



ONE STOP INFO

Ubat & Kosmetik

Oleh :

Cawangan Penguatkuasaan Farmasi (CPF)
Bahagian Perkhidmatan Farmasi Negeri Perlis



PANDUAN PENGGUNAAN

Dokumen ini terbahagi kepada empat bahagian yang mengandungi pautan kepada maklumat merangkumi :



Keperluan Penjualan
dan Pembekalan
Ubat & Kosmetik



Prosedur Pendaftaran
Ubat & Ubat Veterinar



Keperluan Penjualan
dan Pembekalan
Ubat Veterinar



Prosedur Notifikasi
Kosmetik

Beberapa ikon berikut adalah bagi memudahkan ke pautan :



Laman Utama



Kandungan



LAMAN UTAMA

ONE STOP INFO

Ubat & Kosmetik

Sebarang pertanyaan lanjut sila hubungi :

**CAWANGAN PENGUATKUASAAN FARMASI
BAHAGIAN PERKHIDMATAN FARMASI
JABATAN KESIHATAN NEGERI PERLIS**
Jalan Raja Syed Alwi, 01000 Kangar, Perlis.

Tel : 04 – 976 5033 |  : <http://www.pharmacy.gov.my>

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis

ONE STOP INFO

Ubat & Kosmetik

PENAFIAN

Panduan ringkas ini bertujuan untuk memberi maklumat dan pendedahan kepada pihak berkaitan (termasuk penjual, pengilang, agen-agen, stokis atau dropshipper) yang menjadi pembekal; sering mempromosi/mengiklan ubat dan kosmetik atau ingin mendapatkan maklumat pendaftaran berkaitan. Semua maklumat adalah tertakluk kepada akta-akta berkaitan yang dikuatkuasakan.

Namun begitu, panduan ringkas ini masih terikat kepada sebarang perubahan daripada pihak Bahagian Perkhidmatan Farmasi Kementerian Kesihatan Malaysia dari semasa ke semasa.



KANDUNGAN

- 1. Keperluan Penjualan dan Pembekalan Ubat & Kosmetik 7
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 - 1.3 Iklan Perubatan 14
 - 1.4 Hukuman dan Denda bawah Akta Jualan Dadah dan Akta Ubat (Iklan & Penjualan) 1956 17

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- 3. Prosedur Pendaftaran Ubat & Ubat Veterinar 25

- 4. Prosedur Notifikasi Kosmetik 63

Oleh :
 Cawangan Penguatkuasaan
 Farmasi (CPF)
 Bahagian Perkhidmatan Farmasi
 Negeri Perlis

Muka surat ini sengaja dibiarkan kosong



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



Keperluan Penjualan dan Pembekalan Ubat & Kosmetik

Bahagian ini menerangkan dengan lebih lanjut mengenai :

Ubat Berdaftar



Kosmetik Bernotifikasi



Iklan Perubatan



Hukuman dan Denda





APA ITU UBAT ?



Bahan atau persediaan dalam **bentuk dos**

(contoh : tablet, kapsul, sirap)



Digunakan untuk **tujuan perubatan**

(contoh : merawat / menyembuh / mencegah penyakit)



Untuk kegunaan **manusia atau haiwan**

UBAT BERDAFTAR

Ubat berdaftar mempunyai **nombor pendaftaran MAL** dan **Hologram** pada label atau pembungkusannya.

