Medicines and Healthcare Products Regulatory Agency

Early Access to Medicines Scheme (EAMS)

Safe and Timely Access to Medicines for Patients (STAMP)
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MHRA






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Early Access to Medicines

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- A proposal for an Early Access to Medicines Scheme was developed as part of a series of events established by the UK Ministerial Industry Strategy Group (MISG)
- A public consultation on the proposals for a scheme were launched by the MHRA and Department of Health
- The government published the response to the consultation in the March 2014:
  - 52 responses were received
  - Overall, there was overwhelming support for a scheme
  - Addresses a public health need to improve access to important innovative medicines for patients with life threatening or seriously debilitating conditions without adequate treatment options

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Early Access to Medicines

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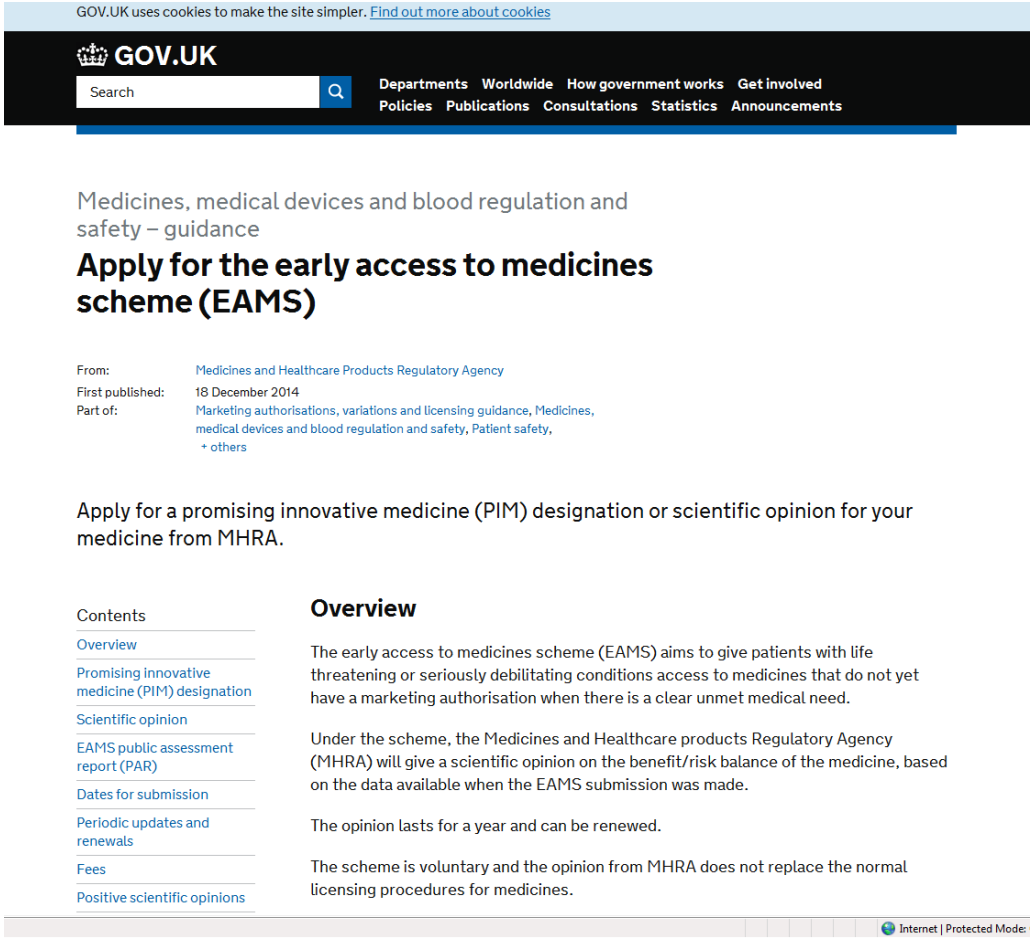
- The MHRA launched the scheme April 2014
- Dedicated MHRA webpage with detailed guidance and application forms/ templates
- EAMS coordinator to ensure swift and efficient operation of the scheme: eams@mhra.gsi.gov.uk
- https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams



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Medicines, medical devices and blood regulation and safety – guidance

Apply for the early access to medicines scheme (EAMS)

From: Medicines and Healthcare Products Regulatory Agency
First published: 18 December 2014
Part of: Marketing authorisations, variations and licensing guidance, Medicines, medical devices and blood regulation and safety, Patient safety, + others

Apply for a promising innovative medicine (PIM) designation or scientific opinion for your medicine from MHRA.

