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No. S 681

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) (AMENDMENT NO. 2) REGULATIONS 2023

In exercise of the powers conferred by section 72 of the Health Products Act 2007, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Therapeutic Products) (Amendment No. 2) Regulations 2023 and come into operation on 1 November 2023.

Amendment of First Schedule

2. In the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016), in the First Schedule —

- (a) in paragraph 1, after the item “Alprazolam”, insert —
“Amineptine”;
- (b) in paragraph 1, after the item “Clonazepam”, insert —
“Clonazolam”;
- (c) in paragraph 1, after the item “Diazepam”, insert —
“Diclazepam”;
- (d) in paragraph 1, after the item “Etilamfetamine”, insert —
“Etizolam”;
- (e) in paragraph 1, after the item “Fenproporex”, insert —
“Flualprazolam
Flubromazolam”;

(f) in paragraph 1, after the item “Pentobarbital”, insert —
“Phenazepam”; and

(g) replace paragraph 2 with —

“2. The stereoisomeric forms or salts of the substances specified in paragraph 1, wherever the existence of such stereoisomeric forms or salts is possible.”.

Amendment of Second Schedule

3. In the Health Products (Therapeutic Products) Regulations 2016, in the Second Schedule —

(a) in Part 1, after the item specified in the first column of the following table, insert the item specified opposite it in the second column of the table:

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Abciximab	Abemaciclib
Abiraterone	Abrocitinib Acalabrutinib
Acitretin	Acidinium
Aflibercept	Agalsidase alfa
Alatrofloxacin	Albutrepenonacog alfa
Aldosterone	Alectinib
Alglucosidase alfa	Alirocumab
Alosetron	Alpelisib
Ambenonium	Ambrisentan
Aminoglutethimide	Aminolevulinic acid
Amitriptyline	Amivantamab
Antazoline	Apalutamide
Apramycin	Apremilast
Arotinolol	Arsenic trioxide
Articaine	Asciminib

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Atenolol	Atezolizumab
Auranofin	Avanafil Avelumab Avibactam
Baclofen	Baloxavir marboxil
Barbituric acid	Baricitinib
Bekanamycin	Belantamab mafodotin
Benperidol	Benralizumab
Bleomycin	Blinatumomab
Bretylium	Brexipiprazole Brigatinib
Bupropion	Burosumab
Cabimicina	Cabotegravir Cabozantinib
Capecitabine	Capmatinib
Carfentanil	Carfilzomib Cariprazine
Ceftizoxime	Ceftolozane
Clonazepam	Clonazolam
Cobicistat	Cobimetinib
Cortisone	Crisaborole
Daclizumab	Dacomitinib
Daptomycin	Daratumumab
Darbepoetin alfa	Darolutamide
Daunorubicin	Davesomeran
Denosumab	Deoxycholic acid
Dichlorphenamide	Diclazepam

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Diethylthiambutene	Difelikefalin
Dimethyl 4-sulphamoylphenyl phosphorothioate	Dimethyl fumarate
Dopamine	Doravirine
Dorzolamide	Dostarlimab
Drotrecogin alfa	Dulaglutide
Duloxetine	Dupilumab Durvalumab
Eculizumab	Edoxaban
Efavirenz	Elasomeran Elbasvir
Emepronium	Emicizumab Empagliflozin
Enflurane	Enfortumab vedotin
Entecavir	Entrectinib
Eptifibatide	Eptinezumab Eravacycline Erdafitinib
Erdosteine	Erenumab
Ertapenem	Ertugliflozin
Escitalopram	Esketamine
Etanercept	Etelcalcetide
Etilamfetamine	Etizolam
Everolimus	Evolocumab
Famprofazone	Famtozinameran Faricimab
Febuxostat	Fedratinib

