Specialist Pharmacy Service New Medicines Newsletter

June 2018

This newsletter is produced by the UKMi horizon scanning service and highlights recent significant medicines regulatory changes. These changes are recorded in the New Medicines section of the SPS website. New medicines monographs added to the SPS website are also listed in this newsletter, plus a Focus section of medicines in development for a specific disease.

More detailed information on medicines expected to launch in the next 12 months and on marketed medicines that are expected to have major new indications approved can be found in Prescribing Outlook – New Medicines.

Regulatory changes in the EU

Launched in the UK

Ferric maltol (*Feraccru*)	Treatment of iron deficiency in adults [licence change]
Dolutegravir + rilpivirine (*Juluca*)	Treatment of HIV-1 infection in adults who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for ≥6 months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor or integrase inhibitor
Insulin lispro biosimilar (*Insulin lispro Sanofi*)	Treatment of adults and children with diabetes mellitus who require insulin for maintenance of normal glucose homeostasis, and for initial stabilisation of diabetes mellitus
Osimertinib (*Tagrisso*)	Monotherapy for first-line treatment of adults with locally advanced or metastatic non-small cell lung cancer with activating EGFR mutations [licence change]
Tofacitinib (*Xeljanz*)	Treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to prior disease-modifying antirheumatic drug therapy – in combination with methotrexate [licence change]

Approved in the EU

Glibenclamide (*Amglidia*)	Treatment of neonatal diabetes mellitus [new oral suspension formulation]
Rucaparib (*Rubraca*)	Monotherapy of adults with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum based chemotherapy, and who are unable to tolerate further platinum based chemotherapy
Sufentanil (*Dzuveo*)	Management of acute moderate-to-severe pain in adults [new formulation]
Tocilizumab (*RoActemra*)	Active moderate-to-severe rheumatoid arthritis, after DMARD failure [new SC autoinjector device]
Trastuzumab biosimilar (*Kanjinti*)	Early and metastatic HER2-positive breast cancer, and HER2-positive metastatic gastric cancer

EU positive opinions

Adalimumab biosimilar (*Halatimoz; Hefiya; Hyrimoz*)	Indications differ in detail between the three brands but include some of the following: rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn´s disease, ulcerative colitis, uveitis and paediatric uveitis
Allopurinol + lesinurad (*Duzallo*)	Treatment of hyperuricaemia in adults with gout who have not achieved target serum uric acid levels with an adequate dose of allopurinol alone [new formulation]
Ataluren (*Translarna*)	Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged ≥2 to 5 years [licence change from use in patients aged ≥5 years]
Axicabtagene ciloleucel (*Yescarta*)	Treatment of adults with relapsed or refractory diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma, after two or more lines of systemic therapy
Brexpiprazole (*Rexulti*)	Treatment of schizophrenia in adults
Brivaracetam (*Briviact*)	Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children aged ≥4 to 16 years with epilepsy [licence change from use in patients aged ≥16 years]

To access monographs, click on the drug name/indication or visit www.sps.nhs.uk

Direct links to short monographs are included

Complete monographs are password protected – please register for access

EU positive opinions (continued)

