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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)*** | |
| Abaloparatide (*Eladynos*)  3mg in 1.5mL prefilled pen | Treatment of osteoporosis in postmenopausal women at increased risk of fracture |
| Aripiprazole (*Abilify Maintena*)  960mg in 3.2mL and 720mg in 2.4mL prefilled syringes | Maintenance treatment of schizophrenia in adult patients stabilised with aripiprazole [new 2-monthly intramuscular formulation] |
| Faricimab (*Vabysmo*)  28.8mg in 0.24mL vial | Treatment of adults with neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema, and visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)  [licence change to include treatment of visual impairment due to macular oedema secondary to retinal vein occlusion] |
| Latanoprost + timolol  (*Vizilatan Duo*)  50mg/5mg in 1mL eye drops | Use in adults (including the elderly) for the reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues |
| Oxybutynin (*Velariq*)  10mg in 10mL prefilled syringe | Suppression of neurogenic detrusor overactivity in children aged ≥6 years and adults, who are managing bladder emptying by clean intermittent catheterisation, not adequately managed with oral anticholinergics [new intravesical formulation] |
| Ranibizumab biosimilar (*Rimmyrah*)  2.3mg in 0.23mL vials | Treatment of neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema, proliferative diabetic retinopathy, visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularisation |
| Risankizumab (*Skyrizi*)  360mg in 2.4mL cartridge with on-body injector and 600mg in 10mL vial | Treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy [new indication] |
| Tafamidis (*Vyndaqel*)  61mg capsule | Treatment of wild-type or hereditary transthyretin amyloidosis in adults with cardiomyopathy [new higher strength capsule formulation with new indication] |
| Tapentadol (*Palexia*)  20mg in 1mL oral solution | Relief of moderate to severe acute pain in children and adolescents aged ≥2 years with a body weight >16kg and in adults, which can be adequately managed only with opioid analgesics [licence change from use only in adults] |
| Tapentadol (*Palexia SR*)  50mg, 100mg, 150mg, 200mg and 250mg tablets | Management of severe chronic pain in children >6 years and adolescents, which can be adequately managed only with opioid analgesics [new indication] |
| Tenecteplase (*Metalyse*)  5,000units (25mg) vial | Use in adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from last known well and after exclusion of intracranial haemorrhage  [new 5,000unit vial formulation with new indication] |
| Ustekinumab biosimilar (*Pyzchiva*)  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 |
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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)* (continued)** | |
| Ustekinumab biosimilar (*Pyzchiva*)  45mg in 0.5mL and 90mg in 1mL prefilled syringes | 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 PUVA (psoralen and ultraviolet A); treatment of moderate to severe plaque psoriasis in children and adolescent patients aged ≥6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies; use 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 |
| Ustekinumab biosimilar (*Uzpruvo*)  45mg in 0.5mL and 90mg in 1mL prefilled syringes | 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 PUVA (psoralen and ultraviolet A); treatment of moderate to severe plaque psoriasis in children and adolescent patients aged ≥6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies; use alone or in combination with MTX for 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 |
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| **Regulatory changes in the UK or EU** | | |
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| ***Approved in the UK*** | | |
| Adalimumab biosimilar (*Amgevita HCF*)  20mg in 0.2mL prefilled syringe, and 40mg in 0.4mL and 80mg in 0.8mL prefilled pen and syringe | | 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, 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) |
| Binimetinib (*Mektovi*)  45mg tablet | | Use in combination with encorafenib for the treatment of adults with unresectable or metastatic melanoma with a BRAF V600 mutation [new higher strength formulation] |
| Crovalimab (*PiaSky*) 340mg in 2mL vial | | Use as monotherapy for the treatment of adult and paediatric patients aged ≥12 years with a weight ≥40kg with paroxysmal nocturnal haemoglobinuria, in patients with haemolysis with clinical symptom(s) indicative of high disease activity, and in patients who are clinically stable after having been treated with a complement component 5 inhibitor for at least the past 6 months |
| Danicopan (*Voydeya*)  50mg and 100mg tablets | | Use as an add-on to ravulizumab or eculizumab for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have residual haemolytic anaemia |
