AGENDA 4.3 - APPROVED VARIATIONS DURING THE 142, 143 & 144TH DRC MEETING

"The following applications for variations have been evaluated and were found to be satisfactory, and recommended by the Drug Registration Committee for endorsement by the BDMCA for approval of variation as stated below"

142 DRC Meeting (153 Applications)						
No	**Application Variation Ref. No.**	**Product Name**	**Active ingredients**	**Product Registration No.**	**Variations**	**Company**
1	(207)/DRU/DRA.Variation/2017	Novoseven® 1mg Powder and Solvent for Solution for injection	Eptacog alfa (activated) 1mg/ml (corresponds to 50KIU/Vial) - 1mg/ml after reconstitution	BRU14071370P	1 - Minor (MiV-PA21) Including Minor (MiV-PA22) - Change of specifications of an excipient including change of test procedure for an excipient 2 - Minor (MiV-PA27) - Change in the test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
2	(208)/DRU/DRA.Variation/2017	Novoseven® Powder and Solvent for Solution for Injection 2mg	Eptacog alfa (activated) 2mg/ml (corresponds to 100KIU/Vial) - 1mg/ml after reconstitution	BRU14021229P	1 - Minor (MiV-PA21) Including Minor (MiV-PA22) - Change of specifications of an excipient including change of test procedure for an excipient 2 - Minor (MiV-PA27) - Change in the test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
3	(38)/DRU/DRA.Variation/2018	Typhim Vi Single Dose	Purified Vi Capsular polysaccharides of Salmonella typhi (Ty2 strain) 25µg/0.5ml	BRU09090313P	1 - Minor (MiV-PA6) - Change of in-process controls applied during the manufacture of the drug substance	Zuellig Pharma (B) Sdn Bhd
4	(39)/DRU/DRA.Variation/2018	Typhim Vi Vaccine (20 doses)	Per 0.5ml - Purified Vi (Capsular Polysaccharide of Salmonella typhi (Ty2 Strain)	BRU09040238P	1 - Minor (MiV-PA6) - Change of in-process controls applied during the manufacture of the drug substance	Zuellig Pharma (B) Sdn Bhd
5	(532)/DRU/DRA.Variation/2018	Xtandi Soft Capsules 40mg	Enzalutamide 40mg	BRU17062217P	1 - Minor (MiV-PA2) - Change in package insert (Date of revision : July 2018)	Medipharm Sdn Bhd
6	(813)/DRU/DRA.Variation/2018	Pariet Tablet 10mg	Sodium Rabeprazole 10mg	BRU11100780P	1 - MaV-1 (incl MiV-PA2) - Additional dosing regimen/inclusion of clinical information extending the usage of the product including update in package insert, new date of revision : December 2017)	Medipharm Sdn Bhd

7	(814)/DRU/DRA.Variation/2018	Pariet Tablet 20mg	Sodium Rabeprazole 20mg	BRU11100779P	1 - MaV-1 (incl MiV-PA2) - Additional dosing regimen/inclusion of clinical information extending the usage of the product including update in package insert, new date of revision : December 2017)	Medipharm Sdn Bhd
8	(828)/DRU/DRA.Variation/2018	Oliclinomel N4-550E Emulsion For Infusion	1000ml of the mixture contain: 20% Lipid emulsion compartment (corresponding to 20g/100ml) (200ml); 40% Glucose solution compartment (corresponding to 40g/100ml) (400ml); 10% Amino acid solution compartment (corresponding to 10g/100ml) (400ml) (for Detailed Formulation referred Formulation referred to Dossier)	BRU17042176NP	1 - Major (MaV-4) - Addition of the manufacturing site of the drug product (amino acid blend) 2 - Minor (MiV-PA2) - Change of package insert (date of revision : February 2017) 3 - Minor (MiV-PA4) - Addition of alternative manufacturing site of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) available) 4 - Minor (miV-PA7) - Change of manufacturing process of the drug substances Serine (CEP available) 5 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd
9	(829)/DRU/DRA.Variation/2018	Oliclinomel N7-1000 Emulsion For Infusion	1000ml of the mixture contain: 20% Lipid emulsion compartment (corresponding to 20g/100ml) (200ml); 40% Glucose solution compartment (corresponding to 40g/100ml) (400ml); 10% Amino acid solution compartment (corresponding to 10g/100ml) (400ml) (for Detailed Formulation referred Formulation referred to Dossier)	BRU17062210NP	1 - Major (MaV-4) - Addition of the manufacturing site of the drug product (amino acid blend) 2 - Minor (MiV-PA2) - Change of package insert (date of revision : February 2017) 3 - Minor (MiV-PA4) - Addition of alternative manufacturing site of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) available) 4 - Minor (miV-PA7) - Change of manufacturing process of the drug substances Serine (CEP available) 5 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd
10	(830)/DRU/DRA.Variation/2018	Oliclinomel N7-1000 Emulsion For Infusion	1000ml of the mixture contain: 20% Lipid emulsion compartment (corresponding to 20g/100ml) (200ml); 40% Glucose solution compartment (corresponding to 40g/100ml) (400ml); 10% Amino acid solution compartment (corresponding to 10g/100ml) (400ml) (for Detailed Formulation referred Formulation referred to Dossier)	BRU17032168NP	1 - Major (MaV-4) - Addition of the manufacturing site of the drug product (amino acid blend) 2 - Minor (MiV-PA2) - Change of package insert (date of revision : February 2017) 3 - Minor (MiV-PA4) - Addition of alternative manufacturing site of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) available) 4 - Minor (miV-PA7) - Change of manufacturing process of the drug substances Serine (CEP available) 5 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd

11	(859)/DRU/DRA.Variation/2018	Simponi Solution for Injection in Pre-filled Syringe 50mg/0.5ml	Golimumab 50mg/0.5ml	BRU15021757P	1 - MiV-PA1 - Change of drug product name	Zuellig Pharma (B) Sdn Bhd
12	(860)/DRU/DRA.Variation/2018	Maxitrol Eye Drops	Per 1ml - Dexamethasone 0.1%; Neomycin Sulphate 3,500IU; Polymyxin B Sulphate 6,000 IU	BRU13081128P	1 - Minor (MiV-PA2) - Change in inner label, outer carton label and package insert (tracking number: TDOC-0051679 Version: 2.0, Date of revision: September 2018) 2 - Minor (MiV-PA35) - Change of storage conditions of drug product (increasing from the current approved storage condition)	Zuellig Pharma (B) Sdn Bhd
13	(863)/DRU/DRA.Variation/2018	Methotrexate Injection BP 50mg in 2ml	Methotrexate 50mg/2ml	BRU12030879P	1 - Major (MaV-2) including MiV-PA2 - Change in inner label, outer carton label and package insert (Version: METHOTREXATE - 0119, Date of Revision : 18 Jan 2019) 2 - Minor (MiV-PA1) - Change of drug product name	Zuellig Pharma (B) Sdn Bhd
14	(864)/DRU/DRA.Variation/2018	Methotrexate Injection BP 1000mg in 10ml	Methotrexate 1000mg/ml	BRU09120383P	1 - Major (MaV-2) including MiV-PA2 - Change in inner label, outer carton label and package insert (Version: METHOTREXATE - 0119, Date of Revision : 18 Jan 2019) 2 - Minor (MiV-PA1) - Change of drug product name	Zuellig Pharma (B) Sdn Bhd
15	(874)/DRU/DRA.Variation/2018	Augmentin Syrup 228mg/5ml	Amoxycillin 200mg/5ml (as trihydrate); Clavulanic acid 28.5mg/5ml (as Potassium Clavulanate)	BRU08030024P	1 - Major (MaV-2) - Change of inner label, outer carton label and package insert (Version: 04, Reference: GDS23/IPI12, Date of revision: 12 June 2018) 2 - Major (MaV-4) - Replacement of the manufacturing site of the drug product 3 - Minor (MiV-PA1) - Change of drug product name 4 - Minor (MiV-PA13) - Change of batch size of non-sterile drug product 5 - Minor (MiV-PA20_ including (MiV-PA19) - Minor change of the manufacturing process for non-sterile product including in-process control and intermediate 6 - Minor (MiV-PA27) - Change in the test procedure of the drug product 7 - Minor (MiV-PA35) - Change of storage conditions of the drug product (increasing from the current approved stoarge condition) 8 - Minor (MiV-PA) - Update of dossier (P7 Conatiner closure system and P8.3 Stability Data Analytical Methods)	Zuellig Pharma (B) Sdn Bhd

16	(875)/DRU/DRA.Variation/2018	Augmentin Syrup 457mg/5ml	Amoxycillin 400mg/5ml (as trihydrate); Clavulanic acid 57mg/5ml (as Potassium Clavulanate)	BRU08030025P	1 - Major (MaV-2) - Change of inner label, outer carton label and package insert (Version: 04, Reference: GDS23/IPI12, Date of revision: 12 June 2018) 2 - Major (MaV-4) - Replacement of the manufacturing site of the drug product 3 - Minor (MiV-PA1) - Change of drug product name 4 - Minor (MiV-PA13) - Change of batch size of non-sterile drug product 5 - Minor (MiV-PA20 including (MiV-PA19) - Minor change of the manufacturing process for non-sterile product including in-process control and intermediate 6 - Minor (MiV-PA27) - Change in the test procedure of the drug product 7 - Minor (MiV-PA35) - Change of storage conditions of the drug product (increasing from the current approved stoarge condition) 8 - Minor (MiV-PA) - Update of dossier (P7 Conatiner closure system and P8.3 Stability Data Analytical Methods)	Zuellig Pharma (B) Sdn Bhd
17	(878)/DRU/DRA.Variation/2018	Depo-Medrol Sterile Aqueous Suspension 40mg/ml	Methylprednisolone Acetate 200mg/5ml	BRU09040237P	1 - Minor(MiV-PA2) - Change of package insert (Date of revision : 15 FEB 2019, Version: DEPO MEDROL-0219) 2 - Minor (MiV-N6) - Change of name and address of manufacturer of the drug substance	Zuellig Pharma (B) Sdn Bhd
18	(899)/DRU/DRA.Variation/2018	Exelon® Patch 5	Rivastigmine base 9mg/5cm (4.6mg/24hours)	BRU10100563P	1 - Major (MaV-3)- Addition of alternative manufacturer of drug substance (where European Pharmacocpoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance	Zuellig Pharma (B) Sdn Bhd
19	(900)/DRU/DRA.Variation/2018	Exelon® Patch 10	Rivastigmine base 18mg/10cm (9.5mg/24hours)	BRU10100562P	1 - Major (MaV-3)- Addition of alternative manufacturer of drug substance (where European Pharmacocpoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance	Zuellig Pharma (B) Sdn Bhd
20	(901)/DRU/DRA.Variation/2018	Exelon® Patch 15	Rivastigmine base 27mg/15cm (in vivo release rate 13.3mg/24h)	BRU15021768P	1 - Major (MaV-3)- Addition of alternative manufacturer of drug substance (where European Pharmacocpoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance 3 - Minor (MiV-N7) - Deletion of the alternative manufacturer(s) for drug substance (intermediate)	Zuellig Pharma (B) Sdn Bhd

21	(902)/DRU/DRA.Variation/2018	Zithromax Film-coated Tablet 250mg	Azithromycin (as dihydrate) 250mg	BRU08120180P	1 - Major (MaV-3)- Addition of alternative manufacturer of drug substance (where European Pharmacocpoeial Certificate of Suitabality (CEP) is not available) 2 - Major (MaV-6) including MiV-PA8 - Change of the specification of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 3 - Minor (MiV-PA5) - Change of batch size of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 4 - Minor (MiV-PA6) - Change of in-process controls applied during the manufacture of the drug sustance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 5 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 6 - Minor (MiV-N6) - Change of name and address of a manufactturer of the drug substance	Zuellig Pharma (B) Sdn Bhd
22	(903)/DRU/DRA.Variation/2018	Zithromax Powder For Oral Suspension 200mg/5ml	Azithromycin (as dihydrate) 200mg/5ml	BRU10100568P	1 - Major (MaV-3)- Addition of alternative manufacturer of drug substance (where European Pharmacocpoeial Certificate of Suitabality (CEP) is not available) 2 - Major (MaV-6) including MiV-PA8 - Change of the specification of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 3 - Minor (MiV-PA5) - Change of batch size of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 4 - Minor (MiV-PA6) - Change of in-process controls applied during the manufacture of the drug sustance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 5 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 6 - Minor (MiV-N6) - Change of name and address of a manufactturer of the drug substance	Zuellig Pharma (B) Sdn Bhd

23	(916)/DRU/DRA.Variation/2018	Minison Tablet 1mg	Prazosin 1mg (as HCl 1.095mg)	BRU13061075P	1 - MiV-PA14 (Minor) - Removal of overage 2 - MiV-PA15 (Minor) - Quantitative change of excipient 3 - MiV-PA24 (Minor) - Change of release specifications of the drug product	Asterix United (B) Sdn Bhd
24	(925)/DRU/DRA.Variation/2018	Lactul Solution 670mg/ml	Lactulose 670mg/ml	BRU14041305NP	1 - MiV-PA2 (Minor) - Change of product labelling (inner label, outer carton and package insert) 2- MiV-PA28 - Addition of primary packaging material and pack size for non-sterile product i.e typr of container 3 - MiV-N9 - Change of release and shelf-life specifications of the drug product following the updates in the compendium	Asterix United (B) Sdn Bhd
25	(927)/DRU/DRA.Variation/2018	Nitroderm TTS 5 (5mg/24hr)	Glyceryl Trinitrate/nitroglycerin 25mg	BRU10020418P	1 - MiV-PA35 - Change of storage conditions of the drug product 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, new date of revision May 2018)	Zuellig Pharma (B) Sdn Bhd
26	(928)/DRU/DRA.Variation/2018	Nitroderm TTS 10	Glyceryl Trinitrate/nitroglycerin 50mg (10mg/24hr)	BRU10040452P	1 - MiV-PA35 - Change of storage conditions of the drug product 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, new date of revision May 2018)	Zuellig Pharma (B) Sdn Bhd
27	(931)/DRU/DRA.Variation/2018	Endoxan Tablet 50mg	Cyclophosphamide anhydrous (as monohydrate) 50mg	BRU13101158P	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision March 2018)	Zuellig Pharma (B) Sdn Bhd
28	(932)/DRU/DRA.Variation/2018	Endoxan Injection 200mg/vial	Cyclophosphamide anhydrous 213.8mg (eq. to anhydrous Cyclophosphamide 200mg)	BRU14041293P	1 - MiV-PA - Change of product labelling (package insert, new date of revision March 2018)	Zuellig Pharma (B) Sdn Bhd
29	(933)/DRU/DRA.Variation/2018	Iodosorb Powder	Cadexomer 99.1% w/w, with Iodine 0.9% w/w	BRU13091135P	1 - MiV-PA2 - Change of product labelling (inner case, pouch label, outer carton)	Mc Quipp Technisell Marketing Sdn Bhd
30	(934)/DRU/DRA.Variation/2018	Travatan Eye Drops 40mcg/ml	Travoprost 40mcg/ml	BRU14031264PS1; BRU14031264PS2	1 - MiV-PA2 - Change of product labelling (inner Label, Pouch, Outer Carton and Package Insert [TDOC-0051871 Version: 2.0], new date of revision March 2018)	Zuellig Pharma (B) Sdn Bhd
31	(936)/DRU/DRA.Variation/2018	Trileptal 600mg Film-coated Tablets	Oxcarbazepine 600mg	BRU14091490P	1 - MiV-PA20 - Minor change of the manufacturing process for non-sterile product	Zuellig Pharma (B) Sdn Bhd
32	(950)/DRU/DRA.Variation/2018	Advagraf Prolonged Release Hard Capsule 0.5mg	Tacrolimus 0.5mg (as monohydrate)	BRU14111550P	1 - Minor (MiV-PA2) - Change of blister label and package insert (Date of revision: July 2018 (CCDSV1.2))	Medipharm Sdn Bhd

