

## December 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](#).

[SPS home](#) | [Contact](#)

## Regulatory changes in the EU

### Launched in the UK

<a href="#">Adalimumab biosimilar</a> ( <i>Imraldi</i> )	Treatment of rheumatoid, juvenile idiopathic and psoriatic arthritis, axial spondyloarthritis, psoriasis, hidradenitis suppurativa, Crohn's disease, ulcerative colitis and uveitis
<a href="#">Canagliflozin</a> ( <i>Invokana</i> )	Treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, as monotherapy or in addition to other medicinal products [Effects on cardiovascular events have been included within sections 4.4, 4.5 and 5.1 of the SPC]
<a href="#">Dulaglutide</a> ( <i>Trulicity</i> )	Use in adults with type 2 diabetes mellitus to improve glycaemic control, as monotherapy or in addition to other medicinal products [Information on combination therapy with SGLT2 inhibitor with or without metformin has been included within sections 4.2 and 5.1 of the SPC]
<a href="#">Exenatide</a> ( <i>Bydureon</i> )	Use in adults with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin [Effects on cardiovascular events have been included within sections 4.4, 4.5 and 5.1 of the SPC]
<a href="#">Fingolimod</a> ( <i>Gilenya</i> )	Single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) in patients aged $\geq 10$ years or with rapidly evolving severe RRMS [licence change from use only in adults]
<a href="#">Guselkumab</a> ( <i>Tremfya</i> )	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy [new patient-controlled injector]
<a href="#">Infliximab biosimilar</a> ( <i>Zessly</i> )	Treatment of rheumatoid arthritis, adult and paediatric Crohn's disease and ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis
<a href="#">Pembrolizumab</a> ( <i>Keytruda</i> )	Adjuvant monotherapy of melanoma in adults with lymph node involvement who have undergone complete resection [licence change]
<a href="#">Semaglutide</a> ( <i>Ozempic</i> )	Treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes
<a href="#">Sodium deoxycholate</a> ( <i>Belkyra</i> )	Treatment of moderate to severe convexity or fullness associated with submental fat in adults when the presence of submental fat has an important psychological impact for the patient
<a href="#">Tenofovir alafenamide</a> ( <i>Vemlidy</i> )	Chronic hepatitis B in adults and adolescents aged $\geq 12$ years with body weight $\geq 35$ kg [new formulation]
<a href="#">Tocilizumab</a> ( <i>RoActemra</i> )	Rheumatoid arthritis and giant cell arteritis [new autoinjector formulation]

### Approved in the EU

<a href="#">Buprenorphine</a> ( <i>Buvidal</i> )	Treatment of opioid dependence within a framework of medical, social and psychological treatment in patients aged $\geq 16$ years [new formulation]
<a href="#">Dengue vaccine</a> ( <i>Dengvaxia</i> )	Prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in individuals aged 9 to 45 years with prior dengue virus infection and living in endemic areas
<a href="#">Doravirine</a> ( <i>Pifeltro</i> )	Treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse-transcriptase inhibitor class – in combination with other antiretroviral medicines
<a href="#">Doravirine + lamivudine + tenofovir disoproxil fumarate</a> ( <i>Delstrigo</i> )	Treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse-transcriptase inhibitor class, lamivudine, or tenofovir [new formulation]

To access monographs, click on the drug name or visit [www.sps.nhs.uk](http://www.sps.nhs.uk)

Direct links to short monographs are included  
Complete monographs are password protected – please [register](#) for access

## Approved in the EU (continued)

<a href="#">Lanadelumab</a> ( <i>Takhzyro</i> )	Routine prevention of recurrent attacks of hereditary angioedema in patients aged ≥12 years
<a href="#">Meropenem + vaborbactam</a> ( <i>Vabomere</i> )	Treatment of adults with complicated urinary tract infection including pyelonephritis, complicated intra-abdominal infection, hospital-acquired pneumonia including ventilator associated pneumonia (including bacteraemia that occurs in association with, or is suspected to be associated with, these infections). Also infections due to aerobic Gram negative organisms in adults with limited treatment options.
<a href="#">Paclitaxel</a> ( <i>Apealea</i> )	Treatment of adults with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer – in combination with carboplatin [new formulation]

