DRUG REGISTRATION UNIT, PRODUCT REGULATION SECTION
MINISTRY OF HEALTH, BRUNEI DARUSSALAM

LIST OF SUBMITTED DRUG REGISTRATION APPLICATIONS (UPDATED NOVEMBER 2026)

No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
1	Hema-Plus 4000 (Prefilled Syringe)	Recombinant Human Erythropoietin (Epoetin-Alfa) 400IU/0.4ml	Siam Bioscience Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	In-Process
2	Leuco-Plus 300 Solution for Injection	Filgrastim 300µg (300MIU)/ml [Recombinant Methionyl Human Granulocyte Colony-Stimulating Factor (r-Met-hu-G-CSF)]	Siam Bioscience Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	In-Process
3	Priacin 40mg Film Coated Tablet	Simvastatin 40mg	Medochemie Ltd, Cyprus	Medicorp Sdn Bhd	In-Process
4	Gensulin M30 (30/70) 100 IU/ml Suspension For Injection (Vial)	1ml contains 100 IU of Biphasic Human Insulin (30% Soluble & 70% Isophane Insulin)	Bioton S.A., Poland	Syarikat Bumimedic	In-Process
5	Gensulin M30 (30/70) 100 IU/ml Suspension For Injection (Cartridge)	1ml contains 100 IU of Biphasic Human Insulin (30% Soluble & 70% Isophane Insulin)	Bioton S.A., Poland	Syarikat Bumimedic	In-Process
6	Gensulin N 100 IU/ml Suspension For Injection (Vial)	1ml contains 100 IU of Isophane Human Insulin	Bioton S.A., Poland	Syarikat Bumimedic	In-Process
7	Gensulin N 100 IU/ml Suspension For Injection (Cartridge)	1ml contains 100 IU of Isophane Human Insulin	Bioton S.A., Poland	Syarikat Bumimedic	In-Process
8	Gensulin R 100 IU/ml Solution For Injection (Vial)	1ml contains 100 IU of Soluble Human Insulin	Bioton S.A., Poland	Syarikat Bumimedic	In-Process
9	Gensulin R 100 IU/ml Solution For Injection (Cartridge)	1ml contains 100 IU of Soluble Human Insulin	Bioton S.A., Poland	Syarikat Bumimedic	In-Process
10	Neufar 75 Capsule	Pregabalin 75mg	PT. Pratapa Nirmala, Indonesia	Medicorp Sdn Bhd	In-Process
11	Krim GPU (Gosok Pijat Urut) Minyak Sereh	Methyl Salicylate 50.00mg, Menthol 10.00mg, Camphor 20.00mg, Citronella Oil 15.00mg, Eucalyptus Oil 5.00mg & Olive Oil 46.50mg	PT Eagle Indo Pharma, indonesia	SP Setia Sdn Bhd	In-Process
12	Krim GPU (Gosok Pijat Urut) Minyak Jahe	Methyl Salicylate 50.00mg, Menthol 10.00mg, Camphor 20.00mg, Ginger Oil 14.00mg, Eucalyptus Oil 5.00mg & Olive Oil 46.50mg	PT Eagle Indo Pharma, indonesia	SP Setia Sdn Bhd	In-Process

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13	Krim GPU (Gosok Pijat Urut) Minyak Pala	Methyl Salicylate 50.00mg, Menthol 10.00mg, Camphor 20.00mg, Nutmeg Oil 15.00mg, Eucalyptus Oil 5.00mg & Olive Oil 46.50mg	PT Eagle Indo Pharma, indonesia	SP Setia Sdn Bhd	In-Process
14	Minyak Urut GPU (Gosok Pijat Urut) Minyak Pala	Methyl Salicylate 192.200mg, Menthol 24.025mg, Camphor 72.075mg, Eucalyptus Oil 24.025mg & Nutmeg Oil 96.100mg	PT Eagle Indo Pharma, indonesia	SP Setia Sdn Bhd	In-Process
15	Ethomid Tablets 250mg	Ethionamide 250mg	Macleods Pharmaceuticals Limited, India	Kingsley Medical Supplies Sdn Bhd	In-Process
16	Forecox-Trac Film Coated Tablet	Rifampicin 150mg, Isoniazid 75mg, Pyrazinamide 400mg, Ethambutol Hydrochloride 275mg	Macleods Pharmaceuticals Limited, India	Kingsley Medical Supplies Sdn Bhd	In-Process
17	Irbesartan Stella 150mg	Irbesartan 150mg	Stellapharm J.V. Co., Ltd. (Branch 1), Vietnam	Medicorp Sdn Bhd	In-Process
18	Irbesartan Stella 300mg	Irbesartan 300mg	Stellapharm J.V. Co., Ltd. (Branch 1), Vietnam	Medicorp Sdn Bhd	In-Process
19	Equfina Film Coated Tablets 50mg	Safinamide 50mg	Meiji Seika Pharma Co., Ltd., Odawara Plant, Japan	DKSH BRN Sdn Bhd	In-Process
