched a public consultation in October 2020 on proposals for changing its asset selection and review methods. The proposals include discontinuing the current modifier for end-of-life treatments and introducing a new disease severity modifier based on QALYs, accepting a greater uncertainty level in certain circumstances (ie, orphan drugs, innovative technologies, etc), and reducing the annual discount rate from 3.5% to 1.5% for transformative therapies. NICE plans to further consult with stakeholders early this year and announce final reforms in the summer. *Published December 2020;* **see here**.

3. Innovative Medicines Fund

Medical breakthroughs of the recent past have resulted in potential cures for some cancers and genetic conditions, but with a glut of such innovative treatments the budget impact is potentially huge, meaning in-need patients may face delayed or restricted access. The Innovative Medicines Fund (IMF) seeks to change this by providing a £500 million ring-fenced cash pool for the most cutting-edge therapies. First proposed in the 2019 Conservative Party Manifesto, the IMF includes the existing £360 million of the Cancer Drugs Fund (CDF) and will likely also follow a 'managed access' approach to ensure treatments prove the value they promise. We keenly await more details. *Published November 2019;* **see here**.

4. New Rare Diseases Framework

Rare diseases present a tremendous burden on patients and, through the lack of structured policies and the fact that collectively they are not rare, also on healthcare systems at large. This 5-year national vision sets out to address the major challenges patients face in 4 priority areas: (i) helping patients get a final diagnosis faster, (ii) increasing awareness of rare diseases among healthcare professionals, (iii) better coordination of care, and (iv) improving access to specialist care, treatments, and drugs. The framework includes the 4 devolved nations of the UK, with the next steps being development of country-level action plans. *Published January 2021;* **see here**.

5. NHS England Commercial Framework for Medicines

Under the 2019 Voluntary Pricing and Access Scheme for Branded Medicines (VPAS), NHS England is developing a commercial framework that sets out how they will collaborate with NICE and the pharmaceutical industry to improve patient access to affordable, transformative medicines that are both clinically and cost-effective. The framework supports NHSE and industry collaboration on finding commercial solutions to address affordability challenges such as patient access schemes, commercial agreements, managed entry agreements, and budget impact tests. The framework will also aid faster market entry for new treatments, supporting uptake and adoption for fairly and responsibly priced medicines. The COVID-19 pandemic delayed the anticipated final version publication in 2020, with the finalised document potentially expected in 2021. *Published January 2020;* **see here**.

6. Real-World Evidence Guidance

Real-world evidence (RWE) has been long touted as a valuable addition to the data collected in more conventional trials, but the uncertainties on the credibility of the information collected has hindered its use in regulatory and reimbursement situations. To partly rectify this, and showcase its pro-innovative stance to manufacturers, the MHRA has published draft guidance that covers simple trials (ie, trials set up to generate RWE) and hybrid trials (ie, trials set up with both RWE and conventional evidence generation), outlining factors to consider when collecting real-world data. The initial draft consultation ended in December last year, with further interesting developments expected in 2021. *Published October 2020;* **see here**.

7. Subscription-based Reimbursement

The challenge of how to encourage and fairly reward development of health innovations that might not be commercially viable is particularly acute for antimicrobial resistance (AMR) where R&D has suffered, despite a high unmet medical need. To incentivize manufacturers, the UK Department of Health has launched a trial subscription-model payment system, paying manufacturers up to £100 million to develop and market novel antibiotics. Two antimicrobials were selected for pilot inclusion, Shionogi's novel Fetcroja® (cefiderocol) and Pfizer's existing Zavicefta™ (ceftazidine with avibactam), with the fee paid based on the value of the antimicrobials, ascribed using a new NICE evaluation framework, rather than the volume sold. The NICE draft framework has been published, with the final scope expected in February 2021. *Published December 2020;* **see here**.

8. Digital Health Technology Evaluations

Digital health technologies have the potential to provide patients with solutions for managing a range of diseases, both alone and in combination with traditional medical approaches, provided they can secure funding. With this in mind, NICE has published its first assessment using the digital health technologies guidance development pilot project. Excitingly, the innovative technology, Zio XT, which allows the patient to go about their normal daily activities while detecting abnormal heart rhythms, has been recommended. NHS organizations are instructed to collect further evidence on the benefits provided by the technology. *Published December 2020;* **see here**.

For more detailed information on any of the initiatives, contact our market access strategy experts.

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