



Important New Evidence Service In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary January 2017

Monthly News Update

Welcome to the KINES Monthly News Update for January 2017. Other recent 'KINES Rapid Updates' have covered:

- A [meta-analysis](#) that has questioned the role of duloxetine in the treatment of stress urinary incontinence
- An [observational study](#) investigating proton pump inhibitors and risk of community acquired pneumonia
- A [Canadian study](#) in which the diagnosis of asthma was re-evaluated in a cohort of adults. Current asthma was excluded in a third of participants completing the study.

Update from NICE:

- NICE has published new guidance on [Antimicrobial stewardship: changing risk-related behaviours in the general population](#). Recommendations that relate to primary care include that both verbal and written advice is given to patients on managing self-limiting infections (*we suggest [Target toolkit resources](#)*) and on the correct use of antibiotics (e.g. not sharing or keeping antimicrobials; returning unused products for safe disposal by a pharmacy; do not dispose in toilets or sinks.). Safety-netting advice should be routinely given (likely symptom duration, action to take if symptoms get worse or there are adverse effects from treatment; when to ask again for medical advice).
- [Mepolizumab \(Nucala\)](#) has been [recommended](#) by NICE as an option for add on treatment for severe refractory eosinophilic asthma in adults. Several restrictions apply, including thresholds for eosinophil counts, optimisation of standard treatment, history of exacerbations, and use of systemic corticosteroids. NICE has also [recommended sofosbuvir–velpatasvir \(Epclusa\)](#) as an option for treating chronic hepatitis C.
- The latest update to the [NICE's Key Therapeutic Topics](#) has been published. New topics are: multimorbidity and polypharmacy; psychotropic medicines in people with learning disabilities whose behaviour challenges; safer insulin prescribing; and medicines optimisation in long-term pain. Dual-therapy with renin-angiotensin system drugs and first-choice antidepressants have been retired as topics. 'Antibiotics for uncomplicated urinary tract infections' has been incorporated into the antimicrobial stewardship topic.
- NICE is currently consulting on new guidance on asthma management. In the latest [draft guidance](#), low dose inhaled corticosteroid (ICS) remains initial maintenance therapy, but, if symptoms persist, the recommendation is to add a leukotriene receptor antagonist (LTRA) (i.e. montelukast or zafirlukast) to an ICS. This differs from current [BTS/SIGN guidance](#), which, for adults, recommends the addition of a long-acting beta-agonist (LABA) to an ICS as initial add-on therapy. This is based on NICE's conclusion that LTRAs and combination LABA/ICS are both clinically effective, but LTRA is a more cost-effective [option](#) (*BTS/SIGN does not consider cost-effectiveness*). NICE's proposed 'step up' sequence for adults is broadly as follows:
Low dose ICS → Low dose ICS + LTRA → fixed dose ICS/LABA (using a low maintenance ICS dose) +/- LTRA → Maintenance and Reliever Therapy (MART) using a low ICS dose +/- LTRA → MART or fixed dose ICS/LABA using a moderate ICS dose → fixed-dose ICS/LABA using a high ICS dose
[Consultation](#) closes on 16 February 2017. The final guideline is expected to be published in June 2017.

Regulatory agency safety update:

- The MHRA has warned there have been several incidents with insertion tubes for [Mirena](#) being mounted the wrong way. The incidents have all been related to one product batch (TU01BPE). Any incorrectly mounted tubes should be reported to the manufacturer.
- MHRA has advised of an increased risk that some patients may experience psychiatric symptoms, including depression and suicidal thoughts, with [apremilast \(Otezla\)](#), a phosphodiesterase-type-4 inhibitor used in the treatment of plaque psoriasis or psoriatic arthritis. Patients should be advised to report mood changes. Benefits and risks of starting or continuing treatment should be assessed where there is a history of psychiatric symptoms, or where patients are taking other medicines likely to cause psychiatric symptoms. Treatment should be stopped if new symptoms occur or existing symptoms worsen. These events are uncommon, with an estimated frequency of between 1 to 10 cases per 1000 treated patients.
- Finally, there are two MHRA updates concerning hepatitis C treatments. The first is that [INR should be monitored](#) closely in patients receiving direct-acting hepatitis C antivirals who are also receiving vitamin K antagonists (e.g. warfarin). This is due possible changes in liver function during treatment. Secondly, the MHRA has reiterated the [EMA's recommendations](#) that all patients should be [screened for hepatitis B](#) before starting treatment with direct-

acting hepatitis C antiviral interferon-free regimens. Patients who are co-infected with hepatitis B and C are at risk of hepatitis B reactivation, and should be monitored and managed according to current clinical guidelines. Patients receiving these treatment regimens should be asked to inform their doctor or pharmacist about hepatitis B infections, as they may need to be monitored more closely.