## EU positive opinions

<a href="#">Beclometasone + formoterol + glycopyrrolate</a> ( <i>Trimbow</i> )	Maintenance treatment of moderate to severe chronic obstructive pulmonary disease in adults who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or a combination of a long-acting beta 2-agonist and a long-acting muscarinic antagonist [licence change to include use in adults not adequately treated by inhaled long-acting beta 2-agonist and long-acting muscarinic antagonist]
<a href="#">Bevacizumab biosimilar</a> ( <i>Zirabev</i> )	Treatment of adults with metastatic carcinoma of the colon or rectum, first-line treatment of adults with metastatic breast cancer, first-line treatment of adults with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology, first line treatment of adults with advanced and/or metastatic renal cell cancer, and treatment of adults with persistent, recurrent, or metastatic carcinoma of the cervix
<a href="#">Brentuximab vedotin</a> ( <i>Adcetris</i> )	Treatment of previously untreated CD30-positive Stage IV Hodgkin lymphoma in combination with doxorubicin, vinblastine and dacarbazine in adults [licence change]
<a href="#">Dasatinib</a> ( <i>Sprycel</i> )	Treatment of paediatric patients with newly diagnosed Philadelphia-positive acute lymphoblastic leukaemia in combination with chemotherapy [licence change]
<a href="#">Lusutrombopag</a> ( <i>Lusutrombopag Shionogi</i> )	Treatment of severe thrombocytopenia in adults with chronic liver disease undergoing invasive procedures
<a href="#">Naldemedine</a> ( <i>Rizmoic</i> )	Treatment of opioid-induced constipation in adults who have previously been treated with a laxative
<a href="#">Ropeginterferon alfa-2b</a> ( <i>Besremi</i> )	Monotherapy of polycythaemia vera without symptomatic splenomegaly in adults
<a href="#">Rucaparib</a> ( <i>Rubraca</i> )	Maintenance monotherapy of platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who are in response (complete or partial) to platinum-based chemotherapy [licence change]
<a href="#">Treosulfan</a> ( <i>Trecondi</i> )	Use 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, in combination with fludarabine [licence change]

## Filed for approval in the EU

<a href="#">Betula verrucosa</a>	Allergic rhinoconjunctivitis
<a href="#">Budesonide + formoterol</a> ( <i>Symbicort Turbohaler</i> )	Mild asthma in adults and adolescents, as needed [licence change]
<a href="#">Dupilumab</a> ( <i>Dupixent</i> )	Moderate-to-severe atopic dermatitis in children aged ≥12 to 17 years who are inadequately controlled with topical therapies [licence change]
<a href="#">Macitentan</a> ( <i>Opsumit</i> )	Chronic, inoperable pulmonary hypertension [licence change]
<a href="#">Mepolizumab</a> ( <i>Nucala</i> )	Severe refractory eosinophilic asthma in adults [new autoinjector formulation]
<a href="#">Olaparib</a> ( <i>Lynparza</i> )	Ovarian cancer – first-line maintenance in high risk advanced BRCAm patients who are in response to first line platinum-based chemotherapy [licence change]
<a href="#">Osilodrostat</a>	Cushing's disease
<a href="#">Pembrolizumab</a> ( <i>Keytruda</i> )	First-line treatment of head and neck (or upper airways tract) cancers [licence change]
<a href="#">Pembrolizumab</a> ( <i>Keytruda</i> )	Metastatic, squamous non-small cell lung cancer – first-line in combination with carboplatin plus paclitaxel or nab-paclitaxel [licence change]

This is a NHS document not to be used for commercial purposes

New Medicines Newsletter is one of several horizon scanning resources produced by UK Medicines Information to support managed introduction of new medicines into the NHS, to help organisations develop medicines management policies and to inform prescribing decisions when a product has been launched. For more information, contact your regional medicines information centre.

Contact [nwmedinfo@nhs.net](mailto:nwmedinfo@nhs.net) if you have a question about this newsletter.

## Filed for approval in the EU (continued)

<a href="#">Pembrolizumab</a> ( <i>Keytruda</i> )	Monotherapy of advanced non-small cell lung cancer, previously untreated with PD-L1 expression ( $\geq 1\%$ ) [licence change]
<a href="#">Relebactam + cilastatin + imipenem</a>	Bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, and complicated intra-abdominal and urinary tract infections [new formulation]
<a href="#">Trifluridine + tipiracil</a> ( <i>Lonsurf</i> )	Metastatic gastric cancer [licence change]