Contents

- Overview
- Promising innovative medicine (PIM) designation
- Scientific opinion
- EAMS public assessment report (PAR)
- Dates for submission
- Periodic updates and renewals
- Fees
- Positive scientific opinions

Overview

The early access to medicines scheme (EAMS) aims to give 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.

Under the scheme, the Medicines and Healthcare products Regulatory Agency (MHRA) will give a scientific opinion on the benefit/risk balance of the medicine, based on the data available when the EAMS submission was made.

The opinion lasts for a year and can be renewed.

The scheme is voluntary and the opinion from MHRA does not replace the normal licensing procedures for medicines.

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- The scheme will cover medicines that are not yet available as licensed treatments
- The scheme is not a substitute for appropriate clinical development and inclusion of patients in well designed clinical studies remains the preferred option, if available in the UK
- Primarily aimed at medicines that have completed Phase III trials, but may be applied to completed Phase II trials in exceptional circumstances
- There is no set limit on the numbers of products entering the scheme provide they fulfil the criteria of the scheme
- The UK scheme will operate within the current regulatory structure and is voluntary
- The medicine is to be provided for free by the company during the scheme

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The EAMS criteria

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The criteria of suitability for an EAMS application are:

- Life threatening or seriously debilitating conditions, without adequate treatment options – high unmet need. This could include drugs intended for the treatment, prevention or diagnosis of diseases
- The medicinal product offers promise - that it is likely to offer benefit or significant advantage over and above existing treatment options
- Potential adverse effects likely to be outweighed by benefit. i.e. the benefit: risk ratio is concluded as being positive
- The Applicant is able and willing to supply the product and to manufacture it to a consistent quality standard (GMP)

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EAMS - Step I & Step II

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- The EAMS is a two step process:
  - Step I the Promising Innovation Medicine (PIM) Designation
  - Step II the Scientific Opinion

- A PIM Designation is an early indication that a medicinal product is a promising candidate for the EAMS

- The PIM 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

- A PIM designation is a prerequisite to enter the EAMS scientific opinion assessment (step II)

- The PIM destination gives:
  - A company reassurance that its clinical development is on ‘track’ by having an early review of its data by the medicines regulator
  - An opportunity to engage with NICE (HTA) and the NHS on patient access issues

