Specialist Pharmacy Service New Medicines Newsletter

September 2019

This newsletter is produced by the UKMi 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.

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New product information

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

Adjuvanted Trivalent Influenza Vaccine	Active immunisation against influenza in the elderly aged ≥65 years, especially for those with an increased risk of associated complications [new Seqirus formulation]
Atezolizumab (*Tecentriq*)	First-line treatment of adults with metastatic non-squamous non-small cell lung cancer (NSCLC) who do not have EGFR-mutant or ALK-positive NSCLC – in combination with nab paclitaxel and carboplatin [new indication]
Bee venom (*Alutard SQ Bee*)	Allergy immunotherapy for patients with a documented history of generalised and/or systemic IgE-mediated allergic reactions due to sensitisation to honey bee venom (*Apis mellifera*), confirmed by skin prick test and/or intradermal test and/or specific IgE test [new formulation]
Diclofenac sodium (*Solacutan*)	For cutaneous treatment of actinic keratoses with a severity grade of 1 or 2 (according to Olsen), preferably on the face or scalp [new generic formulation]
Estriol (*Imvaggis*)	Local treatment of vaginal symptoms of estrogen deficiency in postmenopausal women [new 0.03mg pessary formulation]
Inotersen (*Tegsedi*)	Treatment of stage 1 or stage 2 polyneuropathy in adults with hereditary transthyretin amyloidosis
Insulin aspart (*Fiasp*)	Treatment of diabetes mellitus in adolescents and children aged ≥1 year [licence change from use only in adults]
Olodaterol (*Striverdi Respimat*)	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease [new reusable inhaler formulation that takes refills]
Pembrolizumab (*Keytruda*)	First-line treatment of advanced renal cell carcinoma in adults – in combination with axitinib [new indication]
Ranibizumab (*Lucentis*)	Treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease [new indication]
Tiotropium (*Spiriva Respimat*)	Maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease, and as add-on maintenance bronchodilator treatment in patients aged ≥6 years with severe asthma who experienced one or more severe asthma exacerbations in the preceding year [new reusable inhaler formulation that takes refills]
Tiotropium + olodaterol (*Spiolto Respimat*)	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease [new reusable inhaler formulation that takes refills]
Trifluridine + tipiracil (*Lonsurf*)	Monotherapy of adults with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction, who have been previously treated with ≥2 prior systemic treatment regimens for advanced disease [new indication]
Ustekinumab (*Stelara*)	Treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies [new indication]
Wasp venom (*Alutard SQ Wasp*)	Allergy immunotherapy for patients with a documented history of generalised and/or systemic IgE-mediated allergic reactions due to sensitisation to wasp venom (*Vespula spp.*), confirmed by skin prick test and/or intradermal test and/or specific IgE test [new formulation]

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

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 are 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
Clozapine orodiospersible tablets (*Zaponex*)	Treatment-resistant schizophrenia and in patients with schizophrenia who have severe, untreatable neurological adverse reactions to other antipsychotic agents, including atypical antipsychotics Psychosis during the course of Parkinson's disease, in cases where standard treatment has failed	*Zaponex* orodispersible is for direct oral administration on the tongue and should not be dissolved in water. Clozapine is brand prescribed and patients must be registered with the monitoring service connected to that brand. Some reports indicate that it is possible to switch between brands but there are reports of exacerbation of psychotic symptoms in patients who were switched. Further information on switching is at www.sps.nhs.uk/articles/which-medicines-require-extra-care-when-switching-between-liquid-and-tablet-capsule-formulations/.	Not planned
Influenza vaccine (*Flucelvax Tetra*)	Prophylaxis of influenza in adults and children aged ≥9 years	Only licensed for people aged ≥9 years. Further information on suitability of flu vaccines for different age groups is at www.gov.uk/government/publications/flu-vaccines-for-the-current-season.	Not planned
Teriparatide (*Terrosa*)	Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture	Biological medicines must be prescribed and dispensed by brand name. *Terrosa* is available as a pen with cartridge vs. the originator (*Forsteo*), which is supplied in a pre-filled pen.	Planned

Regulatory changes in the EU

Approved in the EU and/or UK

Cannabidiol (*Epidyolex*)	Adjunctive therapy of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, for patients aged ≥2 years
Larotrectinib (*Vitrakvi*)	Treatment of adult and paediatric patients with solid tumours that display a NTRK gene fusion, who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory treatment options
Rifamycin SV MMX (*Relafalk*)	Treatment of travellers' diarrhoea caused by non-invasive strains of *Escherichia coli* in adults

