

## New chemical Entity Registered (2012-2020)

#	Product Name	Registration Date (ل ف 1)	Dosage form	Strength	Active Ingredient	Drug Store	Marketing Authorization Holder
1	Multaq F.C tab IBD: 31/7/2009 Submission date:14/10/2010	19/6/2012	F.C tab	400mg	Dronedarone	Ulfa Drug Store	Sanofi –Aventis
2	Prolia. IBD: 26/5/2010 Submission date:16/12/2010	4/3/2012	Solution for inj in PFP	60mg/ml	Denosumab	Adatco drug store	Amgen
3	Onglyza IBD: 31/7/2009 Submission date:27/1/2011	17/5/2012	Tab	5mg	Saxagliptin	Shawi & Rushedat Drug Store	Astrazeneca
4	Gilenya IBD: 17/8/2010 Submission date:28/4/2011	15/4/2012	Cap	0.5mg	Fingolimod	The Jordan Drugstore Co	Novartis
5	Brilinta IBD: 3/12/2010 Submission date:12/5/2011	11/7/2012	Tab	90mg	Ticagrelor	Shawi & Rushedat Drug Store	Astrazeneca
6	Jevtana vial IBD: 17/8/2010 Submission date:28/4/2011	22/1/2013	conc. & solvent for infusion.	60mg	Cabazitaxel	Ulfa Drug Store	Sanofi
7	Zytiga IBD: 28/4/2011 Submission date:26/1/2012	10/11/2013	Tablet	250mg	Abitraterone Acetate	Telegraph Drug Store	Janssen-Cilag Inernational

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8	Brinavess IBD: 9/2010 Submission date:27/10/2011	<b>14/3/2013</b>	Concentrate for Solution for infusion	20mg/ml	Vernakalant Hcl	Adatco drug store	MSD LTD
9	Trajenta IBD: 20/5/2011 Submission date: 6/11/2012	<b>9/10/2013</b>	Film coated tablet	5mg	Linagliptin	Arab drug store (shqer)	Boehringer Ingelheim International GmbH, Ingelheim am Rhein
10	Incivo IBD: 23/5/2011 Submission date:13/3/2012	<b>21/10/2013</b>	Film coated tablet	375mg	Telaprevir	Ninos drug store	Janssen-Cilag international
11	Victrelis IBD : 13/5/2011 Submission date : 19/2/2012	<b>21/7/2013</b>	Hard capsule	200mg	Boceprevir	Adatco drug store	MSD/Ltd UK
12	Stivarga IBD : 27/9/2012 Submission date : 14/8/2013 Commission decision date : 2/4/2014	<b>20/5/2014</b>	Film coated tablet	40 mg	Regorafenib	Khori drug store	Bayer Pharma A G / Germany
13	Eylea IBD : 18/11/2011 Submission date : 4/4/2013 Commission decision date : 21/5/2014	<b>6/7/2014</b>	Solution for injection	40mg /ml	aflibercept	Khori drug store	Bayer Pharma A G / Germany
14	Signifor IBD : 24/4/2012 Submission date : 20/5/2013 Commission decision date : 5/11/2014	<b>8/2/2015</b>	Solution for injection	0.3mg /ml 0.6mg /ml 0.9mg/ml	Pasireotide Dispartate	The Jordan Drugstore Co	Novartis Pharma /Switzerland

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15	Zelboraf IBD : 17/8/2011 Submission date : 14/10/2012 Commission decision date : 19/11/2014	<b>4/2/2015</b>	Film coated tablet	240mg	Vemurafenib	Shawi & Rushedat Drug Store	F.hoffman la-Roche /Switzerland
16	Lyxumia IBD : 7/1/2013 Submission Date : 28/11/2013 Commission decision date : 5/8/2015	<b>9/12/2015</b>	Pre-filled Pen	10mcg 20mcg 10&20 mcg	Lixisenatide	Ulfa Drug Store	Sanofi avemtis groupe/ France
17	Exviera IBD : 15/1/2015 Submission Date : 10/2/2015 Commission decision date : 12/8/2015	<b>30/8/2015</b>	Tablet	250 mg	Dasabuvir	Abu sheikha drug store	Abbvie limited / UK
18	Viekirax IBD : 15/1/2015 Submission Date : 10/2/2015 Commission decision date : 19/8/2015	<b>30/9/2015</b>	Tablet	12.5 mg 75mg 50 mg	Ombitasvir Paritaprevir Ritonavir	Abu sheikha drug store	Abbvie limited / UK
19	Giotrif IBD : 2/7/2013 Submission Date : 29/9/2014 Commission decision date : 16/9/2015	<b>26/11/2015</b>	Film coated tablet	20 mg	Afatinib	Arab drug store (shqer)	Boehringer ingelheim international / Germany