| Dantrolene (*Agilus*)  120mg vial | | Use in combination with adequate support measures for the treatment of malignant hyperthermia in adults and children of all ages [new formulation] |
| Iptacopan (*Fabhalta*)  200mg capsule | | Use as monotherapy in the treatment of adults with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia |
| Lecanemab (*Leqembi*)  500mg in 5mL and 200mg in 2mL vials | | Treatment of mild cognitive impairment and mild dementia due to Alzheimer’s disease in adults that are apolipoprotein E ε4 heterozygotes or non-carriers |
| Omalizumab (*Xolair*)  150mg in 1mL and 300mg in 2mL prefilled pens | | Treatment of allergic asthma in adults, adolescents and children aged 6 to 11 years, chronic rhinosinusitis with nasal polyps in adults and chronic spontaneous urticaria in adults [new prefilled pen formulations] *Note: For full details, see* [*SmPC*](https://products.mhra.gov.uk/search/?search=xolair&page=1&doc=Spc&rerouteType=0) |
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| **Regulatory changes in the UK or EU** | | | |
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| ***Approved in the UK* (continued)** | | | |
| Omalizumab (*Xolair*) 75mg in 0.5mL prefilled pen | Treatment of allergic asthma in adults, adolescents and children aged 6 to 11 years and chronic rhinosinusitis with nasal polyps in adults [new prefilled pen formulation]  *Note: For full details, see* [*SmPC*](https://products.mhra.gov.uk/search/?search=xolair&page=1&doc=Spc&rerouteType=0) | | |
| Risankizumab (*Skyrizi*)  180mg in 1.2mL cartridge with on-body injector | Treatment of patients aged ≥16 years with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable, and treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy  [new subcutaneous formulation including with new UC indication] | | |
| Zolbetuximab (*Vyloy*)  100mg vial | Use in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2‑negative gastric or gastro-oesophageal junction adenocarcinoma whose tumours are Claudin 18.2 positive | | |
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| ***Filed for approval in the UK or EU*** | | | |
| Delandistrogene moxeparvovec  (*Elevidys*) | | | Treatment of Duchenne muscular dystrophy in children aged 4 to 7 years [EU] |
| Iptacopan (*Fabhalta*) | | | Use in combination with a renin -angiotensin system inhibitor, for the treatment of adults with complement 3 glomerulopathy [EU] [new indication] |
| Lisocabtagene maraleucel  (*Breyanzi*) | | | Treatment of adults with relapsed or refractory follicular lymphoma who have received two or more prior lines of systemic therapy [EU] [new indication] |
| Semaglutide (*Wegovy*) | | | Treatment of heart failure with preserved ejection fraction in adults with obesity with or without diabetes [EU] [new indication] |
| Smallpox vaccine (*Imvanex*) | | | Active immunisation against smallpox, mpox and disease caused by vaccinia virus in adults and adolescents aged 12 to 17 years [EU] [licence change from use only in adults] |
| Ustekinumab biosimilar  – BAT-2206 | | | Moderate to severe chronic plaque psoriasis in adults and other *Stelara* indications (except ulcerative colitis) [EU] |
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| ***Other UK/EU developments*** | | | |
| Evolocumab  (*Repatha SureClick*) | | | Cardiovascular (CV) disease event reduction in adults with no previous myocardial infarction or stroke at high CV risk – development discontinued (company decision) |
| IMCY-0098 | | | Preservation of beta cell function in adults within 9 weeks of diagnosis of type 1 diabetes mellitus – development discontinued (lack of efficacy) |
| Lisocabtagene maraleucel (*Breyanzi*) | | | Relapsed or refractory diffuse large B-cell lymphoma in adults, third-line plus – UK development discontinued (company decision) |
| Navitoclax | | | Primary or secondary, intermediate-2 or high risk myelofibrosis, first- and second-line – development discontinued (lack of efficacy) |
| Pembolizumab (*Keytruda*) | | | Locally advanced, high-risk cutaneous squamous cell carcinoma in adults, adjuvant monotherapy – development discontinued (lack of efficacy) |
| Pembolizumab (*Keytruda*) | | | Unresected early-stage non-small cell lung cancer in adults, first-line with stereotactic body radiotherapy – development discontinued (lack of efficacy and safety concern) |
| Pembrolizumab + vibostolimab | | | Extensive-stage small cell lung cancer in adults – development discontinued  (lack of efficacy) |
| Potassium bicarbonate + potassium citrate | | | Cystinuria in patients aged ≥6 months – development discontinued (company decision) |
| Valoctocogene roxaparvovec  (*Roctavian*) | | | Treatment of severe haemophilia A (congenital factor VIII deficiency) in adults – UK development discontinued (company decision) |
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