PRAC – Update

PCWP Meeting
EMA, 22 Nov 17

Prsented by: Marco Greco

Public Hearing: a learning process

- Overall positive reaction
- Raised expectations
- Chance for learning and improving

Most relevant ongoing procedures/1

- **PRAC requested to re-examine review of modified-release paracetamol**
- Following the PRAC's recommendation of 1 September 2017, some of the marketing authorisation holders involved with this review have requested a re-examination. Upon receipt of the grounds for their requests, the PRAC has started a re-examination, which is expected to conclude at the PRAC meeting of 27-30 November 2017.

Most relevant ongoing procedures/2

- **PRAC has reccomended further restrictions for multiple sclerosis medicine Zinbryta due to risk of liver damage.**
- EMA and PRAC are recommending further restrictions on the use of the multiple sclerosis medicine Zinbryta (daclizumab) following a review of the medicine's effects on the liver.
- The review found that unpredictable and potentially fatal immune-mediated liver injury can occur during Zinbryta treatment and for up to 6 months after stopping Zinbryta.
- Following theprovisional measures introduced in July 2017, the PRAC adopted final measures aimed to improve liver monitoring and limit use of Zinbryta to patients who have had an inadequate response to at least two disease modifying therapies and cannot be treated with other such therapies.

Most relevant ongoing procedures/3

- **PRAC starts new review of hydroxyethyl-starch containing products**
- The PRAC has started a new review of medicines containing hydroxyethyl-starch (HES).
- These products are used for the management of low blood volume caused by acute blood loss, where treatment with alternative infusion solutions known as ‘crystalloids’ is not considered to be sufficient. HES medicines are given by infusion into a vein and are used as volume expanders to prevent shock following acute bleeding.
- The review has been triggered by results from two studies indicating that HES solutions are being used outside their authorised uses, including in critically ill patients and those with sepsis and kidney injury, despite restrictions introduced in 2013 to reduce the risks of kidney problems and deaths.
- The PRAC invites all stakeholders (e.g. healthcare professionals, patients’ organisations, the general public) to submit data relevant to this procedure.

Most relevant ongoing procedures/4

- **Review of flupirtine-containing medicines started**
- The PRAC has started a new review of the benefits and risks of flupirtine-containing medicines for pain relief.
- Flupirtine is used to treat acute pain for up to two weeks in patients who cannot use other pain medicines such as opioids or nonsteroidal anti-inflammatory medicines (NSAIDs). Additionally, patients should have their liver function monitored weekly to avoid liver problems.
- The review follows evidence that flupirtine is not always being used in line with the restrictions that were introduced after an earlier EMA review in 2013, and of reports of serious liver problems associated with flupirtine use.