EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Feedback from PRAC

April 2018

Key discussions/announcements

1. Outcome of the Valproate Referral (Art 31)

2. Announcement of Public Hearing as part of the Fluoroquinolone/Quinolone Referral (Art 31)

3. Announcement of Referral (Art 31) on Methotrexate

Valproate Referral Recommendations

New measures to avoid Valproate exposure in pregnancy:

Where licensed for migraine or bipolar disorder: –Must not be used in pregnancy. (Now Contraindicated)

For Epilepsy: Must not be used unless the conditions of a new pregnancy prevention programme are met.

A review of treatment to be carried out, at least annually, by a specialist

Introduction of a new risk acknowledgement form that patients and prescribers will go through to confirm that appropriate advice has been given and understood

Visual reminder on packaging which may/may not be a symbol/pictogram

Patient reminder card will be attached to the outer packaging

Ongoing: pregnancy tests; counselling; effective contraception & annual reviews

Public hearing to be organised for quinolone and fluoroquinolone antibiotics

Why - As part of its Art 31 review of quinolone and fluoroquinolone antibiotics

When - On 13th June 2018 (during the June PRAC meeting) Individuals can participate as a speaker or observer.

Three questions to be addressed;

- 1. What is your view on the role of quinolones and fluoroquinolones in the treatment of infections?
- 2. What is your view of the risks associated with quinolone and fluoroquinolone use?
- 3. In your opinion, what further measures could be taken to optimise the safe use of quinolones and fluoroquinolones?

Who- EMA will select speakers based on their experience with these medicines

Aim - to achieve a wide representation of stakeholders across the EU. (Please spread the word among your networks)

Methotrexate - Article 32 Referral.

To review the risk of dosing errors

Methotrexate is used to treat various cancers and various inflammatory conditions

Medication errors due to daily, instead of weekly administration leading to serious adverse events

Will evaluate the effectiveness of risk minimisation measures intended to prevent such errors.

Recommend whether further measures are required

Review will include oral and parenteral preparations

PRAC will liaise with relevant stakeholders as part of the procedure