20	Yuflyma Solution For Injection In Pre-Filled Pen 40mg/0.4ml	Adalimumab 40mg/0.4ml	1) Catalent Belgium SA, Belgium 2) Celltrion Pharm, Inc., Republic of Korea	DKSH BRN Sdn Bhd	In-Process
21	Solmux 500mg Capsule	Carbocisteine 500mg	Unilab Inc, Philippines	Aesthetics Medident Enterprise	In-Process
22	Yuflyma Solution For Injection In Pre-Filled Pen 80mg/0.8ml	Adalimumab 80mg/0.8ml	Celltrion Pharm, Inc., Republic of Korea	DKSH BRN Sdn Bhd	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
23	Klamoks BID 200mg/28mg Dry Powder For Suspension	Amoxicillin Trihydrate equivalent to Amoxicillin 200mg/5ml & Potassium Clavulanate equivalent to Clavulanic Acid 28.5mg/5ml	Bilim Ilaç Sanayii ve Ticaret A.Ş., Turkey	United Pharma Sdn Bhd	In-Process
24	Klamoks 312.5mg Fort Dry Powder For Oral Suspension	Amoxicillin Trihydrate equivalent to Amoxicillin 250mg/5ml & Potassium Clavulanate equivalent to Clavulanic Acid 62.5mg/5ml	Bilim Ilaç Sanayii ve Ticaret A.Ş., Turkey	United Pharma Sdn Bhd	In-Process
25	Klamoks BID 625mg Film Coated Tablet	Amoxicillin Trihydrate equivalent to Amoxicillin 500mg & Potassium Clavulanate equivalent to Clavulanic Acid 125mg	Bilim Ilaç Sanayii ve Ticaret A.Ş., Turkey	United Pharma Sdn Bhd	In-Process
26	Fulvestrant Sandoz Solution For Injection In Pre-Filled Syringe 250mg/5ml	Fulvestrant 250mg/5ml	Fareva Unterach GmbH, Austria	Zuellig Pharma (B) Sdn Bhd	In-Process
27	Moxiclav BIS (400mg+57mg)/5ml Powder For Oral Suspension	Amoxicillin Trihydrate equivalent to Amoxicillin 400mg/5ml & Potassium Clavulanate equivalent to Clavulanic Acid 57mg/5ml	Medochemie Ltd (Factory B) - Oral Facility, Cyprus	Hongkiat Trading & Company	In-Process
28	Sitavio 100mg Film Coated Tablets	Sitagliptin Phosphate Monohydrate 64.250mg equivalent to Sitagliptin 50mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
29	Sitavio 100mg Film Coated Tablets	Sitagliptin Phosphate Monohydrate 128.500mg equivalent to Sitagliptin 100mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
30	Czartan 50mg (Losartan Potassium Tablets USP 50mg)	Losartan Potassium 50mg	Macleods Pharmaceuticals Limited, India	Arbia Pharma	In-Process
31	Meromac 0.5g (Meropenem For Injection USP 0.5g)	Meropenem equivalent to Meropenem (Anhydrous) 0.5g	Macleods Pharmaceuticals Limited, India	Arbia Pharma	In-Process
32	Knowful Film Coated Tablet 800mg	Piracetam 800mg	Y.S.P Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	In-Process
33	Cough-En Rx Linctus	Dextromethorphan HBr 15mg/5ml, Triprolidine Hydrochloride 1.25mg/5ml & Phenylephrine Hydrochloride 5mg/5ml	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
34	Coxeta FC Tablets 90mg	Etoricoxib 90mg	Teva Gyógyszergyár Zrt., Hungary	DCH Auriga (Borneo) Sdn Bhd	In-Process
35	Coxeta FC Tablets 120mg	Etoricoxib 120mg	Teva Gyógyszergyár Zrt., Hungary	DCH Auriga (Borneo) Sdn Bhd	In-Process
36	Aquipta™ Tablet 10mg	Atogepant 10mg	Forest Laboratories Ireland Limited, Ireland	Zuellig Pharma (B) Sdn Bhd	In-Process
37	Aquipta™ Tablet 60mg	Atogepant 60mg	Forest Laboratories Ireland Limited, Ireland	Zuellig Pharma (B) Sdn Bhd	In-Process
38	Viatin Tablet 100mg	Sitagliptin Hydrochloride Hydrate 113.4mg as Sitagliptin 100mg	Korea United Pharm. Inc., Republic of Korea	K-Seri Pharma Sdn Bhd	In-Process
39	Irinocan 100 Concentrate For Solution For Infusion 100mg/5ml	Irinotecan Hydrochloride Trihydrate 20mg/ml	Intas Pharmaceuticals Limited, India	Kingsley Medical Supplies Sdn Bhd	In-Process
