Specialist Pharmacy Service New Medicines Newsletter

August 2020

This newsletter is produced by the SPS horizon scanning service and highlights recent new product launches and significant medicines regulatory changes. Most of 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.

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.

SPS home | Contact

New product information

Launched in the UK (or licence change for existing products)

Bevacizumab biosimilar (*Zirabev*)	Treatment of adults with metastatic carcinoma of the colon or rectum, metastatic breast cancer, unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology, advanced and/or metastatic renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and persistent, recurrent or metastatic carcinoma of the cervix
Elexacaftor+ ivacaftor + tezacaftor (*Kaftrio*)	Use in a combination regimen with ivacaftor 150mg tablets for treatment of cystic fibrosis in patients aged ≥12 years who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or heterozygous for F508del in the CFTR gene with a minimal function mutation [new formulation]
Entrectinib (*Rozlytrek*)	Monotherapy of adults with ROS1-positive, advanced non-small cell lung cancer not previously treated with ROS1 inhibitors
Entrectinib (*Rozlytrek*)	Monotherapy of adult and paediatric patients aged ≥12 years, with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, who have not received a prior NTRK inhibitor and who have no satisfactory treatment options
Etravirine (*Intelence*)	Use in combination with a boosted protease inhibitor and other antiretroviral medicinal products for the treatment of human immunodeficiency virus type-1 infection in antiretroviral treatment experienced adults and in antiretroviral treatment experienced paediatric patients aged ≥2 years [licence change from use only in adults and children aged ≥6 years]
Givosiran (*Givlaari*)	Treatment of acute hepatic porphyria in adults and adolescents aged ≥12 years
Insulin lispro (*Lyumjev*)	Treatment of diabetes mellitus in adults [new ultra-rapid formulation]
Isatuximab (*Sarclisa*)	Use in combination with pomalidomide and dexamethasone, for treatment of adults with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy
Mogamulizumab (*Poteligeo*)	Treatment of adults with mycosis fungoides or Sézary syndrome who have received at least one prior systemic therapy
Nintedanib (*Ofev*)	Treatment of other chronic fibrosing interstitial lung diseases with a progressive phenotype in adults [new indication – previously approved indications are idiopathic pulmonary fibrosis and systemic sclerosis associated interstitial lung disease]
Omalizumab (*Xolair*)	Use as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults with severe chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control [new indication]
Relebactam + cilastatin + imipenem (*Recarbrio*)	Treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options

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

Direct links to short monographs are included

Complete monographs are password protected – please register for access

New product information *(continued)*

Launched in the UK (or licence change for existing products)

Rituximab biosimilar (*Ruxience*)	Treatment of adults with non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis, and pemphigus vulgaris
Secukinumab (*Cosentyx*)	Treatment of moderate to severe plaque psoriasis in children and adolescents aged ≥6 years who are candidates for systemic therapy [licence change from use only in adults]
Semaglutide (*Rybelsus*)	Treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise, as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in combination with other medicinal products for the treatment of diabetes [new oral formulation]
Treosulfan (*Trecondi*)	Use in combination with fludarabine as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation in adults with malignant and non-malignant diseases, and in paediatric patients aged >1 month with malignant diseases [new formulation and new indication]
Vedolizumab (*Entyvio*)	Treatment of adults with moderately to severely active Crohn's disease or ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha antagonist [new subcutaneous formulation]

Recent (or pending) product launches considered for a safety assessment

Each month, SPS utilise a scoring tool to identify which recently launched products are high enough risk to benefit from a full safety assessment. Details of this process can be viewed here. Some products do not warrant a full assessment but safety issues have nonetheless been identified which are considered helpful to take account of when managing entry into the NHS. These are listed below together with details of the products where a full assessment is planned. A list of all published safety assessments can be viewed here.

Generic name (*Trade name*)	Indication(s)	Safety issues identified (NB. not comprehensive)	SPS safety assessment
Delafloxacin (*Quofenix*)	Treatment of acute bacterial skin and skin structure infections in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections	*Quofenex* is a new fluoroquinolone antibiotic and the MHRA safety warning on musculoskeletal and nervous system adverse effects apply. Available as 450mg tablets and 300mg powder for concentrate for solution for infusion in a vial. Women of childbearing potential have to use effective contraception during treatment.	No
Insulin lispro (*Lyumjev*)	Treatment of diabetes mellitus in adults [new ultra-rapid formulation]	A new 'ultra-rapidly acting' formulation of insulin lispro. *Lyumjev* is equipotent to *Humalog* (insulin lispro) on a unit-for-unit basis but its effect is more rapid with a shorter duration of action. Available in three different formulations (cartridges, *Kwikpen* and vial) and two strengths (100units/mL and 200units/mL – *Kwikpen* only). There is a potential risk of confusion between the two available strengths and with other insulin lispro products, particularly at transition of care. Ensure insulin products are prescribed by brand name, followed by the concentration and recommended daily dose in units.	Yes