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20	Entresto IBD : 7/7/2015 Submission Date : 7/7/2015 Commission decision date : 6/1/2016	<b>27/1/2016</b>	Film coated tablet	50mg 100mg 200 mg	Sacubitril/Valsartan	The Jordan Drugstore Co	Novartis Pharma /Switzerland
21	Keytruda IBD : 4/9/2014 Submission Date : 1/7/2015 Commission decision date : 29/6/2016	<b>3/8/2016</b>	Solution for infusion	100mg/4ml	Pembrolizumab	Adatco drug store	MSD/Ltd USA
22	Repatha IBD 17/7/2015 Submission Date : 6/12/2015 Commission decision date : 27/7/2016	<b>30/8/2016</b>	Solution for injection	140mg/ml	Evolocumab	Adatco drug store	Amgen Europe /Netherlands
23	Harvoni IBD : 10/10/2014 Submission Date : 28/10/2015 Commission decision date : 20/7/2016	<b>21/8/2016</b>	Film coated tablet	90mg 400mg	Ledipasvir Sofosbuvir	Beta drug store	Gilead Sciences International LTD/ UK
24	Opdivo IBD : 4/7/2014 Submission Date : 22/10/2015 Commission decision date : 20/7/2016	<b>2/11/2016</b>	Solution for infusion	40mg/4ml	Nivolumab	Orient drug store	Bristol Mayers Squibb NJ /USA
25	Cosentyx IBD : 26/12/2014 Submission Date : 13/4/2015 Commission decision date : 23/11/2016	<b>18/12/2016</b>	Solution for injection	150mg/ml	Secukinumab	The Jordan Drugstore Co	Novartis Pharma AG-Basel /Switzerland

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26	Daklinza IBD : 4/7/2014 Submission Date : 30/3/2015 Commission decision date : 21/9/2016	<b>15/11/2016</b>	Film coated tablet	60mg	Daclatasvir	Orient drug store	Bristol Myers Squibb /UK
27	Jardiance IBD : 17/4/2014 Submission Date :20/9/2015 Commission decision date: 8/2/2017	<b>29/3/2017</b>	Tablet	10 mg 25 mg	Empagliflozin	Arab drug store (shqer)	Boehringer ingelheim international /Germany
28	Blincyto IBD : 3/12/2014 Submission Date : 5/10/2015 Commission decision date : 22/3/2017	<b>25/4/2017</b>	Lyophilized powder in a single-use vial for reconstitution	35 mcg	Binatumomab	Adatco drug store	Amgen Inc/USA
29	Ibrance IBD : 3/2/2015 Submission Date :19/5/2016 Commission decision date : 24/5/2017	<b>17/7/2017</b>	Capsule	75 mg 100 mg 125 mg	Palbociclib	Sabagh drug store	Pfizer Inc/USA
30	Darzalex IBD : 16/11/2015 Submission Date : 22/9/2016 Commission decision date: 5/7/2017	<b>15/11/2017</b>	Concentrate for solution for infusion	400mg /20 ml 100mg /5ml	Daratumumab	Ninos drug store	Janssen –Cilag international NV/Belgium

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31	Kisqali IBD : 13/3/2017 Submission Date : 12/7/2017 Commission decision date : 27/12/2017	<b>11/1/2018</b>	Film Coated tablet	200mg	Ribiciclib	The Jordan Drugstore Co	Novartis pharmaceuticals corporation /USA
32	Tecentriq IBD : 18/5/2016 Submission Date : 24/11/2016 Commission decision date : 14/2/2018	<b>25/3/2018</b>	Concentrate for solution for infusion	1200mg/20ml	Atezolizumab	Shawi & Rushedat Drug Store	F.Hoffman La roche Basel/ Switzerland
33	Ofev IBD : 15/10/2014 Submission Date : 14/4/2016 Commission decision date : 2/5/2018	<b>29/10/2018</b>	Soft gelatin capsule	100mg 150mg	Nintedanib	Arab drug store (shqer)	Boehringer Ingelhiem /Germany
34	Ocrevous IBD : 28/3/2017 Submission Date : 10/5/2017 Commission decision date : 6/6/2018	<b>25/7/2018</b>	Concentrate for solution for infusion	300mg/10ml	Ocrelizumab	Shawi & Rushedat Drug Store	F.Hoffman La roche Basel/ Switzerland
35	Spoilto Respimat IBD : 20/5/2015 Submission Date : 22/6/2016 Commission decision date : 27/6/2018	<b>30/8/2018</b>	Inhalation solution	2.5 microgram	Tiotropium Olodaterol	Arab drug store (shqer)	Boehringer Ingelhiem /Germany
36	Vemlidy IBD : 10/11/2016 Submission Date : 20/11/2017 Commission decision date : 6/2/2019	<b>7/3/2019</b>	Film coated tab	25mg	Tenofovir alafenamide fumarate	Beta drug store	Gilead Sciences International LTD/ UK

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37	Steglatro IBD : 19/12/2017 Submission Date : 30/12/2018 Commission decision date : 13/4/2019	<b>22/4/2019</b>	Tablets	5mg & 15mg	Ertugliflozin	Adatco drug store	MSD/Netherland
38	Tremfya IBD : 13/7/2017 Submission Date : 10/1/2019 Commission decision date : 12/6/2019	<b>11/9/2019</b>	Solution for injection	100mg/1ml	Guselkumab	Ninos drug store	Janssen – Cilag/Belgium

في حال الحاجة للاعتراض على محتويات القائمة ارجو ارسال كتاب رسمي لقسم التسجيل.

**Last reviewed in 30/2/2020**