40	Axcel Clopidogrel-75mg Tablet	(Clopidogrel Bisulphate equivalent to Clopidogrel 75mg	Kotra Pharma (M) Sdn Bhd, Malaysia	Medicorp Sdn Bhd	In-Process
41	Antamin Syrup 4mg/5ml	Chlorpheniramine Maleate 4mg/5ml	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
42	Tenolon 300mg Film Coated Tablet	Tenofovir Disoproxil Fumarate 300mg equivalent to Tenofovir Disoproxil 245mg	Shijiazhuang Lonzeal Pharmaceuticals Co., Ltd., China	Hongkiat Trading & Company	In-Process
43	Canespro Once Daily Bifonazole Anti-Fungal Cream 1% w/w	Bifonazole 1%	GP Grenzach Produktions GmbH, Germany	Zuellig Pharma (B) Sdn Bhd	In-Process
44	Myolid 10 Capsules	Lenalidomide 10mg	Biocon Pharma Limited, India	K-Seri Pharma Sdn Bhd	In-Process
45	Gancebok 10mg/ml Caffeine Citrate Solution For Infusion	Caffeine Citrate 10mg (equivalent to Caffeine 5mg)/ml	Cenexi, France	DKSH BRN Sdn Bhd	In-Process
46	IRINO Injection 100mg/5ml	Irinotecan Hydrochloride 100mg/5ml	Korea United Pharm. Inc., Republic of Korea	K-Seri Pharma Sdn Bhd	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
47	Myfenax Film-Coated Tablets 500mg	Mycofenolate Mofetil 500mg	Teva Pharmaceutical Works Private Limited Company, Hungary	DCH Auriga (Borneo) Sdn Bhd	In-Process
48	TRUQAP 160mg Film-Coated Tablets	Capivasertib 160mg	Astrazeneca AB, Sweden	Zuellig Pharma (B) Sdn Bhd	In-Process
49	TRUQAP 200mg Film-Coated Tablets	Capivasertib 200mg	Astrazeneca AB, Sweden	Zuellig Pharma (B) Sdn Bhd	In-Process
50	Citabol (Gemcitabine Powder For Solution For Infusion 1000mg/Vial)	Each vial contains: Gemcitabine Hydrochloride 1149mg equivalent to Gemcitabine 1000mg	Venus Remedies Limited, India	Kingsley Medical Supplies Sdn Bhd	In-Process
51	Encapon 200 Tablet	Entacapone 200mg	Unison Laboratories Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	In-Process
52	Clopine 25mg Tablets	Clozapine 25mg	Douglas Manufacturing Limited, New Zealand	K-Seri Pharma Sdn Bhd	In-Process
53	Accofil 30 Solution For Injection Or Infusion In A Pre-Filled Syringe 30MU/0.5ml	Filgrastim 30MU/0.5ml	Intas Pharmaceuticals Limited, India	Kingsley Medical Supplies Sdn Bhd	In-Process
54	Accofil 48 Solution For Injection Or Infusion In A Pre-Filled Syringe 48MU/0.5ml	Filgrastim 48MU/0.5ml	Intas Pharmaceuticals Limited, India	Kingsley Medical Supplies Sdn Bhd	In-Process
55	Rexom Folic Acid Tablet 5mg	Folic Acid 5mg	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
56	Paxlovid Film-Coated Tablets	Nirmatrelvir 150mg & Ritonavir 100mg	Nirmatrelvir Tablets: 1) Pfizer Manufacturing Deutschland GmbH, Germany 2) Pfizer Ireland Pharmaceuticals, Ireland Ritonavir Tablets: 1) Hetero Labs Limited, India	Zuellig Pharma (B) Sdn Bhd	In-Process
57	Salvado 0.5 (Tacrolimus Capsules USP 0.5mg)	Tacrolimus 0.5mg	Biocon Pharma Limited, India	K-Seri Pharma Sdn Bhd	In-Process
58	Salvado 5 (Tacrolimus Capsules USP 5mg)	Tacrolimus 5mg	Biocon Pharma Limited, India	K-Seri Pharma Sdn Bhd	In-Process
59	Xolair 75mg/0.5ml Solution For Injection In Pre-Filled Syringe	Omalizumab 75mg/0.5ml	Novartis Pharma Stein AG, Switzerland	Zuellig Pharma (B) Sdn Bhd	In-Process
60	Xolair 150mg/ml Solution For Injection In Pre-Filled Syringe	Omalizumab 150mg/ml	Novartis Pharma Stein AG, Switzerland	Zuellig Pharma (B) Sdn Bhd	In-Process
61	Xolair 300mg/2ml Solution For Injection In Pre-Filled Syringe	Omalizumab 300mg/2ml	Novartis Pharma Stein AG, Switzerland	Zuellig Pharma (B) Sdn Bhd	In-Process
62	MYOLID 5 Capsules	(Lenalidomide 5mg	Biocon Pharma Limited, India	K-Seri Pharma Sdn Bhd	In-Process
