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| **New product information**  |
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| ***Launched in the UK (or licence change for existing products)*** |
| Adalimumab biosimilar (*Amgevita HCF*) 20mg in 0.2mL prefilled syringe, and 40mg in 0.4mL and 80mg in 0.8mL prefilled pens and syringes | Treatment of rheumatoid arthritis in adults, juvenile idiopathic arthritis in patients aged ≥2 years, psoriatic arthritis in adults, axial spondyloarthritis in adults, Crohn’s disease in adults and children aged ≥6 years, ulcerative colitis in adults and children aged ≥6 years, plaque psoriasis in adults and children aged ≥4 years, hidradenitis suppurativa in adults and adolescents aged ≥12 years, and uveitis in adults and children aged ≥2 years *Note: For full details, see* [*SmPC*](https://products.mhra.gov.uk/search/?search=amgevita+hcf&page=1&doc=Spc&rerouteType=0) |
| Artesunate (*Artesunate Amivas*)110mg vial  | Initial treatment of severe malaria in adults and children |
| Cabotegravir (*Apretude*)30mg tablet and 600mg in 3mL vial | Use in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing ≥35kg [new injection and tablet formulations with new indication] |
| Elafibranor (*Iqirvo*)80mg tablet | Treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA |
| Enfortumab vedotin (*Padcev*)20mg and 30mg vials | Use in combination with pembrolizumab, for the first-line treatment of adults with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy [new indication] |
| Flecainide 25mg/5mL oral solution | AV nodal reciprocating tachycardia, arrhythmias associated with Wolff- Parkinson- White Syndrome and similar conditions with accessory pathways; Paroxysmal atrial fibrillation in patients with disabling symptoms when treatment need has been established and in the absence of left ventricular dysfunction; Symptomatic sustained ventricular tachycardia; Premature ventricular contractions and/or non-sustained ventricular tachycardia which are causing disabling symptoms, where these are resistant to other therapy or when other treatment has not been tolerated; Maintenance of normal rhythm following conversion by other means, in people aged ≥12 years [new oral solution formulation, from Colonis Pharma] |
| Fruquintinib (*Fruzaqla*)1mg and 5mg capsules | Treatment of adults with metastatic colorectal cancer who have been previously treated with available therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, with or without an anti-VEGF therapy, and, if RAS wildtype and medically appropriate, an anti-EGFR therapy |
| Levodopa + carbidopa + entacapone (*Lecigon*) 940mg/235mg/940mg in 47mL cartridge | Treatment of advanced Parkinson´s disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results [new intestinal gel formulation] |
| Midazolam (*Buccolam*)10mg in 2mL prefilled oral syringe | Treatment of prolonged, acute, convulsive seizures in adults, adolescents, children and infants aged ≥3 months [licence change from use only in infants, children and adolescents] |
| Nivolumab (*Opdivo*)40mg in 4mL, 100mg in 10mL, 120mg in 12mL and 240mg in 24mL vials | Use in combination with cisplatin and gemcitabine for the first-line treatment of adults with unresectable or metastatic urothelial carcinoma [new indication] |
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| **New product information**  |
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| ***Launched in the UK (or licence change for existing products)* (continued)** |
| Ocrelizumab (*Ocrevus*)920mg in 23mL vial | Treatment of adults with relapsing forms of multiple sclerosis with active disease defined by clinical or imaging features, and early primary progressive multiple sclerosis in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity [new subcutaneous formulation] |
| Pembrolizumab (*Keytruda*)100mg in 4mL vial | Use in combination with enfortumab vedotin, for the first-line treatment of adults with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy [anticipated new indication] *Note: See enfortumab above –* [*Keytuda*](https://products.mhra.gov.uk/search/?search=keytruda&page=1) *SmPC has not yet been updated* |
| Quizartinib (*Vanflyta*) 17.7mg and 26.5mg tablets | Use in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by *Vanflyta* single-agent maintenance therapy for adults with newly diagnosed acute myeloid leukaemia that is FLT3-ITD positive |
| Sacituzumab govitecan (*Trodelvy*)180mg vial | Monotherapy for the treatment of adults with unresectable or metastatic hormone receptor-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting [new indication] |
| Sofosbuvir + velpatasvir + voxilaprevir (*Vosevi*) 200mg/50mg/50mg tablet | Treatment of chronic hepatitis C virus infection in patients aged ≥12 years and weighing ≥30kg [new lower strength formulation] |
| Somapacitan (*Sogroya*)10mg in 1.5mL and 15mg in 1.5mL prefilled pens | Replacement of endogenous growth hormone (GH) in children aged ≥3 years, and adolescents with growth failure due to GH deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD) |
| Ustekinumab biosimilar (*Uzpruvo*) 45mg in 0.5mL and 90mg in 1mL prefilled syringes | 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] |
| Vibegron (*Obgemsa*)75mg tablet | Symptomatic treatment of adults with overactive bladder syndrome |
| von Willebrand factor (*Willfact*)500units in 5mL, 1,000units in 10mL and 2,000units in 20mL vials | Prevention and treatment of haemorrhage or surgical bleeding in patients with von Willebrand disease when desmopressin treatment alone is ineffective or contra-indicated, in all age groups [licence change from use only in people aged ≥12 years] |