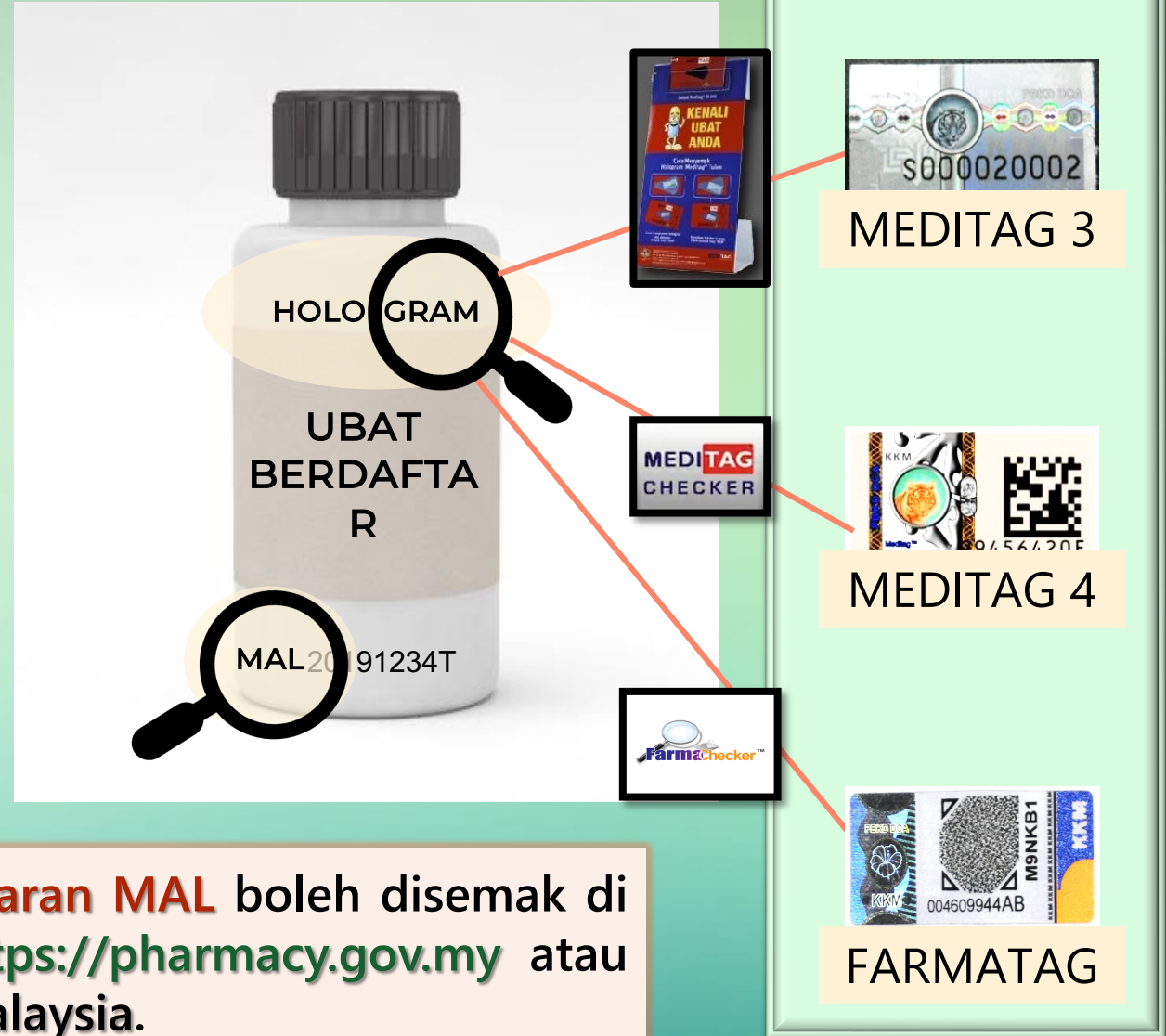
NOMBOR PENDAFTARAN MAL

8 DIGIT

MAL20191234[A/X/T/N]

- A : Ubat terkawal (Ubat preskripsi)
- X : Ubat *over-the-counter* (OTC)
- T : Ubat Tradisional
- N : Suplemen kesihatan

Nombor Pendaftaran MAL boleh disemak di laman web : <https://pharmacy.gov.my> atau aplikasi NPRA Malaysia.



VERSI HOLOGRAM



MEDITAG 3



MEDITAG 4



FARMATAG



APA ITU KOSMETIK ?



Bahan atau persediaan yang digunakan pada **bahagian luaran tubuh manusia** (seperti kulit, rambut, kuku, bibir dan organ genital luar) atau gigi dan rongga mulut



Bertujuan untuk membersihkan, mewangi, memperbaiki atau mencantikkan, menghilangkan bau badan, memelihara atau menjaga bahagian luaran tubuh



Perbedaan Produk Kosmetik & Bukan Kosmetik



Produk yang
membersih



Produk yang
mewangi



Produk yang
mencantikan



Produk yang
menghilangkan
bau badan



Suntikan



Produk yang disapu
untuk tujuan
perubatan



Makanan atau
minuman
untuk tujuan
kecantikan



Produk yang dititis
dalam mata, hidung
dan telinga



KOSMETIK BERNOTIFIKASI

1

Mempunyai Nombor

Notifikasi : **NOT123456789K**

Nombor notifikasi **tidak**
wajib dicetak pada label

Oleh itu, semakan bagi kosmetik
bernotifikasi perlu dibuat melalui laman
web : <http://www.pharmacy.gov.my>
atau melalui **aplikasi NPRA Malaysia**
sahaja.