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Ferric carboxymaltose	Ferric derisomaltose
Filgrastim	Fimasartan
Finasteride	Finerenone
Floxuridine	Flualprazolam
Fluanisone	Flubromazolam
Flutamide	Flutemetamol
Follitropin alfa	Follitropin delta
Framycetin	Fremanezumab
Galantamine	Galcanezumab
Gestronol	Gilteritinib
Glafenine	Glecaprevir
Granisetron	Grazoprevir
Guanoxan	Guselkumab
Idarubicin	Idarucizumab
Imiquimod	Inclisiran
Infliximab	Inotuzumab ozogamicin
Iodine-131	Ioflupane
Irinotecan	Isatuximab Isavuconazonium
Ixabepilone	Ixazomib Ixekizumab
Laropiprant	Larotrectinib
Latanoprost	Latanoprostene
Leflunomide	Lemborexant
Lenograstim	Lenvatinib
Lercanidipine	Letermovir
Linezolid	Lipegfilgrastim

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Liraglutide	Lisdexamfetamine
Lonazolac	Lonocog alfa
Lorazepam	Lorlatinib
L-Pyroglutamyl-L-histidyl-L-proline amide	Lubiprostone Luliconazole
Lumefantrine	Lurasidone Lurbinectedin Luspatercept
Luteinising hormone	Lutetium-177
Maraviroc	Mavacamten
Mepivacaine	Mepolizumab
Methyltestosterone	Methylthionium
Midodrine	Midostaurin Mifepristone
Nebivolol	Necitumumab
Nepafenac	Neratinib Netarsudil
Netilmicin	Netupitant
Nintedanib	Niraparib
Nitroxoline	Nivolumab
Noxythiolin	Nusinersen
Olanzapine	Olaparib
Omeprazole	Omidenepag
Orciprenaline	Orelabrutinib
Oseltamivir	Osimertinib Ospemifene
Oxytocin	Ozanimod

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Paclitaxel	Palbociclib
Panitumumab	Panobinostat
Pegaptanib	Pegaspargase
Pegvisomant	Pemafibrate
Perampanel	Perfluorobutane
Phenaglycodol	Phenazepam
Physostigmine	Pibrentasvir
Pirenzepine	Pirfenidone
Pirprofen	Pitavastatin
Plerixafor	Polatuzumab vedotin
Pomalidomide	Ponatinib
Pralidoxime	Pralsetinib
Ramipril	Ramucirumab
Ranolazine	Rasagiline
Raubasine	Raxtozinameran
Regorafenib	Remdesivir
Retinoic acid	Revefenacin
Ribavirin	Ribociclib
Rifampicin	Rifapentine
Riluzole	Rimegepant
Riociguat	Ripasudil Ripretinib Risankizumab Risdiplam
Romiplostim	Romosozumab
Roxithromycin	Rufinamide
Rupatadine	Rurioctocog alfa pegol

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Ruxolitinib	Sacituzumab govitecan
Sacubitril	Safinamide
Saquinavir	Sarilumab Satralizumab
Selegiline	Selexipag Selinexor Selumetinib Semaglutide
Silver sulphadiazine	Simeprevir
Simfibrate	Simoctocog alfa
Simvastatin	Siponimod
Sodium picosulphate	Sodium pyrophosphate
Sodium valproate	Sodium zirconium
Sotalol	Sotorasib
Tadalafil	Tafamidis
Talampicillin	Talazoparib Taliglucerase alfa
Tegaserod	Tegoprazan
Tenoxicam	Tepotinib
Tetrofosmin	Tezepelumab
Tiotropium	Tipiracil
Tirofiban	Tirzepatide
Tolterodine	Tolvaptan
Tosufloxacin	Tozinameran
Tramadol	Trametinib
Trientine	Trifarotene

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Tubocurarine	Tucatinib Turoctocog alfa
Unoprostone	Upadacitinib
Valaciclovir	Valbenazine
Vedolizumab	Velaglucerase alfa Velpatasvir
Vemurafenib	Venetoclax
Verapamil	Vericiguat
Vigabatrin	Vilanterol
Vismodegib	Vonoprazan
Vortioxetine	Voxilaprevir
Zanamivir	Zanubrutinib

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- (b) in Part 1, before “Bifonazole”, insert “Bictegravir”;
- (c) in Part 1, replace each item specified in the first column of the following table with the item specified opposite it in the second column of the table:

