

March 2019

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](#).

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Regulatory changes in the EU

Launched in the UK

Alirocumab (<i>Praluent</i>)	Use in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors, in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated [licence change]
Beclometasone + formoterol (<i>Fostair NEXTHaler</i>)	Asthma in adults not adequately controlled with inhaled corticosteroid and as needed short-acting beta2-agonist – use as reliever therapy [licence change]
Blinatumomab (<i>Blinicyto</i>)	Monotherapy of adults with Philadelphia chromosome-negative CD19-positive B-precursor acute lymphoblastic leukaemia in first or second complete remission with minimal residual disease $\geq 0.1\%$ [licence change]
Dapagliflozin (<i>Forxiga</i>)	Use in adults for treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI $\geq 27\text{kg/m}^2$, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy [licence change]
Emicizumab (<i>Hemlibra</i>)	Treatment for routine prophylaxis of bleeding episodes in patients of all ages with severe haemophilia A (congenital factor VIII deficiency, FVIII $<1\%$) without FVIII inhibitors [licence change]
Glecaprevir + pibrentasvir (<i>Maviret</i>)	Treatment of chronic hepatitis C virus infection in adolescents aged 12 to <18 years [licence change from use only in adults]
Pembrolizumab (<i>Keytruda</i>)	Use in combination with carboplatin and either paclitaxel or nab-paclitaxel for first-line treatment of metastatic squamous non-small cell lung cancer in adults [licence change]
Rituximab (<i>MabThera</i>)	Treatment of adults with severe, active granulomatosis with polyangiitis (Wegener's) and microscopic polyangiitis [licence change]
Rituximab (<i>MabThera</i>)	Treatment of patients with moderate-to-severe pemphigus vulgaris [licence change]
Trastuzumab biosimilar (<i>Trazimera</i>)	Treatment of early breast cancer, metastatic breast cancer and gastric cancer, all where the tumour is HER2-positive

Approved in the EU

Formoterol + glycopyrronium (<i>Bevespi Aerosphere</i>)	Maintenance bronchodilator treatment to relieve symptoms in adults with chronic obstructive pulmonary disease [new formulation]
Naldemedine (<i>Rizmoic</i>)	Treatment of opioid-induced constipation in adults who have previously been treated with a laxative

EU positive opinions

Andexanet alfa (<i>Ondexxya</i>)	For adults treated with a direct factor Xa inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding
Beta-globin gene therapy (<i>Zynteglo</i>)	Treatment of patients aged ≥ 12 years with transfusion-dependent β -thalassaemia who do not have a $\beta 0/\beta 0$ genotype, for whom haematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen-matched related HSC donor is not available

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

EU positive opinions (continued)

Dupilumab (<i>Dupixent</i>)	Add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, in adults and adolescents aged ≥ 12 years who are inadequately controlled with high dose inhaled corticosteroid plus another medicinal product for maintenance treatment [licence change]
Lenalidomide (<i>Revlimid</i>)	Use as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone for treatment of adults with previously untreated multiple myeloma who are not eligible for transplant [licence change from use only with dexamethasone, or in combination with melphalan and prednisone followed by maintenance with lenalidomide]
Lorlatinib (<i>Lorviqua</i>)	Monotherapy for the treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy, or crizotinib and at least one other ALK TKI
Olaparib (<i>Lynparza</i>)	Monotherapy for the treatment of adults with germline BRCA1/2-mutations, who have HER2-negative locally advanced or metastatic breast cancer [licence change]
Pegvaliase (<i>Palynziq</i>)	Treatment of patients with phenylketonuria aged ≥ 16 years who have inadequate blood phenylalanine control (blood phenylalanine levels >600 micromol/L) despite prior management with available treatment options
Plerixafor (<i>Mozobil</i>)	Use in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children aged 1 to <18 years with lymphoma or solid malignant tumours, either pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired haematopoietic stem cells yield, or who previously failed to collect sufficient haematopoietic stem cells [licence change from use only in adults]
Pomalidomide (<i>Imnovid</i>)	Treatment of adults with multiple myeloma who have received at least one prior treatment regimen including lenalidomide in combination with bortezomib and dexamethasone [licence change from use only in adults who have received at least two prior treatment regimens]
Risankizumab (<i>Skyrizi</i>)	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy
Sotagliflozin (<i>Zynquista</i>)	As an adjunct to insulin therapy to improve glycaemic control in adults with type 1 diabetes mellitus with a body mass index (BMI) ≥ 27 kg/m ² , who have failed to achieve adequate glycaemic control despite optimal insulin therapy
Tenofovir disoproxil (<i>Viread</i>)	Treatment of chronic hepatitis B in patients aged 6 to <12 years who weigh from 28kg to <35 kg, with compensated liver disease and evidence of immune active disease, i.e. active viral replication and persistently elevated serum ALT levels or histological evidence of moderate to severe inflammation and/or fibrosis [licence change from use only in adults and adolescents aged 12 to <18 years]
Volanesorsen (<i>Waylivra</i>)	An adjunct to diet in adults with genetically confirmed familial chylomicronaemia syndrome and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate
Zanamivir (<i>Dectova</i>)	Treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥ 6 months) when the patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient [new formulation]

