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

Risankizumab is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant or contraindicated to tumour necrosis factor-alpha (TNFα) antagonist therapies, vedolizumab and ustekinumab and for the treatment of adolescent patients aged 16 to 17 years with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant or contraindicated to TNFα antagonist therapies.

Information on the Pharmacovigilance system

Prescribing healthcare professionals (HCPs) are able to request enrolment of their patients into the Early Access to Medicines Scheme (EAMS) (**41042/0007**) and access to risankizumab by completing and submitting an electronic Patient Access Form. Prior to enrolment of a patient into the EAMS program, the treating HCP will need to complete electronic training to understand their obligations regarding reporting all adverse events (AEs) and special situations within 24 hours of awareness to AbbVie.

The electronic Patient Access Form will be reviewed to ensure that the eligibility criteria are fulfilled, and AE training completed prior to registering the patient into the EAMS program. Following confirmation of eligibility, each patient will be allocated a unique identifier upon enrolment into the program and the designated vendor (Clinigen) will provide the EAMS materials to the HCP as part of a physician pack containing the following documents:

- EAMS Treatment Protocol – Information on the pharmacovigilance system and requirements for reporting safety data (this document)
- EAMS adverse event reporting form
- EAMS pregnancy reporting form
- EAMS Treatment Protocol – Information for Healthcare Professionals
- EAMS Treatment Protocol – Information for Patients
- Patient Informed Consent Form

The physician pack will include detailed information on the collection and reporting of AEs and all the necessary forms and contact details.

Adverse event/Adverse drug reaction reporting

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

Although not always AEs by regulatory definition, reports of lack of efficacy and at risk scenarios* whether or not there is an associated AE, must be reported.

*At risk scenarios include:

- Exposure during pregnancy (maternal and paternal)
- Exposure during breast-feeding
- Medication errors
- Overdose, Misuse and Extravasation
- Occupational exposure

Prior to enrolment of a patient into the EAMS program, the treating HCP will need to complete electronic training to understand their obligations regarding reporting all AEs and special situations within 24 hours of awareness to AbbVie.

AEs will be reported on the EAMS specific reporting forms and submitted via email to the AbbVie UK Pharmacovigilance department at GBPV@abbvie.com. Additional copies of the AE reporting forms may be accessed via Clinigen Systems portal at https://onlineservices.clinigengroup.com/.

The unique patient number will take the format of RISA-XXNNNN, where RISA represents risankizumab, two letters followed by four random numbers. The unique patient ID number will be used to track patient experience from baseline throughout participation in the EAMS program and will be used on all AE forms submitted to AbbVie. In cases where reported AE information is either incomplete or missing, the AbbVie UK Pharmacovigilance team will implement relevant follow-up activities to enable comprehensive AE assessment and evaluation. Targeted questionnaires will be utilised to follow-up specified AEs of special interest (AESI).

All serious suspected adverse drug reactions (ADRs) will be reported to MHRA within 15 calendar days of receipt. All suspected ADRs with a fatal outcome will be reported to the MHRA within 7 calendar days of receipt, further information will be provided within 8 days. All non-serious suspected ADRs will be reported to MHRA within 90 calendar days of receipt.

If appropriate, all reports will be followed-up as necessary to obtain supplementary detailed information significant for the scientific evaluation of the cases. The data management of all AE/safety information will be in accordance with AbbVie's procedures. In addition, periodic reports will be submitted on a 3-monthly basis for the first year after positive scientific opinion. There will be a one-month period for preparation of the report, e.g., the first periodic report will have a data lock point at 3 months post-opinion and be submitted within 4 months post-opinion. A final periodic report following scientific opinion expiry will be submitted within 1 month after EAMS expiry.

Training for healthcare professionals

All HCPs involved with the management of the EAMS will receive electronic AE reporting training accessed through the Clinigen Systems portal which will include highlighting important risks contained within the Risk Management Plan, in addition to the information they receive in the physician's pack. The training will pay particular attention to ensuring that the HCP can recognise, manage and appropriately report AEs using the EAMS specific AE reporting form. Completion of such training will be documented and kept on record by AbbVie. HCPs will need to attest to have read the AE reporting training with each re-supply request. Additionally, HCPs will be asked to confirm that all AEs experienced since the last re-supply request have been reported or there are no new AEs to report.

HCPs will also be advised through the electronic AE reporting training to educate patients/caregivers to report AEs. In addition, HCPs will be prompted to report any AE associated with the use of risankizumab for 3 months following discontinuation. AbbVie will follow up with HCPs for details of discontinuation or where re-supply of the medicine has not been requested.

Additional information

Mandatory data

The purpose of this data collection is to ensure the safe and effective use of the product in line with the EAMS Treatment Protocol. Following the HCP's registration, HCPs will be requested to confirm that the patient has signed an informed consent form and provide the following baseline characteristics:

- Condition which the product is being used for
- Demography (date of birth, age and gender)
- Diagnosis and severity of Crohn's disease based on clinical assessment
- Medical history including documented recent history of inadequate response to, loss in response to treatment, intolerant or contraindicated to:
    - Tumour necrosis factor (TNF)-α antagonist therapies
    - Vedolizumab (adult patients only)
    - Ustekinumab (adult patients only)
- Dose and duration of treatment
- Underlying co-morbidities
- Documentation of concomitant medications including dose and duration
- All medically confirmed adverse events

Additional data

The data being collected, and their use are described in detail in the 'Patient Access Form'. Entry criteria must be met, and baseline demographic will be provided to AbbVie. No further data will be collected.

Periodic reports

Periodic reports will be submitted on a 3-monthly basis for the first year after positive scientific opinion. There will be a one-month period for preparation of the report, e.g., the first periodic report will have a data lock point at 3 months post-opinion and be submitted within 4 months post-opinion. A final periodic report following scientific opinion expiry will be submitted within 1 month after EAMS expiry.

Contact details

Contact Details for reporting AEs and Special Situations:

Name: AbbVie UK Pharmacovigilance

AE Email Address: GBPV@abbvie.com

AE Telephone Contact: 01628 561092

Contact Email for the EAMS programme (excluding AE reporting):

Clinigen Customer Service UK Email: medicineaccess@clinigengroup.com