

Regarding EAMS scientific opinion Glecaprevir/Pibrentasvir 100mg/40mg film-coated tablets for the treatment of chronic hepatitis C (HCV) infection in adults with compensated cirrhosis and at least one of the following:

- genotypes 1, 4, 5 and 6 with compensated cirrhosis previously treated with NS5A inhibitors
- genotypes 2, 3, 5 or 6 with chronic kidney disease (stage 4 and 5)
- GT 3-infected patients previously treated with peg-interferon, ribavirin, and/or sofosbuvir

Dear Medical Director

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed medicines to UK patients that have a high unmet clinical need. **A positive scientific opinion is only issued by MHRA if the criteria for the EAMS are fulfilled, which includes demonstrating a positive benefit risk balance (quality, safety and efficacy assessment)** and the ability of the Company to supply a medicine according to a consistent quality standard.

EAMS medicines are unlicensed medicines. The term 'unlicensed medicine' is used to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. GMC guidance on prescribing unlicensed medicines can be found below:

<http://www.gmc-uk.org/mobile/14327>

Your attention is drawn to the following EAMS procedural assessment for this medicine at the MHRA. A full assessment of the quality, safety and efficacy of **[Glecaprevir/Pibrentasvir 100mg/40mg film-coated tablets]** has been conducted by the MHRA's assessment teams, including pharmacists, toxicologists, statisticians and medical assessors. This assessment process also includes consideration of the quality, safety and efficacy aspects by the UK independent expert committees including Expert Advisory Groups (EAGs) and the Commission on Human Medicines (CHM):

- The Commission on Human Medicines (CHM) advises ministers on the quality, safety and efficacy of medicinal products. The Chair and Commissioners are appointed in accordance with the Code of Practice for Ministerial Appointments to Public Bodies. The Chair and Commissioners follow a code of practice, in which

they are precluded from holding personal interests. The Commission is supported in its work by Expert Advisory Groups (EAGs), covering various areas of medicine.

<https://www.gov.uk/government/organisations/commission-on-human-medicines/about>

- Chemistry, Pharmacy and Standards EAG, which advises the CHM on the quality in relation to safety and efficacy of medicinal products

<https://www.gov.uk/government/organisations/commission-on-human-medicines/about/membership#chemistry-pharmacy-and-standards-eag>

A Pharmacovigilance system for the fulfilment of pharmacovigilance tasks has been put in place for this EAMS medicine, including a risk management plan. 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. Healthcare professionals should be aware of their obligations to report adverse event information upon enrolment of any patients receiving EAMS medicines in the scheme. They will be required to follow the process which the pharmaceutical company who manufacture the EAMS medicine has in place to enable systematic collection of information on adverse events.

For more detailed information on this EAMS medicine, please refer to the EAMS treatment protocol for healthcare professionals, EAMS treatment protocol for patients and EAMS treatment protocol for pharmacovigilance.

<https://www.gov.uk/government/collections/early-access-to-medicines-scheme-eams-scientific-opinions>