Filed for approval in the EU

Avelumab (<i>Bavencio</i>)	Advanced, unresectable renal cell carcinoma – first-line in combination with axitinib [licence change]
Atezolizumab (<i>Tecentriq</i>)	Extensive-stage small cell lung cancer – first-line in combination with chemotherapy [licence change]
Atezolizumab (<i>Tecentriq</i>)	Triple-negative, metastatic breast cancer – first-line in combination with nab-paclitaxel [licence change]
Belimumab (<i>Benlysta</i>)	Systemic lupus erythematosus in children aged 5 to 17 years [licence change]
Darolutamide	High-risk, non-metastatic, castration-resistant prostate cancer
Entrectinib	Advanced NTRK fusion-positive, ROS1-positive or ALK-positive solid tumours

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Filed for approval in the EU (continued)

Entrectinib	Advanced ROS1-positive non-small cell lung cancer
Gilteritinib (<i>Xospata</i>)	Relapsed or refractory acute myeloid leukaemia with FLT-3 mutation
Imlifidase	Transplant rejection prevention in HLA-sensitised patients
Lifitegrast (<i>Xiidra</i>)	Keratoconjunctivitis sicca (dry eye disease)
Olodaterol (<i>Striverdi Respimat</i>)	Chronic obstructive pulmonary disease [reusable inhaler device that takes refills]
Polatuzumab	Relapsed or refractory diffuse large B-cell lymphoma
Potassium bicarbonate + potassium citrate	Distal renal tubular acidosis [new formulation]
Ranibizumab (<i>Lucentis</i>)	Moderately-severe to severe non-proliferative diabetic retinopathy and proliferative diabetic retinopathy [licence change]
Ranibizumab (<i>Lucentis</i>)	Retinopathy of prematurity [licence change]
Selinexor	Penta-refractory multiple myeloma
Tagraxofusp (<i>Elzonris</i>)	Blastic plasmacytoid dendritic cell neoplasm
Tiotropium (<i>Spiriva Respimat</i>)	Asthma and chronic obstructive pulmonary disease [reusable inhaler device that takes refills]
Tiotropium + olodaterol (<i>Spiolto Respimat</i>)	Chronic obstructive pulmonary disease [reusable inhaler device that takes refills]

Other EU developments

Aducanumab	Alzheimer's disease – development discontinued
Atezolizumab (<i>Tecentriq</i>)	First-line treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer whose tumours have PD-L1 expression $\geq 1\%$ – granted EAMS status in UK
Avelumab (<i>Bavencio</i>)	Locally advanced or metastatic stage IV non-small cell lung cancer, second-line – development discontinued
Avelumab (<i>Bavencio</i>)	Advanced ovarian cancer, first-line in combination with talazoparib – development discontinued
Cemiplimab (<i>Libtayo</i>)	PD-L1-positive ($\geq 50\%$) non-small cell lung cancer, first-line in combination with ipilimumab with or without platinum chemotherapy – development discontinued
Durvalumab (<i>Imfinzi</i>)	Head and neck squamous cell carcinoma, second-line monotherapy and in combination with tremelimumab – development discontinued
Pacritinib (<i>Epjeyv</i>)	Myelofibrosis in patients who have thrombocytopenia – filing withdrawn

