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- **Safety Review of Esmya (Ulipristal)**

The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) is currently reviewing the benefits and risks with Esmya (Ulipristal), following reports of serious liver injury, including liver failure leading to transplantation. link Pending the outcome of the review:

- Esmya treatment should not be initiated in new patients or in patients who have finished a previous treatment course.
- Patients being currently treated with Esmya should be consulted about the issue and a decision made about continuing treatment. If treatment is continued then liver function should be monitored at least monthly. If transaminase levels > 2 times the upper limit of normal then Esmya treatment should stopped and patient closely monitored. Patients must be advised that if they develop any signs or symptoms compatible with liver injury (nausea, vomiting, right hypochondrial pain, anorexia, asthenia, jaundice, etc.), that these need to be investigated immediately and liver function tests performed.
- All patients must have their liver function tested 2-4 weeks after stopping treatment.

- **Warfarin and Miconazole interaction**

The MHRA has issued a reminder that patients taking warfarin should be advised not to use over-the-counter miconazole oral gel (Daktarin) link as it can potentiate the anticoagulant effect of warfarin resulting in increases in INR values (and subsequent bleeding complications). If miconazole oral gel is prescribed in a patient on warfarin, they should be closely monitored and advised that if they experience any sign of bleeding, they should stop miconazole oral gel and seek immediate medical attention.

- **Serious cardiac events associated with high doses of loperamide**

The MHRA has issued a Drug Safety Update about serious cardiac events including QT prolongation, torsades de pointes, and cardiac arrest in patients who have taken high or very high doses of loperamide as a drug of abuse or for self-treatment of opioid withdrawal. link

Does long-term prescribing of Proton Pump Inhibitors (PPIs) need to be reassessed?

An article in the Drugs and Therapeutics Bulletin link reviews the long-term safety of PPIs and considers whether long-term prescribing needs to be reassessed. The article acknowledges that PPIs are very effective for the management of dyspepsia, reflux and peptic ulcer disease, and are generally well tolerated with a low incidence of short-term adverse effects. The concern is that regular use over a long period has become commonplace and may be associated with a number of adverse effects e.g. Clostridium difficile infection, bone fractures, hypomagnesaemia and vitamin B12 deficiency. In the conclusion the DTB recommends that:

- PPIs should only be prescribed where the benefits outweigh the potential long-term risks e.g. oesophageal stricture, Barrett's oesophagus, a history of a bleeding gastrointestinal ulcer and gastroprotection for concomitant use of a NSAID.
- Patients with less severe conditions (e.g. indigestion) should be given advice on lifestyle changes before being offered a PPI. If a PPI is required it should be for the shortest duration at the lowest effective dose.

In those taking PPIs for no clear indication, stopping the PPI should be considered. In order to reduce "rebound symptoms" it may be necessary to gradually reduce the PPI dose. Short term use of an antacid or alginate may be needed to manage rebound symptoms which may mimic the original indication.

- **Outbreaks of Measles**

There were 21,315 cases of measles and 35 deaths recorded in Europe in 2017—a 400% increase on the previous year when there was a record low of 5,273 cases. The UK recently achieved WHO measles elimination status and so the overall risk of measles to the UK population is low. However the ongoing measles outbreaks in Europe remain a challenge as recent measles outbreaks in Leeds, Liverpool, Birmingham, Manchester and Surrey are all linked to the ongoing large outbreaks in Europe. Public Health England is urging anyone planning to travel to Europe to make sure they are up to date with their MMR vaccines. Unvaccinated people travelling to Romania, Italy and Germany, where there are currently large measles outbreaks, are at particularly high risk. The MMR vaccine is available to all adults and children who are not up to date with their two doses. It can be given from six months of age before travel to a high risk country.

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