

New Indication list

No	Date of approval	Product name	MAH	Active ingredient	The new Indication
1.	28/4/2010	Aclasta solution for injection	Novartis	Zoledronic Acid	Hip fractures, glucocorticoid induced osteoporosis, osteoporosis in men.
2.	4/2010	Seroquel tab	Astrazeneca	Queitiapine fumarate	Major depressive episodes in bipolar disorder
3.	4/2010	Nexuim tab	Astrazeneca	Esomeprazole	Prolonged treatment of re-bleeding
4.	5/2010	Herceptin vial 440	Roche	Trastuzumab	In combination w aromatase inhibitor for post-menopausal
5.	2/9/2010	Glivec 100mg & 400mg tab	Novartis	Imatinib	<p>1- Treatment of adults with acute Lymphoblastic leukemia (ALL) in combination with standard chemotherapy.</p> <p>2- Treatment of adult patients with hypereosinophilic syndrome (HES) atypical myelodysplastic / myeloproliferative disease (MDS/MPD) or aggressive systemic mastocytosis (SM) associated with eosinophilia and a platelet derived growth factor (PDGF) receptor alpha or beta mutation or FIP1L 1- PDGFR – alpha fusion protein.</p> <p>3- New indication: adjuvant treatment of adults following resection of non-metastatic malignant GIST.</p> <p>4- New indication: Treatment with unrespectable, recurrent metastasis dermatofibrosarcoma Protuberant (DFSP)</p>
6.	17/5/2011	Tykerb tab	Glaxo welcome	lapatinib	for patients with advanced, metastatic breast cancer that is HER2 positive
7.	29/6/2011	Tarceva	Roche	Erlotinib	Pancreatic cancer

8.	12/11/2011	Aclasta solution for inj	Novartis	Zoledronic Acid	Treatment of osteopenia in postmenopausal women who have at least one risk factor.
9.	23/1/2012	Seroquel XR tab	Astra Zeneca	Quetiapine fumarate	Bipolar disorder including: -Manic episodes associated with bipolar disorder. -Major depressive episodes in bipolar disorder. -Preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episodes has responded to Quetiapine treatment.
10.	25/3/2012	Lyrica cap	Pfizer	Pregabalin	Fibromyalgia
11.	5/3/2013	Plavix 75mg FC tablet	Sanofi	Clopidogrel	Atrial fibrillation
12.	29/5/2013	Afinitor 5mg, 10mg tablet	Novartis	Everolimus	Pancreatic origin
13.	30/6/2014	Afinitor 5mg, 10mg tablet	Novartis	Everolimus	In combination with exemestane for the treatment of postmenopausal women with advanced hormone-receptor positive, HER2-negative breast cancer following failure of treatment with letrozole or anastrozole.
14.	19/8/2014	Lucentis vial	Novartis	Ranibizumab	Visual impairment due to choroidal neovascularization (CNV) secondary to pathological Myopia (PM)
15.	21/8/2014	Botox 100 U vial	Allergan	Botulinum Toxin Type A	Idiopathic Overactive Bladder (IOAD)
16.	31/8/2014	Nexavar 200 mg tablets	Bayer	Sorafenib (as tosylate)	Thyroid cancer (Differentiated Thyroid Carcinoma)
17.	10/11/2013	Cialis 5 mg tablets	Lilly	Tadalafil	Benign prostatic hyperplasia
18.	25/11/2014	Eylea vial	Bayer	Aflibercept	Impaired vision due to Diabetic Macular Oedema (DME)
19.	27/11/2014	Stivarga 40 mg F.C.T	Bayer	Regorafenib	Gastrointestinal Stromal Tumors (GIST)
20.	16/6/2015	Xolair 150mg powder for solution for injection	Novartis	Omalizumab	Chronic Spontaneous Urticaria (CSU).

