Medicines & Healthcare products Regulatory Agency

MHRA

Early Access to Medicines Scheme – Treatment protocol – Information on the pharmacovigilance system and requirements for reporting safety data

Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed medicines and medicines used outside their licence, to UK patients that have a high unmet clinical need. The medicinal products included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life-threatening conditions where there are no adequate treatment options.

The scientific opinion is based on assessment of the information supplied to the MHRA on the benefits and risks of the medicine. As such this is a scientific opinion and should not be regarded as a licensed indication or a future commitment by the MHRA to licence such a medicine, nor should it be regarded as an authorisation to sell or supply such a medicine. A positive scientific opinion is not a recommendation for use of the medicine and should not be interpreted as such. Under EAMS the risk and legal responsibility for prescribing the medicine remains with the physician, and the opinion and EAMS documentation published by the MHRA are intended only to inform physicians' decision making and not to recommend use. An EAMS scientific opinion does not affect the civil liability of the manufacturer or any physician in relation to the product.

As the safety profile of the EAMS medicine may not yet be fully established it is particularly important that any harmful or unintended responses to EAMS medicines are reported. More information about the scheme can be found here:
http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm

Physicians should enroll any patients receiving EAMS medicines in the drug registry put in place by the pharmaceutical company to enable systematic collection of information on adverse events. Suspected adverse drug reactions (ADRs) for any patients can also be reported directly to the MHRA via the Yellow card scheme at www.mhra.gov.uk/yellowcard. When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, outcome and results of any test results or investigations.

The information below is intended for healthcare professionals and is provided by the pharmaceutical company that manufactures the EAMS medicine. It summarises the requirements for clinical monitoring and reporting of adverse events with medicines used under the scheme.

Healthcare professionals should also consult the relevant detailed information provided by the company.

EAMS Indication

Asciminib is indicated for the treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukaemia in chronic phase (Ph+ CMLCP) previously treated with two or more tyrosine kinase inhibitors.

Information on the Pharmacovigilance system

A prescribing physician may request entry of their patients into the Early Access to Medicines Scheme (EAMS Protocol Number CABL001AGB02M) by completing and submitting an Initial Request Form. Upon review of the individual request and fulfilment of the eligibility criteria, Novartis will provide EAMS materials which will include information on the collection and reporting of adverse events.

Adverse event/Adverse drug reaction reporting

All Healthcare Professionals (HCPs) involved in the care of patients on EAMS will be instructed to report all adverse events (AEs) (including initial and follow up reports) within one business day of awareness on the provided electronic adverse event report form. Special situations (SS) with or without an associated AE are to be handled the same as AEs.

An ***AE*** is defined as any untoward medical occurrence in a patient or clinical-trial subject administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Special situations include all cases of pregnant women (or their male partner) taking a drug, breastfeeding women taking a drug, congenital abnormalities in children of parents taking a drug and overdose.

The AE reporting form is available electronically to physicians taking part in this EAMS. Any issues accessing the AE reporting form should be addressed by sending an email to uk.patientsafety@novartis.com. Additional follow-up may be requested on all reports received to obtain further information.

All AEs and SSs reported will be entered into the Novartis safety database and will be linked to the patient by the specific EAMS protocol number and unique patient number.

HCPs should also report all known and suspected adverse drug reactions (ADRs) (i.e. those AEs which are related to the use of asciminib) to the MHRA via the Yellow Card scheme, www.mhra.gov.uk/yellowcard. In addition to this, the EAMS patient ID number should be provided in the report narrative to help the MHRA identify that the AE is related to EAMS product and to help Novartis link the AE report to the correct EAMS patient.

The Scientific Opinion Holder is required to send ADRs suspected to be related to the EAMS products to the MHRA within the agreed timelines.

Training for healthcare professionals

A Physician Pack containing the Treatment Protocol for Healthcare Professionals, the Treatment Protocol for Patients, the Treatment Protocol on Pharmacovigilance Systems, the EAMS AE reporting form and drug exposure during pregnancy form, the safety training slide set and Patient Alert Card will be provided to the HCPs. In addition to the Physician Pack, comprehensive AE and SS training will be provided to all relevant HCPs prior to commencement of patient treatment, focusing on recognising, managing and reporting AEs and SSs during the scheme. Equally, the HCP's obligation to keep their patients fully informed on their treatment will be emphasised. Pertinent patient related supporting documents such as the Patient Alert Card will be provided to facilitate this activity.

Additional risk minimisation materials

Patient Alert Card – This will be given to all patients before they start treatment. It is a wallet-sized card to be carried at all times to show at all medical visits to HCPs other than the prescribers (e.g. emergency HCPs). It has contact details of the treating physician and it alerts other HCPs that the patient is receiving asciminib. It also contains information on the main symptoms of the adverse reactions and highlights the importance of notifying the treating physician immediately if symptoms occur, persist or worsen and also the importance of not attempting to self-treat any symptoms without consulting with an HCP first.

Additional information

Drug registry

The prescribing physician should carefully read the information provided in the rest of this document. Each prescribing physician interested in enrolling a patient in the programme should submit an initial request via the Novartis Grants, External Studies and Managed Access System (GEMS) via https://www.novartis.com/our-focus/healthcare-professionals/managed-access-programs. The prescribing physician will be required to register with Novartis Managed Access Programme Portal and patient details will need to be entered into the portal for each individual application. A unique initial request ID will be assigned to each eligible patient enrolled onto EAMS. This unique initial request ID will be used for future drug re-supply requests and adverse event reporting.

Novartis will request the baseline demographics data at the time of initial application and additional information at the time of re-supply request. The purpose of this data collection (registry) is to ensure the safe and effective use of the product in line with the EAMS Treatment protocols and EAMS scientific opinion.

An EAMS Agreement Letter with Novartis will be required to be signed by the prescribing Physician, the Trust and Novartis. The managed access programme (MAP) Agreement Letter will be signed either on a per patient basis or on a Trust basis. Drug supply will only be shipped once a fully executed MAP Agreement Letter and attestation has been completed.

For patients approved under this scheme and requiring ongoing drug supply, the HCPs will be required to complete the Re-supply Form on GEMS to request further cycles of treatment. The HCPs will be asked for confirmation that they understand and agree to comply with their obligations to report all AEs and SSs to Novartis and that they are complying with this requirement. They will be also asked to confirm that all AEs and SSs experienced since the last re-supply request have been reported or there are no new AEs to report. HCPs will also be requested to confirm at the time of first re-supply request if the patient alert card has been given to the patient and the patient understands the purpose of the Patient Alert Card. HCPs will also be requested to confirm that patient agrees to always carry the Patient Alert Card with them.

For NHS England only - additional requirement for registering a patient:

Following notification from Novartis of eligibility approval, the physician must complete a Blueteq form online and register their patient with NHS England, which is located at https://www.blueteq-secure.co.uk/Trust/default.aspx. Once the Blueteq form has been completed, an approval email will be received by the user and pharmacy stating the request has been approved, also stating an EAMS number. This EAMS number must be communicated back to Novartis.

Mandatory data

The prescribing physician will be requested to provide the following information by completing an Initial Application and Drug Supply Request for each patient to be enrolled on to the programme for eligibility assessment:

- Month and year of birth
- Gender
- Disease/condition to be treated
- Additional information e.g. previous treatment history, concomitant medications and response data

Additional data

Not applicable

Periodic reports

A 3-monthly periodic safety report will be submitted to the MHRA to summarise data on safety and usage of asciminib under the scheme.

Contact details

Contact details: obu.medical@novartis.com

AE reporting: uk.patientsafety@novartis.com (Contact number: 0845 601 1387)