Important New Evidence Service

In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary April 2017

Monthly News Update

Welcome to the KINES Monthly News Update for April 2017. Other recent 'KINES Updates' have discussed:

- A Swedish cohort study, which reported reduced mortality and hospitalisation for heart failure in men receiving erectile dysfunction treatments.
- A meta-analysis finding limited efficacy of non-steroidal anti-inflammatory drugs (NSAIDs) for spinal pain.
- A UK cohort study looking at statin prescribing in people with severe mental illness.

Update from NICE:

- NICE has published new guidance on the management of medicines for adults receiving social care in the community. This wide-ranging guideline covers governance arrangements and joint working between health and social care, assessing the medicines support needs of patients, training and competency of staff, record keeping, ordering, supply, storage and disposal of medicines.
- An evidence summary is also available on the off-label use of inhaled tobramycin for treating exacerbations caused by *Pseudomonas aeruginosa* in non-cystic fibrosis bronchiectasis.

Regulatory agency safety update:

- Safety updates from the MHRA this month included:
    - An article highlighting the recent Patient Safety Alert for valproate, asking all organisations to undertake systematic identification of women and girls taking valproate medicines. Babies born to mothers who take valproate medicines during pregnancy have a 30–40% risk of developmental disability and a 10% risk of birth defects. Yet despite multiple communications to prescribers, there is evidence that women are still not aware of the risk. The European Medicines Agency (EMA) is also currently considering whether further regulatory action for valproate is necessary.
    - A request to healthcare professionals to report any suspected adverse effects, including after discontinuing treatment, with fingolimod (Gilenya) or other treatments for multiple sclerosis. This follows 2 articles describing suspected rebound syndrome in patients stopping fingolimod treatment, some of whom were switched to other treatments.
    - Advice on dose reductions with the leukaemia treatment ponatinib (Iclusig) to reduce the risk of serious vascular occlusive events.
- The EMA has concluded its safety review of the pulmonary arterial hypertension (PAH) treatment selexipag (Uptravi), which was initiated following 5 patient deaths in France. The review found that the death rate was in line with other PAH medicines. The medicine can continue to be used by both new and existing patients, with no changes required to prescribing information.

NHS England/Department of Health/Public Health England:

- Widely covered in last month's press, NHS England is to review low value prescription items, with a view to introducing new guidance for CCGs. The first 10 medicines to be considered are reported to be: co-proxamol; omega 3 and fish oils; lidocaine plasters; rubefacients; liothyronine, tadalafil, doxazosin MR, fentanyl, gluten free foods and travel vaccines.
- NHS England has published the following two sets of guidance about involving people in health care:
    - Patient and public participation in commissioning health and care: statutory guidance for CCGs and NHS England
    - Involving people in their own health and care: statutory guidance for CCGs and NHS England

  The guidelines set out the principles, legal duties and key actions for CCGs and NHS England.
- Public Health England's latest 'Vaccine update' includes details of upcoming addition of hepatitis B to the routine childhood vaccination programme. This will be delivered via the use of a new product (Infanrix hexa [DTaP/IPV/Hib/HepB]), administered at 8, 12 and 16 weeks, and will be available for babies born on or after the 1st August 2017.

Other news:

- The BMA has published a briefing paper on prescribing in chronic pain (Chronic pain: supporting safer prescribing of analgesics) The paper was developed in collaboration with the Faculty of Pain Medicine of the Royal College of Anaesthetists, who also recently published the comprehensive Opioids Aware resource on the use of opioids.
- A new respiratory resource, RightBreathe (www.Rightbreathe.com) has been launched. The tool brings together information on inhalers, spacer devices and respiratory pathways, to help with the selection, prescribing, and on-going use of inhalers. Its overall aim is to optimise medicines use in this increasingly complicated area.
- The Faculty of Sexual and Reproductive Health has released the latest update to its Guideline on Emergency Contraception.

Drug update:

Launched

- Two new oral treatments have been launched for rheumatoid arthritis (RA). Both belong to a new drug class and are inhibitors of Janus kinase (JAK) enzymes, which mediate signalling of multiple cytokines implicated in RA.
    - Baricitinib (Olumiant; Eli Lilly) is licensed for the treatment of moderate to severe active RA in adults who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Olumiant may be used as monotherapy or in combination with methotrexate (MTX) (see SPC for available data on different combinations). The recommended dose is 4 mg once daily; a lower 2 mg dose may be used in some patients. The 28-day treatment cost (28 x 4 mg tablets) is £805.56 (MIMS, Apr-17). Treatment should be initiated by physicians experienced in the diagnosis and treatment of RA.
    - Tofacitinib (Xeljanz; Pfizer) is licensed in combination with MTX for the treatment of moderate to severe active RA in adults who have responded inadequately to, or who are intolerant to one or more DMARDs. It can also be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate. The recommended dose is 5 mg twice daily. The 28-day treatment cost (56 x 5 mg tablets) is £690.03 (MIMS, Apr-17). Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA.
- NICE technology appraisal guidance is in development for both products, and is due to be published in September for baricitinib and December for tofacitinib.

SPC changes / license extensions

- The SPCs for DuoResp Spriomax 160/4.5 and 320/9 inhalers (budesonide/formoterol) have been updated with regard to FEV_1 thresholds specified in the licensed indications for COPD (updated from FEV_1 < 50% predicted normal to FEV_1 <70% predicted). This brings the FEV_1 values in line with those specified for the originator products (Symbicort 200/6 and 400/12 inhalers), to which the DuoResp inhalers are equivalent.

SMC/AWMSG Update *(Please see links for full SMC and AWMSG advice.)*:

- The Scottish Medicines Consortium (SMC) has published the following advice this month:
    - Accepted for use in NHS Scotland: emtricitabine/tenofovir disoproxil (Truvada*; pre-exposure prophylaxis of HIV-1*); insulin aspart (Fiasp; *diabetes*); trastuzumab emtansine (Kadcyla; *single agent use in breast cancer*)
    - Accepted for restricted use: daclizumab (Zinbryta; *multiple sclerosis*); ibrutinib *(*Imbruvica*; chronic lymphocytic leukaemia [CLL]*); ixekizumab (Taltz; *plaque psoriasis*)
    - Not recommended: ofatumumab (Arzerra; *CLL*) tenofovir alafenamide (Vemlidy; *Hepatitis B*) ticagrelor (Brilique; *extended treatment for prevention of atherthrombotic events*)

- The All Wales Medicines Strategy Group Consortium (AWMSG) has published the following advice this month:
    - Recommended as an option: idelalisib (Zydelig; *monotherapy, refractory follicular lymphoma*)