

GVK Biosciences – European Commission recommendation to suspend licences for a number of medicines

Enclosed:

Table 1: Non-critical Products; marketing authorisations suspended

Table 2: Critical products; marketing authorisations NOT suspended

Table 3: All non-critical Products

Table 1: Non-critical Products; marketing authorisations suspended

	Drug substance	Product	Marketing Authorisation Holder	Marketing Authorisation Number
1	Phenoxymethylpenicillin	Phenoxymethylpenicillin 250 mg Film-coated Tablets	Brown and Burk (UK) Limited	PL 25298/0106
		Phenoxymethylpenicillin 250 mg Film-coated Tablets	Morningside Healthcare Limited	PL 20117/0121
2	Fluconazole	Fluconazole 150mg Capsule	Fannin (UK) Limited	PL 20417/0044
		Fluconazole 50 mg Capsules	Aptil Pharma Limited	PL 40378/0165
		Fluconazole 150 mg Capsules		PL 40378/0166

		Fluconazole 200 mg Capsules		PL 40378/0167
3	Hydrocortisone	*Hydrocortisone 10 mg Tablets *Hydrocortisone 20 mg Tablets	Auden McKenzie Limited	PL 17507/0247 PL 17507/0249
4	Tramadol	Aceon (Tramadol) 100 mg Prolonged-release Tablets Aceon (Tramadol) 150 mg Prolonged-release Tablets Aceon (Tramadol) 200 mg Prolonged-release Tablets	Brown and Burke UK Limited	PL 25298/0059 PL 25298/0060 PL 25298/0061
5	Levetiracetam	Levetiracetam Dr Reddy's 250 mg Film-coated Tablets Levetiracetam Dr Reddy's 500 mg Film-coated Tablets Levetiracetam Dr Reddy's 750 mg Film-coated Tablets Levetiracetam Dr Reddy's 1000 mg Film-coated Tablets	Dr Reddy's Laboratories Limited	PL 08553/0435 PL 08553/0436 PL 08553/0437 PL 08553/0438
6	Valsartan	Valsartan 40 mg Film-coated Tablets Valsartan 80 mg Film-coated Tablets Valsartan 160mg Film-coated Tablets	Dr Reddy's Laboratory (UK) Limited	PL 08553/0394 PL 08553/0395 PL 08553/0396

		Valsartan 320mg Film-coated Tablets		PL 08553/0397
7	Irbesartan & combinations	Irbesartan 75 mg Film-coated Tablets Irbesartan 150 mg Film-coated Tablets Irbesartan 300 mg Film-coated Tablets Irbesartan/Hydrochlorothiazide 150mg/12.5 mg Film-coated Tablets Irbesartan/Hydrochlorothiazide 300mg/12.5mg Film-coated Tablets Irbesartan/Hydrochlorothiazide 300mg/25 mg Film-coated Tablets	Fair-Med Healthcare GmbH	PL 20242/0016 PL 20242/0017 PL 20242/0018 PL 20242/0019 PL 20242/0020 PL 20242/0021
		Irbesartan Niche 150 mg Film-coated Tablets Irbesartan Niche 300 mg Film-coated Tablets	Niche Generics Limited	PL 19611/0186 PL 19611/0187
8	Amlodipine	Amlodipine 5 mg Tablets Amlodipine 10 mg Tablets	FDC Pharma	PL 35638/0001 PL 35638/0002
9	Pantoprazole	Pantoprazole 20 mg Gastro-resistant Tablets Pantoprazole 40 mg Gastro-resistant Tablets	Lupin (Europe) Limited	PL 35507/0121 PL 35507/0122
10	Alendronic Acid	Alendronic Acid 70mg Tablets	Ranbaxy (UK) Limited	PL 14894/0465

11	Venlafaxine	Venlasov XL (Venlafaxine) 75 mg Prolonged-release Capsules Venlasov XL (Venlafaxine) 150 mg Prolonged-release Capsules	Waymade Healthcare PLC	PL 06464/2656 PL 06464/2657
12	Clopidogrel	Clopidogrel 75mg Film-coated Tablets	Wockhardt UK Limited	PL 29831/0415

*Auden Mckenzie also market hydrocortisone products under a different Marketing Authorisation Number which is not affected by this issue.

