



New Medicines Newsletter

June 2019

This newsletter is produced by the UKMi horizon scanning service and highlights recent new product launches and 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.

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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New product information

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

Abatacept (<i>Orencia</i>)	Treatment of moderate-to-severe active polyarticular juvenile idiopathic arthritis in paediatric patients aged ≥ 2 years who have had an inadequate response to previous DMARD therapy [licence change for the SC and IV formulations]
Atezolizumab (<i>Tecentriq</i>)	Use in combination with bevacizumab, paclitaxel and carboplatin for first-line treatment of adults with metastatic non-squamous non-small cell lung cancer (NSCLC). In patients with EGFR mutant or ALK-positive NSCLC, atezolizumab is indicated only after failure of appropriate targeted therapies [licence change]
Botulinum A toxin (<i>Xeomin</i>)	Symptomatic treatment of chronic sialorrhoea due to neurological disorders in adults [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 $< 1\%$) with or without FVIII inhibitors – dosing every 4 weeks [licence change]
Insulin glargine + lixisenatide (<i>Suliqua</i>)	Use in combination with metformin for treatment of adults with type 2 diabetes to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product or with basal insulin [new formulation]
Melatonin	Short-term treatment of jet-lag disorder in adults [new formulation and new indication]
Latanaprost + timolol (<i>Fixapost</i>)	Reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues [new single-dose formulation]
Nonacog beta pegol (<i>Refixia</i>)	Treatment and prophylaxis of bleeding in patients aged ≥ 12 years with haemophilia B (congenital factor IX deficiency)
Olaparib (<i>Lynparza</i>)	Maintenance treatment of adults with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy [licence change]

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

Regulatory changes in the EU

Approved in the EU and/or UK

Beta-globin gene therapy (<i>Zynteglo</i>)	Treatment of patients aged ≥12 years with transfusion-dependent β-thalassaemia who do not have a β0/β0 genotype, for whom haematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen-matched related HSC donor is not available
Dacomitinib (<i>Vizimpro</i>)	Monotherapy for first-line treatment of adults with locally advanced or metastatic non-small cell lung cancer with EGFR activating mutations
Ropeginterferon alfa-2b (<i>Besremi</i>)	Monotherapy of polycythaemia vera without symptomatic splenomegaly in adults
Talazoparib (<i>Talzenna</i>)	Monotherapy for treatment of adults with germline BRCA1/2 mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo)adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy.
Turoctocog alfa pegol (<i>Esperoct</i>)	Treatment and prophylaxis of bleeding in patients aged ≥12 years with haemophilia A (congenital factor VIII deficiency) [new formulation]

EU positive opinions

Angiotensin II (<i>Giapreza</i>)	Treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies
Atezolizumab (<i>Tecentriq</i>)	Use in combination with nab-paclitaxel for treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer whose tumours have PD-L1 expression ≥1% and who have not received prior chemotherapy for metastatic disease [licence change and new 840mg formulation]
Betula verrucosa	Allergic rhinoconjunctivitis [new formulation]
Dupilumab (<i>Dupixent</i>)	Treatment of moderate-to-severe atopic dermatitis in adolescents aged ≥12 years who are candidates for systemic therapy [licence change from use only in adults]
Ibrutinib (<i>Imbruvica</i>)	Use in combination with obinutuzumab for treatment of adults with previously untreated chronic lymphocytic leukaemia [licence change from use only as a single agent]
Ibrutinib (<i>Imbruvica</i>)	Use in combination with rituximab for treatment of previously untreated and relapsed/refractory adults with Waldenstrom's macroglobulinemia [licence change from use only as a single agent]
Liraglutide (<i>Victoza</i>)	Treatment of children and adolescents aged 10 to 17 years with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise [licence change from use only in adults]
Ramucirumab (<i>Cyramza</i>)	Treatment of adults with advanced or unresectable hepatocellular carcinoma who have a serum alpha fetoprotein of ≥400ng/ml and who have been previously treated with sorafenib [licence change]

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Filed for approval in the EU

