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 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:
https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams

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

https://yellowcard.mhra.gov.uk/

MHRA
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Information on the Pharmacovigilance system:

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

All Healthcare Professionals (HCPs), (physicians, pharmacists and nurses) involved with the EAMS will be directed to report all serious adverse events (SAEs) and drug related non serious adverse events (NSAEs), Events of Clinical Interest (ECI) 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 process flow
- AE form
- AE query form
- discontinuation form
- ECI guidance document
- Drug Induced Liver Injury (DILI) guidance.

All HCPs, (physicians, pharmacists and nurses) will be requested to report all serious adverse events, events of clinical interest and pregnancies within 24 hours and drug-related non-serious AEs within 5 days.

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 metastatic or unresectable melanoma where there is a clear unmet medical need, prior to licensing of the product 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 and prior therapy will be collected at the point of first drug supply.

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

- Collection of drug-related non-serious adverse events, pre-specified events of clinical interest and serious adverse events.
- Provision of AE reporting instructions and ECI guidance in a comprehensive physician's pack.
- Reminding of physicians to report AEs with each resupply of drug.
- Reconfirmation in the access and re-supply forms of the responsibility to report all SAEs, pre-specified ECIs, drug related NSAEs and any pregnancies and that they are required to be signed by the prescribing physician for each patient. Provision of training to sites on pharmacovigilance obligations and reporting process
- 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 credit-card 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:

pembrolizumabEAMS@merck.com
Telephone number for MSD Medical Information: 01992 467272