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

UPDATE

Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed and 'off label' medicines 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. In some cases the safety profile of the EAMS medicine may not yet be fully established and it is therefore 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

Healthcare professionals should be aware of their obligations to report adverse event information upon enrollment of any patients receiving EAMS medicines in the scheme. They will be required to follow the process which the pharmaceutical company who manufacture the EAMS medicine has in place to enable systematic collection of information on adverse events.

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 medicine. The description below summarises the requirements for clinical monitoring and reporting of adverse events with medicines used under the scheme.

Prescribing doctors should also consult the relevant detailed information provided by the company.

Healthcare professionals can also report suspected adverse drug reactions (ADRs) for any patients, particularly those not enrolled in a study (or scheme), to the pharmaceutical company who manufactures the EAMS medicine or directly to the MHRA via the Yellow card scheme at **www.mhra.gov.uk/yellowcard**

Information on the Pharmacovigilance system

When a prescribing oncologist requests entry into the EAMS scheme they will receive a physician pack which includes information on reporting of adverse events (AEs) and all the necessary forms and contact details.

As each prescribing physician is approved for entry into the EAMS scheme an online account specific to their prescribing centre will be created for an EAMS Portal which has been set up to facilitate management of EAMS. The Portal can be used to submit an online patient access form for each individual patient, order resupply for subsequent cycles of treatment and inform MSD of discontinuation of treatment. In addition all the documents in the physician pack are available on the Portal for Healthcare Professionals (HCPs) to either view or download.

All HCPs, (physicians, pharmacists and nurses) involved with the EAMS will be directed to report any adverse events (AEs) including death due to any cause, and any pregnancies as specified in the relevant documentation in the physicians pack. Specifically for AE reporting this includes:

- patient access form
- resupply form
- safety reporting cover letter
- AE form instructions
- AE form
- AE query form
- discontinuation form
- frequently asked questions

All HCPs, (physicians, pharmacists and nurses) will be requested to report any adverse events, including death due to any cause, and any pregnancies within 24 hours.

When an AE occurs, additional information is collected on the AE reporting form and further follow up will be requested from physicians on all reports received to obtain further information.

Training for Healthcare Professionals (HCPs)

All HCPs (physicians, pharmacists and nurses) involved with the management of the EAMS will receive training in addition to the information they receive in the physician pack on reporting of AEs including AE forms upon set up.

The training pays particular attention to recognising, managing and reporting adverse events.

As part of this training, the HCP receives and is asked to provide a Patient Alert Card to each patient at initiation of their treatment (see below).

Additional information

This provision of pembrolizumab through EAMS is designed to provide early access to this medicine to patients with previously untreated metastatic non-small cell lung cancer where there is a clear unmet medical need, prior to licensing of the product for this use in the UK.

The treating physician will be requested to provide information for each patient receiving pembrolizumab through EAMS. Data such as age, gender, weight, disease status, patient's initials, PDL-1 expression as a tumour proportion score (TPS) as reported on the access form and prior therapy will be collected at the point of access form receipt.

The activities below are additional to spontaneous reporting and are designed to encourage prescribers to report AEs.

- Collection of any adverse events including death due to any cause, and any pregnancies.
- Provision of training to sites on pharmacovigilance obligations and reporting process
- Provision of AE reporting instructions in a comprehensive physician's pack.
- Reconfirmation on the access and re-supply forms of the responsibility to report any AEs, including death due to any cause and any pregnancies and the requirement the forms are to be signed by the prescribing physician for each patient.
- Confirmation on the re-supply form from the treating physician that AEs have been reported or no AEs have been received for that particular patient since the previous supply request.
- Provision of an email reminder to the prescribing physician at each EAMS centre on a four weekly basis reminding them of the AE reporting requirements for EAMS.
- Provision of a patient alert card.

Patient Alert Card

Before treatment starts, all patients will have the scheme explained to them by the physician or specialist nurse and will be given a Patient Alert Card.

The Patient Alert Card is a wallet-sized card and must be carried by the patient at all times. This card summarises the important side effects for which patients need to seek assistance should they occur. In addition it alerts any other healthcare professional that may treat the patient that they are receiving pembrolizumab through an early access scheme, and carries the details of their own oncologist and specialist nurse who will be managing their treatment, out of hours contact details and the pharmaceutical company contact details.

Contact details

Contact details for reporting AEs:
Email Address: pv.uk@merck.com
Facsimile Transmission: 0032 2402 5990
Telephone Contact: MSD Medical Information number (including out of hours): 01992 467272
Contact email for the EAMS programme: pembrolizumabEAMS@merck.com