33	(951)/DRU/DRA.Variation/2018	Advagraf Prolonged Release Hard Capsule 1mg	Tacrolimus 1mg (as monohydrate)	BRU14111551P	1 - Minor (MiV-PA2) - Change of blister label and package insert (Date of revision: July 2018 (CCDSV1.2))	Medipharm Sdn Bhd
34	(952)/DRU/DRA.Variation/2018	Advagraf Prolonged Release Hard Capsule 5mg	Tacrolimus 5mg (as monohydrate)	BRU14111552P	1 - Minor (MiV-PA2) - Change of blister label and package insert (Date of revision: July 2018 (CCDSV1.2))	Medipharm Sdn Bhd
35	(953)/DRU/DRA.Variation/2018	Prograf Capsule 0.5mg	Tacrolimus 0.5mg	BRU12100951P	1 - Minor (MiV-PA2) - Change of blister label and package insert (Date of revision: July 2018 (CCDSV1.2))	Medipharm Sdn Bhd
36	(954)/DRU/DRA.Variation/2018	Prograf Capsule 1mg	Tacrolimus 1mg	BRU14031261P	1 - Minor (MiV-PA2) - Change of blister label and package insert (Date of revision: July 2018 (CCDSV1.2))	Medipharm Sdn Bhd
37	(956)/DRU/DRA.Variation/2018	CoAprovel 150/12.5mg Film-coated Tablet	Irbesartan 150mg, Hydrochlorothiazide 12.5mg	BRU08110163P	1 - Minor (MiV-PA2) - Change of blister label and package insert (Date of revision: April 2018 (CCDS V14 SmPC Sept 17))	Medipharm Sdn Bhd
38	(957)/DRU/DRA.Variation/2018	CoAprovel 300/12.5mg film-coated tablet	Irbesartan 300mg, Hydrochlorothiazide 12.5mg	BRU09010188P	1 - Minor (MiV-PA2) - Change of blister label and package insert (Date of revision: April 2018 (CCDS V14 SmPC Sept 17))	Medipharm Sdn Bhd
39	(958)/DRU/DRA.Variation/2018	CoAprovel 300/25mg film-coated tablet	Irbesartan 300mg, Hydrochlorothiazide 25mg	BRU11080754P	1 - Minor (MiV-PA2) - Change of package insert (Date of revision : April 2018 (CCDS V14 SmPC Sept 17)) 2 - Minor (MiV-PA27) - Change in the test procedure of the drug product	Medipharm Sdn Bhd
40	(959)/DRU/DRA.Variation/2018	B-Mycin cream	Betamethasone dipropionate 0.643mg (eq. to 0.5mg betamethasone); Gentamicin Sulfate 1mg (potency)	BRU15041842P	1 - Major (MaV-6) - Change of the specification of drug product (where European Pharmacopoeial Certificate of Suitability (CEP) is not available)	Asterix United (B) Sdn Bhd
41	(960)/DRU/DRA.Variation/2018	Olmetec 10mg Tablet	Olmesartan Medoxomil 10mg	BRU10060493P	1 - Minor (MiV-PA4) - Addition of manufacturer of intermediates of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is available] 2 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd
42	(961)/DRU/DRA.Variation/2018	Olmetec Tablet 20mg	Olmesartan Medoxomil 20mg	BRU10030440P	1 - Minor (MiV-PA4) - Addition of manufacturer of intermediates of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is available] 2 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd

43	(962)/DRU/DRA.Variation/2018	Olmetec 40 Tablet	Olmesartan Medoxomil 40mg	BRU15081917P	1 - Minor (MiV-PA4) - Addition of manufacturer of intermediates of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is available] 2 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd
44	(963)/DRU/DRA.Variation/2018	Lyrica Capsules 50mg	Pregabalin 50mg	BRU12100949P	1 - Minor (MiV-PA4) - Update of European Pharmacopoeia transmissible spngiform encephalopathy (TSE) Certificate of Suitability (CEP) of gelatin	Zuellig Pharma (B) Sdn Bhd
45	(964)/DRU/DRA.Variation/2018	Lyrica™ 75mg Capsules	Pregabalin 75mg	BRU12060909P	1 - Minor (MiV-PA4) - Update of European Pharmacopoeia transmissible spongiform encephalopathy (TSE) Certificate of Suitability (CEP) of gelatin	Zuellig Pharma (B) Sdn Bhd
46	(965)/DRU/DRA.Variation/2018	Lyrica™150mg Capsules	Pregabalin 150mg	BRU12020870P	1 - Minor (MiV-PA) - Update of European Pharmacopoeia transmissible spongiform encephalopathy (TSE) Certificate of Suitability (CEP) of gelatin	Zuellig Pharma (B) Sdn Bhd
47	(966)/DRU/DRA.Variation/2018	Stalevo 50/12.5/200mg film-coated tablet	Levodopa 50mg, Carbidopa 12.5mg, Entacapone 200mg	BRU11080746P	1 - Minor (MiV-PA) - Update of P8 Stability Data	Zuellig Pharma (B) Sdn Bhd
48	(967)/DRU/DRA.Variation/2018	Stalevo 75/18.75/200mg Film-coated Tablet	Levodopa 75mg, Carbidopa 18.75mg, Entacapone 200mg	BRU14031251P	1 - Minor (MiV-PA) - Update of P8 Stability Data	Zuellig Pharma (B) Sdn Bhd
49	(968)/DRU/DRA.Variation/2018	Stalevo® 100/25/200mg Film-coated Tablet	Levodopa 100mg, Carbidopa 25mg, Entacapone 200mg	BRU11040694P	1 - Minor (MiV-PA) - Update of P8 Stability Data	Zuellig Pharma (B) Sdn Bhd
50	(969)/DRU/DRA.Variation/2018	Stalevo 125/31.25/200mg film-coated tablet	Levodopa 125mg, Carbidopa 31.25mg, Entacapone 200mg	BRU14091517P	1 - Minor (MiV-PA) - Update of P8 Stability Data	Zuellig Pharma (B) Sdn Bhd
51	(970)/DRU/DRA.Variation/2018	Stalevo® 150/37.5/200mg Film-coated Tablet	Levodopa 150mg; Carbidopa 37.5mg; Entacapone 200mg	BRU111008786P	1 - Minor (MiV-PA) - Update of P8 Stability Data	Zuellig Pharma (B) Sdn Bhd
52	(971)/DRU/DRA.Variation/2018	Stalevo 200/50/200mg Film-coated Tablet	Levodopa 200mg; Carbidopa 50mg; Entacapone 200mg	BRU14031252P	1 - Minor (MiV-PA) - Update of P8 Stability Data	Zuellig Pharma (B) Sdn Bhd
53	(972)/DRU/DRA.Variation/2018	Survanta® Beractant (as phospholipids) 25mg/ml	Beractant (as phospholipids) 25mg/ml	BRU12120971P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
54	(973)/DRU/DRA.Variation/2018	Insulatard 100IU/ml Suspension contain 100IU (3.5g) of insulin	1ml of suspension contain 100IU (3.5g) of insulin	BRU15021760PS2	1 - Major (MaV-7) - Change of batch size of sterile drug product	Zuellig Pharma (B) Sdn Bhd

55	(974)/DRU/DRA.Variation/2018	Mixtard® 30 100IU/ml	Insulin Human, rDNA (as Isophane Insulin) 70%, insulin Human, rDNA (as soluble insulin) 30%	BRU14071319PS2	1 - Major (MaV-7) - Change of batch size of sterile drug product	Zuellig Pharma (B) Sdn Bhd
56	(975)/DRU/DRA.Variation/2018	Ketovid Shampoo 2% w/v	Ketoconazole (micronised) 2% w/w	BRU13081127P	1 - Minor (MiV-PA2) - Change of Outer Carton Label, inner label and package insert (Version: VIKET11-2, Revision date: October 2017)	G&H Trading Company
57	(976)/DRU/DRA.Variation/2018	Asmol 2 tablet	Salbutamol 2mg (as sulphate)	BRU14111653P	1 - Minor (MiV-PA2) - Change of Outer carton label	G&H Trading Company
58	(977)/DRU/DRA.Variation/2018	Folic acid 5mg tablet	Folic acid 5mg	BRU15041849NP	1 - Minor (MiV-PA1) - Change of drug product name 2 - Minor (MiV-PA2) - Change of bottle label and package insert (Version:TL632B-R7, Revised on July 2017) 3 - Minor (MiV-PA28) - Change in primary packaging material for non-sterile product 4 - Minor (MiV-PA35) - Change of storage conditions of the drug product (increasing from the current approved storage condition)	G&H Trading Company
59	(978)/DRU/DRA.Variation/2018	Metoclopramide Tablet 10mg	Metoclopramide HCl 10mg	BRU10070512P	1 - Major (MaV-1) - Change in indication of the drug product (Version : CL317B-R6, Revision date: September 2016) 2 - Minor (MiV-PA28) - Addition of primary packaging material for non-sterile product with consquential update in package insert (Version: CL317B-R6, Revision date : September 2016) 3 - Minor (MiV-PA35) - Change of storage conditions of the drug product (increasing from the current approved storage condition) woth consequential change in label artwork (outer carton, inner label and package insert (Version: CL317B-R6, Revision date: September 2016))	G&H Trading Company
60	(979)/DRU/DRA.Variation/2018	Miconazole Cream 2.0% w/w	Miconazole Nitrate 2.0% w/w	BRU08110159P	1 - Minor (MiV-PA2 - Change of outer label, inner label and package insert (Version : EL213A-R7, Revised Date: 11/04/2019) 2 - Minor (MiV-PA35) - Change of storage conditions of the drug product (Increasing from the current approved storage condition)	G&H Trading Company

61	(980)/DRU/DRA.Variation/2018	Nalol Tablet 40mg	Propranolol HCl 40mg	BRU10060498P	1 - Minor (MiV-PA2)- Change of outer label, inner label and package insert (Version : N045R2(E1)	G&H Trading Company
62	(981)/DRU/DRA.Variation/2018	Polarax 2mg Tablet	Dexchlorpheniramine maleate 2mg	BRU10030429P	1 - Minor (MiV-PA28) - Addition of primary packaging material for non-sterile product with consequential update in package insert (date of revision: 21/11/2011, Version: CL 120R9) 2 - Minor (MiV-PA35) - Change of storage conditions of the drug product (Increasing from the current approved storage condition)	G&H Trading Company
63	(982)/DRU/DRA.Variation/2018	Toujeo 300units/ml Solution For Injection In Pre-Filled Pen	Insulin glargine 300units/ml (10.91mg/ml)	BRU16112099P	1 - Major (MaV-6) - Change of specification of drug product (where European pharmacopoeial Certificate of Suitability (CEP) is not available) 2 - Major (MaV-7) - Change of batch size of sterile drug product 3 - Major (MaV-9) - Major change in manufacturing process for the drug product 4 - Major (MaV-15) - Extension of shelf-life of the drug product 5 - Minor (MiV-PA2) - Change of inner label, outer carton label and package insert (DATE OF REVISION: Apr 2018 (EU SmPC Feb 2015))	Medipharm Sdn Bhd
64	(983)/DRU/DRA.Variation/2018	Cernevit Multivitamin Powder for Injection	Each vial contains: Retinol palmitate (VitaminA) 3500 IU, Cholecalciferol (Vitamin D3) 220 IU, DL aplha tocopherol (Vitamin E) 10.2 mg, Ascorbic acid (Vitamin C) 125mg, Cocarboxylase tetrahydrate (Vitamin B1) 5.8mg, Riboflavin sodium phosphate dehydrate (Vitamin B2) 5.67mg, Pyridoxine hydrochloride (Vitamin B6) 5.5mg, Cyanocobalamin (Vitamin B12) 0.006mg, Folic acid 0.414mg, Dexpanthenol 16.15mg, Biotin 0.069mg, Nicotinamide 46mg	BRU15021754P	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance (Vitamin B12 cyanocobalamin)	Zuellig Pharma (B) Sdn Bhd

65	(984)/DRU/DRA.Variation/2018	Stivarga Tablet 40mg	Regorafenib (40mg Regorafenib equivalent to 41.49mg Regorafenib monohydrate)	BRU15111957P	1 - Minor (MiV-PA5) - Change of a batch size of drug substance (where European Pharmacopoeial Certifcate of Suitability (CEP) is not available 2 - Minor (MiV-PA7) - Change of manufacturing process of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available	Zuellig Pharma (B) Sdn Bhd
66	(985)/DRU/DRA.Variation/2018	Dextrose 5% and Sodium Chloride 0.9% Injection USP	Dextrose 5%; Sodium Chloride 0.9%	BRU14011199NP	1 - Minor (MiV-PA2) - Change of package insert (Version:07-19-00-0209, date of revision: February 2018)	Zuellig Pharma (B) Sdn Bhd
67	(986)/DRU/DRA.Variation/2018	5% Dextrose and 0.45% Sodium Chloride Injection, USP	Dextrose 5%; Sodium Chloride 0.45%	BRU14021240NP	1 - Minor (MiV-PA2) - Change of package insert (Version:07-19-00-0209, date of revision: February 2018)	Zuellig Pharma (B) Sdn Bhd
68	(987)/DRU/DRA.Variation/2018	Pentaxim Vaccine	Composition of final container per dose (0.5ml) : TETRAXIM - Purified diphteria toxoid ≥ 30 I.U; Purified tetanus toxoid ≥ 25µg ; Inactivated poliomyeltis virus type1 40 DU, type 2 8DU, type 3 32 DU; Act-HIB - Polysaccharide of Haemophilus influenza type b conjugated to tetanus protein 10µg	BRU11080747PS1, BRU11080747PS2, BRU11080747PS3	1 - Minor (MiV-PA21) - Change of specificatios of an excipient i.e. change in specification of water used during the preparation of the bordetella pertussis working seed lot & update to S2.3 dossier 2 - Minor (MiV-PA) - Replacement of the reference standard lot ued for the titration of pertussis FHA by ELISA method and changes in the FHA antigenicity test	Zuellig Pharma (B) Sdn Bhd
69	(988)/DRU/DRA.Variation/2018	Tetraxim Vaccine	Purified diptheria toxoid ≥ 30IU; purified tetanus tpxoid ≥ 40IU; Bordetella pertusis antigens; Adsorbed purified pertusis toxoid 25µg, Adsorbed purified filamentous haemagglutinin 25µg; Inactivated poliomyelitis virus; Type 1 40 D units, Type 2 8 Dunits, Type 3 32 Dunits	BRU11050700PS1, BRU11050700PS2,	1 - Minor (MiV-PA21) - Change of specificatios of an excipient i.e. change in specification of water used during the preparation of the bordetella pertussis working seed lot & update to S2.3 dossier 2 - Minor (MiV-PA) - Replacement of the reference standard lot ued for the titration of pertussis FHA by ELISA method and changes in the FHA antigenicity test	Zuellig Pharma (B) Sdn Bhd

70	(989)/DRU/DRA.Variation/2018	Hexaxim Suspension for Injection	Per dose (0.5ml): Dipththeria toxoid 30Lf (≥ 20IU), Tetanus toxoid 10Lf (≥ 40IU), Bordetella pertussis antigens: Pertussis toxoid 25µg, Filamentous haemagglutinin 25µg, Polio Virus (Inactivated); Type 1 (Mahoney) 40 DU, Type 2 (MED-1) 8 DU, Type 3 (saukett) 32 DU, Hepatitis B surface antigen 10µg, Haemophilus influenzae type b polysaccharide (Polyribosyltibitol phosphate). 12µg conjugated to Tetanus protein (PRP-T) 22-36µg	BRU15011728P	1 - Minor (MiV-PA21) - Change of specificatios of an excipient i.e. change in specification of water used during the preparation of the bordetella pertussis working seed lot & update to S2.3 dossier 2 - Minor (MiV-PA) - Replacement of the reference standard lot ued for the titration of pertussis FHA by ELISA method and changes in the FHA antigenicity test	Zuellig Pharma (B) Sdn Bhd
71	(992)/DRU/DRA.Variation/2018	Chlorhex 4% antiseptic solution	Chlorhexidine gluconate 4%	BRU15071903NP	1 - Minor (MiV-PA2) - Change of product label (immediate label)	G&H Trading Company
72	(993)/DRU/DRA.Variation/2018	ChlorHex 5% Concentrate Solution	Chlorhexidine gluconate 5% w/v	BRU15041861NP	1 - Minor (MiV-PA2) - Change of product label (immediate label)	G&H Trading Company
73	(994)/DRU/DRA.Variation/2018	Septi-Sol Solution	Chlorhexidine Gluconate 20% Solution - 0.5% w/v; Ethanol 94% - 77% v/v	BRU14121702NP	1 - Minor (MiV-PA2) - Change of product label (immediate label artwork)	G&H Trading Company
74	(995)/DRU/DRA.Variation/2018	Acnotin 10 capsule	Isotretinoin 10mg	BRU17022160P	1 - Minor (MiV-PA2) - Change of outer carton label and package insert (Version: I-I022-H14-00-05, Revised Date: 02/03/2017)	G&H Trading Company
75	(996)/DRU/DRA.Variation/2018	Acnotin 20 capsule	Isotretinoin 20mg	BRU17022161P	1 - Minor (MiV-PA2) - Change of outer carton label and package insert (Version: I-022-H14-00-05, Revised Date: 02/03/2017)	G&H Trading Company
76	(997)/DRU/DRA.Variation/2018	Laxodyl Tablet 5mg	Bisacodyl 5mg	BRU10070510P	1 - MiV-PA35 - Change of storage conditions of the drug product 2 - MiV-PA2 - Change in product labelling (outer carton and package insert, new revision date 04/01/2012; version, L035R1)	G&H Trading Company
77	(998)/DRU/DRA.Variation/2018	Tenol-100	Atenolol 100mg	BRU12110962P	1 - MiV-PA2 - Change in product labelling (outer carton and package insert, new version TL 698A-R2	G&H Trading Company
78	(999)/DRU/DRA.Variation/2018	Maxitrol Eye Ointment	Per g: Neomycin Sulfate 3,500 Iu; Polymyxin B Sulfate 6,000IU; Dexamethasone 0.1%	BRU13061088P	1 - MiV-PA2 - Change in product labelling (package insert [TDOC-0051679 Version 2.0], new date of revision September 2018)	Zuellig Pharma (B) Sdn Bhd
79	(1000)/DRU/DRA.Variation/2018	Exelon capsule 1.5mg	Rivastigmine 1.5mg (as hydrogen tartrate 2.4mg)	BRU10060499P	1 - MiV-PA5 - Increase of batch size of intermediate Dimetol for Exelon drug substance manufactured in Dishman, where CEP is not available 2 - MiV-PA - Minor change in the manufacturing process of the drug substance	Zuellig Pharma (B) Sdn Bhd

