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# Public Consultation on the UK's Early Access to Medicines Scheme Launched

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On 6 August, the U.K. Medicines and Healthcare products Regulatory Agency ("**MHRA**") launched a public consultation on proposed changes to the Early Access to Medicines Scheme ("**EAMS**"). The proposals have been designed to ensure that the EAMS remains relevant and attractive following the UK's exit from the European Union and that patients in the UK with serious and life-threatening conditions are able to access cutting-edge therapies in advance of licensing decisions to advance the interests of patients.

## What is EAMS?

Under regulation 46(1) of the Human Medicines Regulations 2012 (the "**HMRs**"), the sale and supply of unlicensed medicines in the UK is prohibited. EAMS provides a mechanism to bypass this prohibition in order to facilitate the legal supply of unlicensed medicines where there is a clear and defined clinical need.

The scheme currently consists of a two-step process involving the designation by the MHRA of the medicinal product as a promising innovative medicine ("**PIM**"). In order to obtain a PIM designation, the medicinal product must fulfil the following criteria:

- The medicinal product must be intended to treat a life threatening or seriously debilitating condition;
- There must be a high unmet clinical need (i.e. no authorised treatments available, or those that are inappropriate);
- The medicinal product is likely to offer a significant advantage over existing treatments;
- A reasonable expectation that the benefits of the medicinal product will outweigh the potential adverse effects; and
- The applicant must be able to manufacture the product to a consistent quality standard.

Following the PIM designation, a scientific opinion must be sought from the MHRA on the risk/benefit balance of the product based on the clinical data available at that point. If the MHRA issues a positive opinion, the medicinal product can be provided to patients, free of charge, prior to the grant of marketing authorisation ("**MA**"). Positive scientific opinions are published on the MHRA website alongside a public assessment report and a treatment protocol describing how the medicinal product can be used.

Since EAMS was launched in 2014, there have been over 100 PIM designation and 50 applications for scientific opinions. It is estimated that EAMS has facilitated over 1,000 patients' access to cutting edge medicines.

## What changes have been proposed?

The proposals have been designed to ensure that EAMS remains relevant and attractive following the UK's exit from the EU, and that patients in the UK are able to access innovative therapies in advance of licensing decisions. The proposals include:

- Currently, EAMS is entirely non-statutory. The MHRA would like to rectify this by introducing a new provision into the HMRs to provide a specific statutory basis, therefore improving regulatory certainty.

- The introduction of a description of the objectives of EAMS, alongside details of its principles of operation.
- Currently, the type of manufacturing licences held by members of an EAMS supply chain member differs depending on whether the EAMS medicine is unlicensed or an off-label use of a licensed medicine, and whether it is imported to the UK from the EEA or a third country. The MHRA has suggested that this be simplified by permitting the manufacture, assembly or importation of EAMS medicines under any type manufacturing licence for human medicines, provided that the proposed activity falls within its current scope.
- To allow for real-world data collection without the need for a clinical trial authorisation, provided the MHRA has no concerns about such collection. Patients would need to be appropriately consented and have the right to refuse without impacting their ability to join the scheme.
- To provide clarity around the liability for use of EAMS medicines, in line with the General Medical Council recommendations on prescribing unlicensed or off label medicines.
- The inclusion of certain pharmacovigilance requirements into legislation including, but not limited to, the requirement to operate a risk management system describing appropriate pharmacovigilance and risk minimisation activities.

## The consultation

The consultation will run until 17 September 2021.

At this point the MHRA has not stated when the outcome will be communicated but instead that it will consider the responses received after the consultation has closed.