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:
Information on AE/SAEs will be explicitly sought from patients by the healthcare professional at each clinic visit by direct questioning. This includes any problems experienced with administering the medication.

If the healthcare professionals treating patients with Oxervate (EAMS medicine) becomes aware or detects an adverse event or adverse drug reaction in a treated patient, the healthcare professional shall fill in the AE/SAE form with all the available information and forward it to Dompé Drug Safety via email (farmacovigilanza@dompe.com) within:

- 24 hours from awareness if the adverse event is serious
- 7 calendar days from awareness if the adverse event is non-serious.

Special events (such as overdose, medication error, pregnancy and lactation) shall also be reported, even if not associated with an Adverse event.
Samples of the AE/SAE form will be delivered to the healthcare professional together with the EAMS protocol and other relevant documents.

An **Adverse Event** (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product.
An **Adverse Drug Reaction** (ADR) is defined as an adverse experience which is a reasonably likely to have been caused by the drug.
A **Serious Adverse Event** (SAE) is defined as any untoward medical occurrence that at any dose:
☐ results in death,
☐ is life-threatening
☐ requires inpatient hospitalization or prolongation of existing hospitalization,
☐ results in persistent or significant disability/incapacity,
☐ is a congenital anomaly/birth defect,
☐ is an important medical event that based upon appropriate medical judgment, may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

Additional information:
No additional active pharmacovigilance activity is currently ongoing for Oxervate.

Periodic reports:

Safety information will be submitted to the regulatory authorities by Dompé at 3-monthly intervals, in the form of periodic reports. Medication errors and eye infection events will be specifically discussed.

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