80	(1001)/DRU/DRA.Variation/2018	Exelon capsule 3mg	Rivastigmine (as hydrogen tartrate) 3mg	BRU10100559P	1 - MiV-PA5 - Increase of batch size of intermediate Dimetol for Exelon drug substance manufactured in Dishman, where CEP is not available 2 - MiV-PA - Minor change in the manufacturing process of the drug substance	Zuellig Pharma (B) Sdn Bhd
81	(1002)/DRU/DRA.Variation/2018	Exelon capsule 4.5mg	Rivastigmine 4.5mg (as Rivastigmine hydrogen tartrate 7.2mg)	BRU10070520P	1 - MiV-PA5 - Increase of batch size of intermediate Dimetol for Exelon drug substance manufactured in Dishman, where CEP is not available 2 - MiV-PA - Minor change in the manufacturing process of the drug substance	Zuellig Pharma (B) Sdn Bhd
82	(1003)/DRU/DRA.Variation/2018	Exelon capsule 6mg	Rivastigmine 6mg (as hydrogen tartrate 9.6mg)	BRU10060501P	1 - MiV-PA5 - Increase of batch size of intermediate Dimetol for Exelon drug substance manufactured in Dishman, where CEP is not available 2 - MiV-PA - Minor change in the manufacturing process of the drug substance	Zuellig Pharma (B) Sdn Bhd
83	(1004)/DRU/DRA.Variation/2018	Exelon Oral Solution 2mg/ml	Rivastigmine 2mg/ml (as hydrogen tartrate)	BRU10040462P	1 - MiV-PA5 - Increase of batch size of intermediate Dimetol for Exelon drug substance manufactured in Dishman, where CEP is not available 2 - MiV-PA - Minor change in the manufacturing process of the drug substance	Zuellig Pharma (B) Sdn Bhd
84	(1005)/DRU/DRA.Variation/2018	Prevenar 13 Suspension for Injection	Per 0.5ml - Pneumococcal Polysaccharide Serotype 1,3,4, 5,, 6A, 7F, 9V , 14, 18C, 19A, 19F, 23F - 2.2mcg; Pneumococcal Polysaccharide Serotype 6B-4.4mcg	BRU13021008P	1 - Mav-3 - Addition of alternative manufacturing site for drug substance (where CEP is not available) - introduction of Manufacturing Suite 2, Grange Castle, Ireland 2 - MiV-PA8 - Change of the specification of drug substance (Tightening of specification for free accharide for pneumococcal serotype 19A) 3 - MiV-PA - To extend the expiry period for an intermediate in the manufacture of the drug substance (liquid (frozen) Diphtheria CRM $_{197}$ carrier protein), from 36 months to 48months expiry period	Zuellig Pharma (B) Sdn Bhd
85	(1006)/DRU/DRA.Variation/2018	Ovidrel Solution for Injection 250mcg/0.5ml in Pre-filled Syringe	Choriogonadotropin alfa 250mcg/0.5ml	BRU13101155P	1 - MiV-PA2 - Change in product labelling (instruction for use and package insert, new date of revision: July 2018 (CSI 34v5)	G&H Trading Company
86	(1007)/DRU/DRA.Variation/2018	Hovasc tablet 5mg	Amlodipine 5mg (as besilate 6.90mg)	BRU11090778P	1 - MiV-PA35 - Change of storage conditions of the drug product (Increasing from the current approved storage condition) 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, new revision date February 2017)	G&H Trading Company
87	(1008)/DRU/DRA.Variation/2018	Fenagesic Tablet 250mg	Mefenamic acid 250mg	BRU15051870P	1 - MiV-PA2 - Change of product labelling (inner label, outer carton and package insert, version T030R04)	G&H Trading Company
88	(1009)/DRU/DRA.Variation/2018	Paracetamol Codeine Tablet	Paracetamol 500mg and Codeine Phosphate 8mg	BRU15121974P	1 - MiV-PA2 - Change of product labelling (outer carton version T659A-R3, version number 0118-0896)	G&H Trading Company

89	(1010)/DRU/DRA.Variation/2018	Sun-Glizide Tablet 80mg	Gliclazide 80mg	BRU10100567P	1 - MiV-PA2 - Change of product labelling (blister label and package insert, new revision date November 2007 version G110R4)	G&H Trading Company
90	(1011)/DRU/DRA.Variation/2018	Anacaine Injection 2%	Lidocaine Hydrochloride 2%	BRU17052206P	1 - MiV-PA35 - Change of storage conditions of the drug product (Increasing from the current approved storage condition) 2 - MiV-PA2 - Change of product labelling (inner label, outer carton and package insert, new revision date 18.09.2018)	G&H Trading Company
91	(1012)/DRU/DRA.Variation/2018	Shrizine Injection 25mg/ml	Fluphenazine Decanoate BP 25mg/ml	BRU17082239P	1 - MiV-PA35 (inc MiV-PA2) - Change of storage conditions of the drug product (Increasing from the current approved condition; including change in product labelling - outer carton and package insert, new date of revision 08.05.2017)	G&H Trading Company
92	(1013)/DRU/DRA.Variation/2018	Zocol 150mg Capsule	Fluconazole 150mg	BRU17042192P	1 - MiV-PA35 (inc MiV-PA2) - Change of storage conditions of the drug product (Increasing from the current approved condition; including change in product labelling - outer carton and package insert)	G&H Trading Company
93	(01)/DRU/DRA.Variation/2019	Premarin Tablet 0.3mg	Conjugated Estrogens 0.3mg	BRU14071337P	1 - MiV-PA2 - Change of product (package insert, new LPD date 27 May 2016; Premarin - 0516)	Zuellig Pharma (B) Sdn Bhd
94	(02)/DRU/DRA.Variation/2019	Premarin Tablet 0.625mg	Conjugated Estrogens 0.625mg	BRU13101160P	1 - MiV-PA2 - Change of product labelling (package insert, new LPD date 27 May 2016; Premarin-0516)	Zuellig Pharma (B) Sdn Bhd
95	(05)/DRU/DRA.Variation/2019	Eprex 2000 Prefilled Syringe 2000Iu/0.5ml	Epoetin alfa 2,000IU/0.5ml	BRU12110959P	1 - MaV-1 (incl MiV-PA2) - Change of product labelling (package insert, new date of revision: 22 Oct 2018 (based on CCDS 31 Aug 2017 + Add ind MDS))	Zuellig Pharma (B) Sdn Bhd
96	(06)/DRU/DRA.Variation/2019	Eprex 4000 Prefilled Syringe 4000IU/0.4ml	Epoetin alfa 4,000IU/0.4ml	BRU12110955P	1 - MaV-1 (incl MiV-PA2) - Change of product labelling (package insert, new date of revision: 22 Oct 2018 (based on CCDS 31 Aug 2017 + Add ind MDS))	Zuellig Pharma (B) Sdn Bhd
97	(07)/DRU/DRA.Variation/2019	Eprex 10000 Prefilled Syringes 10,000iu/ml	Epoetin alfa 10,000 IU/ml	BRU14091494P	1 - MaV-1 (incl MiV-PA2) - Change of product labelling (package insert, new date of revision: 22 Oct 2018 (based on CCDS 31 Aug 2017 + Add ind MDS))	Zuellig Pharma (B) Sdn Bhd
98	(08)/DRU/DRA.Variation/2019	Exprex 40,000 Prefilled Syringes 40,000iu/1ml	Epoetin alfa 40,000IU/ml	BRU14121673P	1 - MaV-1 (incl MiV-PA2) - Change of product labelling (package insert, new date of revision: 22 Oct 2018 (based on CCDS 31 Aug 2017 + Add ind MDS))	Zuellig Pharma (B) Sdn Bhd
99	(09)/DRU/DRA.Variation/2019	Lobesol Cream	Clobetasol (as propionate) 0.05% w/w	BRU09050258P	1 - MiV-PA35 - Change of storage conditions of the drug product (increasing from the current approved storage condition) 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, new revision date 1405/2018 version EL113R5)	G&H Trading Company
100	(10)/DRU/DRA.Variation/2019	Nifedipine LA Tablet 30mg	Nifedipine 30mg	BRU12020865PS1	1 - MiV-PA4 - Addition of alternative manufacturer of drug substance (where CEP is available) 2 - MiV-PA19 - Deletion of non-significant controls on intermediate products and limits	G&H Trading Company

101	(12)/DRU/DRA.Variation/2019	Cardiprin 100 Tablet	Aspirin 100mg	BRU15091935P	1 - MiV-PA24 and MiV-PA27 - Change in the release and shelf-life specification with update in the test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
102	(13)/DRU/DRA.Variation/2019	Microgynon 30 Tablet	Levonorgestrel 0.15mg, Ethinylestradiol 0.03mg	BRU11010640P	1 - MaV-6 - Change of the specification of drug product (where CEP is not available) 2 - MiV-PA21 - Change of psecifications of an excipient	Zuellig Pharma (B) Sdn Bhd
103	(14)/DRU/DRA.Variation/2019	Difflam Anti-Inflammatory Lozenges (with Anti-bacterial)	Benzydamine Hydrochloride 3 mg; Cetylpyridinium Chloride 1.33mg	BRU14071379P	1 - MaV-15- Extension of shelf-life of the drug product 2 - MiV-PA3 - Replacement of the company responsible for batch release 3 - MiV-N2 - Change of product owner 4 - MiV-PA2 - Change of product labelling (foil label, outer carton and package insert, new date of revision January 2018)	Zuellig Pharma (B) Sdn Bhd
104	(16)/DRU/DRA.Variation/2019	Lanvis® Tablet 40mg	Thioguanin 40mg	BRU14071328P	1 - Minor (MiV-PA2) - Change of package insert (Version: CCDS19/011217, Date of revision : 15 December 2017)	Zuellig Pharma (B) Sdn Bhd
105	(17)/DRU/DRA.Variation/2019	Xarelto™ Film-coated tablet 15mg	Rivaroxaban 15mg	BRU14041287P	1 - Major (MaV-1) - Inclusion of clinical information extending the usage of the product (Version: Xarelto 15mg&20mg_CCDS8a_Nov 2017, Date of revision: Nov 2017)	Zuellig Pharma (B) Sdn Bhd
106	(18)/DRU/DRA.Variation/2019	Xarelto™ Film-coated tablet 20mg	Rivaroxaban 20mg	BRU14041288P	1 - Major (MaV-1) - Inclusion of clinical information extending the usage of the product (Version: Xarelto 15mg&20mg_CCDS8a_Nov 2017, Date of revision: Nov 2017)	Zuellig Pharma (B) Sdn Bhd
107	(19)/DRU/DRA.Variation/2019	Nexavar® 200mg Film-coated Tablets	Sorafenib Tosylate 200mg	BRU11110803P	1 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA27) - Change in the test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
108	(20)/DRU/DRA.Variation/2019	Hydrocort Cream	Hydrocortisone acetate 10g/g (1% w/w)	BRU14071346P	1 - Minor (MiV-PA14) - Removal of overage	Asterix United (B) Sdn Bhd
109	(21)/DRU/DRA.Variation/2019	Doxymycin Capsule 100mg	Doxycycline Hydrochloride 100mg	BRU14081458P	1 - Minor (MiV-PA13) - Change of batch size of non-sterile drug product	Asterix United (B) Sdn Bhd
110	(22)/DRU/DRA.Variation/2019	Stelara Solution for Injection in pre-filled syringe 45mg/0.5ml	Ustekinumab 45mg/0.5ml	BRU12120975PS1 ; BRU12120975PS2	1 - Minor (MiV-PA2) - Change of package insert (Date of revision of the text : 21 March 2019 (Based on CCDS vJan2019)	Zuellig Pharma (B) Sdn Bhd
111	(23)/DRU/DRA.Variation/2019	Invega® Extended-Release Tablet 3mg	Paliperidone 3mg [:ayer 1-0.9mg; Layer 2-2.1mg]	BRU14071373PS1 & BRU14071373PS2	1 - Minor (MiV-PA9) - Change of the test procedure of non-compendial drug subtance 2 - Minor (MiV-PA10) - Change of re-test period for drug substance	Zuellig Pharma (B) Sdn Bhd
112	(24)/DRU/DRA.Variation/2019	Invega® Extended-Release Tablet 6mg	Paliperidone 6mg [Layer 1-1.8mg; Layer 2-4.2g]	BRU14071374PS1 & BRU14071374PS2	1 - Minor (MiV-PA9) - Change of the test procedure of non-compendial drug subtance 2 - Minor (MiV-PA10) - Change of re-test period for drug substance	Zuellig Pharma (B) Sdn Bhd

113	(25)/DRU/DRA.Variation/2019	Invega® Extended-Release Tablet 9mg	Paliperidone 9mg [Layer 1-2.7mg; Layer 2-6.3mg	BRU14071372PS1 & BRU14071372PS2	1 - Minor (MiV-PA9) - Change of the test procedure of non-compendial drug subtance 2 - Minor (MiV-PA10) - Change of re-test period for drug substance	Zuellig Pharma (B) Sdn Bhd
114	(26)/DRU/DRA.Variation/2019	Invokana Film-coated Tablet 100mg	Canagliflozin 100mg (as hemihydrate)	BRU14111650P	1 - Minor (MiV-PA7) - Addition of alternative manufacturing process of the drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA8) - Change of the specification of drug substance	Zuellig Pharma (B) Sdn Bhd
115	(27)/DRU/DRA.Variation/2019	Invokana 300mg FCT	Canagliflozin 300mg (as hemihydrate)	BRU14121699P	1 - Minor (MiV-PA7) - Addition of alternative manufacturing process of the drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA8) - Change of the specification of drug substance	Zuellig Pharma (B) Sdn Bhd
116	(28)/DRU/DRA.Variation/2019	Galvus 50mg Tablet	Vildagliptin 50mg	BRU14031276P	1 - Minor (MiV-PA8) - Change of the specification of drug substance	Zuellig Pharma (B) Sdn Bhd
117	(29)/DRU/DRA.Variation/2019	Natrilix® SR Tablet	Indapamide 1.5mg	BRU09120375P	1 - Minor (MiV-PA2) - Change in package insert (Version : Final_PI_BRU_Natrilix SR_14.04.2018, Date of revision: 14.04.2018)	Zuellig Pharma (B) Sdn Bhd
118	(30)/DRU/DRA.Variation/2019	Apo-Atenidone Tablets 100/25mg	Atenolol 100mg and Chlorthalidone 25mg	BRU18112454P	1 - Minor (MiV-PA28) with consequential Minor (MiV-PA2) - Change in primary packaging material of non-sterile product with consequential change in package insert	Medicorp Sdn Bhd
119	(31)/DRU/DRA.Variation/2019	Opsumit 10mg Film-coated Tablet	Macitentan 10mg	BRU18022310P	1 - Minor (MiV-PA3) - Change in outer carton label 2 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Medipharm Sdn Bhd
120	(32)/DRU/DRA.Variation/2019	Proctosedyl Suppositories	Chinchocaine 5mg; framycetin sulphate 10mg, Hydrocortisone 5mg; Aesculin 10mg	BRU10080531P	1 - Minor (MiV-PA4) - Change of manufacturer of drug substance (Framycetin) [where European Pharmacopoeial Certificate of Suitability (CEP) I available] 2 - Minor (MiV-PA10) - Addition of re-test period for drug substance (hydrocortisone) 3 - Minor (MiV-PA12) - Addition of CEP of drug substance (Hydrocortisone)	Medipharm Sdn Bhd
121	(34)/DRU/DRA.Variation/2019	Telfast-D Extended Release Tablet	Fexofenadine hydrochloride 60mg ; Pseudoephedrine HCl 120mg	BRU10080535PS2	1 - Minor (MiV-PA2) - Change of package insert (Revision Date : Sept 2018 (Based on USPI June 2009/CCDS 9))	Medipharm Sdn Bhd
122	(36)/DRU/DRA.Variation/2019	Galvus Met 50 50/500mg Film-coated Tablet	Vildagliptin 50mg; Metformin HCl 500mg (corresponding to 390mg Metformin)	BRU14031273PS1; BRU14031273PS2	1 - Minor (MiV-PA8) - Change of the specification of drug substance 2 - Minor (MiV-PA) - To reflect the compliance with EU Food Regulation (EU) 231/2012 for drug product excipients (coating premixes) and other editorial changes	Zuellig Pharma (B) Sdn Bhd