Caplacizumab (*Cablivi*)	Treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura, in conjunction with plasma exchange and immunosuppression
Cytarabine + daunorubicin liposomal (*Vyxeos*)	Treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (AML) or AML with myelodysplasia-related changes [new formulation]
Dexmedetomidine (*Dexdor*)	Sedation of non-intubated adults prior to and/or during diagnostic or surgical procedures [licence change]
Doxylamine + pyridoxine	Moderate-to-severe nausea and vomiting in pregnancy in women who do not adequately respond to conservative management [new formulation] (*UK positive opinion only*)
Erenumab (*Aimovig*)	Prophylaxis of migraine in adults who have at least four migraine days per month
Inotersen (*Tegsedi*)	Treatment of stage 1 or stage 2 polyneuropathy in adults with hereditary transthyretin amyloidosis
Lenvatinib (*Lenvima*)	Monotherapy of adults with advanced or unresectable hepatocellular carcinoma who have received no prior systemic therapy [licence change]
Metreleptin (*Myalept*)	Adjunct to diet as a replacement therapy to treat complications of leptin deficiency in lipodystrophy (LD) patients with confirmed congenital generalised LD (Berardinelli-Seip syndrome) or acquired generalised LD (Lawrence syndrome) in adults and children aged ≥2 years. Also with confirmed familial partial LD or acquired partial LD (Barraquer-Simons syndrome) in adults and children aged ≥12 years for whom standard treatments have failed to achieve adequate metabolic control
Neratinib (*Nerlynx*)	Extended adjuvant treatment of adults with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy
Nivolumab (*Opdivo*)	Monotherapy for adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection [licence change]
Rufinamide (*Inovelon*)	Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients aged ≤ 1 year [licence change]
Sirolimus (*Rapamune*)	Treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function [licence change]
Tisagenlecleucel-T (*Kymriah*)	B-cell acute lymphoblastic leukaemia that is refractory, in relapse post-transplant or in second or later relapse, in children and young adults aged ≤ 25 years, and relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy in adults
Tocilizumab (*RoActemra*)	Treatment of chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome in adults and children aged ≥2 years [licence change]
Tofacitinib (*Xeljanz*)	Treatment of adults with moderately-to-severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent [licence change]
Tolvaptan (*Jinarc*)	To slow progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease in adults with CKD stage 1 to 4 (previously 1 to 3) at initiation of treatment with evidence of rapidly progressing disease [licence change]
Trastuzumab biosimilar (*Trazimera*)	Treatment of early breast cancer, metastatic breast cancer and gastric cancer, all where the tumour is HER2-positive
Vestronidase alfa (*Mepsevii*)	Treatment of non-neurological manifestations of mucopolysaccharidosis VII (Sly syndrome)
Vonicog alfa (*Veyvondi)*	Treatment of haemorrhage and surgical bleeding, and prevention of surgical bleeding in adults with von Willebrand disease, when desmopressin treatment alone is ineffective or not indicated

Filed for approval in the EU

Crisaborole (*Eucrisa*)	Treatment of patients with mild-to-moderate atopic dermatitis aged ≥2 years
Delafloxacin (*Baxdela*)	Acute bacterial skin and skin structure infections
Edaravone (*Radicava*)	Amyotrophic lateral sclerosis (motor neurone disease)
Exenatide (*Bydureon*)	Reduction in cardiovascular outcomes in patients with type 2 diabetes mellitus [licence change]

***Filed for approval in the EU* (continued)**	
Lorlatinib	Non-small cell lung cancer, ALK-positive – second-line after previous ALK-inhibitor therapy
Pembrolizumab (*Keytruda*)	Resected, high-risk stage III melanoma – adjuvant therapy [licence change]
Ravulizumab	Paroxysmal nocturnal haemoglobinuria
Risankizumab	Moderate-to-severe chronic plaque psoriasis in adults
Rituximab (*MabThera*)	Moderate-to-severely active pemphigus vulgaris [licence change]
Rucaparib (*Rubraca*)	Maintenance therapy in recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer [licence change]
Talazoparib	Advanced breast cancer, BRAC mutation-positive
Tofacitinib (*Xeljanz XR*)	Moderate-to-severe rheumatoid arthritis in patients who have had an inadequate response or intolerance to methotrexate [modified-release once-daily formulation]
Treprostinil diethanolamine (*Orenitram*)	Pulmonary hypertension

Other EU developments	
Apremilast (*Otezla*)	Ankylosing spondylitis – development discontinued
Axitinib (*Inlyta*)	Renal cell carcinoma, adjuvant therapy in adults at high risk of recurrence – development discontinued
Ciclosporin (*Restaysis*)	Moderate-to-severe keratoconjunctivitis sicca (or dry eye disease) – filing withdrawn
Cytomegalovirus DNA vaccine (*TransVax*)	Cytomegalovirus infections/reactivation in haemopoietic stem cell transplant – development discontinued
Dalbavancin (*Xydalba*)	Community-acquired pneumonia – development discontinued
Eteplirsen (*Exondys*)	Duchenne muscular dystrophy – negative opinion
Lanabecestat	Early-stage Alzheimer's disease – development discontinued
Taselisib	Metastatic breast cancer – development discontinued

