UK’s Early Access to Medicines Scheme now to be put on a legal footing

The Early Access to Medicines Scheme (EAMS) is a vitally important scheme that gives patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation, when there is a clear unmet medical need. The scheme, which has been running since 2014, has to-date granted 100 medicines a Promising Innovative Medicine status and more than 40 Scientific Opinions have been awarded in a variety of therapeutic areas with unmet patient need.

The Scheme is an excellent demonstration of healthcare agencies and industry working together to get ground-breaking treatments to patients more quickly. An example of the scheme in action is Roche’s atezolizumab (Tecentriq), which helps treat people with lung cancer. As a result of the scheme, 63 patients were able to access atezolizumab after a review with their specialist. This meant patients had access to the life-saving treatment around 4 months earlier. EAMS also accelerated access to pembrolizumab for 500 patients with advanced melanoma skin cancer. Most notably during the pandemic, EAMS was responsible for the select use of the first COVID-19 medicine, Gilead’s remdesivir, to shorten hospital stay.

Following an analysis of the responses to the six-week consultation the MHRA launched last year, the UK regulator has prepared a Government response outlining key legislative changes. These changes will provide the UK with an opportunity to maximise the Scheme’s impact by accelerating availability of medicines for patients, reducing the burden on manufacturers supplying EAMS medicines and facilitating the collection of real-world data which may potentially be used as evidence to support regulatory decision making for future authorisations. This will help support more patients benefiting from important EAMS medicinal products and ensure that the UK remains internationally competitive in the pre-market access landscape.

Dr June Raine, Chief Executive of the MHRA said:

“This is a ground-breaking move, demonstrating our commitment to ensuring that patients can have fast access to promising new treatments ahead of normal licensing timeframes. This life-changing scheme, which has remained running throughout the pandemic, gives patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need.

“We have seen positive support for these new changes in the responses to our consultation and a clear indication that patients, clinicians and industry are supportive of introducing a bespoke EAMS provision within the UK medicines legislation. We will now take the steps needed to provide a legislative framework for EAMS. This comprehensive framework will not only benefit patients in need of innovative and cutting-edge treatments but will also provide detailed real-world evidence for our future regulatory

decisions."

"We would like to thank all those who took part in this important consultation which has resulted in making these innovative changes to UK legislation. Your feedback and views were critical in putting together this robust legislation and delivering a legal basis for this vitally important scheme."

Fiona Loud, Policy Director at Kidney Care UK, said:

"As the UK's leading kidney patient support charity, Kidney Care UK frequently hears from families and people who need hope. When new treatments emerge, such as those for rare conditions like Primary Hyperoxaluria Type 1 (PH1), they are often excited but frustrated as they wish to access them as soon as possible. It is good to see this scheme is making this happen. The opportunity to benefit from new treatments early as part of a well-informed and shared decision is both helpful and hopeful. We hope that more people with kidney disease will be able to benefit from new medicines as the EAMs scheme proceeds."

Pamela Healy, Chief Executive at the British Liver Trust said:

"Many patients with liver cancer and liver disease are often diagnosed at an advanced stage when there are limited treatment options. Sometimes, new innovative treatments take a long time to go through the regulatory processes. This early access scheme is extremely important for patients and has the potential to save lives. It means that patients can potentially receive medicines that are deemed safe much more quickly whilst further evidence is collected."

A review of the consultation responses can be found here.

Notes to Editors

1. The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK.
2. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care.
3. Further information on EAMS and a case study on Roche's atezolizumab (Tecentriq) can be found here.
4. A case study on pembrolizumab can be found here.
5. See further information on Gilead's COVID-19 treatment, remdesivir.
6. We carried out a public consultation from the 6 August 2021 to the 17 September 2021 on proposals to clarify the legal basis for EAMS within the Human Medicines Regulations (the HMRs).