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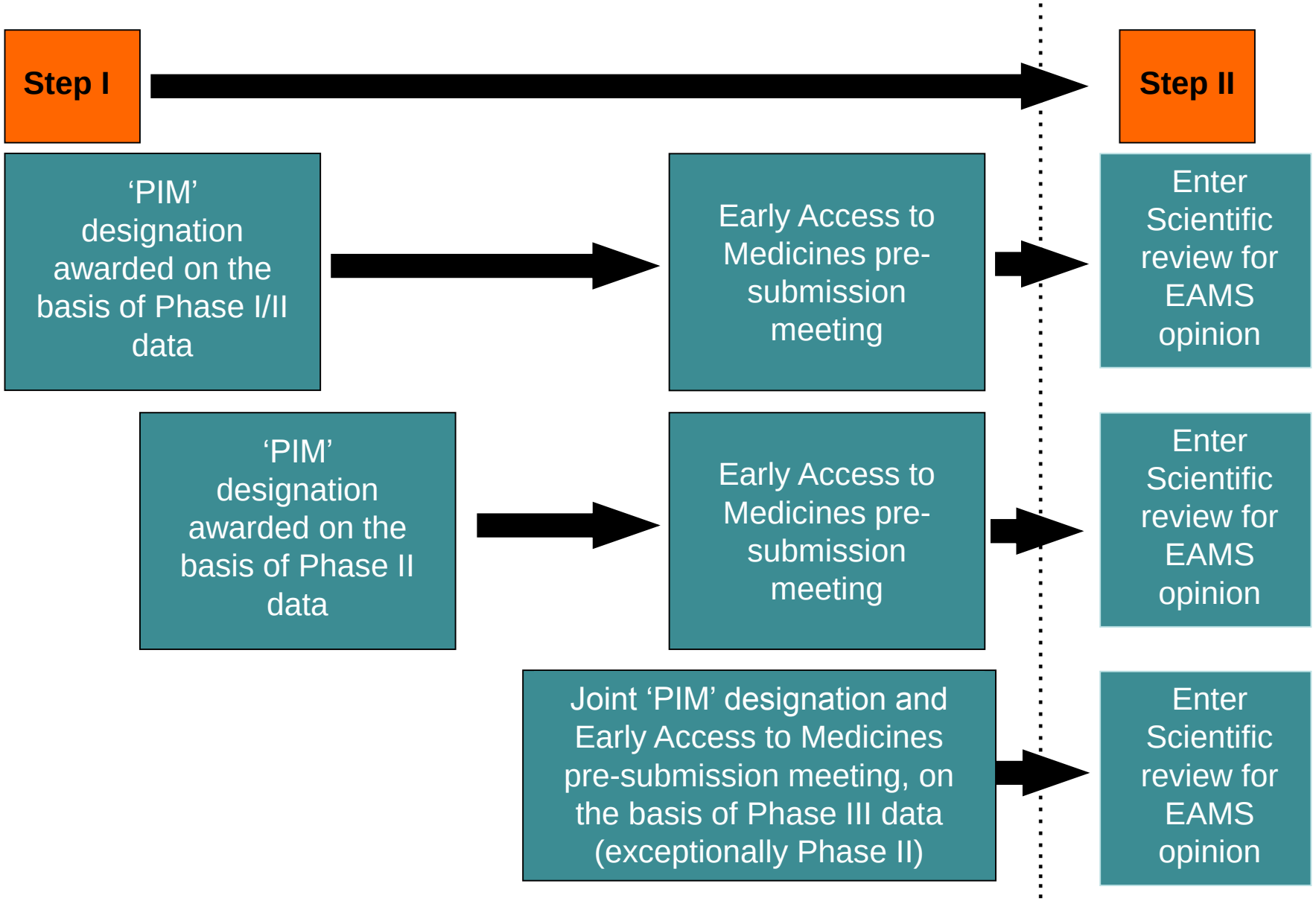
Step I - Promising Innovative Medicine (PIM) Designation



EAMS scientific opinion

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- The MHRA will provide a scientific opinion on new medicines that will treat, diagnose or prevent life threatening, or seriously debilitating conditions without adequate treatment options before they are formally licensed

- The scientific opinion will describe the benefits and risks of the medicine, based on information submitted to the MHRA by the company

- The scientific opinion assessment follows a 75 day or 90 day timetable

- A scientific opinion is only issued if the criteria for the EAMS are considered to be fulfilled and the benefit risk is positive

- The details of the opinion will be made available on the MHRA's website to assist clinicians and patients in making treatment decisions:
  - A public assessment report
  - Treatment protocol for patients
  - Treatment protocol for healthcare professionals
  - Treatment protocol on the pharmacovigilance system