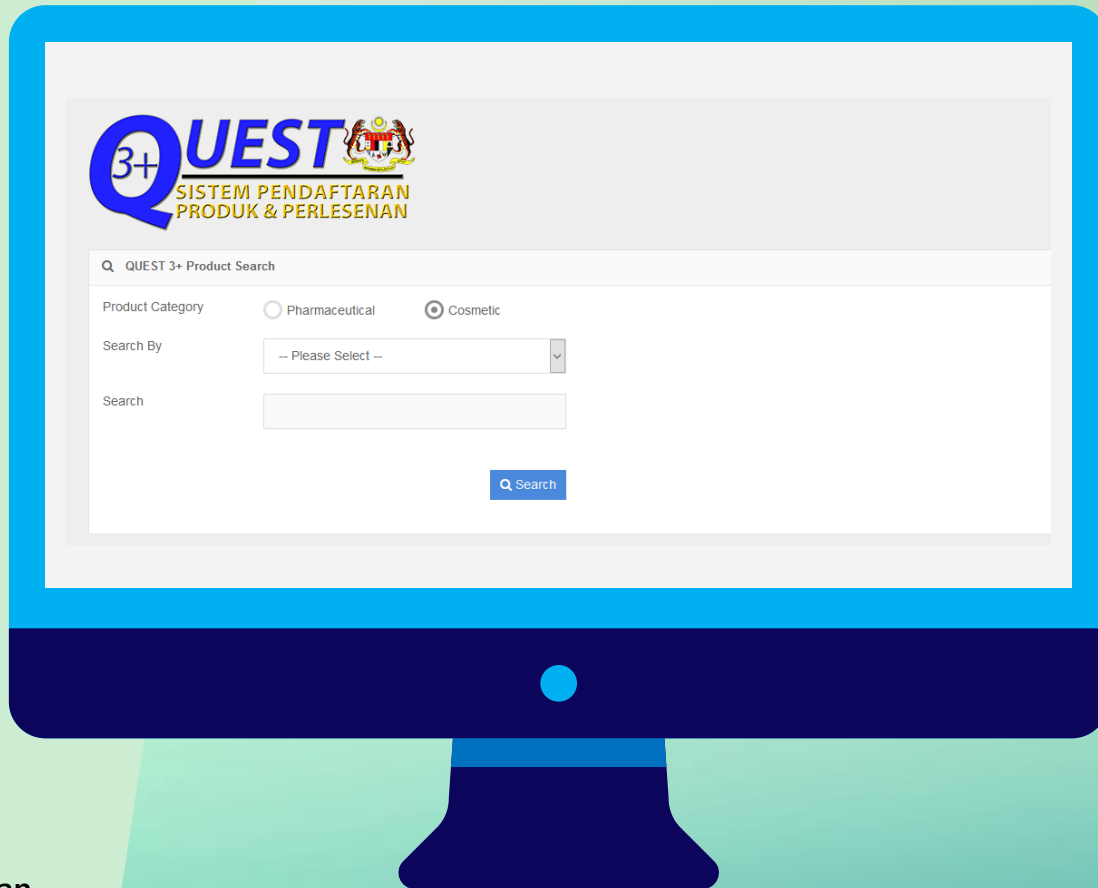
2

Tiada tuntutan perubahan

3

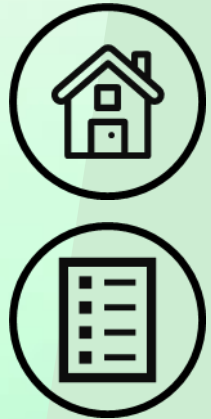
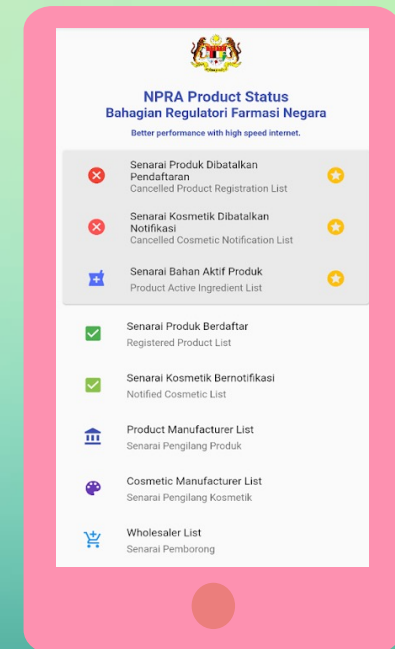
Label dalam Bahasa Malaysia
/ Bahasa Inggeris