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

Regulatory changes in the EU

Approved in the UK/EU

Belantamab mafodotin (*Blenrep*)	Monotherapy for the treatment of multiple myeloma in adults, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy
Bempedoic acid (*Nilemdo*)	Use in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet, in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant or for whom a statin is contraindicated
Bempedoic acid + ezetimibe (*Nustendi*)	Use in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet, in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe, or alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone, or in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin
Bevacizumab biosimilar (*Aybintio*)	Treatment of adults with metastatic carcinoma of the colon or rectum, metastatic breast cancer, unresectable advanced, metastatic or recurrent non-small cell lung cancer, advanced and/or metastatic renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and persistent, recurrent or metastatic carcinoma of the cervix
Bulevirtide (*Hepcludex*)	Treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA-positive adults with compensated liver disease
Buprenorphine + naloxone (*Suboxone sublingual film*)	Substitution treatment for opioid drug dependence, within a framework of medial, social and psychological treatment in adults and adolescents aged >15 years who have agreed to be treated for addiction [new formulation]
Imlifidase (*Idefirix*)	Desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of *Idefirix* should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.
Lefamulin (*Xenleta*)	Treatment of community-acquired pneumonia (CAP) in adults when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of CAP or when these have failed
Pretomanid (*Pretomanid FGK*)	Use in combination with bedaquiline and linezolid, in adults, for treatment of pulmonary extensively drug resistant, or treatment-intolerant or non-responsive multidrug-resistant tuberculosis
Pridinol (*Myopridin*)	Central and peripheral muscle spasms (lumbar pain, torticollis, general muscle pain) in adults
Trastuzumab biosimilar (*Zercepac*)	Metastatic and early breast cancer, and metastatic gastric cancer

Recommended for approval in the UK/EU

Dabigatran etexilate (*Pradaxa*)	Treatment of venous thromboembolism in infants from birth and children aged <18 years [licence change from use only in adults]

Filed for approval in the UK/EU

Cannabidiol (*Epidyolex*)	Epilepsy in patients with tuberous sclerosis complex who experience inadequately-controlled focal seizures – add-on therapy [new indication]
Menotrophin (*Menopur*)	Male and female infertility [new pre-filled pen formulation]

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Regulatory changes in the EU *(continued)*

Filed for approval in the UK/EU (continued)

Risdiplam (*Evrysdi*)	Spinal muscular atrophy
Upadacitinib (*Rinvoq*)	Active ankylosing spondylitis [new indication]

Other UK/EU developments

Abicipar pegol (*Rayoqta*)	Neovascular age-related macular degeneration – development discontinued
Dupilumab (*Dupixent*)	Treatment of children aged 6 to 11 years with severe atopic dermatitis that is not controlled by medicines applied as creams or ointments to the skin – granted Early Access to Medicines Scheme (EAMS) status in UK
Padsevonil	Focal-onset seizures in patients with drug-resistant epilepsy – development discontinued

New monographs (15)

		*UK (EU/US)**
AMT 130	Early manifest Huntington's disease in adults	None (None/PII)
Ansuvimab	Ebola virus infection treatment	None (PIII/Filed)
Blinatumomab (*Blincyto*)	Philadelphia-negative high-risk B-precursor acute lymphoblastic leukaemia in children – in first relapse	PIII (PIII/None)
Budesonide (*Jorveza*)	Eosinophilic oesophagitis in children – new oral suspension formulation	PIII (PIII/None)
Clotrimazole	Fungal infections of the ear (otomycosis) in adults	None (None/PIII)
Cyanocobalamin (*Orobalin*)	Haematological, neurological and other symptoms secondary to vitamin B12 deficiency. Malabsorption of vitamin B12, such as due to the absence of intrinsic factor (pernicious anaemia), stomach resection or disease of the small intestine. It is also indicated during para-aminosalicylic acid therapy, which can cause impaired B12 resorption.	Licensed not launched (None)
Deferiprone (*Ferriprox*)	Transfusional iron overload due to sickle cell disease or other anaemias	PIII (None)
Dihydroergotamine	Migraine – acute treatment	None (None/PIII)
Ensartinib	Advanced or recurrent ALK-rearranged non-small cell lung cancer, previously untreated	PIII (PIII)
Lanadelumab (*Takhzyro*)	Routine prevention of recurrent attacks of hereditary angioedema in patients aged ≥2 years	None (PIII)
MB-CART2019.1	CD20 and CD19-positive, relapsed or resistant diffuse large B-cell lymphoma after first-line therapy in patients ineligible for autologous stem cell transplant	None (PII/None)
Pamrevlumab	Non-ambulatory Duchenne muscular dystrophy	PIII (PIII)
Spesolimab	Generalised pustular psoriasis	None (PIII)
Tapinarof	Plaque psoriasis in adults	None (None/PIII)
Vedolizumab (*Entyvio*)	Acute intestinal graft versus host disease – prevention in patients aged ≥12 years undergoing allogenic haematopoietic stem cell transplantation as treatment for a haematologic malignancy or myeloproliferative disorder	PIII (PIII)

** If trials ongoing in the EU and US are the same phase, only one phase is stated*