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 physician requests entry into the EAMS scheme they will sign a Treatment Access Request form confirming that they will report adverse events to AbbVie.

Once patient eligibility has been confirmed, physicians will receive a Physician's Pack including the EAMS Treatment Protocol which provides:

- information on reporting of adverse events (AEs);
- the adverse event and pregnancy notification reporting forms;
- contact details for reporting to AbbVie.

The treating physician involved with the management of the EAMS will receive training on the reporting of AEs upon set up in addition to the information provided in the EAMS Treatment Protocol. The training pays particular attention to recognising, managing and reporting adverse events.

The EAMS Treatment Protocol directs all healthcare professionals involved with EAMS to report, within 24 hours, any AEs including death, due to any cause, and any pregnancy. The re-supply forms that physicians will receive on a four weekly basis will remind the treating physicians of their reporting obligations to AbbVie and the physician will be required to confirm that all AEs have been reported to AbbVie or that there have been no AEs experienced by that particular patient since the previous supply request. Once treatment has been completed, sustained virologic response **(**SVR) 12 data will be collected, again at this point the physician will be asked to confirm that they have reported all adverse events to AbbVie.

The treating physician will be requested to provide information on the Treatment Access Request form for each patient receiving Glecaprevir/Pibrentasvir through EAMS. Data such as patient identifiers (initials, age, gender), disease history (treatment history, comorbidities, alcohol use), safety data as well as efficacy (SVR12 following completion of treatment) will be collected.

HCPs will be seeing their patients every 4 weeks to check for any adverse reactions, assess if the treatment should be carried on and provide medicine supply for the next 4 weeks of treatment. When an AE occurs, the healthcare professional will be required to collect additional information on the AE Reporting Form and/or Pregnancy Reporting Form and report this to AbbVie. Further follow up, as appropriate, will be requested from healthcare professionals on reports received by AbbVie. Targeted follow-up questionnaires will be sent to the HCP by AbbVie for any adverse event that may be consistent with the following important medical conditions: Hepatitis B virus reactivation, Hepatocellular carcinoma (both recurrent and incident) and hepatic events (i.e. ALT/bilirubin elevation, etc.).

Additional information:

The activities below are additional to spontaneous reporting and are designed to encourage prescribers to report adverse events:

- Collection of any adverse events;
- Provision of training to the treating physician on pharmacovigilance obligations, paying particular attention to recognising, managing and reporting adverse events;
- Provision of adverse event reporting instructions in a comprehensive EAMS Treatment Protocol.
- Confirmation on the re-supply form from the treating physician that adverse events have been reported or no adverse events have been received for that particular patient since the previous supply request.
- Confirmation that adverse events have been reported or no adverse events occurred at the time of reporting SVR12 data to AbbVie.

AbbVie will submit a periodic report every 3 months (whilst the EAMS is ongoing) to the MHRA summarizing any safety findings from the EAMS.

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