ACTS AMENDMENTS ENFORCED BY PHARMACEUTICAL SERVICES DIVISON, MINISTRY HEALTH OF MALAYSIA FOR YEAR 2011-2014

A) Poisons Act 1952 & Regulations

NU.	DATE	GAZETTE NUMBER	AMENDMENT DETAILS
1.	29 April 2014	P.U. (A) 116	***Addition to Poisons List*** Azilsartan, Bilastine, Dapagliflozin, Dolutegravir, Lixisenatide, Mipomersen sodium, Ocriplasmin, Ofatumumab, Perampanel, Rececadotril, Vilanterol
2.	13 March 2014	P.U. (A) 72	***Addition to Poisons List*** Apixaban, Avanafil, Axitinib, Natalizumab, Pertuzumab, Pralatrexate, Regorafenib, Vemurafenib ***Amendments of Poisons*** • Arsenic – Exemption for notified cosmetics containing not more than 5ppm of arsenic and registered products containing not more than 5ppm of arsenic • Mercury - Exemption for notified cosmetics containing not more than 1ppm of mercury and registered products containing not more than 0.5ppm of mercury • Natamycin – exemption for natamycin when use as food additive • Potassium hydroxide – exemption for potassium hydroxide when use as food additive • Sodium hydroxide – exemption for sodium hydroxide when use as food additive
3.	10 July 2013	P.U. (A) 221	***Amendments of Poisons (Psychotropic Substances) Regulations 1989*** **<u>Regulation 19</u>** Amended in Paragraph 19(c) by inserting after the word “name” the words “, identity card number, passport number or any other legal identification document.”. **<u>Regulation 23</u>** Amended in parapgraph (a) by inserting after the words “Licencing Officer” the words “subject to the terms and conditions as he may impose”.

			<u>Regulation 24</u> By substituting for subregulation (2) the following subregulation: "(2) Any room, cabinet, safe or receptacle used to store any psychotropic substance- (a) shall be placed on the premises to which such psychotropic substances relates to the manufacturing, dispensing, compounding, mixing, sale, supply, education, research or chemical analysis only; and (b) shall be locked and unlocked by the person authorized to possess such psychotropic substances, and the keys to such room, cabinet, safe or receptacle shall be kept by him only.".
4.	9 July 2013	P.U. (A) 220	***Addition to Poisons List*** Aflibercept, Belimumab, Calfactant, Decoquinate, Fampridine, Micafungin sodium, Nebivolol, Panitumumab, Ruxolitinib, Vernakalant ***Amendments of Poisons*** • Amorolfine – exemption for all external use preparation containing not more than 5% of Amorolfine • Substituting word 9-methylenethiaxanthene with 9-methylenethioxanthene in item "Chlorprothixene and other substances structurally derived from 9-methylenethiaxanthene; their salt" • Mercury – re-classification item in Group D
5.	11 April 2013	P.U. (A) 136	Amendment of Third Schedule of Poisons Act by **deleting the word Bupropion**
6.	26 March 2013	P.U. (A) 104	***Addition to Poisons List*** Abiraterone, Cinacalcet, Crizotinib, Eribulin mesylate, Golimumab, Palonosetron, Plerixafor, Rilpivirine, Romiplostim, Selamectin ***Amendment of Poisons*** Radium and other radioactive substance – for therapeutic use or diagnostic use

7.	14 August 2012	P.U. (A) 257	***Addition to Poisons List*** Alcaftadine, Antihistamine-Rupatadine, Artesunate, Boceprevir, Cabazitaxel, Clofarabine, Degarelix, Denosumab, Fingolimod, Flunixin, Gimeracil, Indacaterol, Lacosamide, Linagliptin, Melarsomine, Oteracil potassium, Oxyclozanide, Pinaverium, Prucalopride, Rafoxanide, Retigabine, Roflumilast, Tegafur, Ticagrelor, Ulipristal ***Amendment of Poisons*** L-Asparaginase – exempted when used as food additive
8.	8 August 2011	P.U. (A) 266	***Addition to Poisons List*** Asenapine, Azaperone, Dronedarone, Sevelamer, Sugammadex, Tocilizumab, Ustekinumab ***Amendment of Poisons*** Caffeine – Exemption in notified cosmetic and registered product
9.	14 April 2011	P.U. (A) 109	***Addition to Poisons List*** Carbadox, Chlorpromazine, Closantel sodium, Dimetridazole, Febantel, Hydrogen bromide, 4-hydroxy-3-nitrophenylarsonic acid, Ipronidazole, Liraglutide, Morantel tartrate, Olaquindox, Pazopanib, Piperazine, Praziquantel, Ronidazole, Saxagliptin, Teicoplanin, Udenafil, Vancomycin ***Amendments of Poisons*** • Alkaloid–Colchicine – All registered product as Group C and all preparation other than Group C classified as Group A. • Chloroform – Vaterinary preparation for food producing animals as Group A • Dapsone – All registered product as Group B and all preparations other than Group B classified as Group A • Metronidazole – All registered product as Group B and all preparations other than Group B classified as Group A • Substituting item “Phenothiazine and other substances structurally derived from it; their salts; except Dimethoxanate; its salts and Promethazine; its salts and molecular compounds” with “Phenothiazine and other substances structurally derived from it; their salts; except Chlorpromazine, Dimethoxanate; its salts and Promethazine; its salts and molecular compounds” • Substituting item “Phosphorus yellow or white” with Phosphorus

