UK announces Early Access to Medicines Scheme aimed at “breakthrough medicines”

On 14 March 2014, the UK Government announced the Early Access to Medicines Scheme (EAMS), a voluntary and non-statutory scheme that will be launched in April 2014. The EAMS will run in parallel with the existing UK and EU licensing procedures, and is intended to allow patients to access innovative unlicensed or off-label medicines earlier than the current marketing authorisation procedures permit.

The EAMS scheme will apply to medicines that target life threatening or seriously debilitating conditions for which there are no existing treatments, or where existing treatments are unsatisfactory. There must be sufficient quality, safety and efficacy data available to show that the risk:benefit profile of the product is positive, and that the medicine represents a significant advance in the treatment of an unmet need. The EAMS announcement envisages that products will normally be eligible for an early access scientific opinion after Phase III clinical trials, although medicines with exceptional and compelling data may be eligible after Phase II. Products with orphan designation and off-label uses of existing authorised products will be eligible for EAMS.

The EAMS comprises three main stages:

1. **Application for “Promising Innovative Medicine” designation.** Companies with medicines that meet the criteria above may apply to the UK Medicines and Healthcare products Regulatory Agency (MHRA) on the basis of early data (e.g., phase II studies) for their product to be designated as a Promising Innovative Medicine (PIM). PIM designation is analogous to the US’s Breakthrough Therapy Designation, and serves as an early indication that a product may be a candidate for the EAMS. It is hoped that the award of PIM designation could be used by companies to secure investment and confer a greater degree of credibility on the products and companies involved.

2. **Application for an EAMS scientific opinion.** Companies with the appropriate data may apply to MHRA for an EAMS scientific opinion. Precisely what data is required will be determined on a case-by-case basis, although the announcement states that the “MHRA does not want to set criteria that are too prescriptive”. Where the evidence is sufficiently compelling, the MHRA will publish an opinion intended to support prescribers in deciding whether to use the medicine on an unlicensed basis. There is a specific provision that EAMS scientific opinions will be made available to prescribers and patients in the UK, to inform their decision-making.

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or off-label basis. As with any medicine, the ultimate responsibility for deciding whether a patient should use a particular product remains with the prescriber – the intention of the EAMS is to provide prescribers with the information they need in order to make this decision sooner, and outside the confines of clinical trials.

New medicines prescribed under EAMS will be made available free of charge by companies until the marketing authorisation is granted. In order to comply with restrictions on promotion of unlicensed products, it is likely that companies will be restricted from drawing the attention of prescribers to products that have received a positive EAMS opinion. However, information will be published by MHRA on its website and the Government has suggested that professional groups, such as Royal Colleges, could be instrumental in ensuring prescribers are aware of the arrangements. Appropriate pharmacovigilance procedures will be put in place to monitor the use of the product.

3. Licensing and rapid commissioning. The clinical and cost effectiveness of newly authorised medicines in the UK is generally appraised by the National Institute for Health and Care Excellence (NICE), which issues guidance regarding use of such products within the NHS. NHS commissioning bodies are under a legal duty to fund products recommended by NICE. The Government announcement envisages joint parallel scientific advice meetings between MHRA and NICE in relation to clinical development programmes for products that go through EAMS, providing an opportunity for companies to benefit from early engagement with NICE. The announcement also envisages coordination of the processes of appraisal by NICE and commissioning by the NHS, although the precise details of this arrangement are not yet clear.

EAMS will be available in England, but it is not yet known whether the devolved administrations in Scotland, Wales and Northern Ireland will participate. Further MHRA guidance is expected when the scheme launches in April.

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