Table 2: Critical products; marketing authorisations NOT suspended

	Drug substance	Product	Marketing Authorisation Holder	Marketing Authorisation Number
1	Alendronic Acid	Alendronic acid 10mg tablets Alendronic acid 70mg tablets	Accord Healthcare Limited	PL 20075/0070 PL 20075/0071
2	Metoclopramide	Metoclopramide Hydrochloride 10 mg Tablets	Accord Healthcare Limited	PL 20075/0331
3	Dexamethasone	Dexamethasone 2 mg Tablets	Auden McKenzie Limited	PL 17507/0053
4	Clonazepam	Clonazepam Auden 500 microgram Tablets Clonazepam Auden 2mg	Auden McKenzie Limited	PL 17507/0071 PL 17507/0080

		Tablets		
5	Clobazam	Clobazam Auden 10mg Tablets	Auden McKenzie Limited	PL 17507/0075
6	Thiamine	Tyvera 50 mg Tablets Thiamine 50mg Tablets Tyvera 100 mg Tablets Thiamine 100mg Tablets	Auden McKenzie Limited	PL 17507/0056 PL 17507/0057
7	Dipyridamole	Attia (Dipyridamole) 200mg Modified-Release Capsules, Hard	Dr Reddy's Laboratories (UK) Limited	PL 08553/0458
8	Pioglitazone	Pioglitazone Dr Reddy's 15 mg Tablets Pioglitazone Dr Reddy's 30 mg Tablets Pioglitazone Dr Reddy's 45 mg Tablets	Dr Reddy's Laboratories (UK) Limited	PL 08553/0441 PL 08553/0442 PL 08553/0443
9	Donezapil	Donepezil Hydrochloride 5 mg Orodispersible Tablet Donepezil Hydrochloride 10	Generics (UK) Limited	PL 04569/1061 PL 04569/1062

		mg Orodispersible Tablet		
10	Repaglinide	Repaglinide Mylan 0.5 mg Tablets Repaglinide Mylan 1 mg Tablets Repaglinide Mylan 2 mg Tablets	Generics (UK) Limited	PL 04569/1371 PL 04569/1372 PL 04569/1373
11	Rizatriptan	Rizatriptan 10 mg Orodispersible Tablets	Generics (UK) Limited	PL 04569/1149
12	Metformin Hydrochloride	Metabet (Metformin Hydrochloride) SR 1000 mg Prolonged-release Tablets Bolamyn (Metformin Hydrochloride) SR 1000 mg Prolonged-release Tablets	Morningside Healthcare Limited	PL 20117/0184

Table 3: All non-critical Products

	Drug substance	Product	Marketing Authorisation Holder	Marketing Authorisation Number
1	Escitalopram	Escitalopram 10 mg Film-coated Tablets Escitalopram 20 mg Film-coated Tablets	Brown and Burk (UK) Limited	PL 25298/0109 PL 25298/0111
2	Phenoxymethylpenicillin	Phenoxymethylpenicillin 250 mg Film-coated Tablets	Brown and Burk (UK) Limited	PL 25298/0106
		Phenoxymethylpenicillin 250 mg Film-coated Tablets	Morningside Healthcare Limited	PL 20117/0121
3	Fluconazole	Fluconazole 150mg Capsule	Fannin (UK) Limited	PL 20417/0044
		Fluconazole 50 mg Capsules	Aptil Pharma Limited	PL 40378/0165
		Fluconazole 150 mg Capsules		PL 40378/0166
		Fluconazole 200 mg Capsules		PL 40378/0167
4	Esomeprazole	Esomeprazole 20 mg Gastro-resistant Capsules, Hard	Generics (UK) Ltd	PL 04569/1268
		Esomeprazole 40 mg Gastro-resistant Capsules, Hard		PL 04569/1269

