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:
http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm

Healthcare professionals should enroll any patients receiving EAMS medicines in the registry which the pharmaceutical company will have in place to enable systematic collection of information on adverse events.

Suspected adverse drug reactions (ADRs) for any patients, particularly those not enrolled in a study (or registry), can 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. Alternatively, healthcare professionals can report ADRs which occur in patients not enrolled in any study (or registry) directly to the pharmaceutical company who manufactures the EAMS medicine.

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.

Information on the Pharmacovigilance system:

When a prescribing physician requests access for a patient into EAMS, they will receive a set of programme materials from the company which will include detailed information on the collection and reporting of adverse events (AEs) and all the necessary forms and contact details:

- Prescribing Guidance for physician
- Information for the patient
- Patient Treatment Request Form
- Terms of Supply of Product
- EAMS supply form
- Data Collection and Safety Reporting Treating Physician Training (including electronic tool instructions)
- Patient alert card

All Healthcare Professionals involved in EAMS will be instructed to report to the company all serious adverse events (SAEs) within 24 hours and all non-serious adverse events within 7 days of first knowledge of such events. Certain AEs may require additional information and further details will be requested from physicians either at the time of the initial report or as required.

Training for Healthcare Professionals (HCPs)

All prescribing physicians involved with the management of the EAMS will receive training on reporting of AEs and the use of the electronic reporting tool. The training pays particular attention to recognising, managing and reporting AEs.

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 sacubitril/valsartan through EAMS is designed to provide early access to this medicine to patients with symptomatic heart failure with reduced ejection fraction where there is a clear unmet medical need, prior to licensing of this product in the UK.

The prescribing physicians will be requested to provide anonymised patient data for each patient enrolled in EAMS prior to start of treatment. This includes:
• Patient age
• Patient gender
• Previous treatment and current medications
• Underlying co-morbidities

At 1 month, 3 months and 3 monthly thereafter following commencement of treatment, the company will collect updated patient data on the electronic reporting tool. This will also include, the start date of treatment, drug dose, stop date of treatment if applicable and new concomitant medications. The prescribing physicians will report AEs as per the training provided or specify at the routine patient visit that there have been no AEs.

Patient Alert Card
Before treatment starts, all patients will have the scheme explained to them by the prescribing physician 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 most important side effect for which patients need to seek assistance should they occur and carries the details of their own physician who will be managing their treatment.

In addition the card alerts any other healthcare professional that may treat the patient that they are receiving sacubitril/valsartan through an early access scheme. The pharmaceutical company contact details are also included.

Contact details:

Telephone number for Novartis Pharmaceuticals UK Limited Medical Information: 01276 698370

Email: medinfo.uk@novartis.com