2012

GENERAL GUIDELINE ON APPLICATION FOR POISONS LICENCE, PERMIT & IMPORT/EXPORT AUTHORISATION FOR CONTROLLED SUBSTANCES

PHARMACEUTICAL SERVICES DIVISION
MINISTRY OF HEALTH MALAYSIA

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1.0 TYPE of LICENCE, PERMIT or APPROVAL

No	Type of licence, permit or authorisation	Place to submit the application
1	Poisons Licence Type A	Pharmaceutical Services Division at the State level *(Refer Annex A for list of addresses)*
2	Poisons Licence Type B	
3	Poisons Licence Type E	
4	Permit to purchase and use psychotropic substances	
5	Permit to purchase, store and use NaOH	
6	Permit to purchace and use psychotropic substances (Burphenorphine dan Methadone)	
7	Wholesale Dangerous Drugs Licence	Pharmaceutical Services Division, Ministry of Health Malaysia, Lot 36, Jalan Universiti, 46350, Petaling Jaya, Selangor
8	Import/Export Authorisation for Dangerous Drugs and Psychotropics Substances	
9	Import/Export Authorisation for test kit containing Dangerous Drugs or Psychotropics Substances	
10	Authorisation to export Dextromethorphan preparations	
11	Authorisation to import/export controlled substances *(Refer Annex B for list of item)*	Through online system www.epermit.dagangnet.my
12	Authorisation to Import *medicine making machine*	Through online system www.epermit.dagangnet.my

2.0 LICENSING PROCESS

2.1 Application process

- Application form and supporting documents check list can be downloaded from www.pharmacy.gov.my or collect it from the nearest Pharmaceutical Services Division office.

- Only **complete** application form and supporting documents will be processed.

- Authorisation to import/eksport controlled substances and import of *medicine making machine,* application shall be done through online system www.epermit.dagangnet.com

2.2 Inspection of premises

- Inspection of premises will be conducted in the case of application of poisons licence type A/B/E, Permit to purchase and use psychotropic substances, permit to purchase, store and use NaOH, permit to purchase and use psychotopc substances (Burphenorphine dan Methadone) and Wholesale Dangerous Drugs Licence.

- Inspection can be done via appointment or on the spot.

2.3 Interview

- Interview is mandatory for new application of poisons licence type B. The questions asked cover the aspect of storing, selling, labeling and recording of poisons under the Poisons Act 1952. Only applicant who pass the interview would be considered for issuance of the licence.

3.0 WHO SHOULD APPLY

No	Name of licence, permit or authorisation	Applicant
1	Poisons Licence Type A	Pharmacist registered with the Pharmacy Board of Malaysia or Pharmacist with the qualification recognized by the State health Director of Sabah or Sarawak.
2	Poisons Licence Type B	(i) Applicant who wishes to import and sell poisons for industrial use. Applicant must be a Malaysia citizen with a minimum qualification of Sijil Pelajaran Malaysia (SPM). As for *precursors, arsenic and cyanides,* minimum qualification is Diploma in Science based. (ii) Feed miller who used antibiotics/poisons for the purpose of to be added into the animal feed.
3	Poisons Licence Type E	Applicant wish to import NaOH in large quantities for own factory use. Applicant must be Malaysia citizen.
4	Permit to purchase and use psychotropic substances	Applicant wish to purchase and use psychotropic substances for own factory use. Applicant must be Malaysia citizen. *(Psychotropic substances are substances listed in the 3rd Schedule of Poisons Act 1952)*
5	Permit to purchase, store and use NaOH	Applicant wish to purchase, store and use NaOH for own use. Applicant must be Malaysia citizen.

6	Permit to purchase and use psychotropic substances (Burphenorphine and Methadone)	Medical Officer (doctor) who wish to purchase and use Burphenorphine and/or Methadone for opiates drug replacement therapy. Medical Officer (doctor) must be registered with the Malaysian Medical Council (MMC)
7	Dangerous Drugs Wholesale Licence	Pharmacist who wish to sell dangerous drugs by wholesale. Pharmacist must possess poisons licence type A.
8	Import/Export Authorisation for Dangerous Drugs and Psychotropics Substances	(i) Pharmacist must possess poisons licence type A. (ii) In the case of import (other than for lab use) authorisation will only be given to those having valid import quota issued by the Pharmaceutical Services Division, Ministry of Health Malaysia.
9	Import/Export Authorisation for test kit containing Dangerous Drugs or Psychotropics Substances	Pharmacist must possess poisons licence type A
10	Authorisation to export Dextromethorphan preparations	Pharmacist must possess poisons licence type A. Permission must already being granted by the Competent Authority of the importing country.
11	Authorisation to import/export controlled substances	Applicant wish to import/export precursors or controlled substances under the Custom (Prohibition of Import and Export) Order, as listed in Annex B.
12	Authorisation to Import *medicine making machine*	Applicant posses Manufacturing Licence or written approval from National Pharmaceutical Control Bureau

4.0 CRITERIA FOR APPROVAL OF LICENCE, PERMIT & AUTHORISATION

4.1 Applicant must comply to **ALL** provisions in the Poisons Act 1952 and its Regulations.

4.2 Premise inspected found to be suitable

4.3 Obtained **more than 50%** marks in the interview.
(first time applying for poisons licence type B)

4.4 Complete the application form and supporting documents.

5.0 CLOSING

It is hope that this Guideline will help to facilitate the applicants on licence, permit and import/export authorization application. Any questions regarding the application could be directed to Pharmaceutical Services Division office at head quarter or state level. *(Please refer to Annex A for list of addresses)*