5	Hydrocortisone	Hydrocortisone 10 mg Tablets Hydrocortisone 20 mg Tablets	Auden McKenzie Limited	PL 17507/0247 PL 17507/0249
6	Fexofenadine	Fexofenadine Hydrochloride 120mg Film-coated Tablets Fexofenadine Hydrochloride 180mg Film-coated Tablets	Fannin (UK) Limited	PL 20417/0041 PL 20417/0042
7	Tramadol	Aceon (Tramadol) 100 mg Prolonged-release Tablets Aceon (Tramadol) 150 mg Prolonged-release Tablets Aceon (Tramadol) 200 mg Prolonged-release Tablets	Brown and Burke UK Limited	PL 25298/0059 PL 25298/0060 PL 25298/0061
8	Levetiracetam	Levetiracetam Dr Reddy's 250 mg Film-coated Tablets Levetiracetam Dr Reddy's 500 mg Film-coated Tablets Levetiracetam Dr Reddy's 750 mg Film-coated Tablets	Dr Reddy's Laboratories Limited	PL 08553/0435 PL 08553/0436 PL 08553/0437 PL 08553/0438

		Levetiracetam Dr Reddy's 1000 mg Film-coated Tablets		
9	Valsartan	Valsartan 40 mg Film-coated Tablets Valsartan 80 mg Film-coated Tablets Valsartan 160mg Film-coated Tablets Valsartan 320mg Film-coated Tablets	Dr Reddy's Laboratory (UK) Limited	PL 08553/0394 PL 08553/0395 PL 08553/0396 PL 08553/0397
10	Irbesartan & combinations	Irbesartan 75 mg Film-coated Tablets Irbesartan 150 mg Film-coated Tablets Irbesartan 300 mg Film-coated Tablets Irbesartan/Hydrochlorothiazide 150mg/12.5 mg Film-coated Tablets Irbesartan/Hydrochlorothiazide 300mg/12.5mg Film-coated Tablets Irbesartan/Hydrochlorothiazide 300mg/25 mg Film-coated Tablets	Fair-Med Healthcare GmbH	PL 20242/0016 PL 20242/0017 PL 20242/0018 PL 20242/0019 PL 20242/0020 PL 20242/0021
		Irbesartan Niche 150 mg Film-coated Tablets Irbesartan Niche 300 mg Film-coated Tablets	Niche Generics Limited	PL 19611/0186 PL 19611/0187
		Irbesartan 75 mg Film-coated Tablets	Torrent Pharma GmbH	PL 20658/0073

		<p>Irbesartan 150 mg Film-coated Tablets</p> <p>Irbesartan 300 mg Film-coated Tablets</p> <p>Irbesartan/Hydrochlorothiazide 150/12.5 mg Film-coated Tablets</p> <p>Irbesartan/Hydrochlorothiazide 300/12.5 mg Film-coated Tablets</p> <p>Irbesartan/Hydrochlorothiazide 300/25 mg Film-coated Tablets</p>		<p>PL 20658/0074</p> <p>PL 20658/0075</p> <p>PL 20658/0072</p> <p>PL 20658/0086</p> <p>PL 20658/0087</p>
11	Amlodipine	<p>Amlodipine 5 mg Tablets</p> <p>Amlodipine 10 mg Tablets</p>	FDC Pharma	<p>PL 35638/0001</p> <p>PL 35638/0002</p>
12	Pantoprazole	<p>Pantoprazole 20 mg Gastro-resistant Tablets</p> <p>Pantoprazole 40 mg Gastro-resistant Tablets</p>	Lupin (Europe) Limited	<p>PL 35507/0121</p> <p>PL 35507/0122</p>
13	Alendronic Acid	Alendronic Acid 70mg Tablets	Ranbaxy (UK) Limited	PL 14894/0465
14	Venlafaxine	<p>Venlasov XL (Venlafaxine) 75 mg Prolonged-release Capsules</p> <p>Venlasov XL (Venlafaxine) 150 mg Prolonged-release Capsules</p>	Waymade Healthcare PLC	<p>PL 06464/2656</p> <p>PL 06464/2657</p>

15	Clopidogrel	Clopidogrel 75mg Film-coated Tablets	Wockhardt UK Limited	PL 29831/0415
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