63	MYOLID 15 Capsules	Lenalidomide 15mg	Biocon Pharma Limited, India	K-Seri Pharma Sdn Bhd	In-Process
64	MYOLID 25 Capsules	Lenalidomide 25mg	Biocon Pharma Limited, India	K-Seri Pharma Sdn Bhd	In-Process
65	Goldfish Brand Medicated Oil	Menthol 16% w/w, Mehtyl Salicylate 30% w/w, Camphor Powder 5% w/w	Alpine Medical Industries Sdn Bhd, Malaysia	Yuh Hua Trading Company	In-Process
66	Axcel Glimepiride-2mg Tablet	Glimepiride 2mg	Kotra Pharma (M) Sdn Bhd, Malaysia	Medicorp Sdn Bhd	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
67	KS Penem Injection 0.5g	Meropenem 500mg	Shenzhen Haibin Pharmaceutical Co., Ltd., P.R. China	K-Seri Pharma Sdn Bhd	In-Process
68	KS Penem Injection 1.0g	Meropenem 1000mg	Shenzhen Haibin Pharmaceutical Co., Ltd., P.R. China	K-Seri Pharma Sdn Bhd	In-Process
69	Eagle Brand Yellow Balm	Menthol 15.5%; Eucalyptus Oil 19.5%; Methyl Salicylate 8.0%; Camphor 4.0%; Peppermint Oil 10.0%	PT Eagle Indo Pharma, Indonesia	SP Setia Sdn Bhd	In-Process
70	Eagle Brand Muscle Rub	Menthol 14.5% w/w & Methyl Salicylate 30.0% w/w	Borden Company (Private) Limited, Singapore	SP Setia Sdn Bhd	In-Process
71	GPU Krim Hot	Methyl Salicylate 6%; Menthol 2.5%; Camphor 2.5%; Eucalyptus Oil 0.5%; Olive Oil 4.5%	PT Eagle Indo Pharma, Indonesia	SP Setia Sdn Bhd	In-Process
72	Gonal-F 450 IU/0.72ml (33 mcg/0.72 mL) Solution For Injection In Pre-Filled Pen	Each pre-filled multidose pen contains 450 IU (equivalent to 33 micrograms) of Follitropin Alfa in 0.72 ml	Merck Serono S.p.A., Italy	G & H Trading Company	In-Process
73	Oledron (Zoledronic Acid Concentrate For Solution For Infusion 4mg./5ml)	Each 5ml vial contains Zoledronic Acid Monohydrate equivalent to Zoledronic Acid 4mg	Gland Pharma Limited, India	K-Seri Pharma Sdn Bhd	In-Process
74	Axcel Fusidic Acid-B Cream (New Formula)	Fusidic Acid (Micronised) 2% w/w & Betamethasone as Valerate (Micronised) 0.1% w/w	Kotra Pharma (M) Sdn Bhd, Malaysia	Medicorp Sdn Bhd	In-Process
75	Glevo Tablets 500mg	Levofloxacin Hemihydrate equivalent to Levofloxacin 500mg	Glenmark Pharmaceuticals Ltd, India	Kingsley Medical Supplies Sdn Bhd	In-Process
76	Ovidrel 250mcg/0.5ml Solution For Injection In Pre-Filled Syringe	Each pre-filled syringe contains 250 micrograms (approximately 6,500 IU) Choriogonadotropin Alfa in 0.5 mL solution	Merck Serono S.p.A., Italy	G & H Trading Company	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
77	Rivoxan 15 Film-Coated Tablet	Rivaroxaban 15mg	Unison Laboratories Co., Ltd., Thailand	K-Seri Pharma Sdn Bhd	In-Process
78	Starflu-75 (Oseltamivir Capsule 75mg)	Starflu-75 (Oseltamivir Capsule 75mg)	Strides Pharma Science Limited, India	Bio-Kallyntiko Company	In-Process
79	Tremfya 200mg/20ml Concentrate For Solution For Infusion	Each vial contains Guselkumab 200mg/20ml	Cilag AG, Switzerland	Zuellig Pharma (B) Sdn Bhd	In-Process
80	Tremfya 200mg/2ml PushPen Solution For Injection In Pre-Filled Pen	Guselkumab 200mg/2ml	Cilag AG, Switzerland	Zuellig Pharma (B) Sdn Bhd	In-Process
81	Meglumine Gadoterate Solution For Intravenous Injection 0.5mml/ml	Gadoteric Acid 0.27932g/ml & Meglumine 0.0976g/ml	Indian Immunologicals Ltd, India	DKSH BRN Sdn Bhd	In-Process
82	Lormalzi Concentrate For Solution For Infusion 350mg/20ml	Donanemab 17.5mg/ml	Lilly France, France	Zuellig Pharma (B) Sdn Bhd	In-Process
83	Cifoban 136mmol/L Solution For Infusion	1000ml contains: Sodium Citrate 40.0g	Fresenius Medical Care Deutschland GmbH, Germany	Medix Supliers	In-Process