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New Medicines *Newsletter*

Recommended for approval in the EU

Avelumab (*Bavencio*)	First-line treatment of adults with advanced renal cell carcinoma in combination with axitinib [new indication]
Belimumab (*Benlysta*)	Add-on therapy in patients aged ≥5 years with active, autoantibody-positive systemic lupus erythematosus with a high degree of disease activity (e.g., positive anti dsDNA and low complement) despite standard therapy [licence change from use only in adults]
Dulaglutide (*Trulicity*)	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 [licence change to reflect glycaemic and cardiovascular benefits of dulaglutide by removing reference to the surrogate goal "to improve glycaemic control"]
Dupilumab (*Dupixent*)	Add-on therapy with intranasal corticosteroids for the treatment of adults with severe chronic rhinosinusitis with nasal polyposis for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control [new indication]
Gilteritinib (*Xospata*)	Monotherapy for the treatment of adults who have relapsed or refractory acute myeloid leukaemia with a FLT3 mutation
Infliximab biosimilar (*Remsima SC*)	In combination with methotrexate, for the reduction of signs and symptoms of rheumatoid arthritis as well as improvement in physical function in adults with active disease when response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate, and in adults with severe, active and progressive disease not previously treated with methotrexate or other DMARDs [new subcutaneous 120mg formulation]
Netarsudil mesilate (*Rhokiinsa*)	Reduction of elevated intraocular pressure in adults with primary open-angle glaucoma or ocular hypertension
Ranibizumab (*Lucentis*)	Treatment of proliferative diabetic retinopathy in adults [new indication]

Filed for approval in the EU

Rivaroxaban (*Xarelto*)	Venous thromboembolism in children [licence change]
Secukinumab (*Cosentyx*)	Severe active non-radiographic axial spondyloarthritis in adults who have responded inadequately to conventional therapy [new indication]

Other EU developments

Adalimumab biosimilar – M923	Psoriasis, rheumatoid arthritis and other *Humira* indications – development discontinued
Elenbecestat	Alzheimer's disease – development discontinued
Rovalpituzumab tesirine (*Rova-T*)	Small cell lung cancer – development discontinued

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New monographs (27)		*Phase in EU (US)*
Antisense K-ras RNA gene therapy	Unresectable, locally advanced pancreatic cancer	None (PII)
AR101	Peanut allergy in children aged 1 to 3 years	PIII (PIII)
AT-001	Diabetic cardiomyopathy	PIII (PIII)
Baloxavir marboxil (*CapEndo*)	Type A and B influenza – prophylaxis in people aged ≥12 years exposed to a household member	PIII (PIII)
Belantamab mafodotin	Relapsed or refractory multiple myeloma – monotherapy of adults whose prior therapy included a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody	PII (PII)
Cefepime + VNRX-5133	Complicated urinary tract infection	PIII (PIII)
Durvalumab (*Imfinzi*)	Advanced metastatic non-small cell lung cancer (EGFR/ALK w/t) – first-line monotherapy in combination with chemotherapy	PIII (PIII)
Durvalumab (*Imfinzi*)	Advanced metastatic non-small cell lung cancer (EGFR/ALK w/t) – first-line in combination with tremelimumab and chemotherapy	PIII (PIII)
Durvalumab (*Imfinzi*)	Extensive small cell lung cancer – first-line in combination with platinum-based chemotherapy	PIII (PIII)
Evobrutinib	Relapsing multiple sclerosis	PIII (PIII)
Idecabtagene vicleucel	Relapsed or refractory multiple myeloma (MM) in adults who have received at least two but no greater than four prior MM regimens	PIII (PIII)
Istradefylline (*Nourianz*)	Parkinson's disease	PIII (Approved)
Ixekizumab (*Taltz*)	Moderate to severe chronic plaque psoriasis in children aged 6-17 years	PIII (PIII)
Lurasidone (*Latuda*)	Schizophrenia in children and adolescents aged ≥13 years	PIII (PIII)
Narsoplimab	Atypical haemolytic uraemic syndrome in patients aged ≥12 years	PIII (PIII)
Natalizumab biosimilar – PB006	Relapsing-remitting multiple sclerosis	PIII (PIII)
Nirogacestat	Desmoid tumour or aggressive fibromatosis (fibroma)	PIII (PIII)
Olaparib (*Lynparza*)	Advanced ovarian cancer – first-line in combination with bevacizumab	PIII (None)
Olaparib (*Lynparza*)	Ovarian cancer (irrespective of BRCA status) – second-line after platinum therapy in combination with cediranib	None (PIII)
Olaparib (*Lynparza*)	Metastatic castration-resistant prostate cancer in all-comers – first-line in combination with abiraterone	PIII (PIII)
Olaparib (*Lynparza*)	Platinum-resistant recurrent ovarian cancer (all-comers) – second- and third-line	None (PIII)
Selinexor (*Xpovio*)	Recurrent and advanced endometrial cancer – maintenance treatment after first or second-line chemotherapy	PIII (None)
Tazemetostat	Epithelioid sarcoma	PIII (Filed)
Tebentafusp	Uveal melanoma	PII (PII)
Tepotinib	Advanced non-small cell lung cancer with mesenchymal–epithelial transition (MET) exon 14 skipping mutations or MET amplification	PII (PII)
Tezacaftor + ivacaftor (*Symkevi*)	Cystic fibrosis, homozygous or heterozygous for F508del mutation in patients aged ≥12 years who discontinued treatment with *Orkambi*	PIII (PIII)
Vonicog alfa (*Veyvondi*)	Prophylactic treatment in adults with von Willebrand disease	PIII (PIII)

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