## Other EU developments

<a href="#">Adalimumab biosimilar</a> ( <i>Fyzoclad</i> )	Rheumatoid arthritis and other <i>Humira</i> indications – filing withdrawn
<a href="#">Andecaliximab</a>	Advanced gastric cancer or gastroesophageal junction adenocarcinoma – development discontinued
<a href="#">Atezolizumab</a> ( <i>Tecentriq</i> )	Metastatic non-squamous non-small cell lung cancer with EGFR/ALK mutations – granted Early Access to Medicines (EAMS) status in UK
<a href="#">Atrasentan</a> ( <i>Xinlay</i> )	Diabetic nephropathy – development discontinued
<a href="#">Autologous osteoblastic cells</a> ( <i>Preob</i> )	Early-stage femoral head osteonecrosis – development discontinued
<a href="#">Avelumab</a> ( <i>Bavencio</i> )	Platinum-resistant/refractory ovarian cancer – development suspended
<a href="#">Bevacizumab biosimilar – BI-695502</a>	Non-small cell lung cancer and colorectal cancer – development discontinued
<a href="#">Canakinumab</a> ( <i>Ilaris</i> )	Secondary prevention of cardiovascular events – filing withdrawn
<a href="#">Colorectal cancer vaccine</a> ( <i>OncovAX</i> )	Colorectal cancer – development discontinued
<a href="#">Darbepoetin alfa</a> ( <i>Aranesp</i> )	Treatment of anaemia in adults with low transfusion demand in low or intermediate-1-risk myelodysplastic syndromes – development discontinued
<a href="#">Denosumab</a> ( <i>XGEVA</i> )	Prevention of bone metastases in patients with breast cancer – development discontinued
<a href="#">Depatuxizumab mafodotin</a>	Relapsed glioblastoma multiforme – development discontinued
<a href="#">Durvalumab</a> ( <i>Imfinzi</i> )	Advanced urothelial cancer, PD-L1-positive, second-line – development discontinued
<a href="#">Ibrutinib</a> ( <i>Imbruvica</i> )	Diffuse large B-cell lymphoma – development discontinued
<a href="#">Lenalidomide</a> ( <i>Revlimid</i> )	Follicular lymphoma, first-line with rituximab – development discontinued ( <i>UK only</i> )
<a href="#">Lubinetectedin</a> ( <i>Zepsyre</i> )	Platinum-resistant ovarian cancer – development discontinued
<a href="#">Napabucasin</a>	Gastric or gastroesophageal adenocarcinoma – development discontinued
<a href="#">Nintedanib</a> ( <i>Vargatef</i> )	Colorectal cancer, ovarian cancer and malignant pleural mesothelioma – development discontinued
<a href="#">Niraparib</a> ( <i>Zejula</i> )	Relapsed HER2-negative, BRAC-positive breast cancer – development discontinued
<a href="#">Nivolumab</a> ( <i>Opdivo</i> )	Advanced small cell lung cancer, second-line with ipilimumab – development discontinued
<a href="#">Paclitaxel albumin</a> ( <i>Abraxane</i> )	Breast cancer (neoadjuvant therapy), pancreatic cancer (adjuvant therapy), squamous non-small cell lung cancer (maintenance therapy) – development discontinued
<a href="#">Pembrolizumab</a> ( <i>Keytruda</i> )	Locally advanced or metastatic, PD-L1 positive gastric and gastroesophageal junction adenocarcinoma, after $\geq 2$ prior lines of therapy – development discontinued
<a href="#">Regorafenib</a> ( <i>Stivarga</i> )	Colorectal cancer, adjuvant therapy for two years, following completion of at least four months of standard adjuvant therapy – development discontinued
<a href="#">Rivaroxaban</a> ( <i>Xarelto</i> )	Prevention of cardiovascular disease in patients with chronic heart failure and significant coronary artery disease – development discontinued
<a href="#">Rocapuldencel-T</a>	Metastatic renal cell carcinoma – development discontinued
<a href="#">Rovalpituzumab tesirine</a> ( <i>Rova-T</i> )	Small cell lung cancer, DLL3-positive, after at least two prior treatments, including a platinum-based chemotherapy – development discontinued
<a href="#">Tocilizumab</a> ( <i>RoActemra</i> )	Systemic sclerosis (scleroderma) – development discontinued
<a href="#">Tofacitinib</a> ( <i>Xeljanz</i> )	Moderate-to-severe rheumatoid arthritis in methotrexate-naive patients – development discontinued

This is a NHS document not to be used for commercial purposes

New Medicines Newsletter is one of several horizon scanning resources produced by UK Medicines Information to support managed introduction of new medicines into the NHS, to help organisations develop medicines management policies and to inform prescribing decisions when a product has been launched. For more information, contact your regional medicines information centre.

Contact [nwmedinfo@nhs.net](mailto:nwmedinfo@nhs.net) if you have a question about this newsletter.