84	Amval 5mg/80mg Film Coated Tablets	Amlodipine Besylate 6.934mg equivalent to Amlodipine 5mg; Valsartan 80mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
85	Amval 5mg/160mg Film Coated Tablets	Amlodipine Besylate 6.934mg equivalent to Amlodipine 5mg; Valsartan 160mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
86	Amval 10mg/160mg Film Coated Tablets	Amlodipine Besylate 13.868mg equivalent to Amlodipine 10mg; Valsartan 160mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
87	Imaver 100mg Film Coated Tablets	Imatinib Mesylate 119.47mg (as Beta Crystals) equivalent to Imatinib 100mg	Novugen Oncology Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
88	Imaver 400mg Film Coated Tablets	Imatinib Mesylate 447.88mg (as Beta Crystals) equivalent to Imatinib 400mg	Novugen Oncology Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
89	Iroprone 500mg Film Coated Tablets	Deferiprone 500mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
90	Ricovir 300mg Tablets	Tenofovir Disoproxil Fumarate 300mg	Mylan Laboratories Limited, India	Kingsley Medical Supplies Sdn Bhd	In-Process

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91	Genexiban (Apixaban Film-Coated Tablets 2.5mg)	Apixaban 2.5mg	Dr. Reddy's Laboratories Limited, India	United Pharma Sdn Bhd	In-Process
92	Genexiban (Apixaban Film-Coated Tablets 5mg)	Apixaban 5mg	Dr. Reddy's Laboratories Limited, India	United Pharma Sdn Bhd	In-Process
93	Divigel 0.1% Gel	Estradiol Hemihydrate 0.1%	Orion Corporation, Finland	Emergent Trading & Supplies	In-Process
94	Metforza Tablets 500mg	Metformin Hydrochloride 500mg	Granules India Limited, India	AmiproSimpor Sdn Bhd	In-Process
95	Metforza Tablets 850mg	Metformin Hydrochloride 850mg	Granules India Limited, India	AmiproSimpor Sdn Bhd	In-Process
96	Metforza Tablets 1000mg	Metformin Hydrochloride 1000mg	Granules India Limited, India	AmiproSimpor Sdn Bhd	In-Process
97	Febricol-Rx Tablet	Chlorpheniramine Maleate 2mg; Phenylephrine Hydrochloride 5mg; Paracetamol 500mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
98	Omeprazole For Injection 40mg (Lyophilised)	Each vial contains: Omeprazole Sodium equivalent to Omeprazole 40mg	Naprod Life Science Pvt. Ltd., India	AmiproSimpor Sdn Bhd	In-Process
99	Daxitran 110mg Hard Capsules	Dabigatran Etexilate Mesylate equivalent to Dabigatran Etexilate 110mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
100	Daxitran 150mg Hard Capsules (Dabigatran Etexilate Mesylate equivalent to Dabigatran Etexilate 150mg)	Daxitran 150mg Hard Capsules (Dabigatran Etexilate Mesylate equivalent to Dabigatran Etexilate 150mg)	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
101	Ig Vena 50 g/l Solution For Infusion	1ml of solution contains 50mg of Human Normal Immunoglobulin	Kedrion S.p.A., Italy	DKSH BRN Sdn Bhd	In-Process
102	Comtan Tablet 200mg	Entacapone 200mg	Orion Corporation, Finland	Emergent Trading & Supplies	In-Process
103	Omlyclo 150mg Solution For Injection In Pre-Filled Syringe	1ml pre-filled syringe contains 150mg of Omalizumab	Celltrion Pharm Inc, Republic of Korea	DKSH BRN Sdn Bhd	In-Process

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104	Uman Albumin 200 g/l Solution For Infusion	Solution containing Total Plasma Proteins to 20% of which Human Albumin at least to 95%	Kedrion S.p.A., Italy	DKSH BRN Sdn Bhd	In-Process
105	Dyna Aqueous Cream	White Soft Paraffin 15% w/w; Liquid Paraffin 6% w/w; Cetomacrogol Emulsifying Wax 9.5% w/w	Dynapharm (M) Sdn Bhd, Malaysia	Medicorp Sdn Bhd	In-Process
