UKMi Observatory
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Observatory of recent safe medication practice research, reports, and publications

Presented by
Sarah Cavanagh, Acting Director East Anglia Medicines Information
sarah.cavanagh@ipswichhospital.nhs.uk
(Slides prepared by Natalie Johnston)
MHRA

• **Class 3 Medicines Recall: Lynparza capsule 50mg (olaparib):** AstraZeneca is recalling batch NG327 as the level of olaparib polymorphic form L exceeds the registered specification limit.

• **Aquilon series of nebulisers – CE mark withdrawn and supply ceased:** Manufactured by AFP Medical – do not use affected nebulisers as they have been manufactured to unknown standards and their safety cannot be verified (MDA/2018/008).

• **Class 4 Medicines Defect Information:** **Bleo-Kyowa, powder for solution for injection, 15,000 IU:** Caution in Use - Distribute to Hospital Pharmacy, Ward, Chemotherapy Unit and Clinic Level. (EL (18) A/05)

• **Drug Safety Update - Head lice eradication products: risk of serious burns if treated hair is exposed to open flames or other sources of ignition, eg, cigarettes.** Pharmacists should tell people about the risk of fire when they discuss head lice eradication options.
• EMA recommends immediate suspension and recall of multiple sclerosis medicine Zinbryta (daclizumab) following urgent review. Evidence indicates risk of serious inflammatory brain disorders: 12 reports of serious inflammatory brain disorders worldwide, including encephalitis and meningoencephalitis. Three of the cases were fatal.

• Prostate cancer medicine Xofigo (radium-223 dichloride) must not be used with Zytiga (abiraterone acetate) and prednisone/prednisolone: ongoing clinical study shows an increased risk of death and fractures with the combination.
• **Letter to Healthcare Professionals - ellaOne (ulipristal acetate) post-marketing surveillance:** Pregnancy registry to provide data in terms of safety and pregnancy outcome in pregnancies exposed to ellaOne.

• **Letter to Healthcare Professionals - Ocaliva▼ (obeticholic acid):** Reinforced differential dosing recommendations in primary biliary cholangitis (PBC) patients with moderate and severe hepatic impairment.

• **Letter to Healthcare Professionals – ERWINASE (crisantaspase):** Vials from batch 186G* should be used with a 5-micron filter needle due to particulate matter which was observed bound to the stopper and/or present on the lyophilized cake of some vials of ERWINASE.

• **Letter to Healthcare Professionals - Velcade (bortezomib) 3.5 mg vials:** Potential defect of rotating and/or loose metal cap therefore potential risk to sterility.
• **Letter to Healthcare Professionals – Esyma (ulipristal acetate):** Restrictions on the use and important new warnings of serious liver injury and recommendations for liver monitoring

• **Letter to Healthcare Professionals - Eperzan ▼ (albiglutide):** Reminder letter regarding discontinuation. Commercial supplies will no longer be available in the UK from 1st July 2018.

• **Other communication - Inhixa (enoxaparin):** Due to a rare misalignment during manufacture, a small proportion of INHIXA syringes have a pre-activated needle guard. Not deemed to present a risk to patients.
• **Rivastigmine patch (Exelon/Prometax)** - Instructions for use and a patient diary including medication record sheets for patients that have been prescribed Exelon Patch or Prometax Patch (rivastigmine transdermal system) to ensure the correct use of the patch.

• **Risk Minimisation Material for use of tenofovir disoproxil in adults and adolescent children with chronic hepatitis B** - Important advice pertinent to all tenofovir disoproxil products is provided on the management of potential renal effects, monitoring, dose adjustment, and when to interrupt treatment. Advice also covers management of bone effects of the drug in adolescent patients.

• **Risk minimisation materials for Gilenya (fingolimod) tablets** - Fingolimod causes transient heart rate reduction and may cause AV conduction delays following initiation of treatment. All patients should be monitored for a minimum of 6hrs on treatment initiation. The manufacturer has provided a prescriber checklist and patient reminder cards.
Drug shortages and discontinuations

• **Shortage of Ketamine (Ketalar®) 10mg injection**
  Pfizer, as the sole licensed supplier, is currently experiencing supply problems with Ketalar 10mg/ml in the UK. The 10mg/ml is anticipated to be out of stock from the end of March until the end of April. Supplies of the 50mg/ml product are unaffected and will remain available during this time. Imports are available; this memo discusses risk management issues related to their use. [https://www.sps.nhs.uk/articles/shortage-of-ketamine-ketalar%c2%a8-injection-all-strengths/](https://www.sps.nhs.uk/articles/shortage-of-ketamine-ketalar%c2%a8-injection-all-strengths/)