10.	20 January 2011	P.U. (A) 10	***Amendments of Poisons (Psychotropic Substances) Regulations 1989*** **<u>Regulation 12</u>** By amending subregulation 12(1) by substituting for paragraph (b) the following paragraph: "(b) subject to regulation 12A, a registered medical practitioner, registered dentist Division I or veterinary surgeon;". **<u>New Regulation 12A</u>** 12A. A licensed pharmacist or a pharmacist in the public service shall not sell or supply buprenorphine and methadone to a registered medical practitioner, registered dentist Division I or veterinary surgeon for purpose other than the medical or dental treatment of a particular patient or animal treatment of a particular animal, as the case may be, unless a permit to purchase and use psychotropic substance under regulation 15 has been issued to the registered medical practitioner, registered dentist Division I or veterinary surgeon.". **<u>Regulation 14</u>** By inserting after subregulation (1) the following subregulation: "(2) Notwithstanding subregulation (1), a permit to purchase and use psychotropic substance shall be issued to a registered medical practitioner, a registered dentist Division I or a veterinary surgeon relating to buprenorphine and methadone for the purpose as may be specified by the Licensing Officer in the permit.". **<u>New regulation 21A</u>** By inserting after regulation 21 the following regulation: 21A. The person authorised to be in possession of psychotropic substance referred to in paragraphs 3(2)(a) to (f), (h) and (k) shall keep and maintain a register to be called the "Register of Psychotropic Substance Received, Delivered or Administered .". **<u>Regulation 22</u>** By substituting for paragraph (b) the following paragraph: "(b) shall enter in the register every quantity of psychotropic substance received, delivered or administered, as the case may be, by him whether for the purpose of sale, supply, administration or any other purpose, the total stock of such psychotropic substance in his possession, the name and address of the supplier or the recipient of such psychotropic substance and the date on which such psychotropic substance was received, delivered or administered by

			him or the reference number of the patient or client such psychotropic substance was administered to.”.
11.	13 January 2011	P.U. (A) 6	***Addition to Poisons List*** Bambuterol, Bitolterol, Broxaterol, Clenbuterol, Fenoterol, Griseofulvin, Norephedrine, Nystatin, Phenethylamine, Pirbuterol, Reproterol, Salbutamol, Terbutaline, Tretoquinol, Tulobuterol ***Amendmenst of Poions*** • Adenosine – exemption preparation containing adenosine from natural sources and in notified cosmetic • Formoterol – All preparations for use in animal feeds as Group A • Mercury – exemption in registered product • Procaterol – All preparations for use in animal feeds as Group A • Rimiterol – All preparations for use in animal feeds as Group A • Salmeterol – All preparations for use in animal feeds as Group A

B) Sale of Drugs Act 1952 and Regulations

NU.	DATE	GAZETTE NUMBER	AMENDMENT DETAILS
1.	28 March 2013	P.U. (A) 105	***Amendments of Control of Drugs and Cosmetics Regulation 1984*** **<u>Subregulation 7(1A)</u>** By amending in subregulation 7(1A) by inserting after paragraph (g) the following paragraph: "(h) which contains any metal contaminant unless naturally occurs, which contained in any traditional medicine as specified in column (1) of Table I to the Schedule in a proportion not greater than the maximum permitted proportion specified opposite the substance in column (2) of the Table.". **<u>New regulation 7A</u>** By inserting after regulation 7, the following regulation: 7A. No person shall manufacture, sell, supply, import, possess or administer any traditional medicine which contains any substance as set out in Table II to the Schedule.". **<u>Amendment of Schedule</u>** By inserting after Form 5, the following table: "TABLE I (Regulation 7) MAXIMUM PERMITTED PROPORTION OF NATURALLY OCCURING METAL CONTAMINANT IN TRADITIONAL MEDICINE *(1) Substance (Metal Contaminant)* — *(2) Maximum permitted proportion* Arsenic — 5.0 mg/kg or 5.0 mg/litre or 5.0 ppm