123	(37)/DRU/DRA.Variation/2019	Galvus Met 50/850mg Film-cotaed Tablet	Vildagliptin 50mg; Metformin HCl 850mg (corresponding to 660mg Metformin)	BRU14031275PS1; BRU14031275PS2	1 - Minor (MiV-PA8) - Change of the specification of drug substance 2 - Minor (MiV-PA) - To reflect the compliance with EU Food Regulation (EU) 231/2012 for drug product excipients (coating premixes) and other editorial changes	Zuellig Pharma (B) Sdn Bhd
124	(38)/DRU/DRA.Variation/2019	Galvus Met 50/1000mg Film-cotaed Tablet	Vildagliptin 50mg; Metformin HCl 1000mg (corresponding to 780mg Metformin)	BRU14031274PS1; BRU14031274PS2	1 - Minor (MiV-PA8) - Change of the specification of drug substance 2 - Minor (MiV-PA) - To reflect the compliance with EU Food Regulation (EU) 231/2012 for drug product excipients (coating premixes) and other editorial changes	Zuellig Pharma (B) Sdn Bhd
125	(39)/DRU/DRA.Variation/2019	Invokana Film-coated Tablet 100mg	Canagliflozin 100mg (as hemihydrate)	BRU14111650P	1 - Minor (MiV-PA2) - Change in package insert (Date of revision : 30 May 2018 (Based on CCDS v01Aug2017))	Zuellig Pharma (B) Sdn Bhd
126	(40)/DRU/DRA.Variation/2019	Invokana 300mg FCT	Canagliflozin 300mg (as hemihydrate)	BRU14121699P	1 - Minor (MiV-PA2) - Change in package insert (Date of revision : 30 May 2018 (Based on CCDS v01Aug2017))	Zuellig Pharma (B) Sdn Bhd
127	(41)/DRU/DRA.Variation/2019	Orgalutron Solution for Injection 0.25mg/0.5ml	Ganirelix acetate 0.25mg/0.5ml	BRU10120602P	1 - Minor (MiV-PA2) - Change in package insert (Version: S-CCDS-MK-8761-INJ-122018_SIN, date of revision: December 2018)	Zuellig Pharma (B) Sdn Bhd
128	(43)/DRU/DRA.Variation/2019	Zenalb 20%	Human albumin 20%w/v	BRU16011987P	1 - Minor (MiV-PA2) - Change of patient information leaflet (Version: ABL27, Leaflet was last approved in November 2012)	Medipharm Sdn Bhd
129	(44)/DRU/DRA.Variation/2019	Zenalb 20%	Human albumin 20%w/v	BRU16011987P	1 - Minor (MiV-PA) - Registration of an updated PMF Certificate (2nd Step Procedure)	Medipharm Sdn Bhd
130	(45)/DRU/DRA.Variation/2019	Zenalb 20%	Human albumin 20%w/v	BRU16011987P	1 - Minor (MiV-PA22) - Change of a test procedure for an excipient (Octanoic Acid)	Medipharm Sdn Bhd
131	(46)/DRU/DRA.Variation/2019	Imovax Polio Vaccine	Inactivated Polio Virus : Type 1 (40DU/0.5ml), Type 2 (80DU/0.5ml), Type 3 32DU/0.5ml)	BRU09100330P	1 - Minor (MiV-PA2) - Change of outer carton label	Zuellig Pharma (B) Sdn Bhd
132	(47)/DRU/DRA.Variation/2019	Tetavax Suspension for Injection (single dose 0.5ml)	Purified Tetanus Toxoid	BRU09030218P0.5gS & BRU09030218P0.5gA	1 - Minor (MiV-PA2) - Change of outer carton label	Zuellig Pharma (B) Sdn Bhd
133	(49)/DRU/DRA.Variation/2019	Glucophage XR 500mg Extended Release Tablet	Metformin HCl 500mg	BRU13071101P	1 - Minor (MiV-PA20) - Minor change of the manufacturing process for non-sterile product	Zuellig Pharma (B) Sdn Bhd
134	(54)/DRU/DRA.Variation/2019	Gardasil 9, Suspension for injection	Each 0.5mL dose contains; HPV Type 6 L1 Protein…30 µg HPV Type 11 L1 Protein..40µg HPV Type 16 L1 Protein…60µg| HPV Type 18 L1 Protein..40µg HPV Type 31 L1 Protein..20µg HPV 33 L1 Protein..20µg HPV Type 45 L1 Protein..20µg HPV Type 52 L1 Protein..20µg HPV Type 58 L1 Protein..20µg	BRU18032323P	1 - Minor (MiV-PA2) - Change in inner label and outer carton label	Zuellig Pharma (B) Sdn Bhd

135	(55)/DRU/DRA.Variation/2019	Velcade™ 3.5mg for Injection	Bortezomib 3.5mg	BRU13091143P	1 - Minor (MiV-PA2) - Change in outer carton label	Zuellig Pharma (B) Sdn Bhd
136	(56)/DRU/DRA.Variation/2019	Elonva Solution for Injection 150mcg/0.5ml	Corifollitrophin alfa 150mcg/0.5ml	BRU13061087P	1 - Minor (MiV-PA8) and MiV-PA27 - Change in the test procedure of non-compendial drug substance and drug product	Zuellig Pharma (B) Sdn Bhd
137	(57)/DRU/DRA.Variation/2019	Elonva Solution for Injection 100mcg/0.5ml	Corifollitrophin alfa 100mcg/0.5ml	BRU14031268P	1 - Minor (MiV-PA8) and MiV-PA27 - Change in the test procedure of non-compendial drug substance and drug product	Zuellig Pharma (B) Sdn Bhd
138	(58)/DRU/DRA.Variation/2019	Essentiale Forte N Capsule	Phospholipids fatty mass 392mg (equivalent to 300mg phospholipids from soya beans containing 76% of (3-sn-phosphatidyl choline)	BRU11050708NP	1 - Minor (MiV-PA28) - Change in primary packaging material for non-sterile product	Medipharm Sdn Bhd
139	(61)/DRU/DRA.Variation/2019	Camazol Tablet 5mg	Carbimazole 5mg	BRU13091140P	1 - MiV-PA2 - Change of product labelling (outer carton)	Hongkiat Trading & Company
140	(62)/DRU/DRA.Variation/2019	Colimix Syrup	Per 5ml - Simethicone (activated dimethicone) 50mg; dicy;comine HCl 5mg	BRU10040454NP	1 - MiV-PA2 - Change of product labelling (package insert, new revision date : 18 Sep 2018)	Hongkiat Trading & Company
141	(63)/DRU/DRA.Variation/2019	Pegasys Pre-filled syringe 180mcg/0.5ml	Peginterferon alfa-2a 180mcg/0.5ml	BRU13041058P	1 - MiV-PA24 - Change of release and shelf-life specifications of the drug product 2 - MiV-PA27 - Change in the test procedure of the drug product (including replacement or addition of a test procedure) 3 - MiV-PA- Additional of back up quality testing site	Hongkiat Trading & Company
142	(64)/DRU/DRA.Variation/2019	Inox Capsule 100mg	itraconazole 100mg	BRU13031042P	1 - MiV-PA35 - Change of storage conditions of the drug product (increasing from the current approved storage condition) 2 - MiV-PA - Change of product labelling (outer carton and package insert, new revision date March 2017 version VIINO00--(MY)_2)	G&H Trading Company
143	(68)/DRU/DRA.Variation/2019	Zenalb 20%	Human albumin 20%w/v	BRU16011987P	1 - MiV-PA20 - Minor change of the manufacturing process for non-sterile product	Medipharm Sdn Bhd
144	(70)/DRU/DRA.Variation/2019	Telfast 6mg/ml Oral suspension	Fexofenadine hydrochloride 6mg/ml	BRU12090937P	1 - MiV-PA33 - Replacement of measuring device for oral liquid dosage forms and other dosage form	Medipharm Sdn Bhd
145	(73)/DRU/DRA.Variation/2019	Voltaren 75mg/3mg solution for injection	Diclofenac Sodium 75mg/3ml	BRU09040235P	1 - MiV-PA7 - Change of manufacturing process of the drug substance (where CEP is not available)	Zuellig Pharma (B) Sdn Bhd
146	(78)/DRU/DRA.Variation/2019	Lyrica Capsules 50mg	Pregabalin 50mg	BRU12100949P	1 - MiV-PA35 - Change of storage conditions of the drug product (increasing from the current approved storage condition) 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, new date of revision 19 March 2019 version LYRICA-0319)	Zuellig Pharma (B) Sdn Bhd

147	(79)/DRU/DRA.Variation/2019	Lyrica Capsules 75mg	Pregabalin 75mg	BRU12060909P	1 - MiV-PA35 - Change of storage conditions of the drug product (increasing from the current approved storage condition) 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, new date of revision 19 March 2019 version LYRICA-0319)	Zuellig Pharma (B) Sdn Bhd
148	(80)/DRU/DRA.Variation/2019	Lyrica 150mg Capsules	Pregabalin 150mg	BRU12020870P	1 - MiV-PA35 - Change of storage conditions of the drug product (increasing from the current approved storage condition) 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, new date of revision 19 March 2019 version LYRICA-0319)	Zuellig Pharma (B) Sdn Bhd
149	(139)/DRU/DRA.Variation/2019	NovoSeven Powder and Solvent for Solution for Injection 2mg	"Eptacog Alfa (Activated) 2mg/vial (corresponds to 100 KIU/vial), 1mg/ml after reconstitution 1KIU equals 1000 IU (international Units) eptacog alfa (activated) is recombinant coagulation factor Vlla (rFVLLa) with a molecular mass of approximately 50,000 Dalton produced in baby hamster kidney cells (BHK Cells) by recombinant DNA technology.'	BRU14021229P	1 - MaV-4 - Addition of the manufacturing site of the drug product	Zuellig Pharma (B) Sdn Bhd
150	(140)/DRU/DRA.Variation/2019	NovoSeven 1mg Powder and Solvent for Solution for Injection	"Eptacog Alfa (Activated) 2mg/vial (corresponds to 50 KIU/vial), 1mg/ml after reconstitution	BRU14071370P	1 - MaV-4 - Addition of the manufacturing site of the drug product	Zuellig Pharma (B) Sdn Bhd
151	(154)/DRU/DRA.Variation/2019	Prevenar 13 Suspension for Injection	Per 0.5ml - Pneumococcal Polysaccharide Serotype 1,3,4, 5,, 6A, 7F, 9V , 14, 18C, 19A, 19F, 23F - 2.2mcg; Pneumococcal Polysaccharide Serotype 6B-4.4mcg	BRU13021008P	1 - MiV-PA24 - Change of release specifications of the drug product	Zuellig Pharma (B) Sdn Bhd

152	(404)/DRU/DRA.Variation/2019	Simponi Solution for Injection in Pre-filled Syringe 50mg/0.5ml	Golimumab 50mg/0.5ml	BRU15021757P	1 - MaV-4 - Addition of the manufacturing site of the drug product 2 - MaV-9 - Major change in the manufacturing process for drug product 3 - MiV-PA35 - Change of storage conditions of the drug product (increasing from the current approved stoarge condition) 4 - MaV-15 - Extension of shelf-life of the drug product 5 - MiV-PA5 - Change of batch size of drug substance (where CEP is not available) 6 - MiV-PA7 - Change of manufacturing process of the drug substance (where CEP is not not available) 7 - MaV-1 (incl MiV-PA2) - Change and/or additional indication/dosing regimen including change of product labelling (outer carton and packagd insert, new date of revision 25 Aug 2019 (based on CCDS vFeb2019)	Zuellig Pharma (B) Sdn Bhd
153	(405)/DRU/DRA.Variation/2019	Simponi Solution for Injection 100mg/1.0ml	Golimumab 100mg/1.0ml	BRU18062365P	1 - MaV-4 - Addition of the manufacturing site of the drug product 2 - MaV-9 - Major change in the manufacturing process for drug product 3 - MiV-PA35 - Change of storage conditions of the drug product (increasing from the current approved stoarge condition) 4 - MaV-15 - Extension of shelf-life of the drug product 5 - MiV-PA5 - Change of batch size of drug substance (where CEP is not available) 6 - MiV-PA7 - Change of manufacturing process of the drug substance (where CEP is not not available) 7 - MaV-1 (incl MiV-PA2) - Change and/or additional indication/dosing regimen including change of product labelling (outer carton and packagd insert, new date of revision 25 Aug 2019 (based on CCDS vFeb2019)	Zuellig Pharma (B) Sdn Bhd

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No	Application Variation Ref. No.	Product Name	Active ingredients	Product Registration No.	Variations	Company
1	(849)/DRU/DRA.Variation/2017	Anafranil 25mg Tablets	Clomipramine Hydrochloride	BRU10070514P	1 - Minor (MiV-PA21) - Change of specifications of an excipients 2 - Minor (MiV-PA25) - Replacement of ink used for product marking: Printing Ink Brown 3 - Minor (MiV-PA20) including Minor (MiV-PA19) - Minor change of the manufacturing process for non-sterile product including change of in-process controls applied during the manufacture of the drug product 4 - Minor (MiV-PA28) - Change in primary pacakging for non-sterile product 5 - Minor (MiV-PA (others) - Update to P.1 document (Description and Composition) 6 - Minor (MiV-PA2) - Change in folding box (outer carton)	Zuellig Pharma (B) Sdn Bhd
2	(613)/DRU/DRA.Variation/2018	Keppra Concentrate for solution for (infusion) / intravenous	Levetiracetam 500mg/5ml	BRU14021245P	1 - Major (MaV-3) - Addition of alternative manufacturer of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is not available 2 - Major (MaV-9) - Major change in manufacturing process for the drug product 3 - Major (MaV-12) - Change in primary packaging material for sterile product 4 - Minor (MiV-PA2) - Change in package insert (Version Number : Keppra v05, Reference : NCDS09, Date of local revision : 30 November 2018) 5 - Minor (MiV-PA8) - Change of specification of drug substance 6 - Minor (MiV-PA24) - Change of release and shelf-life specifications of the drug product 7 - Minor (MiV-PA35) - Change of storage conditions of the drug product (increasing from the current approved storage conditionj	Zuellig Pharma (B) Sdn Bhd

3	(904)/DRU/DRA.Variation/2018	Metformin Tablet 500	MetforminHCl 500mg	BRU09120380P	1 - Major (MaV-4) and Minor (MiV-N2) - Replacement of the manufacturing site of the drug product and product owner 2 - Minor (MiV-PA1) - Change of drug product name 3 - Minor (MiV-PA2) - Change of Inner label, outer carton label and package insert [(Ref: RA. CCM Metformin Hydrochloride Tablet 500mg. 002 (16.05.2016)] 4 - Minor (MiV-PA4) - Addition of alternative manufacturer of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is available) 5 - Minor (MiV-PA25) - Change of description on the tablets	K-Seri Pharma Sdn Bhd
4	(11)/DRU/DRA.Variation/2019	Solbid tablet 10mg	Isosorbide Dinitrate 10mg	BRU17122266P	1 - MiV-PA35 - Change of storage conditions of the drug product (increasing form the current approved storage condition) 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, new date of revision 21.04.2016 version Pm02044/05-16	G&H Trading Company
5	(71)/DRU/DRA.Variation/2019	Resolor film-coated tablet 1mg	Prucalopride 1mg (as succinate 1.321mg)	BRU14111589P	1 - MiV-PA2 - Change of product labelling (oiter carton)	Zuellig Pharma (B) Sdn Bhd
6	(72)/DRU/DRA.Variation/2019	Resolor film-coated tablet 2mg	Prucalopride 2mg (as succinate 2.642mg)	BRU15071904P	1 - MiV-PA2 - Change of product labelling (outer carton)	Zuellig Pharma (B) Sdn Bhd
7	(84)/DRU/DRA.Variation/2019	Zocor 10mg Tablet	Simvastatin 10mg	BRU10090545P	1 - Minor (MiV-PA2) - Change in package insert (Version: SG-MK0733-T-122018, Date of revision: December 2018)	Zuellig Pharma (B) Sdn Bhd
8	(85)/DRU/DRA.Variation/2019	Zocor 20mg Film-coated Tablet	Minor (MiV-PA2) - Change in package insert (version: SG-MK0733-T-122018, Date or revision: December 2018)	BRU10110584P	1 - Minor (MiV-PA2) - Change in package insert (Version : SG-MK0733-T-122018, date of revision: December 2018)	Zuellig Pharma (B) Sdn Bhd
9	(86)/DRU/DRA.Variation/2019	Simvastatin 40mg	Minor (MiV-PA2) - Change in package insert (Version : SG-MK0733-T-122018, Date of revision : December 2018)	BRU10090546P	1 - Minor (MiV-PA2) - Change in package insert (Version: SG-MK0733-T-122018, Date of revision: December 2018)	Zuellig Pharma (B) Sdn Bhd
10	(87)/DRU/DRA.Variation/2019	Vytorin™ Tablets 10mg/10mg	Ezetimibe 10mg; Simvastatin 10mg	BRU10100579PS2	1 - Minor (MiV-PA2) - Change in package insert (Version: SG-MK0653A-122018, Date of revision : December 2018) and patient information leaflet (Version : SG-PPI-MK0653A-T-122018, Date of revision: December 2018)	Zuellig Pharma (B) Sdn Bhd
11	(859)/DRU/DRA.Variation/2018	Simponi Solution for Injection in Pre-filled Syringe 50mg/0.5ml	Golimumab 50mg/0.5ml	BRU15021757P	1 - MiV-PA1 - Change of drug product name	Zuellig Pharma (B) Sdn Bhd