• **Shortage of co-trimoxazole for infusion 16 mg/ 80mg per mL**
  Aspen they are out of stock of co-trimoxazole injection until June 2018. This memo discusses the course of action to be taken to conserve stock for critical areas, use of imports, and alternative treatment options. [https://www.sps.nhs.uk/articles/shortage-of-septrin-co-trimoxazole-for-infusion-16-mg-80mg-per-ml/](https://www.sps.nhs.uk/articles/shortage-of-septrin-co-trimoxazole-for-infusion-16-mg-80mg-per-ml/)
Drug shortages and discontinuations

- **Shortage of Xylocaine (lidocaine) 10 mg Spray**
  Aspen, the sole supplier is out of stock until the end of March 2018. This memo provides advice on how to manage the shortage and potential alternative treatment options. [https://www.sps.nhs.uk/articles/shortage-of-xylocaine-lidocaine-10-mg-spray/](https://www.sps.nhs.uk/articles/shortage-of-xylocaine-lidocaine-10-mg-spray/)

- **Shortage of salbutamol injection 500 micrograms (0.5mg) in 1ml (Ventolin®)**
  GSK, the sole supplier of salbutamol injection, has reported a problem with supply, predicted to be from 5th March until week commencing 16th March. [https://www.sps.nhs.uk/articles/shortage-of-salbutamol-injection-500-micrograms-0-5mg-in-1ml-ventolin/](https://www.sps.nhs.uk/articles/shortage-of-salbutamol-injection-500-micrograms-0-5mg-in-1ml-ventolin/)
Demo brand of magnesium sulfate injection (supplied by Kent): Risk of incorrect dosing/administration from misinterpretation of packaging

NW Regional QA have been made aware of a serious clinical incident involving magnesium sulfate 50% 10ml ampoules (500mg per mL), 50 pack size.

Please ensure users are made aware of this as appropriate.
Independent report

**Medication errors: Short Life Working Group report**

Recommendations to reduce medication-related harm in England.

Published 23 February 2018
From: Department of Health and Social Care

Documents

- Report of the Short Life Working Group on reducing medication-related harm
  - PDF, 204KB, 24 pages

Related content
- Policy
- Patient safety

National guidance, publications and resources

• Medicines Use and Safety Update – March 2018

• FDA Drug Safety Communication: FDA review finds additional data supports the potential for increased long-term risks with antibiotic clarithromycin (Biaxin) in patients with heart disease
  The FDA is advising caution before prescribing the antibiotic clarithromycin (Biaxin) to patients with heart disease because of a potential increased risk of heart problems or death that can occur years later.

• Archived NPSA alerts now available through SPS website -
This month’s papers - overview


This month’s papers - overview

- Lee et al. **Pediatric Medication Safety in the Emergency Department** *American Academy of Pediatrics*
  http://pediatrics.aappublications.org/content/141/3/e20174066..info


  http://www.ajhp.org/content/75/5_Supplement_1/S1.long?ssocomponent=Info&ssosso-checked=true

- Cheung S et al. **Audit on the Use of Dangerous Abbreviations, Symbols, and Dose Designations in Paper Compared to Electronic Medication Orders: A Multicenter Study** *Annals of Pharmacotherapy.*
  https://www.researchgate.net/publication/320888385_Audit_on_the_Use_of_Dangerous_Abbreviations_Symbols_and_Dose_Designations_in_Paper_Compared_to_Electronic_Medication_Orders_A_Multicenter_Study
This month’s papers - overview


- Brantley A et al Bridging gaps in care: Implementation of a pharmacist-led transitions-of-care program Am J Health Syst Pharm. http://www.ajhp.org/content/75/5_Supplement_1/S1?sso-checked=true

Help Shape the future of NHS patient safety investigations

Help shape the future of NHS patient safety investigations

We have launched an engagement exercise seeking views on how and when the NHS should investigate Serious Incidents
An observational feasibility study of a new anaesthesia drug storage tray

• Medication errors in anaesthetics are serious
• This study used ‘rainbow trays’ in theatres to reduce drug errors related to anaesthesia
• Each compartment colour-coded by drug class
• The aim is:
  • to reduce errors in selection
  • and reduce ‘syringe swap’
• 30 cases observed at 3 NHS Trusts
• 20 of which used the ‘rainbow trays’
• Qualitative analysis then used through interview of anaesthetists after observation

Conclusion
Using ‘rainbow trays’ in clinical practice would be feasible and has the potential to reduce drug errors, however, more research is needed into the actual effect of using these trays on the prevalence of drug errors.