			Cadmium 0.3 mg/kg atau 0.3 mg/litre atau 0.3 ppm Lead 10.0 mg/kg atau 10 mg/litre atau 10.0 ppm Mercury 0.5mg mg/kg atau 0.5mg/litre atau 0.5 ppm TABLE II (Regulation 7A) PROHIBITED SUBSTANCES IN TRADITIONAL MEDICINE The following substances are prohibited in traditional medicine: 1. Caffeine 2. Nicotinamide 3. Paracetamol 4. Poison within the meaning of the Poisons Act 1952 [*Act 366*]".

C) Registration of Pharmacist Act 1951 and Regulations

NU.	DATE	GAZETTE NUMBER	AMENDMENT DETAILS
1.	13 August 2012	P.U. (A) 255	***Amendment of Second Schedule*** By substituting for Second Schedule with the following schedule: "SECOND SCHEDULE" [Subsection 6A(2)] LIST OF PREMISES 1. Government premises Any hospital and health clinic which fulfil the criteria for the purpose of training as specified by the Pharmacy Board and obtain its approval. 2. Non-govermental premises Any private hospital, pharmaceutical manufacturer, retail pharmacy and higher educational institution which fulfil the criteria for the purpose of training as specified by the Pharmacy Board and obtain its approval".
2.	19 July 2012	P.U. (A) 216	***Amendment of the First Schedule*** Amended in relation to the country "Malaysia", by inserting after the item "University of Nottingham Malaysia Campus" and the particulars relating to it the following item and particulars: "Cyberjaya University Collage of Medical Sciences Bachelor of Pharmacy (Hons)".
3.	21 July 2011	P.U. (A) 248	***Corrigendum of Second Schedule*** by substitutes the word "Beufort" appearing in subparagraph 2(a) the word "Beaufort".
4.	20 July 2011	P.U. (A) 245	***Amendment of the First Schedule*** The First Schedule to the Registration of Pharmacist Act 1951 is amended: (a) in relation to "Malaysia", by inserting after the item "Universiti Islam Antarabangsa Malaysia" and the item relating to it the following items:

			Name of institution granting qualification — *Description of qualification* "International Medical University — Bachelor of Pharmacy (Hons) International Medical University twinning with University of Strathclyde — Master of Pharmacy University of Nottingham Malaysia Campus — Master of Pharmacy"; and (b) in relation to "Japan", by inserting after the item "Kumamoto University" and the item relating to it the following items: *Name of Institution granting qualification* — *Description of qualification* "Tohuku University — Bachelor of Pharmacy Hokkaido University — Bachelor of Pharmacy Tokyo University of Science — Bachelor of Pharmacy".
5.	18 July 2011	P.U. (B) 364	***Notification of exemption under section 11E*** to the following persons from the requirement of section 11D: (a) any person who holds a Doctor of Philosophy in pharmacy; or (b) any person who holds a certificate issued by the Board of Pharmaceutical Specialties, United States of America.
6.	26 April 2011	P.U. (A) 147	***Amendment of the Second Schedule*** The Second Schedule to the Registration of Pharmacist Act 1951 is amended: • By inserting after items 10, 44, 47 and 53 the following items, respectively: "10A. Hospital Kepala Batas, Pulau Pinang 44A. Hospital Kuala Lipis, Pahang 47A. Hospital Hulu Terengganu, Terengganu 53A. hospital Beuford, Sabah"; and • By deleting items 1, 8, 9, 14, 19, 20, 21, 32, 36, 38, 44, 47, 50, 53, 60 and 65

7.	10 February 2011	P.U. (A) 41	***Amendment of the First Schedule*** The First Schedule to the Registration of Pharmacist Act 1951 is amended in relation to "Malaysia", by inserting after the item "Universiti Islam Antarabangsa Malaysia" and the item relating to it the following items: *Name of Institution granting qualification* — *Description of qualification* "AIMST University — Bachelor of Pharmacy (Hons) UCSI University — Bachelor of Pharmacy (Hons)".