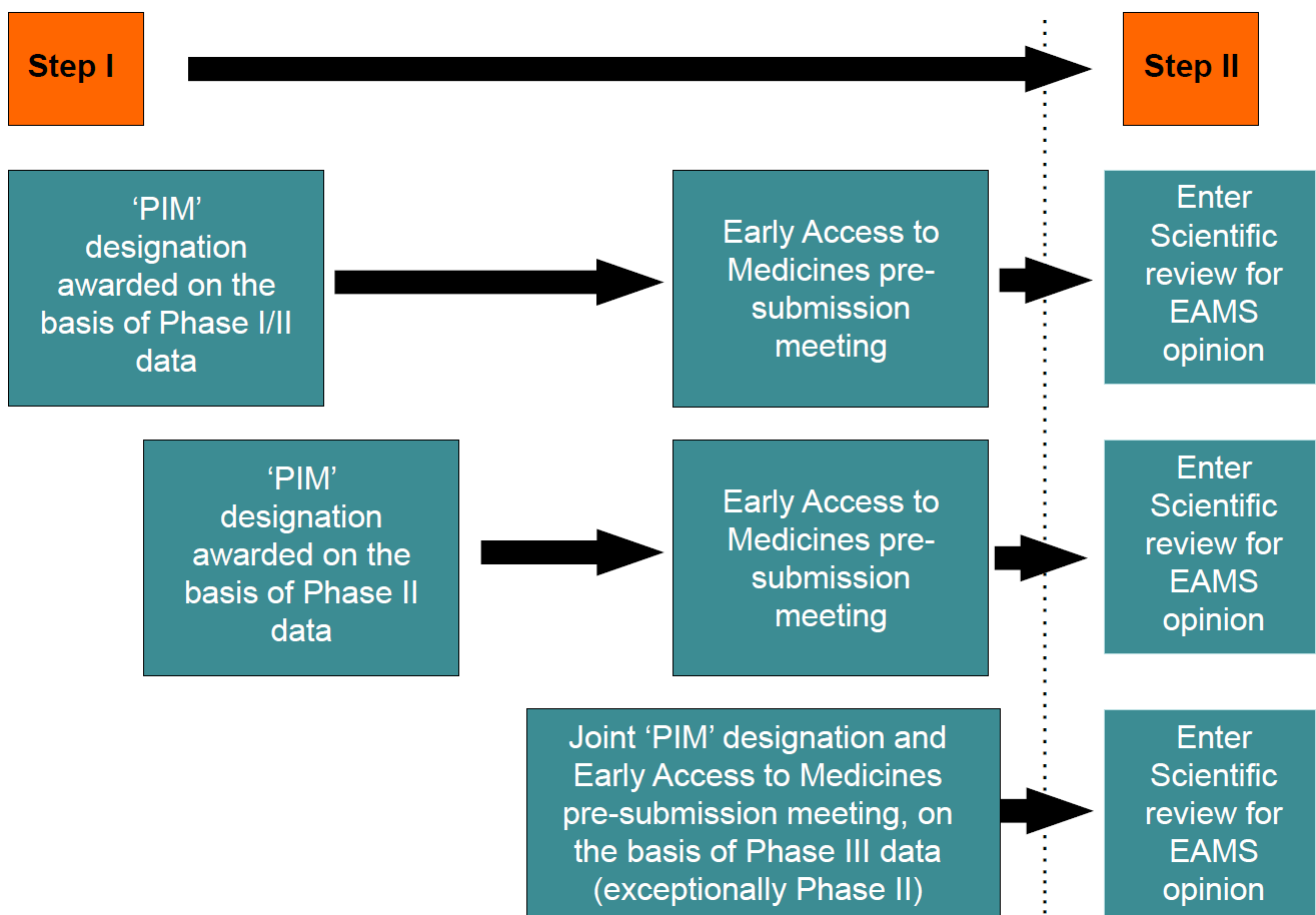


Promising Innovative Medicine (PIM) Designation - Step I of Early Access to Medicines Scheme (EAMS)

What is a Promising Innovative Medicine (PIM) designation?

A Promising Innovative Medicine Designation is an early indication that a medicinal product is a promising candidate for the Early Access to Medicines Scheme (EAMS), intended for the treatment, diagnosis or prevention of a life-threatening or seriously debilitating condition with the potential to address an unmet medical need. The designation will be issued after an MHRA scientific designation meeting on the basis of non-clinical and clinical data available on the product, in a defined disease area. Following designation, the applicant is expected to complete a clinical development programme within a reasonable time period, in order to continue with an application under the EAMS (step II). A designation is a prerequisite to enter the EAMS scientific opinion assessment step.