12	(88)/DRU/DRA.Variation/2019	Vytorin™ Tablets 10mg/20mg	Minor (MiV-PA2) - Change in package insert (version: SG-MK0733-T-122018, Date or revision: December 2018)	BRU10090544PS2	1 - Minor (MiV-PA2) - Change in package insert (Version : Sg-MK0643A-122018, Date of revision: December 2018) and patient information leaflet (Version: SG-PPi-MK0963A-T-122018, Date of revision : December 2018)	Zuellig Pharma (B) Sdn Bhd
13	(89)/DRU/DRA.Variation/2019	Elomet Cream 0.1%	Mometasone Furoate 0.1%	BRU10090555PS1; BRU10090555PS2	1 - Minor (MiV-PA20) - Minor change of the manufacturing process for non-sterile product	Zuellig Pharma (B) Sdn Bhd
14	(90)/DRU/DRA.Variation/2019	Singulair Tablet 4mg	Montelukast 4mg (as sodium 4.16mg)	BRU10090539P	1 - Minor (MiV-PA2) - Change of package insert (Version: SG-MK0476-MF-112018, Date of revision: January 2019)	Zuellig Pharma (B) Sdn Bhd
15	(91)/DRU/DRA.Variation/2019	Singulair Oral Granules 4mg	Montelukast Sodium (free acid equivalent) 4mg	BRU10090542PS2	1 - Minor (MiV-PA2) - Change of package insert (Version: SG-MK0476-MF-112018, Date of revision: January 2019)	Zuellig Pharma (B) Sdn Bhd
16	(92)/DRU/DRA.Variation/2019	Singulair® Tablet 10mg	Montelukast (as sodium) 10mg	BRU10070516P	1 - Minor (MiV-PA2) - Change of package insert (Version: SG-MK0476-MF-112018, Date of revision: January 2019)	Zuellig Pharma (B) Sdn Bhd
17	(93)/DRU/DRA.Variation/2019	Singulair® Chewable Tablet 5mg	Montelukast (as sodium) 5mg	BRU10070517P	1 - Minor (MiV-PA2) - Change of package insert (Version: SG-MK0476-MF-112018, Date of revision: January 2019)	Zuellig Pharma (B) Sdn Bhd
18	(94)/DRU/DRA.Variation/2019	Kadcyla Powder for Concentrate for Solution for Infusion 100mg/vial	Trastuzumab emtansine 100mg	BRU18012295PS1; BRU18012295PS2	1 - Minor (MiV-PA) - Introduction of a new secondary working reference material 2 - Minor (MiV-PA) - Addition of linearity as system suitability criterion for potency by bioassay	Medipharm Sdn Bhd
19	(95)/DRU/DRA.Variation/2019	Kadcyla Powder for Concentrate for Solution for Infusion 106mg/vial	Trastuzumab emtansine 160mg	BRU18012296PS1; BRU18012296PS2	1 - Minor (MiV-PA) - Introduction of a new secondary working reference material 2 - Minor (MiV-PA) - Addition of linearity as system suitability criterion for potency by bioassay	Medipharm Sdn Bhd
20	(96)/DRU/DRA.Variation/2019	Amoxicap 250 capsule	Amoxicillin (as trihydrate 287mg) 250mg	BRU17082233P	1 - Minor (MiV-PA30) - Addition of pack size for non-sterile product with consequential update in product labelling and package insert	G&H Trading Company
21	(97)/DRU/DRA.Variation/2019	Imach Injection 1ml	Chlorpheniramine maleate 10mg/1ml	BRU18112461P	1 - Minor (MiV-PA35) - Change of storage conditions of the drug product (increasing from the current approved storage condition) with consequential update in product labelling and package insert	G&H Trading Company
22	(98)/DRU/DRA.Variation/2019	Polytet Eye Ointment	Each gram contains: Polymyxin B sulphate 6900 unit eq to Polymyxin B 6000 units Oxytetracycline hydrochloride 5.94mg eq to Oxytetracycline 5mg	BRU18092411P	1 - Minor (MiV-PA35) - Change of storage conditions of the drug product (increasing from the current approved storage condition) with consequential update in product labelling and package insert	G&H Trading Company
23	(99)/DRU/DRA.Variation/2019	Azarga Eye Drops Suspension	Brinzolamide 10mg/ml Timolol maleate 5mg/ml	BRU17022146P	1 - Minor (MiV-PA2) - Change in package insert (Tracking number: TDOC-0016184, Version: 3.0, Date of revision: January 2018)	Zuellig Pharma (B) Sdn Bhd
24	(100)/DRU/DRA.Variation/2019	Voltaren 12.5mg Suppositories	Diclofenac Sodium 12.5mg	BRU09060264P	1 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance (Diclofenac Sodium fine) [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	Zuellig Pharma (B) Sdn Bhd

25	(101)/DRU/DRA.Variation/2019	Voltaren Suppository 25mg	Diclofenac (as Sodium) 25mg	BRU09040233P	1 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance (Diclofenac Sodium fine) [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	Zuellig Pharma (B) Sdn Bhd
26	(102)/DRU/DRA.Variation/2019	Voltaren Suppository 50mg	Diclofenac Sodium 50mg	BRU09060265P	1 - Minor (MiV-PA7) - Change of manufacturing process of the drug substance (Diclofenac Sodium fine) [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	Zuellig Pharma (B) Sdn Bhd
27	(103)/DRU/DRA.Variation/2019	Patanol 0.1% Olopatadine Hydrochloride Sterile Ophthalmic Solution	Olopatadine (as HCl) 0.1%	BRU14031263PS1; BRU14031263PS2	1 - Minor (MiV-PA2) - Change of inner label and outer carton label	Zuellig Pharma (B) Sdn Bhd
28	(104)/DRU/DRA.Variation/2019	Travatan ®Eye Drops 40mcg/ml	Travoprost 40mcg/ml	BRU14031264PS1; BRU14031264PS2	1 - Major (MaV-6) - Change of the specification of drug product (where European Pharmacopoeial Certificate of Suitability (CEP) is not available)	Zuellig Pharma (B) Sdn Bhd
29	(105)/DRU/DRA.Variation/2019	Voltaren 75mg/3mg solution for injection	Diclofenac Sodium 75mg/3ml	BRU09040235P	1 - Minor (MiV-PA2) - Change of package insert (Tracking Number : 2017-PSB/GLC-0907-s, Date of revision: 6 Feb-2018)	Zuellig Pharma (B) Sdn Bhd
30	(106)/DRU/DRA.Variation/2019	Voltaren 12.5mg Suppositories	Diclofenac Sodium 12.5mg	BRU09060264P	1 - Minor (MiV-PA2) - Change of package insert (Tracking Number : 2017-PSB/GLC-0907-s, Date of revision: February 2018)	Zuellig Pharma (B) Sdn Bhd
31	(107)/DRU/DRA.Variation/2019	Voltaren Suppository 25mg	Diclofenac (as Sodium) 25mg	BRU09040233P	1 - Minor (MiV-PA2) - Change of package insert (Tracking Number : 2017-PSB/GLC-0907-s, Date of revision: February 2018)	Zuellig Pharma (B) Sdn Bhd
32	(108)/DRU/DRA.Variation/2019	Voltaren 50mg Suppositories	Diclofenac Sodium 50mg	BRU09060265P	1 - Minor (MiV-PA2) - Change of package insert (Tracking Number : 2017-PSB/GLC-0907-s, Date of revision: February 2018)	Zuellig Pharma (B) Sdn Bhd
33	(118)/DRU/DRA.Variation/2019	Praxbind Solution for Injection/infusion 50mg/ml	Idarucizumab 50mg/ml	BRU17062218P	1 - Minor (MiV-PA2) - Change of outer carton label	Hongkiat Trading & Company
34	(232)/DRU/DRA.Variation/2019	Strepsils Max Blackcurrant Lozenge	Hexylresocinol 2.4mg	BRU15011733NP	1 - MaV-4 - Addition or replacement of the manufacturing site of the drug product (including addition of repacker) 2 - MiV-PA1 - Change of drug peoduct name 3 - MiV-PA2 - Change of Product labelling (outer carton, pouch label and blister label)	Syarikat Aliaa Sdn Bhd
35	(238)/DRU/DRA.Variation/2019	Sandimmun Neoral Capsule 25mg	Ciclosporin A 25mg	BRU13071114P	1 - MiV-PA8 - Change of the specification of drug substance 2 - MiV-PA9 - Change of the test procedure of non-compendial drug substance	Zuellig Pharma (B) Sdn Bhd
36	(239)/DRU/DRA.Variation/2019	Sandimmun Neoral Capsule 100mg	Ciclosporin 100mg	BRU13101156P	1 - MiV-PA8 - Change of the specification of drug substance 2 - MiV-PA9 - Change of the test procedure of non-compendial drug substance	Zuellig Pharma (B) Sdn Bhd

37	(240)/DRU/DRA.Variation/2019	Sandimmun Neoral Oral Solution 100mg/ml	Ciclosporin A 100mg/ml	BRU11090767P	1 - MiV-PA8 - Change of the specification of drug substance 2 - MiV-PA9 - Change of the test procedure of non-compendial drug substanc	Zuellig Pharma (B) Sdn Bhd
38	(255)/DRU/DRA.Variation/2019	SW-Dexasone Tablet	Dexamethasone 0.5mg	BRU15121973P	1 - MiV-PA35 - Change of storage conditions of the drug product 9increasing from the current approved storage condition)	G&H Trading Company
39	(263)/DRU/DRA.Variation/2019	Cervagem Pessary 1mg	Gemeprost 1mg	BRU10050473P	1 - MiV-PA2 - Change of product labelling (outer carton and package insert, new date of revision : Feb 2019 based on CDS V1 UK SmPC Feb 2012)	Medipharm Sdn Bhd
40	(279)/DRU/DRA.Variation/2019	Monoclox 500mg Powder for Solution for Injection or Infusion	Cloxacillin sodium equivalent to cloxacillin 500mg	BRU170722233P	1 - MiV-PA2 - Change of product labelling (inner label, outer carton and package insert, new date of revision : 10/2018)	Medicorp Sdn Bhd
41	(389)/DRU/DRA.Variation/2019	Sunolut Tablet 5mg	Norethisterone 5mg	BRU11040682P	1 - MiV-PA35 - Change of storage conditions of the drug product (increasing from the current approved storage condition)	G&H Trading Company

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No	**Application Variation Ref. No.**	**Product Name**	**Active ingredients**	**Product Registration No.**	**Variations**	**Company**
1	(413)/DRU/DRA.Variation/2017	Exforge HCT 5/160/12.5mg Film-coated Tablet	Amlodipine 5mg (as besylate); Valsartan 160mg; Hydrochlorothiazide 12.5mg	BRU14081421PS1 & BRU14081421PS	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance 2 - Minor (MiV-PA24) including MiV-PA27 - Change of release and shelf-life specification including change in test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
2	(414)/DRU/DRA.Variation/2017	Exforge HCT 5/160/25mg Film-coated Tablet	Amlodipine 5mg (as besylate); Valsartan 160mg; Hydrochlorothiazide 25mg	BRU14081422PS1 & BRU14081422PS	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance 2 - Minor (MiV-PA24) including MiV-PA27 - Change of release and shelf-life specification including change in test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd

3	(415)/DRU/DRA.Variation/2017	Exforge HCT 10/160/12.5mg Film-coated Tablet	Amlodipine 10mg (as besylate); Valsartan 160mg; Hydrochlorothiazide 12.5mg	BRU14081419PS1 & BRU14081419PS	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance 2 - Minor (MiV-PA24) including MiV-PA27 - Change of release and shelf-life specification including change in test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
4	(416)/DRU/DRA.Variation/2017	Exforge HCT 10/160/25mg Film-coated Tablet	Amlodipine 10mg (as besylate); Valsartan 160mg; Hydrochlorothiazide 25mg	BRU14081420PS1 & BRU14081420PS	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance 2 - Minor (MiV-PA24) including MiV-PA27 - Change of release and shelf-life specification including change in test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
5	(417)/DRU/DRA.Variation/2017	Exforge HCT 10/320/25mg Film-coated Tablet	Amlodipine 10mg (as besylate); Valsartan 320mg; Hydrochlorothiazide 25mg	BRU14081423PS1 & BRU14081423PS	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance 2 - Minor (MiV-PA24) including MiV-PA27 - Change of release and shelf-life specification including change in test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
6	(373)/DRU/DRA.Variation/2018	Glucophage® Tablet 500mg	Metformin HCl 500mg	BRU12090939P	1 - Major (MaV-2) - Change of package insert (Date of revision : June 2017 (Based on CCDS V7.0)	Zuellig Pharma (B) Sdn Bhd
7	(374)/DRU/DRA.Variation/2018	Glucopage® Tablet 850mg	Metformin HCl 850mg (Metformin 662.9mg)	BRU13010997P	1 - Major (MaV-2) including minor (MiV-PA2) - Change of blister label, outer carton and package insert (Date of revision: June 2017 (Based on CCDS V7.0)	Zuellig Pharma (B) Sdn Bhd

8	(790)/DRU/DRA.Variation/2018	Efexor® XR 37.5mg Capsule	Venlafaxine Hydrochloride 37.5mg	BRU12060917P	1 - Major (MaV-6) - Change of the specification of drug product (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA8) - Change of the specification of drug substance 3 - Minor (MiV-PA15) - Quantitative change of excipient (Microcrystalline Cellulose and Hypromellose) 4 - Minor (MiV-PA20) - Minor change of the manufacturing process of non-sterile product 5 - Minor (MiV-PA27) - Change in the test procedure of the drug product 6 - Minor (MiV-N6) - Change of the name of the manufacturer of drug substance 7 - Minor (MiV-N7) - Withdrawal/deletion of the alternative manufacturer(s) of drug substance	Zuellig Pharma (B) Sdn Bhd
9	(791)/DRU/DRA.Variation/2018	Efexor XR 75 Capsule	Venlafaxine (as HCl) 75mg	BRU12080932P	1 - Major (MaV-6) - Change of the specification of drug product (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA8) - Change of the specification of drug substance 3 - Minor (MiV-PA15) - Quantitative change of excipient (Microcrystalline Cellulose and Hypromellose) 4 - Minor (MiV-PA20) - Minor change of the manufacturing process of non-sterile product 5 - Minor (MiV-PA27) - Change in the test procedure of the drug product 6 - Minor (MiV-N6) - Change of the name of the manufacturer of drug substance 7 - Minor (MiV-N7) - Withdrawal/deletion of the alternative manufacturer(s) of drug substance	Zuellig Pharma (B) Sdn Bhd

10	(792)/DRU/DRA.Variation/2018	Efexor XR 150mg Capsule	Venlafaxine (as Hydrochloride) 150mg	BRU12110954P	1 - Major (MaV-6) - Change of the specification of drug product (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 2 - Minor (MiV-PA8) - Change of the specification of drug substance 3 - Minor (MiV-PA15) - Quantitative change of excipient (Microcrystalline Cellulose and Hypromellose) 4 - Minor (MiV-PA20) - Minor change of the manufacturing process of non-sterile product 5 - Minor (MiV-PA27) - Change in the test procedure of the drug product 6 - Minor (MiV-N6) - Change of the name of the manufacturer of drug substance 7 - Minor (MiV-N7) - Withdrawal/deletion of the alternative manufacturer(s) of drug substance	Zuellig Pharma (B) Sdn Bhd
11	(833)/DRU/DRA.Variation/2018	Binocrit Solution for Injection 2000 IU/ml in Pre-filled Syringe	Epoetin Alfa 2,000 IU/ml	BRU14111546P	1 - Minor (MiV-PA2) - Change in outer carton and package insert (Date of revision : 30 November 2016, CDS: CDS Version 11) 2 - Minor (MiV-PA) - Addition of subcutaneous route of administration 3 - Minor (MiV-PA9) - Change of the test procedure of non-compendial drug substance 4 - Minor (MiV-PA) - Replacement of Erythropoeitin Biological Reference Preparation (BRP) in physicochemical analysis 5 - Minor (MiV-PA) - Update to registration document	Zuellig Pharma (B) Sdn Bhd
12	(834)/DRU/DRA.Variation/2018	Binocrit Solution for Injection 4000 IU/0.4ml in Pre-filled Syringe	Epoetin Alfa 4,000 IU/0.4ml	BRU14111547P	1 - Minor (MiV-PA2) - Change in outer carton and package insert (Date of revision : 30 November 2016, CDS: CDS Version 11) 2 - Minor (MiV-PA) - Addition of subcutaneous route of administration 3 - Minor (MiV-PA9) - Change of the test procedure of non-compendial drug substance 4 - Minor (MiV-PA) - Replacement of Erythropoeitin Biological Reference Preparation (BRP) in physicochemical analysis 5 - Minor (MiV-PA) - Update to registration document	Zuellig Pharma (B) Sdn Bhd

13	(917)/DRU/DRA.Variation/2018	Dynastat Powder and Solvent for Solution for Injection 40mg	Parecoxib (as Sodium) 40mg	BRU14111553P	1 - MaV-2 (inc MiV-PA2) - Change of content of product labelling (outer carton and package insert - LPD Date : 10 September 2018, Date of Revision: 10 September 2018, version: DYNASTAT-0918) 2 - MiV-PA1 - Change of drug product name 3 - MiV-PA18 - Deletion of the solvent/diluent for the drug product 4 - MiV-PA31 - Change of outer carton pack sizes for a drug product	Zuellig Pharma (B) Sdn Bhd
14	(15)/DRU/DRA.Variation/2019	Magrilan 20mg capsules	Fluoxetine 20mg (as Hydrochloride)	BRU14091489P	1 - MiV-PA17 - Replacement of the colouring agent of the product i.e. gelatin capsules (with consequential update in product description) 2 - MiV-PA34 - Reduction of shelf-life of the drug product 3 - MiV-PA35 - Change of storage conditions of the drug product (Increasing from the current approved storage condition)	Hongkiat Trading & Company
15	(33)/DRU/DRA.Variation/2019	Proctosedyl Ointment	Cinchocaine hydrochloride 0.5%; Framycetin sulphate 1.0%; Hydrocotisone 0.5%; Aesculin 1.0%	BRU10100561P	1 - Minor (MiV-PA8) including MiV-PA9 - Change of specification and test procedure of drug substance (Aesculin) 2 - Minor (MiV-PA10) - Change of re-test period for drug substance (hydrocortisone) 3 -Minor (MiV-PA12) - Revision of CEP of drug substance (framycetin) and Introduction of CEP of drug substance (Hydrocortisone and Cinchocaine hydrochloride) 4 - Minor (MiV-PA8) - Update of specification of drug substance (Framycetin)	Medipharm Sdn Bhd
16	(65)/DRU/DRA.Variation/2019	Crotamiton Cream 10% w/w	Crotamiton 10% w/w	BRU18072380NP	1 - MiV-PA1 - Change of drug product name 2 - MiV-PA35 - Increase of storage conditions of the drug product from the current approved storage condition	G&H Trading Company
17	(66)/DRU/DRA.Variation/2019	Properazine Tablet 5mg	Prochlorperazine maleate 5mg	BRU11090762P	1 - MiV-PA35 - Update of storage conditions of the drug product 2 - MiV-PA2 - Change of product labelling (bottle label and package insert, new revision date 02/11/2011 version T066R2) 3 - MiV-PA28 - Addition of primary packaging material for non-sterile product (type of container-blister pack)	G&H Trading Company

