

Feedback from the PRAC

PCWP/HCPWP joint meeting, 28 June 2017

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Referrals

Started

Valproate:

Use in pregnancy and women of childbearing age. To consider if risks of these medicines require further restrictions of use

Concluded

Gadolinium:

Concluded assessment of gadolinium agents used in body scans and recommends regulatory actions, including suspension for some marketing authorisations

Factor VIII:

Concluded that there is no clear and consistent evidence of a difference in inhibitor development between the two classes of factor VIII medicines.

Referrals

Ongoing

Paracetamol S/R Products:

Risk of B/R

Products containing Lactose of Bovine origin for IV/IM use:

Cows milk protein and potential for severe reaction with patients allergic to cows milk.

Systemic & Inhaled Quinolones & Fluorquinolones:

Reviewing serious side effects mainly affecting muscles, joints and the nervous system

Retinoids:

Evaluate measures currently in place for pregnancy prevention and for minimising the possible risk of neuropsychiatric disorders.

Signals

Uptravi:

Concluded that the data examined did not suggest an increase in mortality with Uptravi and the medicine can continue to be used by both new and existing patients.

Loperamide:

Signal of serious cardiac events with high doses of loperamide from abuse and misuse.

Leflunomide:

Signal of falsely decreased ionised calcium levels

Temozolomide:

Signal of meningoencephalitis herpetic

High Strength and Fixed Combination Insulin containing products:

Signal of potential increased risk of medication error associated with pre-filled pens and cartridges presentations, leading to inadequate diabetes control