106	Nicardia-XL-30 (Nifedipine Extended Release Tablets USP 30mg)	Nifedipine 30mg	Unique Pharmaceutical Laboratories, India	K-Seri Pharma Sdn Bhd	In-Process
107	Saphnelo 120mg/0.8ml Solution For Injection In Pre-Filled Pen	Each pre-filled pen contains Anifrolumab 120mg in 0.8ml (150mg/ml)	AstraZeneca AB, Sweden	Zuellig Pharma (B) Sdn Bhd	In-Process
108	Racser Cream 5%	Each gram contains: Lidocaine 25mg & Prilocaine 25mg	Galentic Pharma (India) Private Limited, India	Gem Pharma Sdn Bhd	In-Process
109	Jubbonti Solution For Injection In Pre-Filled Syringe 60mg/ml	1ml pre-filled syringe contains Denosumab 60mg (60mg/ml)	Novartis Pharmaceutical Manufacturing GmbH, Austria	Zuellig Pharma (B) Sdn Bhd	In-Process
110	Solmux 100mg/5ml Syrup	Each 5ml contains: Carbocisteine 100mg	Amherst Laboratories, Inc., Philippines	Bio-Kallyntiko Company	In-Process
111	Avazet 10mg/20mg Film Coated Tablets	Ezetimibe 10mg; Atorvastatin Calcium Trihydrate 21.65mg equivalnt to Atorvastatin 20mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
112	Avazet 10mg/40mg Film Coated Tablets	Ezetimibe 10mg; Atorvastatin Calcium Trihydrate 43.30mg equivalnt to Atorvastatin 40mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
113	Mucolix Elixir	Each 5ml contains: Bromhexine Hydrochloride 4mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
114	Rosuvor Film Coated Tablet 10mg	Rosuvastatin Calcium 10.4mg equivalent to Rosuvastatin 10mg	Y.S.P Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	In-Process
115	YSP Shincort Injection 10mg/ml	Each ml contains: Triamcinolone Acetonide 10mg)	Y.S.P Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	In-Process
116	Pharmaniaga Noradrenaline 1mg/ml Injection	Each ml contains 1mg of Noradrenaline as Noradrenaline Acid Tartrate	Pharmaniaga Lifescience Sdn Bhd, Malaysia	G & H Trading Company	In-Process

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117	Varexa Film-Coated Tablet 2.5mg	Apixaban 2.5mg	Duopharma Manufacturing (Bangi) Sdn Bhd, Malaysia	Hongkiat Trading & Company	In-Process
118	Varexa Film-Coated Tablet 5mg	Apixaban 5mg	Duopharma Manufacturing (Bangi) Sdn Bhd, Malaysia	Hongkiat Trading & Company	In-Process
119	Salmodex Syrup	Each 5ml contains: Salbutamol 2mg (as Salbutamol Sulphate); Bromhexine Hydrochloride 4mg	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	K-Seri Pharma Sdn Bhd	In-Process
120	Novtel 80mg Tablets	Telmisartan 80mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
121	Palavo Suspension 120mg/5ml	Each 5ml contains Paracetamol 120mg	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
122	Duoflow 0.5mg/0/4mg Hard Capsules	Each capsule contains: Dutasteride 0.5mg; Tamsulosin Hydrochloride 0.4mg	Laboratorios Leon Farma S.A., Spain	Gem Pharma Sdn Bhd	In-Process
123	Ansonide Nasal Spray 27.5mcg/Dose	Fluticasone Furoate 27.5mcg/dose (equivalent to 0.055% w/v)	HOE Pharmaceuticals Sdn Bhd, Malaysia	G & H Trading Company	In-Process
124	Myopine Eye Drops 0.01% w/v	Atropine Sulphate 0.01% w/v	Xepa-Soul Pattinson (Malaysia) Sdn Bhd, Malaysia	DKSH BRN Sdn Bhd	In-Process
125	Vasoten F.C. Tablets 5mg	Bisoprolol Fumarate 5mg	Synmosa Biopharma Corporation, Synmosa Plant, Taiwan	Gem Pharma Sdn Bhd	In-Process
126	Rotaqor Film Coated Tablet 10mg	Atorvastatin Calcium Trihydrate 10.825mg equivalent to Atorvastatin 10mg	Lek S.A., Poland	Zuellig Pharma (B) Sdn Bhd	In-Process
127	Rotaqor Film Coated Tablet 20mg	Atorvastatin Calcium Trihydrate 21.65mg equivalent to Atorvastatin 20mg	Lek S.A., Poland	Zuellig Pharma (B) Sdn Bhd	In-Process