## New monographs (34)

Phase in EU (US)

<a href="#">Acalabrutinib</a> ( <i>Calquence</i> )	Mantle cell lymphoma – first-line	PIII (PIII)
<a href="#">Alectinib</a> ( <i>Alecensa</i> )	ALK-positive non-small cell lung cancer – adjuvant therapy	PIII (PIII)
<a href="#">Aprocitan</a>	Resistant hypertension	PIII (PIII)
<a href="#">Balovaptan</a>	Autism spectrum disorder	PIII (PIII)
<a href="#">Bempegaldesleukinum</a>	Advanced renal cell carcinoma – first-line with nivolumab	None (PIII)
<a href="#">Benegrastim</a>	Severe neutropenia, resulting from chemotherapy	PIII (PIII)
<a href="#">Carbetocin</a>	Prader-Willi syndrome-associated hyperphagia and other linked symptoms (obsessive compulsive symptoms and anxiety) – intranasal formulation	PIII (PIII)
<a href="#">Citric acid + lactic acid + potassium bitartrate</a> ( <i>Amphora</i> )	Contraception	None (PIII)
<a href="#">CNTX-4975</a>	Moderate-to-severe knee osteoarthritis pain	PIII (PIII)
<a href="#">DBV712</a>	Severe IgE-mediated peanut allergy in children aged 1 to 3 years	PIII (PIII)
<a href="#">Dupilumab</a> ( <i>Dupixent</i> )	Eosinophilic oesophagitis in adults and adolescents	None (PIII)
<a href="#">Efpeglenatide</a>	Prevention of cardiovascular events in patients with type 2 diabetes at high cardiovascular risk	PIII (PIII)
<a href="#">Eryaspase</a> ( <i>Eryasp, Grasp</i> )	Pancreatic cancer – second- line as add on to standard of care treatment	PIII (PIII)
<a href="#">HTT ASO</a>	Huntington's disease	PIII (PIII)
<a href="#">Hydrogen peroxide</a> ( <i>Eskata</i> )	Seborrhoeic keratosis	Filed (Launched)
<a href="#">Isatuximab</a>	Multiple myeloma – first-line induction in transplant-eligible patients in combination with bortezomib, lenalidomide and dexamethasone, followed by lenalidomide maintenance	PIII (None)
<a href="#">Napabucasin</a>	Previously treated advanced colorectal cancer	None (PIII)
<a href="#">Napabucasin</a>	Metastatic pancreatic ductal adenocarcinoma – with nab-paclitaxel and gemcitabine	PIII (PIII)
<a href="#">Nimotuzumab</a> ( <i>CIMAher</i> )	Pancreatic cancer – first-line with gemcitabine	PIII (None)
<a href="#">Niraparib</a> ( <i>Zejula</i> )	Advanced ovarian cancer - first-line maintenance therapy following first line platinum-based chemotherapy response	PIII (PIII)
<a href="#">Nitric oxide</a>	Acne vulgaris	None (PIII)
<a href="#">Odevixibat</a>	Progressive familial intrahepatic cholestasis	PIII (PIII)
<a href="#">Ofranergene obadenovec</a>	Recurrent platinum-resistant ovarian cancer	None (PIII)
<a href="#">Olaparib</a> ( <i>Lynparza</i> )	Advanced ovarian cancer – maintenance for 2 years	PIII (None)
<a href="#">Olaparib</a> ( <i>Lynparza</i> )	Platinum-sensitive, germline BRCA1/2 mutation-positive, relapsed ovarian cancer – monotherapy after ≥ 2 lines of platinum-based chemotherapy	PIII (PIII)
<a href="#">Potassium bicarbonate + potassium citrate</a>	Distal renal tubular acidosis	PIII (PIII)
<a href="#">Ranibizumab</a>	Wet age-related macular degeneration – port delivery system	None (PIII)
<a href="#">Ranibizumab biosimilar – SB11</a>	Neovascular age-related macular degeneration	PIII (PIII)
<a href="#">Riloncept</a>	Recurrent symptomatic pericarditis	PIII (PIII)
<a href="#">Sarilumab</a>	Giant cell (temporal) arteritis	None (PIII)
<a href="#">Sarilumab</a>	Polymyalgia rheumatica	None (PIII)
<a href="#">Serlopitant</a>	Chronic pruritus, any cause	PIII (PIII)
<a href="#">Tisagenlecleucel-T</a> ( <i>Kymriah</i> )	Relapsed/refractory diffuse large B-cell lymphoma – second-line	PIII (PIII)
<a href="#">Trastuzumab deruxtecan</a>	Metastatic breast cancer, HER2-positive	None (PIII)

This is a NHS document not to be used for commercial purposes

New Medicines Newsletter is one of several horizon scanning resources produced by UK Medicines Information to support managed introduction of new medicines into the NHS, to help organisations develop medicines management policies and to inform prescribing decisions when a product has been launched. For more information, contact your regional medicines information centre.

Contact [nwmedinfo@nhs.net](mailto:nwmedinfo@nhs.net) if you have a question about this newsletter.