18	(67)/DRU/DRA.Variation/2019	Zenalb 20%	Human albumin 20%w/v	BRU16011987P	1 - MiV-PA5 - Change of in-process batch size of drug substance (where CEP is not available) 2 - MiV-PA Others - Update of dossiers	Medipharm Sdn Bhd
19	(69)/DRU/DRA.Variation/2019	Zenalb 20%	Human albumin 20%w/v	BRU16011987P	1 - MaV-7 - Increase of batch size of sterile drug product	Medipharm Sdn Bhd
20	(109)/DRU/DRA.Variation/2019	Esmeron® Injection 50mg/5ml (10mg/ml)	Rocuronium Bromide 50mg/5ml	BRU10120613PS1 & BRU10120613PS2	1 - Minor (MiV-PA35) with consequential MiV-PA2 - Change of storage conditions of the drug product (increasing from the current approved storage condition) with consequential change in package insert (Version: S-CCDS-MK8085-Soi-072018, Date of revision: January 2019)	Zuellig Pharma (B) Sdn Bhd
21	(114)/DRU/DRA.Variation/2019	Solu-Medrol Sterile Powder 500mg	Methyprednisolone (as Sodium succinate) 500mg	BRU10020402P	1 - Major (MaV-2) - Change of outer carton label, inner label and package insert (Version: SOLU-MEDROL-0219, Date of Revision : 27 FEB 2019) 2 - Minor (MiV-PA27) - Change in the test procedure of the drug product 3 - Minor (MiV-PA35) - Change of storage conditions of the drug product (increasing from the current approved storage condition) 4 - Minor (MiV-N6) - Change of the name of the manufacturer of drug substance	Zuellig Pharma (B) Sdn Bhd
22	(115)/DRU/DRA.Variation/2019	Azoren 20mg/5mg Film-coated Tablet	Olmesartan medoxomil 20mg and Amlodipine (as amlodipine besylate) 5mg	BRU15061889P	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd
23	(116)/DRU/DRA.Variation/2019	Azoren 40mg/5mg Film-coated Tablet	Olmesartan medoxomil 40mg and Amlodipine (as amlodipine besylate) 5mg	BRU15061891P	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd
24	(117)/DRU/DRA.Variation/2019	Azoren 40mg/10mg Film-coated Tablet	Olmesartan medoxomil 40mg and Amlodipine (as amlodipine besylate) 10mg	BRU15061890P	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd

25	(119)/DRU/DRA.Variation/2019	Xolair 75mg powder for solution for injection	Omalizumab 75mg Reconstituted Xolair contains 125mg/ml of omalizumab (75mg in 0.6ml)	BRU16102083P	1 - MiV-PA6 - Change of in-process controls during drug substance manufacturing process (where CEP is not available) i.e. change in bioburden in-process control testing & minor change in CHOP in-process testing method 2 - MiV-PA8 - Change of the speciification of raw material Dibasic Sodium Phosphate Anhydrous and the material prosep vA (protein A) used during the purification process of drug substance	Zuellig Pharma (B) Sdn Bhd
26	(120)/DRU/DRA.Variation/2019	Xolair Powder and Solvent for Solution for Injection	Omalizumab 150mg	BRU14091481P	1 - MiV-PA2 - Change of product labelling (Addition of new inner label) 2 - MiV-PA6 - Change of in-process controls during drug substance manufacturing process (where CEP is not available) i.e. change in bioburden in-process control testing & minor change in CHOP in-process testing method 3 - MiV-PA8 - Change of the specification of raw material Dibasic Sodium Phosphate Anhydrous and the material prosep vA (protein A) used during the purification process of drug substance	Zuellig Pharma (B) Sdn Bhd
27	(123)/DRU/DRA.Variation/2019	Seebri Breezhaler 50mcg Inhalation Powder Hard Capsules	Glycopyrronium bromide 63mcg (corresponding to 50 mcg Glycopyrronium)	BRU16062049P	1 - Minor (MiV-PA22) including MiV-PA21 - Change of specifications and analytical procedure of an excipient (lactose monohydrate) 2 - Minor (MiV-PA) - Change in the current primary conatiner/closure system packaging configuration used to store pharmaceutical intermediate (NVA237) 3 - Minor (MiV-PA) - Update of stability study of six batches packaged in Novartis Farmaceutica S.A., Spain covering storage period up to 24 months	Zuellig Pharma (B) Sdn Bhd
28	(124)/DRU/DRA.Variation/2019	Holoxan for Injection	Ifosfamide 1g	BRU13021028P	1 - Minor (MiV-PA2) - Change of Patient Information Leaflet (Revision date : Jan 2019)	Zuellig Pharma (B) Sdn Bhd
29	(125)/DRU/DRA.Variation/2019	Pataday Olopatadine Ophtalmic Solution 0.2%	Olopatadine hydrochloride 2.22mg (eq. to Olopatadine 2mg (0.2%)	BRU14121677P	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision March 2018; TDOC-0050045 Version:1.0)	Zuellig Pharma (B) Sdn Bhd

30	(126)/DRU/DRA.Variation/2019	Galvus Met 50/500mg Film-coated Tablet	Vildagliptin 50mg; Metformin HCl 500mg (corresponding to 390mg Metformin)	BRU14031273PS1; PS2	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision: 14 March 2018)	Zuellig Pharma (B) Sdn Bhd
31	(127)/DRU/DRA.Variation/2019	Galvus Met 50/850mg Film-coated Tablet	Vildagliptin 50mg; Metformin HCl 850mg (corresponding to 660mg Metformin)	BRU14031275PS1; PS2	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision: 14 March 2018)	Zuellig Pharma (B) Sdn Bhd
32	(128)/DRU/DRA.Variation/2019	Galvus Met 50/1000mg Film-coated Tablet	Vildagliptin 50mg; Metformin HCl 1000mg (corresponding to 780mg Metformin)	BRU14031274PS1; PS2	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision: 14 March 2018)	Zuellig Pharma (B) Sdn Bhd
33	(129)/DRU/DRA.Variation/2019	Zymar (gatifloxacin ophthalmic solution) 0.3%	Gatifloxacin 0.3%	BRU15091930P	1 -Minor (MiV-PA9) - Change of the test procedure of non-compendial drug substance 2 - Minor (MiV-PA27) - Change in the test procedure of the drug product	Zuellig Pharma (B) Sdn Bhd
34	(132)/DRU/DRA.Variation/2019	Avastin 100mg/4ml	Bevacizumab 25mg/ml (Humanised anti-VEGF monoclonal antibody)	BRU14111585PS1, PS2, PS3, PS4	1 -MiV-PA9 - Change of the test procedure and in process control of non-compendial drug substance	Hongkiat Trading & Company
35	(133)/DRU/DRA.Variation/2019	Avastin Concentrate For Solution For Infusion 400mg/16ml	Bevacizumab 400mg/16ml	BRU13061083PS1, PS2, PS3, PS4, PS5	1 -MiV-PA9 - Change of the test procedure and in process control of non-compendial drug substance	Hongkiat Trading & Company
36	(135)/DRU/DRA.Variation/2019	Dormicum Injection 15mg/3ml	Midazolam 15mg/3ml	BRU14071363P	1 Minor (MiV-PA24) and MiV-PA27 - Change of release and shelf-life specifications of the drug product and Change in the test procedure of the drug product	Hongkiat Trading & Company
37	(143)/DRU/DRA.Variation/2019	Pregnyl® 5000IU Powder and Solvent for Injection	Human chorionic gonadotrophin 5000IU/ampoule Diluent-0.9% sodium chloride	BRU12050905P	1 Minor (MiV-PA9) including MiV-PA - Change of test procedure of non-compendial drug subtance including update of information in dossier	Zuellig Pharma (B) Sdn Bhd
38	(146)/DRU/DRA.Variation/2019	Entresto 50mg Film-coated Tablets	Sacubitril 24.3mg & Valsartan 25.7mg	BRU18032324P	1 MiV-PA2 - Change of product labelling (package insert ; new date of revision: December 2017) 2 - MiV-PA Others - Update in information for the drug subtance dossiers 3 - MaV-15 - Extension of shelf-life of the drug product 4 - MiV-PA21 and MiV-PA22 - Update in specification and testing monograph of excipient	Zuellig Pharma (B) Sdn Bhd

39	(147)/DRU/DRA.Variation/2019	Entresto 100mg Film-coated Tablets	Sacubitril 48.6mg & Valsartan 51.4mg	BRU18032325P	1 MiV-PA2 - Change of product labelling (package insert ; new date of revision: December 2017) 2 - MiV-PA Others - Update in information for the drug subtance dossiers 3 - MaV-15 - Extension of shelf-life of the drug product 4 - MiV-PA21 and MiV-PA22 - Update in specification and testing monograph of excipient	Zuellig Pharma (B) Sdn Bhd
40	(148)/DRU/DRA.Variation/2019	Entresto 200mg Film-coated Tablets	Sacubitril 97.2mg & Valsartan 102.8mg	BRU18032326P	1 MiV-PA2 - Change of product labelling (package insert ; new date of revision: December 2017) 2 - MiV-PA Others - Update in information for the drug subtance dossiers 3 - MaV-15 - Extension of shelf-life of the drug product 4 - MiV-PA21 and MiV-PA22 - Update in specification and testing monograph of excipient	Zuellig Pharma (B) Sdn Bhd
41	(150)/DRU/DRA.Variation/2019	Gadovist Injection 1.0mmol/ml	Gadobutrol pure 604.72mg & Calcium sodium butrol 0.513mg	BRU15090933P	1 - Minor (MiV-PA22) - Change of a test procedure for an excipient (gadolinium oxide)	Zuellig Pharma (B) Sdn Bhd
42	(151)/DRU/DRA.Variation/2019	Gadovist Injection 1.0mmol/ml Prefilled syringe 5.0ml	Gadobutrol pure 604.72mg & Calcium sodium butrol 0.513mg	BRU15090932P	1 - Minor (MiV-PA22) - Change of a test procedure for an excipient (gadolinium oxide)	Zuellig Pharma (B) Sdn Bhd
43	(152)/DRU/DRA.Variation/2019	Garasent 80mg Injection	Gentamicin 40mg/ml (as Sulphate)	BRU08030030P	1 - Minor (MiV-PA2) - Change of outer carton label, inner label and package insert [version GARASENT Inj (14.12.2017)] 2 - Minor (MiV-PA31) - Change of outer carton pack sizes for a drug product (Addition of pack size) 3 - Minor (MiV-PA35) - Change of storage conditions of the drug product (Increasing from the current approved storage condition) 4 - Minor (MiV-N9) - Change of release and shelf-life specifications of the drug product, follwing the updates in the compendium	K-Seri Pharma Sdn BHd
44	(153)/DRU/DRA.Variation/2019	Prostin E2 Vaginal Tablet 3mg	Dinoprostone 3mg	BRU12100942P	1 MiV-PA2 - Change of product labelling (package insert ; new date of revision: 16 JUL 2018 Prostin E2-0618)	Zuellig Pharma (B) Sdn Bhd

45	(155)/DRU/DRA.Variation/2019	Ibrance Capsules 75mg	Palbociclib 75mg	BRU18042345P	1 - MaV-1 (inc MiV-PA2) - Change of content of product labelling (package insert, new date of revision 16 JAN 2019 version Ibrance-0119)	Zuellig Pharma (B) Sdn Bhd
46	(156)/DRU/DRA.Variation/2019	Ibrance Capsules 100mg	Palbociclib 100mg	BRU18042346P	1 - MaV-1 (inc MiV-PA2) - Change of content of product labelling (package insert, new date of revision 16 JAN 2019 version Ibrance-0119)	Zuellig Pharma (B) Sdn Bhd
47	(157)/DRU/DRA.Variation/2019	Ibrance Capsules 125mg	Palbociclib 125mg	BRU18042347P	1 - MaV-1 (inc MiV-PA2) - Change of content of product labelling (package insert, new date of revision 16 JAN 2019 version Ibrance-0119)	Zuellig Pharma (B) Sdn Bhd
48	(158)/DRU/DRA.Variation/2019	Pristine Shampoo 2% w/w	Ketoconazole 2% w/w	BRU17022157P	1 -Minor (MiV-PA35) - Change of storage conditions of the drug product (Increasing from the current approved storage condition)	Hongkiat Trading & Company
49	(159)/DRU/DRA.Variation/2019	Pristinex Cream 2% w/w	Ketoconazole 2% w/w	BRU10050470P	1 -Minor (MiV-PA35) with consequential MiV-PA2 - Change in storage conditions of the drug product (increasing from the current approved storage condition) with consequential change in product label [outer carton, inner label and package insert (version dated 08-Dec-2017)]	Hongkiat Trading & Company
50	(160)/DRU/DRA.Variation/2019	Bena® Expectorant	Diphenhydramine hydrochloride 14mg/5ml and ammonium chloride 135mg/5ml	BRU16022010P	1 - Minor (MiV-PA2) - Change in inner label and outer carton label	Hongkiat Trading & Company
51	(161)/DRU/DRA.Variation/2019	Hemo Rid™ Tablet	Miconised Disomin 450mg; Micronised Hesperidine 50mg	BRU09090328NP	1 - Minor (MiV-PA2) - Change inner foil label, outer carton label and package (Version: 1500008807 N.1, Date of revision: July 2019)	Hongkiat Trading & Company
52	(162)/DRU/DRA.Variation/2019	Uractonum 25mg Tablet	Spironolactone 25mg	BRU18022311P	1 - Minor (MiV-PA4) - Addition of alternative manufacturer of drug substance (where European Pharmacopoeial Certificate of Suitability (CEP) is available)	Hongkiat Trading & Company
53	(163)/DRU/DRA.Variation/2019	Ospamox 250mg/5ml granules for suspension	Amoxycillin 250mg (as trihydrate 287mg)	BRU15011714P	1 -Minor (MiV-PA15) - Qualitative or quantitative change of excipient	Zuellig Pharma (B) Sdn Bhd
54	(165)/DRU/DRA.Variation/2019	Curam 1000mg tablet	Amoxycillin 875 (as trihydrate); clavulanic acid 125mg (as potassium clavulanate)	BRU15041845P	1 -Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance (potassium clavulanate)	Zuellig Pharma (B) Sdn Bhd

55	(166)/DRU/DRA.Variation/2019	Menveo Powder & Solution for Solution for Injection	One dose (0.5ml of the reconstituted vaccine) contains: Originally contained in the powder: Meninggococcal group A Oligosaccharide 19micrograms (Conjugated to Corynebacterium diphtheria CRM197 protein 16.7 to 33.3 micrograms) Originally contained in the solution: Meninggococcal group C ogliosaccharide 5micrograms (Conjugated to Corynebacterium diphtheria CRM197 protein...7.1 to 12.5 micrograms); Meninggococcal group W135 oligosaccharide 5micrgrams (Conjugated to Corynebacterium diphtheria CRM197 protein 3.3 to 8.3 micrograms); Meninggococcal group Y ogliosaccharide 5 micrograms (conjugated to Corynebacterium diphtheria CRM197 protein...5.6 to 10.0. micrograms)	BRU14031269P	1 -Major (MaV-3) - Change of alternative manufacturer of working seed storage location for drug subtance (Men-W PS) (where European Pharmacopoeial Certificate of Suitability (CEP is not available) 2 - Minor (MiV-PA6) - Change of in-process controls applied during the manufacture of the drug substance (MenW-CRM Conjugate) (where European Pharmacopoeial Certifcate of Suitability (CEP) is not available) 3 - Minor (MiV-PA8) -Change of the specification of drug substance (MenW-CRM Conjugate) 4 - Minor (MiV-PA9) - Change of the test procedure of non-compendial drug substance (MenW-CRM Conjugate and MenW-PS)	Zuellig Pharma (B) Sdn Bhd

