JFDA-RDU&PV- AML01092020
Version 11.0

List of Medicinal Products Under Additional Mointoring

Related Information

Additional monitoring explained:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000365.jsp

Brand Name	Active Ingredient	Reason	Registeration Date in Jordan	Column1
Amgevita	Adalimumab	New biological	**08/04/2019**	
Tecentriq	Atezolizumab	New Active Substance	**25/03/2018**	
Blincyto	Blinatumomab	New Active Substance	**25/04/2017**	
Volopem	Bosutinib	Authority Required**	**06/10/2019**	
Cabometyx	Cabozantinib	New Active Substance	**20/03/2018**	
Kyprolis	Carfilzomib	New Active Substance	**14/05/2017**	
Reagila cap	Cariprazine HCl	New Active Substance	**02/07/2020**	
Zavicefta	Ceftazidime / avibactam	New active substance	**06/02/2019**	
Combined hormonal contraceptives containing chlormadinone	Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	PASS		
Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I)	Cyproterone acetate and Ethinylestradiol	PASS		

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Darzalex 100mg/5ml	Daratumumab	New Active Substance	**05/11/2017**	
Exviera	Dasabuvir	New Active Substance, PASS	**30/08/2015**	
Exjade	Deferasirox	PASS	**20/06/2006**	
Hemlibra	Emicizumab	New active substance and *new biological*	**11/02/2019**	
Glyxambi	Empagliflozin/linagliptin	New active substance	**15/08/2018**	
Joxane PFS	Enoxaparin	Biosimilar	**13/10/2019**	
Steglatro	Ertugliflozin	New active substance	**16/05/2019**	
Intravenous iron-containing medicinal products	Ferric carboxymaltose, iron dextran, sodium ferric gluconate, iron	PASS		
Gilenya	Fingolimod	PASS	**15/04/2012**	
Melior	Fingolimod	Postmarketing Surveillance	**25/04/2017**	Postmarketing Surveillance
Tremfya 100mg/ml PFS	Guselkumab	New Active Substance	**03/10/2019**	
Hydroxyethyl starch (HES)-containig products	Hydroxyethyl starch	PASS	**…….**	
Glivec	Imatinib	PASS	**09/12/2004**	
Harvoni	Ledipasvir/ sofobuvir	New Active Substance, PASS	**21/08/2016**	
Revlimid	Lenalidomide	PASS	**31/01/2013**	
Sotira Capsule	Linalidomide	Authority Required**	**10/08/2017**	
Lenvima (4, 10) mg Cap	Lenvatinib	New Active Substance	**10/11/2019**	
Penthrox	Methoxyflurane	PASS	**24/02/2019**	
Medikinet retard	Methylphenidate hydrochloride	PASS	**16/01/2014**	
Rydapt	Midostaurin	New active substance	**28/01/2019**	

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Tysabri	Natalizumab	PASS*	**10/11/2008**	
Ocrevus 300mg/10ml vial	Ocrelizumab	New Active Substance	**25/07/2018**	
Viekirax	Ombitasvir/Paritaprevir/ ritonavir	New Active Substance, PASS*	**03/09/2015**	
Tagrisso FCT	Osimertinib	New Active Substance	**08/03/2018**	
Ibrance 100mg	Palbociclib	New Active Substance	**17/07/2017**	
Iclusig	Ponatinib	PASS[1]	**14/04/2019**	
Kisqali FCT	Ribociclib	New Active Substance	**11/01/2018**	
Truxima	Rituximab	New biological	**20/01/2019**	
Tromax 10mg/ml	Rituximab	Authority Required**	**18/03/2018**	Postmarketing Surveillance
Xarelto	Rivaroxaban	PASS*	**07/12/2009**	
Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide-containing medicinal products)	Sodium valproate, valproic acid, valproate semisodium, valpromide	PASS		
Epclusa	Sofosbuvir/velpatasvir	New active substance	**03/01/2019**	
Targocid and associated names	Teicoplanin	PASS*		
Vemlidy	Tenofovir alafenamide	New active substance	**11/04/2019**	
Thiocolchicoside-containing medicinal products	Thiocolchicoside	PASS		
Xeljanz	Tofacitinib	New Active Substance	**15/05/2016**	
Herzuma	Trastuzumab	New biological	**05/05/2019**	

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Lonsurf	Trifluridine / tipiracil	New active substance	**17/04/2018**	
Anoro Ellipta 62.5mcg/25mcg	Vilanterol/Umeclidinium	New Active sub/PASS*	**06/09/2017**	

*the company that markets the medicine is required to carry out additional studies, for instance, to provide more data on long-term use of the medicine or on a rare side effect seen during clinical trials.

** JFDA requires to be additionally monitored

Added **Removed**