128	Rotaqor Film Coated Tablet 40mg	Atorvastatin Calcium Trihydrate 43.3mg equivalent to Atorvastatin 40mg	Lek S.A., Poland	Zuellig Pharma (B) Sdn Bhd	In-Process

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LIST OF SUBMITTED DRUG REGISTRATION APPLICATIONS (UPDATED NOVEMBER 2026)

No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
129	Mili Syrup 250mg/5ml	Each 5ml contains: Paracetamol 250mg	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	In-Process
130	Beta-N Cream	Betamethasone 17-Valerate equivalent to Betamethasone 0.1% w/w; Neomycin Sulphate 0.5% w/w	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	In-Process
131	Bedapt 500mg (Daptomycin For Injection 500mg Per Vial)	Daptomycin 500mg/Vial	Biological E. Limited, India	K-Seri Pharma Sdn Bhd	In-Process
132	Tragliptin Film Coated Tablets 5mg	Linagliptin 5mg	Sinil Pharmaceutical Co., Ltd., Republic of Korea	Syarikat Bumimedic	In-Process
133	Rexom Neomycin Cream 0.5%	Neomycin Sulphate 0.5% w/w	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	In-Process
134	Rexom Hydrocortisone Neomycin Cream	Hydrocortisone Acetate 0.5% w/w; Neomycin Sulphate 0.5% w/w	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	In-Process
135	Pharmaniaga Flumazenil 0.1mg/ml Injection	Flumazenil 0.5mg/5ml	Pharmaniaga Lifescience Sdn Bhd, Malaysia	G & H Trading Company	In-Process
136	Novtel 40mg Tablets	Telmisartan 40mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
137	Rivax 10mg Film Coated Tablets	Rivaroxaban 10mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
138	Rivax 15mg Film Coated Tablets	Rivaroxaban 15mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
139	Rivax 20mg Film Coated Tablets	Rivaroxaban 20mg	Novugen Pharma Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
140	Vabysmo Solution For Injection In Pre-Filled Syringe 6mg/0.05ml	Each pre-filled syringe contains Faricimab 21mg in 0.175ml solution	Vetter Pharma-Fertigung GmbH & Co. KG, Germany	DKSH BRN Sdn Bhd	In-Process
141	Atostin Film Coated Tablet 20mg	Each film coated tablet contains: Atorvastatin Calcium Trihydrate 21.65mg equivalent to Atorvastatin 20mg	Y.S.P Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	In-Process
142	Atostin Film Coated Tablet 40mg	Each film coated tablet contains: Atorvastatin Calcium Trihydrate 43.3mg equivalent to Atorvastatin 40mg	Y.S.P Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	In-Process
143	Homecare Noflux Lozenges	Lysozyme Chloride 80mg & Pyridoxine Hydrochloride 40mg	Y.S.P Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	In-Process
144	YSP Colchicine Tablet 0.6mg	Colchicine 0.6mg	Y.S.P Industries (M) Sdn Bhd, Malaysia	Asterix United (B) Sdn Bhd	In-Process
145	Mynotil 250mg Film Coated Tablets	Mycophenolate Mofetil 250mg	Novugen Oncology Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
146	Mynotil 500mg Film Coated Tablets	Mycophenolate Mofetil 500mg	Novugen Oncology Sdn Bhd, Malaysia	Syarikat Bumimedic	In-Process
147	Amgevita Solution For Injection In Prefilled Autoinjector 40mg/0.4ml	Adalimumab 40mg/0.4ml	Amgen Manufacturing Limited LLC, USA	DKSH BRN Sdn Bhd	In-Process
148	Amgevita Solution For Injection In Prefilled Syringe 20mg/0.2ml	Adalimumab 20mg/0.2ml	Amgen Manufacturing Limited LLC, USA	DKSH BRN Sdn Bhd	In-Process
149	Palvored 75 (Palbociclib Capsules 75mg)	Palbociclib 75mg	Dr. Reddy's Laboratories Limited, India	United Pharma Sdn Bhd	In-Process