56	(167)/DRU/DRA.Variation/2019	Menveo Powder & Solution for Solution for Injection	One dose (0.5ml of the reconstituted vaccine) contains: Originally contained in the powder: Meninggococcal group A Oligosaccharide 19micrograms (Conjugated to Corynebacterium diphtheria CRM197 protein 16.7 to 33.3 micrograms) Originally contained in the solution: Meninggococcal group C ogliosaccharide 5micrograms (Conjugated to Corynebacterium diphtheria CRM197 protein...7.1 to 12.5 micrograms); Meninggococcal group W135 oligosaccharide 5micrgrams (Conjugated to Corynebacterium diphtheria CRM197 protein 3.3 to 8.3 micrograms); Meninggococcal group Y ogliosaccharide 5 micrograms (conjugated to Corynebacterium diphtheria CRM197 protein...5.6 to 10.0. micrograms)	BRU14031269P	1 -Major (MaV-3) - Change of alternative manufacturer of working seed storage location for drug substance (Men-A PS) (where European Pharmacopoeial Certificate of Suitability (CEP is not available) 2 - Minor (MiV-PA6) - Change of in-process controls applied during the manufacture of the drug substance (MenA-CRM) (where European Pharmacopoeial Certifcate of Suitability (CEP) is not available) 3 - Minor (MiV-PA7) - Change of manufacturing process of drug substance (MenA) (where European Pharmacopoeial Certificate of Suitability (CEP) is not available) 4 - Minor (MiV-PA8) - Change of the specification of drug substance (MenA-CRM Conjugate) 5- Minor (MiV-PA9) - Change of the test procedure of non-compendial drug substance (MenA-CRM Conjugate and MenA-PS)	Zuellig Pharma (B) Sdn Bhd
57	(171)/DRU/DRA.Variation/2019	Acipan Injection 1mg/ml (1ml ampoule)	Atropine Sulphate 1mg/ml	BRU17052209P	1 -Minor (MiV-PA2) - Change of outer carton label and package insert (Version: Acipan Injection 1mg/ml (1ml amp) [18 JULY 2017]) 2 - Minor (MiV-PA35) - Change of storage conditions of the drug product (Increasing from the current approved storage condition) 3 - Minor (MiV-N9) - Change of release and shelf-life specifications of the drug product, following the updates in the compendium	K-Seri Pharma Sdn BHd
58	(172)/DRU/DRA.Variation/2019	Puregon 50IU/0.5ml Solution for Injection	Follitrophin Beta (recombinant follicle-stimulating hormone (FSH) 50IU/0.5ml	BRU11040680PS2	1 -MiV-Others - To include secondary reference standard Follitropin Beta Secondary Reference Standard (SRS) Lot SRS-0000682817	Zuellig Pharma (B) Sdn Bhd
59	(173)/DRU/DRA.Variation/2019	Puregon 100IU/0.5ml Solution for Injection	Follitrophin Beta (recombinant follicle-stimulating hormone (FSH) 100IU/0.5ml	BRU11100781PS2	1 -MiV-Others - To include secondary reference standard Follitropin Beta Secondary Reference Standard (SRS) Lot SRS-0000682817	Zuellig Pharma (B) Sdn Bhd

60	(174)/DRU/DRA.Variation/2019	Puregon 300IU/0.36ml Solution for Injection	Recombinant follicle-stimulating hormone (FSH) (follitrophin beta) [Org 32489] 600Iu/0.72ml	BRU11120817P	1 -MiV-Others - To include secondary reference standard Follitropin Beta Secondary Reference Standard (SRS) Lot SRS-0000682817	Zuellig Pharma (B) Sdn Bhd
61	(175)/DRU/DRA.Variation/2019	Puregon 600IU/0.72ml Solution for Injection	Recombinant follicle-stimulating hormone (FSH) (follitrophin beta) [Org 32489] 600Iu/0.72ml	BRU11040675P	1 -MiV-Others - To include secondary reference standard Follitropin Beta Secondary Reference Standard (SRS) Lot SRS-0000682817	Zuellig Pharma (B) Sdn Bhd
62	(176)/DRU/DRA.Variation/2019	Puregon 900IU/1.08ml Solution for Injection	Recombinant follicle-stimulating hormone (FSH) (follitrophin beta) [Org 32489]	BRU12030877P	1 -MiV-Others - To include secondary reference standard Follitropin Beta Secondary Reference Standard (SRS) Lot SRS-0000682817	Zuellig Pharma (B) Sdn Bhd
63	(177)/DRU/DRA.Variation/2019	Gardasil Vaccine (Syringe)	Per 0.5ml dose - HPV Type 6 L1 protein 20mcg; HPV Type 11 L1 protein 40mcg; HPV Type 16 L1 protein 40mcg; HPV Type 18 L1 protein 20mcg	BRU11110802P	1 -MiV-PA2 - Change of product labelling (inner label)	Zuellig Pharma (B) Sdn Bhd
64	(178)/DRU/DRA.Variation/2019	Avastin 100mg/4ml	Bevacizumab 25mg/ml (Humanised anti-VEGF monoclonal antibody)	BRU14111585PS1, PS2, PS3, PS4	1 -MiV-PA27 - Replacement in the test procedure of the drug product (i.e for Product Identity Method, from Capillary Zone Electrophoresis to LYS-c peptide map)	Hongkiat Trading & Company
65	(179)/DRU/DRA.Variation/2019	Avastin Concentrate For Solution For Infusion 400mg/16ml	Bevacizumab 400mg/16ml	BRU13061083PS1, PS2, PS3, PS4, PS5	1 -MiV-PA27 - Replacement in the test procedure of the drug product (i.e for Product Identity Method, from Capillary Zone Electrophoresis to LYS-c peptide map)	Hongkiat Trading & Company
66	(180)/DRU/DRA.Variation/2019	Curam 625mg Film-coated Tablet	Amoxicillin 500mg; Clavulanic acid as potassium salt 125mg	BRU14121663P	1 - MiV-PA12 - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance (Potassium clavulanate)	Zuellig Pharma (B) Sdn Bhd
67	(181)/DRU/DRA.Variation/2019	Kaletra Film-coated Tablet 200mg/50mg	Lopinavair 200mg; Ritonavir 50mg	BRU13021026P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
68	(182)/DRU/DRA.Variation/2019	Sevorane Inhalation Liquid	Sevoflurane 100% v/v	BRU14081416PS1; PS2	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
69	(183)/DRU/DRA.Variation/2019	Exviera 250mg Film Coated Tablets	Dasabuvir (as sodium monohydrate) 250mg	BRU16112101P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd

70	(184)/DRU/DRA.Variation/2019	Viekirax 12.5mg/75mg/50mg Tablets	Ombitasvir - 12.5mg (In the form of Ombitasvir Extrudate) Ritonavir - 50mg (In the form of Ritonavir Extrudate) Paritaprevir - 75mg (In the form of Paritaprevir Extrudate)	BRU17052202P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
71	(185)/DRU/DRA.Variation/2019	Synagis 100mg/ml Solution for Injection	Palivizumab 100mg/ml	BRU18012293P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
72	(186)/DRU/DRA.Variation/2019	Humira 40mg/0.4ml Solution for Injection	Adalimumab 40mg/0.4ml	BRU18112460P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
73	(187)/DRU/DRA.Variation/2019	Zemplar Injection	Paricalcitol 5mcg/ml	BRU15031811P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
74	(188)/DRU/DRA.Variation/2019	Lucrin depot 3.75mg Injection	Leuproprelin acetate 3.75mg	BRU14071388P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
75	(189)/DRU/DRA.Variation/2019	Lucrin depot 11.25mg Injection	Leuproprelin acetate 11.25mg	BRU14071389P	1 - Minor (MiV-PA29) - Addition of a manufacturer for secondary packaging	Zuellig Pharma (B) Sdn Bhd
76	(190)/DRU/DRA.Variation/2019	Atrovent N 20µg/ puff Metered Dose Inhaler	Ipratropium bromide anydrous 20mcg (as monohydrate 21mcg)	BRU09080308P	1 - Minor (MiV-PA2) - Change of package insert [Version: 0260-019 (MY&SG) dated 19/04/2018]	Hongkiat Trading & Company
77	(191)/DRU/DRA.Variation/2019	Metalyse Injection 10,000 units	tenecteplase 10,000units (50mg)	BRU09090327P	1 - MiV-PA Others - Extension of the shlef life of the secondary reference standard / working standard	Hongkiat Trading & Company
78	(194)/DRU/DRA.Variation/2019	Ecocort Cream	Econazole Nitrate 1% w/w; Triamcinolone Acetonide 0.1% w/w	BRU08070094P	1 - MiV-PA2 - Change of product labelling (inner label and outer carton)	G&H Trading Company
79	(195)/DRU/DRA.Variation/2019	Revlimid Capsules 5mg	Lenalidomide 5mg	BRU13010998PS1;PS2	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision 07/02/2019 and patient information leaflet, new revision date February 2019)	Zuellig Pharma (B) Sdn Bhd
80	(196)/DRU/DRA.Variation/2019	Revlimid Capsules 10mg	Lenalidomide 10mg	BRU13101161PS1; PS2	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision 07/02/2019 and patient information leaflet, new revision date February 2019)	Zuellig Pharma (B) Sdn Bhd
81	(197)/DRU/DRA.Variation/2019	Revlimid Capsules 15mg	Lenalidomide 15mg	BRU13101161PS1; PS2	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision 07/02/2019 and patient information leaflet, new revision date February 2019)	Zuellig Pharma (B) Sdn Bhd
82	(198)/DRU/DRA.Variation/2019	Revlimid Capsules 25mg	Lenalidomide 25mg	BRU13071108PS1, PS2	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision 07/02/2019 and patient information leaflet, new revision date February 2019)	Zuellig Pharma (B) Sdn Bhd

83	(199)/DRU/DRA.Variation/2019	Emend Tri-Pack Capsule	Each capsule either contains Aprepitant 80mg or 125mg	BRU14081417PS1 ; PS2	1 - MiV-PA2 - Change of product labelling (blister foil) - only applicaple for the Indonesia packaging site	Zuellig Pharma (B) Sdn Bhd
84	(200)/DRU/DRA.Variation/2019	Elonva Solution for Injection 100mcg/0.5ml	Corifollitropin alfa 100mcg/0.5ml	BRU14031268P	1 - MiV-PA2 - Change of product labelling - i) package insert, new date of revision Feb 2019 (SG-CCDS-MK 8962-SOi-022019) and ii) patient information leaflet, new date of revision feb 2019 (SG-CCPPI-MK8962-SOi-022019)	Zuellig Pharma (B) Sdn Bhd
85	(201)/DRU/DRA.Variation/2019	Elonva Solution for Injection 150mcg/0.5ml	Corifollitropin alfa 150mcg/0.5ml	BRU13061087P	1 - MiV-PA2 - Change of product labelling - i) package insert, new date of revision Feb 2019 (SG-CCDS-MK 8962-SOi-022019) and ii) patient information leaflet, new date of revision feb 2019 (SG-CCPPI-MK8962-SOi-022019)	Zuellig Pharma (B) Sdn Bhd
86	(203)/DRU/DRA.Variation/2019	Humalog KwikPen 100units/ml	Insulin Lispro 100units/ml	BRU14071330P	1 - MaV-7 - Change of batch size of sterile drug product	Zuellig Pharma (B) Sdn Bhd
87	(206)/DRU/DRA.Variation/2019	Prevenar 13 Suspension for Injection	Per 0.5ml - Pneumococcal Polysaccharide Serotype 1,3,4,5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F - 2.2mcg; Pneumococcal Polysaccgaride Serotype 6B-4.4mcg	BRU13021008P	1 - MiV-PA - Change of the supplier of bone charcoal used in sucrose manufacture	Zuellig Pharma (B) Sdn Bhd
88	(207)/DRU/DRA.Variation/2019	Risperdal Tablet 1mg	Risperidone 1mg	BRU15081923P	1 - MiV-PA29 - Addition of Zuellig Pharma Specialty Solutions Group Pte. Ltd. For secondary packaging site	Zuellig Pharma (B) Sdn Bhd
89	(208)/DRU/DRA.Variation/2019	Risperdal Tablet 2mg	Risperidone 2mg	BRU15081924P	1 - MiV-PA29 - Addition of Zuellig Pharma Specialty Solutions Group Pte. Ltd. For secondary packaging site	Zuellig Pharma (B) Sdn Bhd
90	(209)/DRU/DRA.Variation/2019	Risperdal Solution 1mg/ml	Risperidone 1mg/ml	BRU14111655P	1 - MiV-PA29 - Addition of Zuellig Pharma Specialty Solutions Group Pte. Ltd. For secondary packaging site	Zuellig Pharma (B) Sdn Bhd
91	(215)/DRU/DRA.Variation/2019	Axcel Paracetamol-250 Suspension (strawberry)	Paracetamol 250mg/5ml	BRU17032175NP	1 - MiV-PA24 - Update on the specifications and reference method of the drug product 2 - MiV-PA27 - To replace and update the test procedure of the drug product	Medicorp Sdn Bhd

92	(216)/DRU/DRA.Variation/2019	Prismasol BO	Each 1000ml contains (before reconstitution) : Calcium chloride dihydrate 5.145g, Magnesium chloride hexahydrate 2.033g, Lactic acid 5.4g, Sodium chloride 6.45g & Sodium bicarbonate 3.09g	BRU15011750NP	1 - MiV-PA2 - Change of product labelling (package insert)	Medicorp Sdn Bhd
93	(217)/DRU/DRA.Variation/2019	Yondelis® Powder for Injection 1mg/vial	Trabectedin 0.05mg/ml	BRU14071368P	1 - Minor (MiV-PA2) - Change of package insert (Date of revision: 25 Oct 2018 (Based on CCDSv14 Aug 2018))	Zuellig Pharma (B) Sdn Bhd
94	(218)/DRU/DRA.Variation/2019	Kisqali 200mg Film-Coated Tablet	Ribociclib succinate equivalent to 200mg ribociclib	BRU18112466P	1 - MiV-PA - Update of Stability data for Drug product and Drug substance	Zuellig Pharma (B) Sdn Bhd
95	(220)/DRU/DRA.Variation/2019	Tasigna Capsule 150mg	Nilotinib (as hydrochloride, monohydrae) 150mg	BRU14041302P	1 - MiV-PA - Update of stability report from 24 months to 36 months	Zuellig Pharma (B) Sdn Bhd
96	(221)/DRU/DRA.Variation/2019	Tasigna Capsule 200mg	Nilotinib (as hydrochloride, monohydrae) 200mg	BRU14041303P	1 - MiV-PA - Update of stability report from 24 months to 36 months	Zuellig Pharma (B) Sdn Bhd
97	(222)/DRU/DRA.Variation/2019	Exforge Tablet 5mg/80mg	Amlodipine 5mg (as besylate 6.94mg); Valsartan 80mg	BRU09090329P	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision 19 September 2018)	Zuellig Pharma (B) Sdn Bhd
98	(223)/DRU/DRA.Variation/2019	Exforge Tablet 5mg/160mg	Amlodipine 5mg (as besylate 6.94mg); Valsartan 160mg	BRU10010388P	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision 19 September 2018)	Zuellig Pharma (B) Sdn Bhd
99	(224)/DRU/DRA.Variation/2019	Exforge 10/160mg FC Tablet	Amlodipine 10mg (as besylate); Valsartan 160mg	BRU10080523P	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision 19 September 2018)	Zuellig Pharma (B) Sdn Bhd
100	(225)/DRU/DRA.Variation/2019	Lucentis 10mg/ml Solution for Injection	Ranibizumab 10mg/ml	BRU14071375P	1 - MiV-PA8 - Change of the specification of drug substance 2 - MiV-PA9 - Change of the test procedure of non-compendial drug substance 3 - MiV-PA19 - Update of in-process controls applied during the manufacture of the drug product (inlcuding tightening and addition of new in-process test)	Zuellig Pharma (B) Sdn Bhd
101	(226)/DRU/DRA.Variation/2019	Seebri Breezhaler 50mcg Inhalation Powder Hard Capsules	Glycopyrronium bromide 63mcg (corresponding to 50 mcg Glycopyrronium)	BRU16062049P	1 - MaV-4 - Addition of the manufacturing site of the drug product	Zuellig Pharma (B) Sdn Bhd

102	(227)/DRU/DRA.Variation/2019	Voltaren 50mg tablets	Diclofenac Sodium 50mg	BRU09060263P	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision February 2018)	Zuellig Pharma (B) Sdn Bhd
103	(228)/DRU/DRA.Variation/2019	Cataflam 1.5% Oral Drops Suspension	Diclofenac Sodium 15mg/ml	BRU09030219P	1 - MiV-PA2 - Change of product labelling (package insert, new date of revision February 2018)	Zuellig Pharma (B) Sdn Bhd
104	(230)/DRU/DRA.Variation/2019	Anafranil 25mg Tablet	Clomipramine HCl 25mg	BRU10070514P	1 - MiV-PA35 (inc MiV-PA2) - Increase of storage conditions of the drug product, with consequential update in product label (outer carton and package insert, new date of revision : December 2018)	Zuellig Pharma (B) Sdn Bhd
105	(236)/DRU/DRA.Variation/2019	Motilium tablets 10mg	Domperidone 10mg	BRU14021218P	1 - MiV-PA10- Change of retest period for drug substance 2 - MiV-PA Others - Update in packaging description of drug substance	Zuellig Pharma (B) Sdn Bhd
106	(237)/DRU/DRA.Variation/2019	Motilium Suspension 1mg/ml	Domperidone 1mg/ml	BRU14031267P	1 - MiV-PA10- Change of retest period for drug substance 2 - MiV-PA Others - Update in packaging description of drug substance	Zuellig Pharma (B) Sdn Bhd
107	(241)/DRU/DRA.Variation/2019	Cosentyx 150mg Solution for Injection in Pre-filled Pen	Secukinumab 150mg	BRU17062215P	1 - MiV-PA - Update of the assembly and quality control testing sited for the drug product	Zuellig Pharma (B) Sdn Bhd
108	(245)/DRU/DRA.Variation/2019	Recormon-Prefilled Syringe 4000IU/0.3ml	Erythropoetin Beta 4,000iu/0.3ml	BRU13031047P	1 - MiV-PA2 -Change of product labelling (package insert new date of revision Feb 2019)	Medipharm Sdn Bhd
109	(246)/DRU/DRA.Variation/2019	Recormon-Prefilled Syringe 2000IU/0.3ml	Erythropoetin Beta 2,000iu/0.3ml	BRU13031045P	1 - MiV-PA2 -Change of product labelling (package insert new date of revision Feb 2019)	Medipharm Sdn Bhd
110	(249)/DRU/DRA.Variation/2019	Campto 40mg/2ml Injection	Irinotecan hydrochloride trihydrate 40mg/2ml	BRU10110597P	1 - MiV-PA2 -Change of product labelling (outer carton and package insert; new date of revision 17 SEP 2018 CAMPTO-0116; CDS v14 dated 19 July 2018)	Zuellig Pharma (B) Sdn Bhd
111	(250)/DRU/DRA.Variation/2019	Campto 100mg/5ml Injection	Irinotecan hydrochloride trihydrate	BRU11080748P	1 - MiV-PA2 -Change of product labelling (outer carton and package insert; new date of revision 17 SEP 2018 CAMPTO-0116; CDS v14 dated 19 July 2018)	Zuellig Pharma (B) Sdn Bhd