When can I apply for PIM Designation?

Applicants may apply when data from early stages in a clinical development indicates that the medicinal product fulfils the designation criteria, namely the product is likely to demonstrate significant benefit for patients in life-threatening or seriously debilitating conditions.

Can we apply for a new indication for an already marketed drug?

Yes.

What are the PIM designation criteria?

All three criteria which must be fulfilled in order to gain a PIM designation are:

Criterion 1

- a. The condition should be:
- Life-threatening or
 - Seriously debilitating

The severity of the disease should be justified based on objective and quantifiable medical or epidemiologic information, in terms of mortality and morbidity, with special emphasis on patient quality of life.

- b. With high unmet need:
- There is no method of treatment, diagnosis or prevention available or
 - Existing methods have serious limitations

A critical review of the methods of treatment, diagnosis or prevention currently available in clinical practice in the UK should be provided, including an evaluation of the performance of these methods based on quantifiable data (e.g. data on survival, disease progression/relapses, or patient-reported outcomes). The Applicant should provide a justification for why current methods are not adequate.

Criterion 2

The medicinal product is likely to offer major advantage over methods currently used in the UK.

The Applicant should submit preliminary evidence, based on non-clinical and clinical data, indicating that the advantage and magnitude of effect claimed for the product is predicted to be of significant relevance to the patient and will address their unmet need. A well-argued evaluation of the likelihood of achievement of the product's claims should be provided, based on the totality of information available at the time of designation. Depending on the product, this may include, but not restricted to, direct or indirect comparison to existing therapies/ standard of care in the UK, or evidence of a potential treatment effect in the aetiology of the condition or similar efficacy but better overall tolerability compared to existing therapies.

Criterion 3

The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance. A positive benefit risk balance should be based on preliminary scientific evidence, as justified by the applicant, that the safety profile of the medicinal product is likely to be manageable and acceptable in relation to the estimated benefits.

How do I apply?

Companies seeking a PIM designation should complete the PIM designation template in full, indicating how the product fulfils the criteria of designation. Completed forms should be sent electronically to the MHRA's EAMS coordinator (eams@mhra.gsi.gov.uk). For the joint PIM designation/ pre-submission meeting, both a PIM designation application template and a pre-submission meeting template should be submitted at the time of the request.

What are the fees?

The fee for the designation meeting is equivalent to a safety and clinical development scientific advice meeting.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Feespayablefortheregulationofmedicines/Scientificadvicemeetings/index.htm>

All fees become payable within 30 days following written notice from the MHRA requiring payment of those fees.

What happens next?

Your submitted designation application will be reviewed by the assessment team and an agreed designation meeting date will be set (normally within 4 weeks of the receipt of your request). The focus of the designation meeting is restricted to the potential of the medicinal product to fulfil the three criteria and is expected to last for up to one hour. The meeting will normally be face to face at the MHRA's offices in London, although teleconference facilities can be arranged if this is the Applicant's preferred option. Separate scientific advice meetings can be requested from the MHRA at any stage in the development of the product for other aspects (quality, non-clinical, statistical, pharmacokinetic, efficacy and safety, pharmacovigilance).

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Otherusefultoolsandservicesandinformation/Scientificadviceforlicenceapplicants/index.htm>

Following the designation meeting, the assessment team will make a recommendation to the internal scientific consistency review group, which will advise the Director of Licensing on whether to grant a designation or not.

What happens if I am awarded a designation?

You will receive a positive designation letter, which will include your unique EAMS number. This number must be included with any future application for an EAMS scientific opinion step*. You will be encouraged to utilise the MHRA's scientific advice service and innovation office to help you with your on-going and future development plans.

*Entry into step II of the EAMS is dependent on maintenance of the designation criteria and it should be noted a positive PIM designation is not binding to a positive scientific opinion in step II.

What happens if I am not awarded a designation?

You will receive a letter explaining why it was considered your proposal did not fulfil the designation criteria. You may still find it helpful to utilise the MHRA's scientific advice service and innovation office to help you with your ongoing and future development plans.

Are designation opinions published?

No, the MHRA will not publish positive or negative designations. The MHRA may publish information on the number of designation meetings carried out.

Do designation opinions expire?

No, the designation is a statement at one point in time, that the product shows promise in a particular patient setting and is suitable for future application to the EAMS scientific opinion step.