150	Palvored 100 (Palbociclib Capsules 100mg)	Palbociclib 100mg	Dr. Reddy's Laboratories Limited, India	United Pharma Sdn Bhd	In-Process
151	Palvored 125 (Palbociclib Capsules 125mg)	Palbociclib 125mg	Dr. Reddy's Laboratories Limited, India	United Pharma Sdn Bhd	In-Process
152	Vaxcel Polymycin E 1M IU Powder For Injection, Infusion Or Inhalation	Each vial contains: Colistimethate Sodium 1 Million IU	Kotra Pharma (M) Sdn Bhd, Malaysia	Medicorp Sdn Bhd	In-Process
153	Xgeva Solution For Injection In Pre-Filled Syringe 120mg/ml	Each pre-filled syringe contains Denosumab 120mg in 1.0ml of solution (120mg/ml)	Amgen Manufacturing Limited LLC, USA	DKSH BRN Sdn Bhd	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
154	Lastinem-500 (Imipenem & Cilastatin Powder For Solution For Infusion 500mg/500mg)	Each vial contains: Sterile Imipenem equivalent to Anhydrous Imipenem 500mg & Sterile Cilastatin Sodium equivalent to Cilastatin 500mg	Venus Remedies Limited, India	Kingsley Medical Supplies Sdn Bhd	In-Process
155	Lumakras Film-Coated Tablet 120mg	Sotorasib 120mg	Patheon Inc, Canada	DKSH BRN Sdn Bhd	In-Process
156	Norvita IV 1mg/ml Concentrate For Solution For Infusion	Each ml contains: Norephinephrine Bitartrate eq. to Norephinephrine 1mg	Able Medical Company Limited, Thailand	Kingsley Medical Supplies Sdn Bhd	In-Process
157	Tevimbra Concnetrate For Solution For Infusion 100mg/10ml	Each 10ml vial contains Tislelizumab 100mg	BeOne Guangzhou Biologics Manufacturing Co., Ltd., China	DKSH BRN Sdn Bhd	In-Process
158	Cavsamir (Sevelamer Carbonate Tablets 800mg)	Sevelamer Carbonate 800mg	Dr. Reddy's Laboratories Limited, India	G & H Trading Company	In-Process
159	Tylin (Tigecycline Powder For Solution For Infusion 50mg/Vial)	Each vial contains: Tigecycline 50mg	Gufic Biosciences Limited, India	Hongkiat Trading & Company	In-Process
160	Rexicale Calcium Carbonate 500mg Tablets	Calcium Carboante 500mg	KCK Pharmaceutical Industries Sdn Bhd, Malaysia	Kingsley Medical Supplies Sdn Bhd	In-Process
161	Semistauro (Midostaurin Soft Capsule 25mg)	Midostaurin 25mg	Dr. Reddy's Laboratories Limited, India	& H Trading Compar	In-Process
162	Pomagen Capsules 1mg	Pomalidomide 1mg	Lotus Pharmaceutical Co., Ltd., Nantou Plant, Taiwan	Emergent Trading & Supplies	In-Process
163	Pomagen Capsules 2mg	Pomalidomide 2mg	Lotus Pharmaceutical Co., Ltd., Nantou Plant, Taiwan	Emergent Trading & Supplies	In-Process
164	Pomagen Capsules 3mg	Pomalidomide 3mg	Lotus Pharmaceutical Co., Ltd., Nantou Plant, Taiwan	Emergent Trading & Supplies	In-Process

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No	Product Name	Active Ingredients	Manufacturer	Applicant	Application Status
165	Pomagen Capsules 4mg	Pomalidomide 4mg	Lotus Pharmaceutical Co., Ltd., Nantou Plant, Taiwan	Emergent Trading & Supplies	In-Process
166	Tremfya 100mg/1ml PushPen Solution For Injection In Pre-Filled Pen	Each pre-filled pen contains Guselkumab 100mg in 1ml	Cilag AG, Switzerland	Medicorp Sdn Bhd	In-Process
167	Pomarza 2 (Pomalidomide Capsules 2mg)	Pomalidomide 2mg	Dr. Reddy's Laboratories Limited, India	United Pharma Sdn Bhd	In-Process
168	Pomarza 4 (Pomalidomide Capsules 4mg)	Pomalidomide 4mg	Dr. Reddy's Laboratories Limited, India	United Pharma Sdn Bhd	In-Process
169	Rybrevant Fastpro 160mg/ml Solution For Injection	One vial of 10ml contains Amivantamab 1600mg (160mg/ml	Cliag AG, Switzerland	Medicorp Sdn Bhd	In-Process
170	Etcamah 75mg Film-Coated Tablets	Camizestrant 75mg	Patheon Manufacturing Services LLC, USA	Zuellig Pharma (B) Sdn Bhd	In-Process