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| **Regulatory changes in the UK or EU**  |
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| ***Approved in the UK*** |
| Donanemab (*Kisunla*)350mg in 20mL vial | Treatment of mild cognitive impairment and mild dementia due to Alzheimer’s disease in adults that are apolipoprotein E ε4 heterozygotes or non-carriers |
| Eplontersen (*Wainzua*)45mg in 0.8mL prefilled pen | Treatment of hereditary transthyretin-mediated amyloidosis in adults with Stage 1 and 2 polyneuropathy |
| Erdafitinib (*Balversa*)3mg, 4mg and 5mg tablets | Use as monotherapy for the treatment of adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting  |
| Faricimab (*Vabysmo*)21mg in 0.175mL prefilled syringe | Treatment of adults with neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema, visual impairment due to macular oedema secondary to retinal vein occlusion [new prefilled syringe formulation] |
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| **Regulatory changes in the UK or EU**  |
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| ***Approved in the UK* (continued)** |
| Liraglutide biosimilar (*Liraglutide Adalvo*)18mg in 3mL prefilled pen | Treatment of adults, adolescents and children aged ≥10 years 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, and in addition to other medicinal products for the treatment of diabetes |
| Lisocabtagene maraleucel (*Breyanzi*) 5.1-322 × 106 CAR+ viable T cells in 4.6mL vials (CD4+ and CD8+ cell components in separate vials) | Treatment of adults with diffuse large B-cell lymphoma, high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma and follicular lymphoma grade 3B, who relapsed within 12 months from completion of, or are refractory to, first-line chemoimmunotherapy [new indication] |
| KP.2 (*Comirnaty KP.2 30 micrograms/dose*)6-dose multi-dose vial and single-dose prefilled syringe | Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals aged ≥12 years |
| Sugemalimab (*Eqjubi*)600mg in 20mL vial | Use in combination with platinum-based chemotherapy for the first-line treatment of adults with metastatic non-small cell lung cancer with no sensitising EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations |
| Tocilizumab biosimilar (*Tofidence*) 80mg in 4mL vial, 200mg in 10mL vial and 400mg in 20mL vial | Use as monotherapy or in combination with methotrexate (MTX) for treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX; treatment of moderate to severe active RA in adults who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease- modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists; treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation; use as monotherapy or in combination with MTX for treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients aged ≥2 years, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids; treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients aged ≥2 years, who have responded inadequately to previous therapy with MTX [IV formulation] |
| Ustekinumab biosimilar (*Uzpruvo*) 130mg in 26mL vial | Treatment of adults with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies, and 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 |
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| ***Recommended for approval in the UK or EU*** |
| Bulevirtide (*Hepcludex*) | Treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult and paediatric patients aged ≥3 years weighing ≥10kg with compensated liver disease [EU] [licence change from use only in adults] |
| Buprenorphine (*Buprenorphine Neuraxpharm*) | Substitution treatment of opioid drug dependence, within a comprehensive therapeutic monitoring framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged ≥15 years, who have agreed to be treated for addiction [EU] [new sublingual film formulation] |
| Catumaxomab (*Korjuny*)  | Intraperitoneal treatment of malignant ascites in adults with epithelial cellular adhesion molecule-positive carcinomas, who are not eligible for further systemic anticancer therapy [EU] |
| Concizumab (*Alhemo*) | Routine prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors aged ≥12 years, or haemophilia B (congenital factor IX deficiency) with FIX inhibitors aged ≥12 years [EU] |
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| **Regulatory changes in the UK or EU**  |
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| ***Recommended for approval in the UK or EU* (continued)** |
| Eliglustat (*Cerdelga*) | For paediatric patients with Gaucher disease type 1 aged ≥6 years with a minimum body weight of 15kg, who are stable on enzyme replacement therapy, and who are CYP2D6 poor metabolisers, intermediate metabolisers or extensive metabolisers [EU] [new indication and new 21mg capsule formulation] |
| Eplontersen (*Wainzua*) | Treatment of hereditary transthyretin-mediated amyloidosis in adults with Stage 1 and 2 polyneuropathy [EU] |
| Influenza vaccine (*Fluad*) | Prophylaxis of influenza in adults aged ≥50 years [EU] |
| Influenza vaccine (*Flucelvax*) | Prophylaxis of influenza in adults and children aged ≥2 years [EU] |
| Linzagolix (*Yselty*) | Use in adult women of reproductive age for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis [EU] [new indication] |
| Ribociclib (*Kisqali*) | Use in combination with an aromatase inhibitor for the adjuvant treatment of patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative early breast cancer at high risk of recurrence. In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with a luteinising hormone-releasing hormone agonist [EU] [new indication] |