Annex A: Addresses of Pharmaceutical Services Division office

Bahagian Perkhidmatan Farmasi Kementerian Kesihatan Malaysia Lot 36, Jalan Univesiti, 46350, Petaling Jaya, Selangor. (Head Quarter)	Tel: 03-78413200 Fax: 03-79682251
Bahagian Perkhidmatan Farmasi Negeri Perlis Jabatan Kesihatan Negeri Perlis Lot 217, Jalan Raja Syed Alwi, Mukim Utan Aji, 01000, Kangar, Perlis.	Tel: 04-9765033 Fax: 04-9770548
Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Negeri Kedah Lebuhraya Sultanah Bahiyah, 05250 Alor Setar, Kedah.	Tel: 04-7321635 / 7326834 Fax: 04-7307313
Pejabat Timbalan Pengarah Kesihatan Negeri (Farmasi) Tingkat 8, Bangunan Persekutuan, Jalan Anson, 10400, Pulau Pinang.	Tel: 04-2292319 Fax: 04-2280314
Cawangan Penguatkuasa Farmasi Jabatan Kesihatan Negeri Perak Tingkat 10, Bangunan Maybank Trust, No 28, Jalan Tun Sambathan, 34000, Ipoh, Perak.	Tel: 05-2555994 Fax: 05-2532734
Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Negeri Selangor Tingkat 15, Wsima MBSA, Persiaran Perbandaran, 40000, Shah Alam, Selangor.	Tel: 03-55101051 Fax: 03-55108977
Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Negeri Tingkat 2, Bangunan Tabuing Haji, Komplels Terminal One, Jalan Lintang, 70000, Seremabn, Negeri Sembilan.	Tel: 06-7622036 Fax: 06-7646148

Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Negeri Melaka Tingkat 3, Wisma Persekutuan, Jalan Business City, Bandar MITC, 75450, Ayer Keroh, Melaka.	Tel: 06-2345979 / 2345980 Fax: 06-2345975
Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Negeri Johor 10-02 Tingkat 10, Menra MSC Cyberport, 5 Jalan Bukit Meldrum, 80300, Johor Bharu, Johor.	Tel: 07-2272801 Fax: 07-2236146
Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Negeri Pahang B4 & B6, Jalan Dato' Lim Hoe Lek 1 25200, Kuantan, Pahang.	Tel: 09-5146412 Fax: 09-5137769
Jabatan Kesihatan Negeri Trengganu Bahagian Perkhidmatan Farmasi Tingkat 8, Menra Yayasan Islam Trengganu, Jalan Sultan Omar, 20300, Kuala Trengganu, Trengganu.	Tel: 09-6222627 / 6301722 Fax: 09-6227486
Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Negeri Kelantan Lot 125-128, Taman Maktab, Pengkalan Chepa, 16100, Kota Bharu, Kelantan.	Tel: 09-7730586 Fax: 09-7746817
Pejabat Pengarah Jabatan Kesihatan Negeri Sarawak Jalan Tun Abanag Haji Openg 93590, Kuching, Sarawak.	Tel: 082-257552 Fax: 082-256566
Jabatan Kesihatan Negeri Sabah Bahagian Perkhidmatan Farmasi Tingkat 6, Rumah Persekutuan, Jalan Mat Salleh, 88590, Kota Kinabalu, Sabah.	Tel: 088-265960/ 256749 Fax:088-223024
Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Wilayah Persekutuan K.Lumpur & Putrajaya Jalan Chenderasari, 50590 Kuala Lumpur.	Tel: 03-26940701 Fax: 03-269368776

Bahagian Perkhidmatan Farmasi Jabatan Kesihatan Negeri Jalan Tanjung Teras, 87007, Wilayah Persekutuan Labuan	Tel: 087-411702 / 411416 Fax: 087-411298 / 412342

ANNEX B: List of controlled substances required import/export authorisation

No	Controlled chemical substances	Import authorisation required	Export authorisation required
(A) Precursors			
1	Acetic Anhydride	√	√
2	Ephedrine and its salts	√	√
3	Pseudoephedrine and its salts	√	√
4	Norephedrine and its salts	√	√
5	Lysergic acid and its salts	√	√
6	Piperonal	√	√
7	Safrole	√	√
8	Ergometrine (INN) and its salts	√	√
9	Ergotamine (INN) and its salts	√	√
10	Potassium Permanganate	√	√
11	N-acetylanthranilic acid	√	√
12	Isosafrole	√	√
13	1-(1,3-Benzodioxol-5-yl) propan-2-one (3,4-methylenedioxy-phenyl-2-propanone)	√	√
14	Phenylacetone (Phenylpropan-2-one) (1-phenyl-2-propanone)	√	√
15	Phenylacetic acid and its salts	X	√
16	Anthranilic acid and its salts	X	√
17	Piperidine and its salts	X	√
18	Diethyl ether (ethyl ether)	X	√

19	Hydrogen Chloride (Hydrochloric acid)	X	√
20	Sulphuric acid	X	√
21	Acetone	X	√
22	Toluene	X	√
23	Butanone (methyl ethyl ketone)	X	√
24	Medicaments containing Ephedrine / Pseudoephedrine whether or not put up for retails	√	√
(B) Controlled chemicals/other controlled substances			
25	Acetyl Bromide / Acetyl Chloride	√	√
26	Arsenic Trichloride	√	√
27	Caffeine and its salts	√	X
28	Clenbuterol	√	X
29	Formoterol	√	X
30	Salbutamol / Salmeterol / Terbutaline	√	X
31	Preparations of a kind used in animal feeding containing Salbutamol, Clenbuterol, Salmeterol, Terbutaline or Formoterol	Not Allowed to import	√

Note: √ Authorisation required
X Authorisation not required