NHS England/Department of Health/Public Health England:

- Public Health England's (PHE) latest edition of [Health Matters](#) calls for further action on high blood pressure. GP teams are being asked to increase opportunistic blood pressure testing and prioritise detection, treatment and management, as part of local cardiovascular disease prevention strategies.
- PHE has published a fact for health professionals on [HPV vaccination and cervical cancer](#), which addresses some common myths about the vaccine.

Other news:

- Specialist Pharmacy Services has produced a [document](#) listing the various information resources that are available to help answer medicines-related questions. The document may be of use to pharmacists taking on new roles in general practices.
- Asthma UK has published the findings of its [latest annual survey](#). Responses indicated that provision of asthma action plans had increased (received by 42% of respondents in 2016 compared with 24% in 2013). The proportion of respondents receiving the 3 measures of basic care (*annual asthma review, a written asthma action plan, checking inhaler technique*) was also up (33% for 2016), although, as pointed out in the report, two thirds of respondents indicated they had not received this basic level of care.
- The UK Inhaler Group, a coalition of not-for-profit organisations and professional societies with an interest in promoting the correct use of inhaled therapies, has issued an [inhaler standards and competency document](#). It provides a framework to support and help assess standards in healthcare professionals who provide advice to patients on inhaler technique. The document includes criteria to assess healthcare professionals' competency, as well as checklists to evaluate patients' proficiency.

Drug Update:

SPC changes / license extensions

- The license for [Symbicort Turbohaler \(budesonide/formoterol fumarate\) 100/6](#) has been extended to include the use of Symbicort Maintenance and Reliever Therapy (SMART) in adolescents (12 years and older).
- [Fluenz Tetra](#) (influenza nasal spray vaccine) is now contraindicated where there is a history of severe allergic reaction to eggs or to egg proteins.

Launched

- [Qtern](#), a combination tablet containing 5 mg saxagliptin and 10 mg dapagliflozin, has been launched for the treatment of type 2 diabetes. It is indicated for use when metformin and/or sulphonylurea and one of the monocomponents of Qtern do not provide adequate glycaemic control, or where patients are already treated with the free combination of dapagliflozin and saxagliptin. The cost of Qtern work out less than the combined cost of the monocomponents (28 day costs: Qtern £49.56; 5 mg saxagliptin + 10 mg dapagliflozin £68.19 [*MIMS, Jan-16*])
- The glucagon-like peptide 1 (GLP-1) receptor agonist [liraglutide \(Saxenda\)](#) has been launched for use in weight management. The licensed indication is as an adjunct to diet and exercise for weight management in adults with a BMI of: $\geq 30\text{kg/m}^2$ (obese); or $\geq 27\text{kg/m}^2$ to $< 30\text{kg/m}^2$ (overweight) with at least one weight-related comorbidity. The 30-day treatment cost for a maintenance dose of 3 mg daily is £196.20 (*MIMS Jan-16*).

On the Horizon:

- Final approval has been given for [Fiasp](#), a new formulation of insulin aspart (NovoRapid), which, according to the manufacturer, has new excipients to provide earlier insulin action. [Suliqua](#), a fixed-ratio combination of insulin glargine and the GLP-1 receptor agonist lixisenatide, has also received final approval. It is licensed for use in type 2 diabetes in combination with metformin, where metformin alone or combined with another oral glucose lowering agent or basal insulin have failed to improve glycaemic control. Launches in Europe will commence in the first half of 2017 for Fiasp and the second quarter of 2017 for Suliqua.

SMC/AWMSG Update (Please see below verdicts for full advice.):

- The All Wales Medicines Strategy Group has accepted the following for restricted use in NHS Wales: [isavuconazole](#) (Cresemba; *treatment of aspergillosis and mucormycosis*); [fingolimod](#) (Gilenya; *multiple sclerosis*); [adalimumab](#) (Humira; *Crohn's in children*); [ivacaftor granules](#) (Kalydeco granules; *cystic fibrosis in children*)
- The Scottish Medicines Consortium (SMC) has published the following advice this month:
 - Accepted for use in NHS Scotland: [elbasvir-grazoprevir](#) (Zepatier; *hepatitis C*);
 - Accepted for restricted use: [buprenorphine transdermal patch](#) (Butec; *chronic non-malignant pain*); [dalbavancin](#) (Xydalba; *skin infection*); [deferasirox](#) (Exjade; *iron overload*); [eltrombopag](#) (Revolade; *idiopathic thrombocytopenic purpura in children*); [pembrolizumab](#) (Keytruda; *non-small cell lung carcinoma*)
 - Not recommended: [carfilzomib](#) (Kyprolis; *multiple myeloma*); [daratumumab](#) (Darzalex, *multiple myeloma*); [oestrogens, conjugated, bazedoxifene acetate](#) (Duavive; *oestrogen deficiency*)