- The opinion will be valid for one year, renewable if necessary and appropriate

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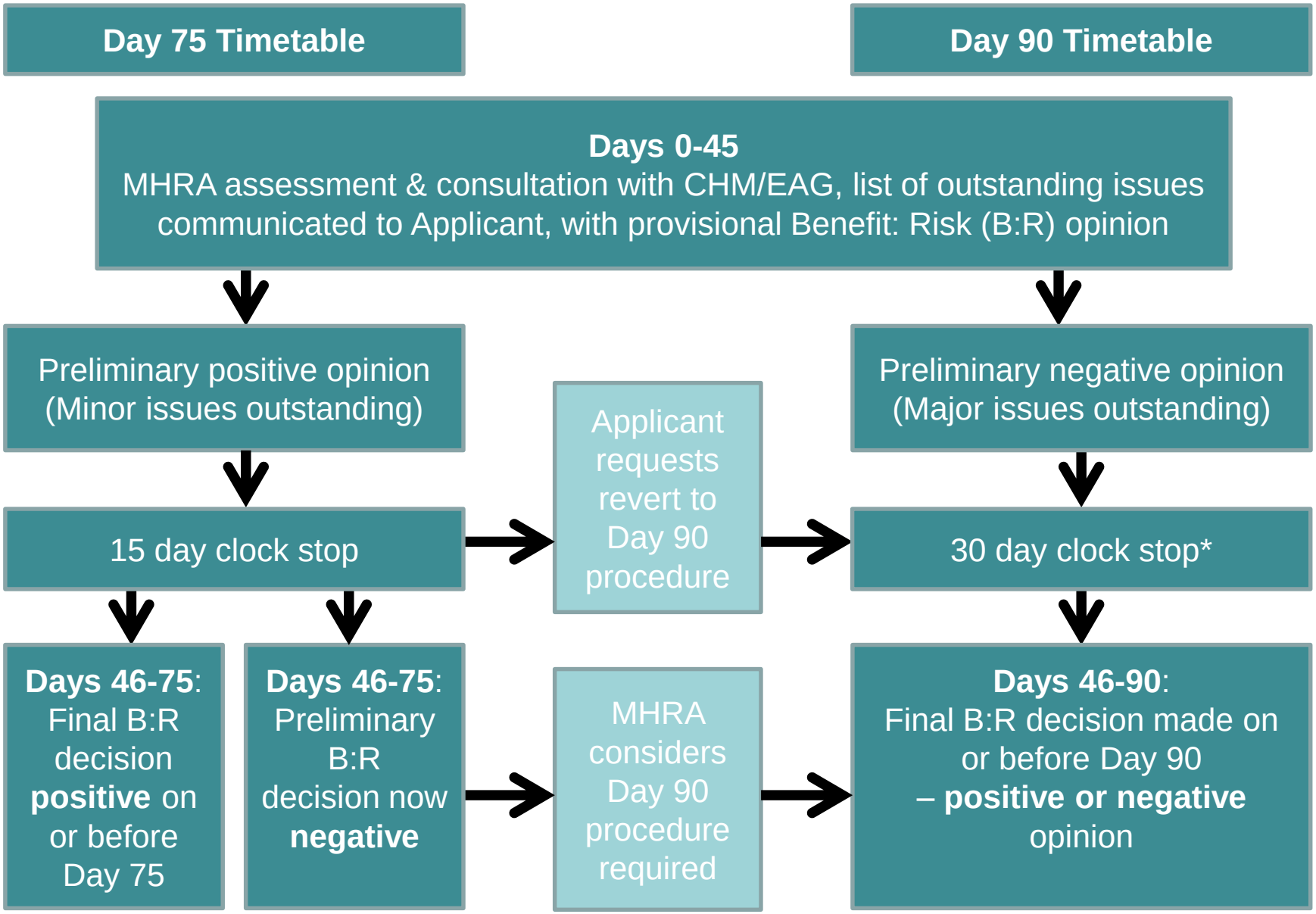

*in exceptional circumstances, the Applicant can request additional 30 days (30+30)

EAMS Summary

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- Open for applications since April 2014
- Aim to give 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
- First PIM designation was given in September 2014 for a cell therapy in the treatment of glioblastoma:
  - 7 PIM designations given so far
  - Only numbers published on the EAMS webpage, not details of companies or products
- The scientific opinion will describe the benefits and risks of the medicine and support the prescriber and patient to make a decision on using the medicine before its licence is approved

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EAMS Summary

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- First scientific opinion given in March 2015 for Pembrolizumab for the treatment of advanced melanoma
- Patients will be able to access important medicines before they are licensed and prescribers will have greater confidence in the safety and efficacy of prescribing

Information on the EAMS scientific opinion given to pembrolizumab (MK-3475), including the public assessment report.

Documents

Pembrolizumab (MK-3475) EAMS public assessment report

PDF, 78.6KB, 3 pages

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Treatment protocol for patients

PDF, 94.2KB, 5 pages

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Treatment protocol for healthcare professionals

PDF, 180KB, 13 pages

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Treatment protocol on the pharmacovigilance system

PDF, 80.9KB, 3 pages

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Thank You

Questions?

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