112	(251)/DRU/DRA.Variation/2019	Campto 300mg/15ml Injection	Irinotecan hydrochloride trihydrate 300mg/15ml	BRU14091528P	1 - MiV-PA2 -Change of product labelling (outer carton and package onsert; new date of revision 17 SEP 2018 CAMPTO-0116; CDS v14 dated 19 July 2018)	Zuellig Pharma (B) Sdn Bhd
113	(261)/DRU/DRA.Variation/2019	Herceptin Powder for Injection 440mg/vial	Trastuzuman 440mg	BRU15061888P	1 - Minor (MiV-PA2) - Change of package insert (Version: INF/INJ-HER-2019 02-0, Date of revision: Feb 2019)	Medipharm Sdn Bhd
114	(262)/DRU/DRA.Variation/2019	Herceptin Solution for Injection 600mg/5ml	Trastuzumab 600mg/5ml	BRU19012505P	1 - Minor (MiV-PA2) - Change of package insert (Version: INF/INJ-HER-2019 02-0, Date of revision: Feb 2019) 2- Minor (MiV-PA22) - Change of a test procedure for an excipient (rHuPH20) 3 - Minor (MiV-PA) - Registration of companies as rHuPH20 cell bank stirage and distribution, and as bulk rHuPH20 site of storage and distribution	Medipharm Sdn Bhd
115	(266)/DRU/DRA.Variation/2019	Avamys® Nasal Spray	Fluticasone Furoate (micronised) 27.5µg/spray	BRU11050699P	1 - Minor (MiV-PA2) - Change of inner label and package insert (Version: Avamys v03, Date of revision: 20 June 2018) 2 - Minor (MiV-PA28) - Change in primary packaging material non-sterile product	Zuellig Pharma (B) Sdn Bhd
116	(267)/DRU/DRA.Variation/2019	HBVaxPro® 5mcg/0.5ml Injection	Hepatitis B surface Antigen 5mcg/0.5ml	BRU14091513P	1 - Minor (MiV-PA2) - Change of outer carton and package insert (Version: SG-V232-I-052018, Date of revision: March 2019)	Zuellig Pharma (B) Sdn Bhd
117	(268)/DRU/DRA.Variation/2019	HBVaxPro® 10mcg/1.0ml Injection	Hepatitis B surface Antigen 10mcg/1.0ml	BRU14091514P	1 - Minor (MiV-PA2) - Change of outer carton and package insert (Version: SG-V232-I-052018, Date of revision: March 2019)	Zuellig Pharma (B) Sdn Bhd
118	(269)/DRU/DRA.Variation/2019	HBVaxPro® 40mcg/1.0ml Injection	Hepatitis B surface Antigen 40mcg/1.0ml	BRU14091515P	1 - Minor (MiV-PA2) - Change of outer carton and package insert (Version: SG-V232-I-052018, Date of revision: March 2019)	Zuellig Pharma (B) Sdn Bhd
119	(270)/DRU/DRA.Variation/2019	Requip tablet 0.25mg	Ropinirole 0.25mg (as Hydrochloride)	BRU14071411P	1 - Minor (MiV-PA2) - Change of package insert (Version: Requip IR v05, Date of revision: 15 March 2019)	Zuellig Pharma (B) Sdn Bhd
120	(271)/DRU/DRA.Variation/2019	Requip® Tablet 1mg	Ropinirole (as Hydrochloride) 1mg	BRU13081122P	1 - Minor (MiV-PA2) - Change of package insert (Version: Requip IR v05, Date of revision: 15 March 2019)	Zuellig Pharma (B) Sdn Bhd

121	(272)/DRU/DRA.Variation/2019	TobraDex® Eye Ointment	Tobramycin 0.3%, Dexamethasone 0.1%	BRU14071326P	1 - Minor (MiV-PA2) - Change of package insert (Version: TDOC-0050744 Version 3.0, Date of revision: 25 January 2019)	Zuellig Pharma (B) Sdn Bhd
122	(273)/DRU/DRA.Variation/2019	TobraDex® Eye Drops Suspension	Tobramycin 0.3%, Dexamethasone 0.1%	BRU14081467P	1 - Minor (MiV-PA2) - Change of package insert (Version: TDOC-0050744 Version 3.0, Date of revision: 25 January 2019)	Zuellig Pharma (B) Sdn Bhd
123	(274)/DRU/DRA.Variation/2019	Signifor LAR 20mg Powder and Solvent for Suspension for Injection	Pasireotide 20mg (as pamoate)	BRU18122477P	1 - Minor (MiV-PA2) - Change of package insert (Date of revision: January 2018)	Zuellig Pharma (B) Sdn Bhd
124	(275)/DRU/DRA.Variation/2019	Signifor LAR 40mg Powder and Solvent for Suspension for Injection	Pasireotide 40mg (as pamoate)	BRU18122478P	1 - Minor (MiV-PA2) - Change of package insert (Date of revision: January 2018)	Zuellig Pharma (B) Sdn Bhd
125	(276)/DRU/DRA.Variation/2019	Signifor LAR 60mg Powder and Solvent for Suspension for Injection	Pasireotide 60mg (as pamoate)	BRU18122479P	1 - Minor (MiV-PA2) - Change of package insert (Date of revision: January 2018)	Zuellig Pharma (B) Sdn Bhd
126	(278)/DRU/DRA.Variation/2019	Axcel Mefenamic Acid Capsules	Mefenamic acid 250mg	BRU14021234P	1 - Major (MaV-15) - Extension of shelf-life of the drug product	Medicorp Sdn Bhd
127	(284)/DRU/DRA.Variation/2019	Oliclinomel N4-550E Emulsion For Infusion	1000ml of the mixture contain: 20% Lipid emulsion compartment (corresponding to 20g/100ml) (200ml); 40% Glucose solution compartment (corresponding to 40g/100ml) (400ml); 10% Amino acid solution compartment (corresponding to 10g/100ml) (400ml) (For Detailed Formulation reffered to Dossier)	BRU17042176NP	1 - Minor (MiV-PA2) - Change in package insert (Date of revision : Mar 2019)	Zuellig Pharma (B) Sdn Bhd
128	(285)/DRU/DRA.Variation/2019	Oliclinomel N7-1000E Emulsion For Infusion	1000ml of the mixture contain: 20% Lipid emulsion compartment (corresponding to 20g/100ml) (200ml); 40% Glucose solution compartment (corresponding to 40g/100ml) (400ml); 10% Amino acid solution compartment (corresponding to 10g/100ml) (400ml) (For Detailed Formulation reffered to Dossier)	BRU17032168NP	1 - Minor (MiV-PA2) - Change in package insert (Date of revision : Mar 2019)	Zuellig Pharma (B) Sdn Bhd

129	(286)/DRU/DRA.Variation/2019	Oliclinomel N7-1000E Emulsion For Infusion	1000ml of the mixture contain: 20% Lipid emulsion compartment (corresponding to 20g/100ml) (200ml); 40% Glucose solution compartment (corresponding to 40g/100ml) (400ml); 10% Amino acid solution compartment (corresponding to 10g/100ml) (400ml) (For Detailed Formulation reffered to Dossier)	BRU17062210NP	1 - Minor (MiV-PA2) - Change in package insert (Date of revision : Mar 2019)	Zuellig Pharma (B) Sdn Bhd
130	(287)/DRU/DRA.Variation/2019	Kogrel 75mg Film Coated Tablet	Clopidogrel 75mg (as bisulfate 97.875mg)	BRU14111611P	1 - Minor (MiV-PA12) - Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Zuellig Pharma (B) Sdn Bhd
131	(288)/DRU/DRA.Variation/2019	Cellcept Tablet 500mg	Mycophenolate mofetil 500mg	BRU14111627P; BRU14111627PS2	1 - Minor (MiV-PA2) - Change in package insert (Version : INF/ORAL-CEL-2019 02-0, Date of revision : Feb 2019)	Hongkiat Trading & Company
132	(289)/DRU/DRA.Variation/2019	Pamorelin 22.5mg Powder for Suspension for Injection	Triptorelin (peptide base) 22.5mg equivalent to triptorelin embonate	BRU17052195P	1 - Major (MaV-1) - Additional indication extending the usage of the product (Date of Revision : May 2017)	Hongkiat Trading & Company
133	(290)/DRU/DRA.Variation/2019	Unasyn 0.75mg IM/IV	Ampicillin (as sodium) 500mg; Sulbactam (as sodium) 250mg	BRU09010181P	1 - Minor (MiV-PA2) - Change in package insert (Version: UNASYN IMIV-0618, Date of revision: 28 June 2018)	Zuellig Pharma (B) Sdn Bhd
134	(291)/DRU/DRA.Variation/2019	Unasyn IM/IV 1.5g	Sulbactam (as sodium 546.4mg) 500mg & Ampicillin (as sodium 1084.6mg) 1000mg	BRU09070275P	1 - Minor (MiV-PA2) - Change in package insert (Version: UNASYN IMIV-0618, Date of revision: 28 June 2018)	Zuellig Pharma (B) Sdn Bhd
135	(292)/DRU/DRA.Variation/2019	Unasyn 3.0g IM/IV	Ampicillin (as sodium) 2000mg; Sulbactam (as sodium) 1000mg	BRU09010182P	1 - Minor (MiV-PA2) - Change in package insert (Version: UNASYN IMIV-0618, Date of revision: 28 June 2018)	Zuellig Pharma (B) Sdn Bhd
136	(293)/DRU/DRA.Variation/2019	Prevenar 13 Suspension for Injection	Per 0.5ml - Pneumococcal Polysaccharide Serotype 1,3,4,5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F - 2.2mcg; Pneumococcal Polysaccgaride Serotype 6B-4.4mcg	BRU13021008P	1 - Minor (MiV-PA2) - Change in package insert (Version: PREVENAR 13 - 0419, Date of revision : 26 April 2019)	Zuellig Pharma (B) Sdn Bhd
137	(295)/DRU/DRA.Variation/2019	Xtandi Soft Capsules 40mg	Enzalutamide 40mg	BRU17062217P	1 - Major (MaV-1) - Additional of indication extending the usage of the product (Date of Revision :January 2019)	Medipharm Sdn Bhd

138	(296)/DRU/DRA.Variation/2019	Noxafil 100mg tablet	Posaconazole 100mg	BRU16072058P	1 - Minor (MiV-PA2) - Change in blister label 2- Minor (MiV-PA) - Update of information on P7 Container Closure System	Zuellig Pharma (B) Sdn Bhd
139	(297)/DRU/DRA.Variation/2019	Zyprexa 5mg tablet	Olanzapine 5mg	BRU13011005P	1 - Minor (MiV-PA10) - Change of re-test period for drug substance (Olanzapine)	Zuellig Pharma (B) Sdn Bhd
140	(298)/DRU/DRA.Variation/2019	Zyprexa ™ Tablet 10mg	Olanzapine 10mg	BRU12120973P	1 - Minor (MiV-PA10) - Change of re-test period for drug substance (Olanzapine)	Zuellig Pharma (B) Sdn Bhd
141	(299)/DRU/DRA.Variation/2019	Sodium Chloride injection 0.9%, USP	Sodium Chloride 0.9%	BRU14041314NP; BRU14041314NPS2	1 - Minor (MiV-PA2) - Change of bag label	Zuellig Pharma (B) Sdn Bhd
142	(303)/DRU/DRA.Variation/2019	Dulcolax 5mg Tablet	Bisacodyl 5mg	BRU10010390NPS3	1 - Major (MaV-6) and MiV-PA24 - Change of release and shelf-life specifications of the drug product where CEP is not available	Hongkiat Trading & Company
143	(305)/DRU/DRA.Variation/2019	Depo-Provera Vial 150mg/3ml	Medroxyprogesterone acetate 150mg	BRU11050701P	1 -Minor (MIV-PA2) - Change in package insert (Version : DEPO-PROVERA-0918, Date of revision : 04 SEP 2018)	Zuellig Pharma (B) Sdn Bhd
144	(306)/DRU/DRA.Variation/2019	Risperdal Tablet 1mg	Risperidone 1mg	BRU15081923P	1 -Minor (MIV-PA2) - Change in inner label, outer carton and package insert (Date of revision : 04 July 2018 (CCDS 07 May 2018)) due to supply switch from Malaysia to Singapore	Zuellig Pharma (B) Sdn Bhd
145	(307)/DRU/DRA.Variation/2019	Risperdal Tablet 2mg	Risperidone 2mg	BRU15081924P	1 -Minor (MIV-PA2) - Change in inner label, outer carton and package insert (Date of revision : 04 July 2018 (CCDS 07 May 2018)) due to supply switch from Malaysia to Singapore	Zuellig Pharma (B) Sdn Bhd
146	(308)/DRU/DRA.Variation/2019	Risperdal Solution 1mg/ml	Risperidone 1mg/ml	BRU14111655P	1 -Minor (MIV-PA2) - Change in inner label, outer carton and package insert (Date of revision : 04 July 2018 (CCDS 07 May 2018)) due to supply switch from Malaysia to Singapore	Zuellig Pharma (B) Sdn Bhd
147	(319)/DRU/DRA.Variation/2019	Puregon® 50IU/0.5ml Solution for Injection	Follitrophin Beta (recombinant follicale-stimulating hormone (FSH) 50IU/0.5ml	BRU11040680PS2	1 -MiV-PA9 - Change of the test procedure of non-compendial drug substance	Zuellig Pharma (B) Sdn Bhd
148	(320)/DRU/DRA.Variation/2019	Puregon® 100IU/0.5ml Solution for Injection	Follitrophin Beta (recombinant follicale-stimulating hormone (FSH) 100IU/0.5ml	BRU11100781PS2	1 -MiV-PA9 - Change of the test procedure of non-compendial drug substance	Zuellig Pharma (B) Sdn Bhd
149	(321)/DRU/DRA.Variation/2019	Puregon® 300IU/0.36ml Solution for Injection	Recombinant follicle-stimulating hormone (FSH) (follitrophin beta) [Org 32489] 600iu/0.72ml	BRU11120817P	1 -MiV-PA9 - Change of the test procedure of non-compendial drug substance	Zuellig Pharma (B) Sdn Bhd

150	(322)/DRU/DRA.Variation/2019	Puregon® 600IU/0.72ml Solution for Injection	Recombinant follicle-stimulating hormone (FSH) (follitrophin beta) [Org 32489] 600iu/0.72ml	BRU11040675P	1 -MiV-PA9 - Change of the test procedure of non-compendial drug substance	Zuellig Pharma (B) Sdn Bhd
151	(323)/DRU/DRA.Variation/2019	Puregon® 900IU/1.08ml Solution for Injection	Follitropin Beta (recombinant follicle-stimulating hormone FSH) [Org 32489]	BRU12030877P	1 -MiV-PA9 - Change of the test procedure of non-compendial drug substance	Zuellig Pharma (B) Sdn Bhd
152	(324)/DRU/DRA.Variation/2019	Adenocor Injection 6mg/2ml	Adenosine 6mg/2ml	BRU09020198P	1- MaV-6 - Change of specification of drug product (without CEP) 2 - MiV-PA27 - Update in the test procedure of the drug product	Medipharm Sdn Bhd
153	(325)/DRU/DRA.Variation/2019	Maalox Plus Suspension	Per 5ml - Aluminium hydroxide 225mg; Magnesium hydroxide 200mg; Simethicone USP 25mg	BRU10030436NP	1- MaV-4 - Change of the manufacturing site of the finished product 2 - MiV-PA19 and MiV-PA20 - Change in the manufacturing process and in-process controls applied during the manufacture of the drug product	Medipharm Sdn Bhd
154	(682)/DRU/DRA.Variation/2019	Regpara tablets 25mg	Cinacalcet hydrochloride 27.55mg eqv to Cinacalcet 25mg	BRU17112262P	1 -MiV-PA29 - Addition of a manufacturer for secondary packaging 2 - MiV-PA2 - Change of product labelling (outer carton and package insert, version KKAPSG/P/RG/1809 new revision date : November 2018)	K-Seri Pharma Sdn BHd