22.	3/9/2015	Pradaxa 150mg	Boehringer Ingelheim	Dabigatran Etexilate	Deep vienthrombosis (DVT), pulmonary embolism (PE), prevention of recurrent DVT &PE in adults.
23.	21/9/2015	Spiriva respimat 2.5µg tablet	Boehringer Ingelheim	Tiotropium	Helps people who have asthma to breath more easily.
24.	27/10/2015	Prolia solution for injection	Amgen	Denosumab	Treatment of osteoporosis in men .
26.	17/11/2015	Somatuline Autogel 90mg, 60mg &120mg	IPSEN pharma	Lanreotide	Gastroenteropanceriatic Newroendecies Tumers (GEP-NET)
.27	20/3/2016	Multihance (10,15,20ml)	Bracco S.P.A	Gadobenate Dimeglumine	MRI for breast
28.	31/3/2016	Eylea 40mg/ml solution for injection	Bayer pharma	Aflibercept	1. Branch RVO(BRVO) & RVO (CRVO). 2.impaired vision due to myopic choroidal neovascularization (myopic CNV)
29.	14/4/2016	Avastin 100mg/4ml & 400mg/6ml	Roche	Bevacizumab	1. Ovarian cancer for relapsing platinum resistant 2. Cervical cancer.
30.	25/4/2016	Dysport powder for solution for injection (300IU)	Ipsen	Clostridium (Bot.Toxin Type A Toxin)	1. Prevent the muscles which cause frown lines from contracting. 2. Used in adults under 65 years to temporarily improve the appearance of any moderate to severe gallbladder lines.
31.	17/5/2016	Prograf capsules	Hikma	Tacrolimus	Transplantation of heart.
32.	23/6/2016	Invanz 1gm powder for solution	MSD	Ertapenem	Complicated urinary tract infection including pyelonephritis
33.	10/7/2016	Xgeva solution for injection 70mg/ml	Amgen	Denosumab	Treatments of adults& skeletally mature adolescents with giant cell tumor of bone that is unresectable or when surgical resection is likely to result in severe morbidity)
34.	25/10/2016	Humira 40mg/.8ml PFS	Vetter pharma	Adalimumab	Treatment of active moderate to severe hudradenitis suppurative (acne inversa) in adult patients with an inadequate response to conventional systemic

					HS therapy.
35.	13/12/2016	Zemplar 2mcg soft gelatin cap	Abbvie	Paricalcitol	Chronic kidney disease stage 5
36.	9/2/2017	Vfend powder for solution for infusion 200mg vial	Pfizer	Voriconazole	-Treatment of candidemia in non-neutropenic patients. -(prophylaxis of invasive fungal infections in high risk HSCT recipients)
37.	6/11/2017	Humira 40mg/0.8ml solution for injection	AbbVie	Adalimumab	Noninfectious affecting the back of the eye
38.	7/1/2018	Inegy 10/20mg & 10/40mg tablet	MSD	Simvastatin & Ezetimibe	Heart disease , Inegy reduces the risk of heart attack, stroke , surgery to increase heart blood flow or hospitalization for chest pain .
39.	18/1/2018	Opdivo Injection solution for infusion 40mg/4ml & 100mg/10ml	Bristol Myers	Nivolumab	Recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum based therapy.
40.	26/4/2018	Revolade 25 mg F.C Tablet	Novartis Pharma	Eltrombopag Olamine	1. treatment of thrombocytopenia in patients with chronic hepatitis C virus (HCV) infection 2. treatment of cytopenias in adult patients with acquired severe aplastic anaemia (SAA)
41.	3/6/2018	Gazyva 1000 mg / 40 ml Vial	Hoffmann -La Roche	Obinutuzumab	in the treatment of patients with follicular lymphoma (FL) in combination with bendamustine.
42.	4/6/2018	Keytruda 100mg/4 ml Solution of injection(vial)	MSD	Pembrolizumab	-adult and pediatric patients with refractory classical Hodgkin lymphoma (CHL) -Urothelial Carcinoma
43.	11/7/2018	Xalkori (Crizotinib) 200 & 250 mg Capsule	Pfizer	crizotinib	The treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC)
44.	24/7/2018	Perjeta 420 mg/ 14 ml	Roche diagnostic	Pertuzumab	In combination with Herceptin & docetaxl for neoadjuvant treatment of patients with HER2-Positive , locally advanced , inflammatory breast cancer or early breast cancer at high risk of recurrence

