Operation of the Early Access to Medicines Scheme (EAMS) in NHS Scotland

The early access to medicines scheme (EAMS) is a UK wide scheme that 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. The Area Drug and Therapeutics Collaborative, as part of Healthcare Improvement Scotland, develops operational guidance to support the use of EAMS medicines in the NHS in Scotland. Details of the scheme are available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

Pharmaceutical companies apply for, and must be granted, Promising Innovative Medicine (PIM) designation before submission for an EAMS scientific opinion.

Under the scheme, the 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 EAMS scheme is voluntary for companies making submissions to MHRA. The scientific opinion from MHRA does not replace the normal licensing procedures for medicines.

Pharmaceutical companies are invited to attend a meeting with representatives of the Area Drug and Therapeutics Collaborative (as representatives of NHS Scotland) and the Scottish Medicines Consortium (SMC) as a single point of contact to develop the EAMS operational guidance for NHS Scotland and as an opportunity to discuss the SMC health technology assessment process.
Frequently asked questions

- **What does Promising Innovative Medicine (PIM) mean?**
  The PIM designation gives an indication that a product may be eligible for the EAMS based on early clinical data. Note it could be several years before the product is licensed and that not all medicines with PIM status progress to participate in the EAMS. All companies with a medicine with PIM status will be invited to attend a meeting with ADTCC and SMC to discuss operational delivery of EAMS and the implication of EAMS on future health technology assessment.

- **What is the ADTC Collaborative EAMS operational guidance?**
  The operational guidance is developed by the ADTC Collaborative to assist NHS boards in Scotland with the local management of access to these medicines via EAMS. Companies which have applied for EAMS for their medicines, will be supplied with an operational guidance template for completion and discussion with ADTCC in order to agree the national operational guidance in Scotland.

  The guidance highlights the key operational issues for the EAMS medicine for health boards including; supply arrangements; patient information; pharmacovigilance requirements; and the EAMS termination arrangements.

- **What does preliminary positive opinion (or preliminary negative opinion) at ‘Day 45’ mean?**
  Following assessment by MHRA, at day 45 in the application process the pharmaceutical company may receive:

  1. A confidential preliminary positive opinion for their medicine (i.e. minor issues outstanding), and will have a 15 day ‘clock stop’ put in place.
  2. A confidential preliminary negative opinion (i.e. major issues outstanding), and will have a 30 day ‘clock stop’ put in place. In exceptional circumstances, the company can also request additional 30 days clock stop.

- **What does positive (or negative) scientific opinion at ‘Day 75 or Day 90’ mean?**
  Following preliminary positive scientific opinion and 15 day ‘clock stop’, the MHRA assessment process continues until final Benefit: Risk decision is either positive on or before Day 75, in which case the EAMS period starts. If the Benefit: Risk decision is now negative, the
MHRA considers the Day 90 procedure is required. The applicant can also ask during the 15 day ‘clock stop’ period to revert to the Day 90 procedure.

Following preliminary negative scientific opinion, and either 30 days (and possible additional 30 days) ‘clock stop’, medicines will then continue through the MHRA assessment process until the final Benefit: Risk decision is made on or before Day 90, either positive or negative opinion. If the opinion is positive, the EAMS period starts.

A positive or a negative scientific opinion at Day 75 or Day 90 is published on the MHRA website.

A positive scientific opinion is valid for one year; the company can apply for an extension to this period.

- **How long is the EAMS period?**
  While the scheme was originally intended to be in place for 12-18 months for eligible medicines, in practice the EAMS periods have been very brief with some in place for only a few weeks.

- **Do SMC or ADTCC have any influence on the length of the EAMS period?**
  The length of the EAMS period depends on when the company submits an application for the EAMS scheme and on when the marketing authorisation is issued. SMC and ADTCC have no influence on this process.

- **When does the company decide to apply to the European Medicines Agency (EMA) for their Marketing Authorisation (MA)?**
  The company generally applies to EMA for their product’s MA in parallel with the PIM/EAMs activity. When the EMA MA is granted the medicine is no longer available for new patients under the EAMS. However patients in Scotland already on treatment may continue to receive the medicine free of charge in line with the termination arrangements outlined in the operational guidance.

- **When can SMC receive submissions from pharmaceutical companies?**
  SMC welcome submissions from pharmaceutical companies any time after the CHMP positive opinion is issued. The CHMP opinion on a medicine is issued in a different timeframe and is independent of the MHRA EAMS opinion.
The company may decide to apply for Marketing Authorisation (MA) in parallel with PIM / EAMS processes. The duration of EAMS period is variable and will end when MA is granted.