New monographs (35)

Phase in EU (US)

ACP001	Treatment of growth hormone deficiency in children and adults	PIII (PIII)
APL2	Dry age-related macular degeneration	None (PIII)
Autologous ADA SCID gene therapy	Adenosine deaminase deficiency (ADA) in patients with severe combined immunodeficiency due to ADA	None – PII UK (PII)
Aztreonam + avibactam	Serious gram-negative bacterial infections in adults	PIII (PIII)
Baloxavir marboxil (<i>Xofluza</i>)	Type A and B influenza in patients at high risk of complications	PIII (PIII)
BAN2401	Early Alzheimer's disease	PII (PIII)
Belimumab (<i>Benlysta</i>)	Lupus nephritis in adults uncontrolled on standard care	PIII (PIII)
Belimumab (<i>Benlysta</i>)	Systemic lupus erythematosus in adults – in combination with rituximab [subcutaneous formulation]	PIII (PIII)
Bictegravir + emtricitabine + tenofovir alafenamide (<i>Biktarvy</i>)	HIV infection in children and adolescents aged >6 years	None (PIII)

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New monographs (continued)		Phase in EU (US)
Buprenorphine + naloxone (Suboxone Film)	Opioid dependence, substitution treatment in adults and adolescents aged >15 years [sublingual film formulation]	None (P11)
Cantharidin	Molluscum contagiosum	None (P111)
Daratumumab (Darzalex)	Newly diagnosed multiple myeloma in adults who are not suitable for stem cell transplant – in combination with lenalidomide and dexamethasone	P111 (Filed)
Daratumumab (Darzalex)	Multiple myeloma – first-line in transplant ineligible patients in combination with bortezomib, lenalidomide and dexamethasone	P111 (P111)
Daratumumab (Darzalex)	Smouldering multiple myeloma	P111 (P111)
Dostarlimab	Stage III or IV ovarian cancer – first-line	P111 (P111)
Durvalumab (Imfinzi)	Locally advanced, unresected non-small cell lung cancer – in combination with chemoradiation therapy	P111 (None)
JZP-258	Idiopathic hypersomnia	None (P111)
Meningococcal groups A + C + W135 + Y vaccine (Men Quad TT)	Meningitis ACYW prevention in toddlers and above	P111 (P111)
Osimertinib (Tagrisso)	Locally advanced, unresectable, EGFR-positive stage III non-small cell lung cancer in adults whose disease has not progressed following platinum-based chemoradiation therapy	P111 (P111)
OTL-200	Pre-symptomatic early onset (late infantile and early juvenile) metachromatic leukodystrophy	P111 (None)
Pembrolizumab (Keytruda)	Advanced small cell lung cancer – third-line monotherapy	P11 (Filed)
Pioglitazone	Sudden sensorineural hearing loss in adults [intratympanic gel and modified-release tablet formulations]	P111 (None)
Pneumococcal vaccine	Pneumococcal infection – prevention in children and adolescents [15-valent formulation]	P11 (P111)
Pneumococcal vaccine	Pneumococcal infection – prevention [20-valent formulation]	None (P111)
Ponatinib (Iclusig)	Philadelphia chromosome positive acute lymphoblastic leukaemia – first-line	P111 (P111)
PRN1008	Pemphigus vulgaris and pemphigus foliaceus	P111 (P111)
Selexipag (Upravi)	Pulmonary arterial hypertension – IV formulation	P111 (P111)
Terzepatide	Type 2 diabetes mellitus	P111 (P111)
Ticagrelor (Brilique)	Sickle cell disease in children aged 2 to 18 years	P111 (P111)
Tofacitinib (Xeljanz)	Ankylosing spondylitis in adults who have responded inadequately to conventional therapy	P111 (P111)
Trastuzumab deruxtecan	Metastatic HER2-low breast cancer	P111 (P111)
Trastuzumab emtansine (Kadcyla)	Operable HER2-positive early breast cancer – in combination with pertuzumab	P111 (P111)
Upadacitinib	Crohn's disease	P111 (P111)
Veverimer	Metabolic acidosis in patients with chronic kidney disease	P111 (P111)
VGX-3100	Cervical dysplasia caused by human papillomavirus types 16 and 18	P111 (P111)

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