45.	2/8/2018	Stivarga 40mg tablet	Bayer Pharma AG	Regorafenib	Liver cancer in patients who have been previously treated with another anticancer medicine sorafenib
46.	27/8/2018	Stelara 90 mg/1ml 45 mg/0.5ml solution for injection PFS	Janssen-Cilag International	Ustekinumab	Second line treatment "moderate to severe Crohn's disease-in adults"
47.	23/9/2018	Ecalta 100 mg powder for conc. For solution for infusion	Pfizer	Anidulafungin	Prescribe in adult to treat a type of fungal infection of the blood or other internal organs called candidiasis
48.	3/10/2018	Fycompa (2,4,6,8,10,12 mg) tablet	HIKMA	Peramanel	Generalized seizures
49.	28/10/2018	Decapeptyl P.R 11.25mg & 22.5mg powder and solvent for suspension for injection	Ipsen	Triptorelin	In children: for treatment of central precocious)
50.	28/10/2018	Decapeptyl P.R 3.75mg powder and solvent for suspension for injection	Ipsen	Triptorelin	As adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in women at high risk of recurrence who are confirmed as pre-menopausal after completion of chemotherapy
51.	28/10/2018	Foster pressurized inhalation solution (100/6mcg)	Chiesi Farmaceutici	Beclomethasone dipropionate & formoterol fumarate dehydrate	use of foster in patients with severe COPD (fev1<50% predicted normal) and a history of repeated exacerbation who have significant symptoms despite regular therapy with long-acting bronchodilators.
52.	28/10/2018	Xarelto 10mg FCT	Bayer AG	Rivaroxaban	Treatment of deep vein thrombosis and pulmonary embolism
53.	19/11/2018	Primolut nor 5mg tablet	Bayer Pharma AG	Norethisterone Acetate 5	-Secondary amenorrhea -Endometriosis
54.	26/11/2018	Simponi 50mg/.05ml	Baxter pharmaceutical solutions	Golimumab	In children weighing at least 40Kg, simponi is used for treatment of polyarticular Juvenile arthritis

55.	11/2/2019	Opdivo injection 40mg/4ml & 100mg/10ml solution for infusion	Bristol Myers	Nivolumab	-Urothelial carcinoma -Colorectal cancer (CRC) -Hepatocellular carcinoma (HCC)
56.	13/2/2019	Glivec 100 & 400 FCT	Novartis pharma AG	Imatinib	Adult patients with relapsed or refractory ph +ALL as monotherapy)
57.	20/2/2019	Zovirax 200mg & 800mg tablets	GlaxoSmithkline	Aciclovir	Treatment of severe herpes simplex virus infections of the skin and mucous membranes including initial and recurrent genital herpes: "except neonatal HSV and severe HSV infection in children with reduced immune response
58.	18/9/2019	Keytruda 100mg/4ml	MSD	Pembrolizumab	- Cervical cancer - Hepatocellular carcinoma HCC
59.	11/6/2020	Keytruda 100mg/4ml	MSD	Pembrolizumab	.1 Adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection. .2 NSCLC .3 Metastatic small cell lung cancer (SCLC) 4. First-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC). 5. Metastatic or with unresectable, recurrent HNSCC 6. Merkel Cell Carcinoma 7. Renal Cell Carcinoma
60.	24/9/2020	Imuran 50 Tablet	Aspen	Azathioprine	treat inflammatory bowel disease (Chron's disease or ulcerative colitis).
61.	17/11/2020	Opdivo 100mg/10ml & 40mg/4ml solution for infusion	Bristol myers	Nivolumab	small cell lung cancer

62.	17/11/2020	Yervoy 200mg/40ml & 50mg/10ml solution for infusion	Bristol myers	Ipilimumab	1. NSCLC, 2.Hepatocellular carcinoma, 3.Rectal carcinoma
63.	19/11/2020	Visipaque 270mgI/ml & 320mgI/ml solution for infusion	GE healthcare AS	Iodixanol	1.Gastrointestinal tract studies 2. Arthrography and Hysterosalpingography (HSG)
64.	20/12/2020	Tecentriq 1200mg/20ml concentrate for solution for infusion	F.Hoffmann La-Roche	Atezolizumab	1.Non-small cell lung cancer 2.Small cell lung cancer
65.	24/12/2020	Glypressin 1mg/8.5 ml solution for injection	Ferring	Terlipressin	Hepatorenal Syndrome

Note: If you have any objection please don't hesitate to contact us

Registration Department

Drug Directorate

Jordan Food & Drug Administration