

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

A prescribing oncologist may request entry of their patients into the atezolizumab Early Access to Medicines Scheme (EAMS) by completing and submitting an Initial Application and Drug Supply Request Form. Upon review of the individual request and fulfilment of the eligibility criteria, Roche will provide EAMS materials which will include information on the collection and reporting of adverse events.

All Healthcare Professionals (HCP's) involved in the care of patients on EAMS will be instructed to report all adverse events (AE), adverse drug reactions (ADR), special situations (SS) (whether or not there is an associated AE) and any pregnancies within 24 hours of awareness as specified in the Safety Reporting Cover Letter in the physicians pack. The adverse event reporting form is also included in the physician pack. Healthcare Professional can request additional copies of this AE reporting form by sending email to welwyn.atezolizumabeams@roche.com. Additional follow-up may be requested on all reports received to obtain further information.

All adverse events reported will be entered into the Roche safety database and will be linked to the patient by the specific EAMS protocol number and unique patient number.

Training for Healthcare Professionals (HCPs)

In addition to the Physician Pack, a comprehensive AE and SS training will be provided to all relevant HCP's prior to commencement of patient treatment, focusing on recognising, managing and reporting AE/SS/pregnancies during the scheme. Equally, the HCP's obligation to keep their patients fully informed on their treatment will be emphasised. Pertinent patient related supporting documents such as the Patient Alert Card will be provided to facilitate this activity.

Additional information

Provision of atezolizumab through the EAMS is designed to provide early access to this medicine for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma after disease progression following one prior platinum-containing chemotherapy regimen regardless of its setting (neoadjuvant, adjuvant, or metastatic) prior to licensing the product in the UK for this indication.

The prescribing oncologist will be requested to provide the following information by completing an Initial Application and Drug Supply Request for each patient to be enrolled on to the program for eligibility assessment:

- Patient's initials
- Year of birth
- Gender
- Diagnosis (including staging information)
- Histology
- PD-L1 test results (if available)*
- ECOG Performance Status
- Previous treatment history for urothelial carcinoma
- Comorbidities
- Concomitant medications

* The EAMS indication covers all comers, irrespective of PD-L1 status, however the Ventana PD-L1 (SP142) assay is also provided by Roche as a part of the scheme to help prescribing oncologists determine which patient may benefit most from treatment with atezolizumab. If there are no suitable samples available or the PD-L1 test cannot be performed for other reasons or where the prescribing oncologist feels that atezolizumab to be the best option for a specific patient regardless of PD-L1 status, the prescribing oncologists should indicate this at the time of initial application.

For patients approved under this scheme and requiring ongoing drug supply, the HCPs will be required to complete the Re-supply Form provided in the physician pack to request further two treatment cycles. The HCPs will be requested to provide some additional information including the start date of treatment, the dates of treatment cycles since last supply and any new concomitant medications. The HCPs will also be asked for confirmation that they understand and agree with the obligations to report all adverse events to Roche and that they are complying with this requirement. They will be also asked to confirm that all adverse events experienced since the last re-supply request have been reported.

A 3-monthly periodic safety report will be submitted to the MHRA to summarise data on safety and usage of atezolizumab under the scheme

Patient Alert Card

Prior to commencing treatment on EAMS, all patients will receive all the necessary information regarding the scheme and their treatment. Patients will be provided with a Patient Alert Card which is a wallet-sized card that must be carried by the patient at all times during treatment and for at least 5 months after completing treatment with atezolizumab. The card summarises that they are currently receiving atezolizumab, the important side effects for which patients need to seek assistance should they occur, details of the patient's treating oncologist managing their treatment, out of hours contact details and the company contact details.

Contact details

Contact details for reporting Adverse Events/Special Situations/Pregnancies:

SAE Email Address: welwyn.uk_dsc@roche.com

SAE Facsimile Transmission: +44 1707 367582

SAE TELEPHONE CONTACT: +44 1707 367554

Name: UK Drug Safety Centre

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

welwyn.atezolizumabeams@roche.com