| Sarilumab (*Kevzara*) | Treatment of polymyalgia rheumatica in adults who have had an inadequate response to corticosteroids or who experience a relapse during corticosteroid taper [EU] [new indication] |
| Tislelizumab (*Tevimbra*) | Use in combination with platinum-based chemotherapy for the first-line treatment of adults with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma whose tumours express PD‑L1 with a tumour area positivity score ≥5% [EU] [new indication] |
| Tislelizumab (*Tevimbra*) | Use in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of adults with human epidermal growth factor receptor 2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumours express PD‑L1 with a tumour area positivity score ≥5% [EU] [new indication] |
| Ustekinumab biosimilar (*Absimky*) | Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or psoralen and ultraviolet A; treatment of moderate to severe plaque psoriasis in children and adolescents aged ≥6 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies; alone or in combination with MTX, for the treatment of active psoriatic arthritis in adults when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate; treatment of adults with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies; and 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 [EU] |
| Ustekinumab biosimilar (*Imuldosa*) | Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or psoralen and ultraviolet A; treatment of moderate to severe plaque psoriasis in children and adolescents aged ≥6 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies; alone or in combination with MTX, for the treatment of active psoriatic arthritis in adults when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate; and treatment of adults with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies [EU] |
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| **Regulatory changes in the UK or EU**  |
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| ***Filed for approval in the UK or EU*** |
| Aflibercept biosimilar – AVT06 | Wet age-related macular degeneration and other *Eylea* indications – to be confirmed [EU] |
| Daratumumab (*Darzalex*) | Use in combination with bortezomib, lenalidomide, and dexamethasone for the treatment of adults with newly diagnosed multiple myeloma [EU] [new indication] |
| Denosumab biosimilar – AVT03 | Postmenopausal osteoporosis and other *Prolia* indications [EU] |
| Denosumab biosimilar – AVT03 | Prevention of skeletal related events in adults with advanced malignancies involving bone and other *Xgeva* indications [EU] |
| Insulin glargine biosimilar (*Basalin*) | Treatment of type 1 and 2 diabetes mellitus in adults, adolescents and children aged ≥2 years [EU] |
| Insulin lispro biosimilar (*Prandilin*) | Treatment of type 1 and 2 diabetes mellitus in adults and children [EU] |
| Lifileucel (*Amtagvi*) | Treatment of unresectable or metastatic melanoma in patients who have previously been treated with at least one systemic therapy, including a PD-1 blocking antibody and if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor [EU] |
| Nemolizumab (*Nemluvio*) | Moderate to severe prurigo nodularis in adults [UK] |
| Octreotide (*Oclaiz*) | Treatment of acromegaly in adults [EU] [new subcutaneous formulation] |
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| ***Other UK/EU developments*** |
| Abemaciclib (*Verzenios*) | Advanced, HR-positive, HER2-negative breast cancer, following relapse/progression on or after treatment with a CDK4/6 inhibitor and endocrine therapy, in adults, with fulvestrant – UK development discontinued (company decision) |
| Ataluren (*Translarna*) | Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged ≥2 years – confirmation of the previous recommendation to not renew the conditional licence in the EU |
| Avacincaptad pegol (*Izelvay*) | Treatment for geographic atrophy secondary to age-related macular degeneration in adults – EU filing withdrawn |
| Bimatoprost (*Durysta*) | Glaucoma and ocular hypertension, in adults, sustained-release implant – UK development discontinued (company decision) |
| Belantamab mafodotin (*Blenrep*) | Use as 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 – UK licence withdrawn |
| Gemcitabine  | Muscle invasive bladder cancer in adults, intravesical delivery system with cetrelimab – development discontinued (lack of efficacy) |
| Ianalumab  | Autoimmune hepatitis in adults – development discontinued (company decision) |
| Leukocyte interleukin (*Multikine*) | Newly diagnosed, locally advanced, squamous cell carcinoma of head and neck in adults, neoadjuvant therapy with cyclophosphamide, indometacin and zinc – UK development discontinued (company decision) |
| Ligelizumab  | Prevention of food allergic reactions – development discontinued (company decision) |
| Masitinib (*Masitinib AB Science*) | Early-stage amyotrophic lateral sclerosis in adults – not approved in EU |
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| **Regulatory changes in the UK or EU**  |
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| ***Other UK/EU developments* (continued)** |
| Nivolumab (*Opdivo*) | Locally advanced, non-resectable stage III non-small cell lung cancer in adults, first-line with chemoradiotherapy then nivolumab and ipilimumab – development discontinued (lack of efficacy) |
| Selpercatinib (*Retsevmo*) | Advanced relapsed or refractory, RET fusion-positive solid tumours in people aged 12 years and older, last-line – UK development discontinued (company decision) |
| Sisunatovir  | Treatment of respiratory syncytial virus (RSV) infection in adults and children with risk factors for severe RSV – development discontinued (company decision) |
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