New monographs (9)		***Phase in EU (US)***
Axicabtagene ciloleucel (*Yescarta*)	Relapsed/refractory diffuse large B-cell lymphoma – second-line	PIII (PIII)
Benralizumab (*Fasenra*)	Severe bilateral nasal polyposis in patients who are symptomatic despite standard therapy	PIII (PIII)
Bis-choline tetrathiomolybdate	Wilson's disease or hepatolenticular degeneration	PIII (PIII)
E2027	Lewy body dementia	PIII (PIII)
Gefapixant	Chronic cough, including cough with idiopathic pulmonary fibrosis	PIII (PIII)
Givosiran	Acute hepatic porphyrias	PIII (PIII)
Halobetasol propionate + tazarotene (*Duobrii*)	Plaque psoriasis	None (Filed)
Pembrolizumab (*Keytruda*)	Recurrent or metastatic, PD-L1 positive cervical cancer	PIII (Launched)
Polihexanide	Acanthamoeba keratitis in patients aged ≥13 years	PIII (None)

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Contact nwmedinfo@nhs.net if you have a question about this newsletter.

***Focus:* Drugs in development for pain**		***Phase in EU (US)***
Amitriptyline + ketamine (*AmiKet*)	Topical tricyclic antidepressant and an NMDA antagonist	None (PII)
Amitriptyline + oxymetazoline + ketoprofen	Intraarticular tricyclic antidepressant, decongestant and non-steroidal anti-inflammatory drug	PIII (PIII)
Bupivacaine (*Exparel*)	Sustained release local anaesthetic infiltration	PII (Launched)
Bupivacaine (*XaraColl*)	Biodegradable and fully resorbable collagen-bupivacaine matrix implant	None (PIII)
Buprenorphine	SC opioid mu receptor agonist and opioid kappa receptor antagonist given once weekly or once monthly	None (PIII)
Buprenorphine	Sublingual opioid mu receptor agonist and opioid kappa receptor antagonist	None (Filed)
Buprenorphine (*Belbuca*)	Transmucosal long-acting opioid mu receptor agonist and opioid kappa receptor antagonist	None (Launched)
Cebranopadol	Oral first-in-class nociceptin receptor (also known as ORL-1 or opioid receptor like-1) agonist and opioid mu receptor agonist	PIII (None)
Celecoxib + tramadol	Oral fixed dose combination of an anti-inflammatory drug celecoxib and a centrally acting weak synthetic opioid mu receptor agonist and to a lesser extent opioid delta and kappa receptors agonist	PIII (PIII)
Difelikefalin (*Korsuva*)	IV peptidergic, long-acting opioid kappa receptor agonist	None (PIII)
Disodium zoledronate	Oral farnesyl pyrophosphate synthase enzyme inhibitor	Discontinued
Nabiximols (*Sativex*)	Buccal combination of two cannabinoids, CBD (cannabidiol) and THC (delta 9 tetrahydrocannabinol)	Discontinued
Neridronic acid	IV farnesyl pyrophosphate synthase enzyme inhibitor	PIII (PIII)
NKTR-181	Oral first-in-class, PEGylated opioid mu receptor agonist	None (PIII)
Oliceridine (*Olinvo*)	IV first-in-class opioid mu receptor G protein pathway selective modulator	None (Filed)
Sufentanil (*Dzuveo*)	Sublingual opioid analgesic	Approved (Filing withdrawn)
Tanezumab	SC nerve growth factor inhibitor – cancer pain due to bone metastases / chronic low back pain	PIII (None) / PIII (PIII)
Tizanidine (*Tizaspray*)	Intranasal skeletal muscle relaxant that stimulates alpha-2 adrenergic receptors in the central nervous system	PIII (None)

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