Apalutamide (<i>Erleada</i>)	Metastatic, castration-sensitive prostate cancer in adult men – in combination with androgen deprivation therapy [licence change]
Bedaquiline (<i>Sirturo</i>)	Multi-drug resistant tuberculosis in children and adolescents – add-on therapy [licence change]
Dapagliflozin (<i>Forxiga</i>)	Reduction in cardiovascular outcomes in patients with type 2 diabetes [licence change]
Deferiprone (<i>Ferriprox</i>)	Pantothenate kinase-associated neurodegeneration [licence change]
Doxorubicin liposomal (<i>ThermoDox</i>)	Inoperable hepatocellular carcinoma [new formulation]
Dulaglutide (<i>Trulicity</i>)	Preventing cardiovascular events and death in patients with type 2 diabetes [licence change]
Dupilumab (<i>Dupixent</i>)	Nasal polyposis and chronic sinusitis in adults [licence change]
Galcanezumab (<i>Emgality</i>)	Prevention of cluster headache [licence change]
Glasdegib (<i>Daurismo</i>)	Acute myeloid leukaemia in older patients or with comorbidities precluding intensive chemotherapy – first-line in combination with low dose cytarabine
Glycopyrronium + indacaterol + mometasone	Asthma in adults [new formulation]
Insulin lispro	Type 1 and type 2 diabetes [new ultra-rapid formulation]
Lenalidomide (<i>Revlimid</i>)	Use in combination with rituximab for relapsed or refractory follicular lymphoma or marginal zone lymphoma [licence change]
Pembrolizumab (<i>Keytruda</i>)	Metastatic renal cell carcinoma – first-line in combination with axitinib [licence change]
Rituximab biosimilar – PF-05280586	Follicular lymphoma, with low tumour burden and all licensed cancer indications of originator product
Rituximab biosimilar – PF-05280586	Rheumatoid arthritis and all licensed non-cancer indications of originator product
Tafamidis (<i>Vyndaqel</i>)	Transthyretin cardiomyopathy
Trastuzumab biosimilar (<i>Tuznue</i>)	HER2-positive breast cancer and gastric or gastroesophageal junction adenocarcinoma in adults
Trastuzumab emtansine (<i>Kadcyla</i>)	HER2-positive early breast cancer – adjuvant monotherapy [licence change]

Other EU developments

Atezolizumab (<i>Tecentriq</i>)	First-line treatment of adults with extensive-stage small cell lung cancer, in combination with carboplatin and etoposide – granted Early Access to Medicines Scheme (EAMS) status in UK
Cannabidiol (<i>Epidyolex</i>)	West syndrome (infantile spasms) in infants aged 1 month to 24 months – development discontinued
Eltrombopag (<i>Revolade</i>)	Severe aplastic anaemia, first-line – negative opinion
Herpes zoster vaccine	Prevention of Herpes zoster (shingles) and related complications in immunocompromised individuals (e.g. cancer, AIDS, organ transplant patients)
Infliximab biosimilar – ABP 710	Rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and ulcerative colitis – filing withdrawn

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Other EU developments (continued)

Ixazomib (Ninlaro)	Relapsed or refractory systemic light chain amyloidosis – development discontinued
Polatuzumab vedotin (Polivy)	Use in combination with bendamustine and rituximab for treatment of relapsed/refractory diffuse large B-cell lymphoma in adults who are not eligible for haematopoietic stem cell transplant – granted Early Access to Medicines Scheme (EAMS) status in UK
Romosozumab (Evenity)	Postmenopausal osteoporosis and osteoporosis in men – negative opinion
Selonsertib	Non-alcoholic steatohepatitis – development discontinued

New monographs (23)

		Phase in EU (US)
APL2	Paroxysmal nocturnal haemoglobinuria	PIII (PIII)
Apremilast (Otezla)	Genital plaque psoriasis in adults	PIII (PIII)
Apremilast (Otezla)	Mild-to-moderate plaque psoriasis in adults	None (PIII)
Apremilast (Otezla)	Plaque psoriasis in children aged 6 to 17 years	PIII (PIII)
Apremilast (Otezla)	Plaque psoriasis of the scalp in adults	None (PIII)
ATB200 + AT2221	Glycogen storage disease type II (Pompe disease) – first-line	PIII (PIII)
Avexitide (Exendin)	Post-bariatric hypoglycaemia	PIII (PIII)
Botulinum A toxin (Botox)	Treatment of lower limb muscle spasticity in children aged 2 to 17 years with cerebral palsy and stroke	PIII (Filed)
Botulinum A toxin (Botox)	Treatment of upper limb muscle spasticity in children aged 2 to 17 years with cerebral palsy and stroke	PIII (Launched)
Diazepam (Valtoco)	Epilepsy – intermittent use for acute repetitive or cluster seizures	None (Filed)
Dulaglutide (Trulicity)	Type 2 diabetes – 3mg and 4.5mg new dosing regimen	PIII (PIII)
Edasalonexent	Duchenne muscular dystrophy	PIII (PIII)
Etrasimod	Ulcerative colitis	PIII (PIII)
Faricimab	Neovascular (wet) age-related macular degeneration	PIII (PIII)
Lenvatinib (Lenvima)	Endometrial cancer – first-line with pembrolizumab	None (PIII)
Lenvatinib (Lenvima)	Advanced hepatocellular carcinoma – first-line with pembrolizumab	PIII (PIII)
Lenvatinib (Lenvima)	Malignant melanoma – first-line with pembrolizumab	PIII (PIII)
Lenvatinib (Lenvima)	Non-squamous non-small cell lung cancer – first-line with pembrolizumab	None (PIII)
Narsoplimab	Immunoglobulin A nephropathy (Berger disease)	PIII (PIII)
Pemigatinib	Intrahepatic cholangiocarcinoma with fibroblast growth factor receptor rearrangements	PIII (PIII)
Regorafenib (Stivarga)	Glioblastoma	None (PIII)
Secukinumab (Cosentyx)	Psoriatic arthritis, axial manifestations	PIII (PIII)
Trastuzumab biosimilar – EG12014	HER2-positive breast cancer	PIII (PIII)

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