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Acetanilide; alkyl acetanilides	Acetanilide
Benactyzine; its quarternary compounds	Benactyzine
Bendamustine hydrochloride	Bendamustine
Benztropine and its homologues	Benztropine
Bevonium methyl sulphate	Bevonium
Bicisate dihydrochloride	Bicisate

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Buphenine hydrochloride	Buphenine
Butropium bromide	Butropium
Chromium [51CR] Edetate	Chromium [51CR]
Dabigatran etexilate mesylate	Dabigatran
Dextrothyroxine sodium	Dextrothyroxine
Dithienylallylamines; dithienyl-alkylallylamines	Dithienylallylamines
Ecothiopate iodide	Ecothiopate
Eltrombopag olamine	Eltrombopag
Ephedrine; its optical isomers	Ephedrine
Eribulin mesylate	Eribulin
Etofylline clofibrate	Etofylline
Fludarabine phosphate	Fludarabine
Fosaprepitant dimeglumine	Fosaprepitant
Gadobenate dimeglumine	Gadobenic acid
Lanthanum carbonate hydrate	Lanthanum carbonate
Liothyronine sodium	Liothyronine
Mercaptopurine; derivatives of mercaptopurine	Mercaptopurine
Methadone (amidone)	Methadone
Methanthelinium bromide	Methantheline
Methyl 5-aminolevulinate hydrochloride	Methyl aminolevulinate
Methylnaltrexone bromide	Methylnaltrexone
Minoxidil	Minoxidil (other than topical preparations)

<i>First column</i>	<i>Second column</i>
<i>Item</i>	<i>Item</i>
Morphine methylbromide; morphine N-oxide and other pentavalent nitrogen morphine derivatives	Morphine
N-Acetylaspartyl glutamic acid sodium salt	N-Acetylaspartyl glutamic acid; spaglumatic acid
Poldine methylsulphate	Poldine
Protamine sulphate	Protamine
Radium-223 chloride	Radium-223
Sodium molybdate	Sodium molybdate [99Mo]
Streptomycin and its derivatives	Streptomycin
Sulphonal; alkyl sulphonals	Sulphonal
Thiazinamium methylsulphate	Thiazinamium
Thiouracil; its alkyl derivatives	Thiouracil
Urea	Urea [13C] Urea [14C]
Yttrium-90 chloride	Yttrium-90

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(d) in Part 1, delete the following items:

Alphacalcidol
Desferrioxamine mesylate
Dextromethorphan
Diethanolamine fusidate
Gadoxetate
Histrelin
Isoconazole

Leucovorin
Meglumine gadoterate
Miconazole
N-Benzoyl sulphanilamide
Nicotinic acid
p-Aminobenzene-sulphonamide
Thyroid gland, the active principles of;

(e) in Part 1, at the end, insert —

“*Note:* The stereoisomeric forms or salts of the substances specified in Part 1, wherever the existence of such stereoisomeric forms or salts is possible, are also active ingredients for the purpose of this Part.”;

(f) in Part 2, replace item 6 with —

“6. Vaccine antigens”;

(g) in Part 3, after the item “Dexchlorpheniramine”, insert “Dextromethorphan”;

(h) in Part 3, after the item “Flunarizine”, insert “Isoconazole”;

(i) in Part 3, after the item “Mebeverine”, insert “Miconazole”; and

(j) in Part 3, at the end, insert —

“*Note:* The stereoisomeric forms or salts of the substances specified in Part 3, wherever the existence of such stereoisomeric forms or salts is possible, are also active ingredients for the purpose of this Part.”.

[G.N. Nos. S 219/2017; S 119/2018; S 92/2019;
S 969/2020; S 732/2021; S 1081/2021; S 458/2022;
S 436/2023]

Made on 18 October 2023.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

[401:04/01-000; AG/LEGIS/SL/122D/2020/4 Vol. 2]

(To be presented to Parliament under section 72(5) of the Health Products Act 2007).