Laman Web



ATAU

Aplikasi NPRA Malaysia



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis

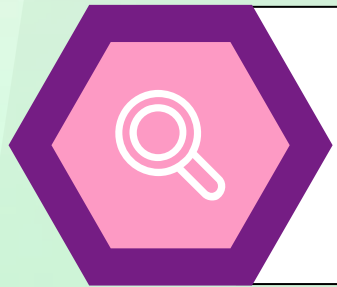


PASTIKAN IKLAN UBAT / PERKHIDMATAN PERUBATAN

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



Mempunyai **kelulusan** daripada Lembaga Iklan Ubat (LIU)



No. Kelulusan KKKLIU dan Tarikh Tamat Kelulusan* **dipaparkan**



Tempoh kelulusan iklan masih **sah** (Iklan sah untuk tempoh **3 tahun kalendar**)



*Tarikh Tamat Kelulusan perlu dipaparkan adalah hasil pindaan Peraturan-peraturan Lembaga Iklan Ubat bermula bagi iklan yang diluluskan daripada 15 Februari 2020.

IKLAN PERUBATAN YANG **TIDAK** BOLEH DIIKLANKAN

1. 20 jenis penyakit **TIDAK** boleh diiklankan

- Penyakit/kerosakkan buah pinggang
- Penyakit/kerosakan jantung
- Kencing Manis
- Sawan
- Lumpuh
- Batuk Kering
- Asma/Lelah
- Kusta
- Barah
- Pekak
- Ketagihan Dadah
- Hernia
- Penyakit Mata
- Darah Tinggi
- Sakit Mental
- Kemandulan
- Frigiditi
- Lemah fungsi seks (Impotent)
- Penyakit Kelamin
- Kelemahan urat saraf atau lain timbul daripada hubungan seks



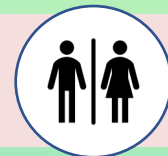
2. Amalan Kontrasepsi



3. Memperbaiki keadaan / fungsi buah pinggang



4. Membaiki fungsi / seksual manusia



5. Pengguguran anak





HUKUMAN & DENDA

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis

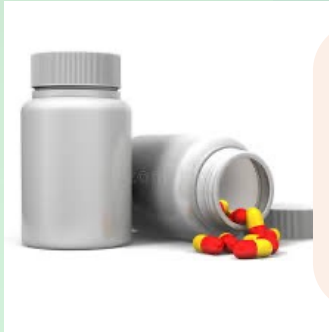


TAHUKAH ANDA ?

DI BAWAH AKTA JUALAN DADAH 1952, INDIVIDU ATAU SYARIKAT YANG MENGILANG, MENJUAL, MENGEDAR, MENGIMPORT, MEMILIKI ATAU MENGGUNAKAN UBAT-UBATAN YANG TIDAK BERDAFTAR ADALAH MELANGGAR PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984.



HUKUMAN & DENDA



MENGILANG / MENJUAL / MEMBEKAL /
IMPORT / MEMILIKI

Ubat Tidak Berdaftar dan
Kosmetik Tidak Bernotifikasi



Individu



Bagi kesalahan kali pertama, denda tidak melebihi RM 25 000 ATAU penjara tidak melebihi 3 tahun ATAU kedua-duanya sekali.



Bagi kesalahan berikutnya, denda tidak melebihi RM50 000 ATAU penjara tidak melebihi 5 tahun ATAU kedua-duanya sekali.



Body Corporate

Bagi kesalahan kali pertama, denda tidak melebihi RM 50 000 ;
Bagi kesalahan berikutnya, denda tidak melebihi RM100 000 ringgit.





KESALAHAN MENJUAL ATAU MEMILIKI PRODUK TIDAK BERDAFTAR



RM 50,000
(bagi syarikat)



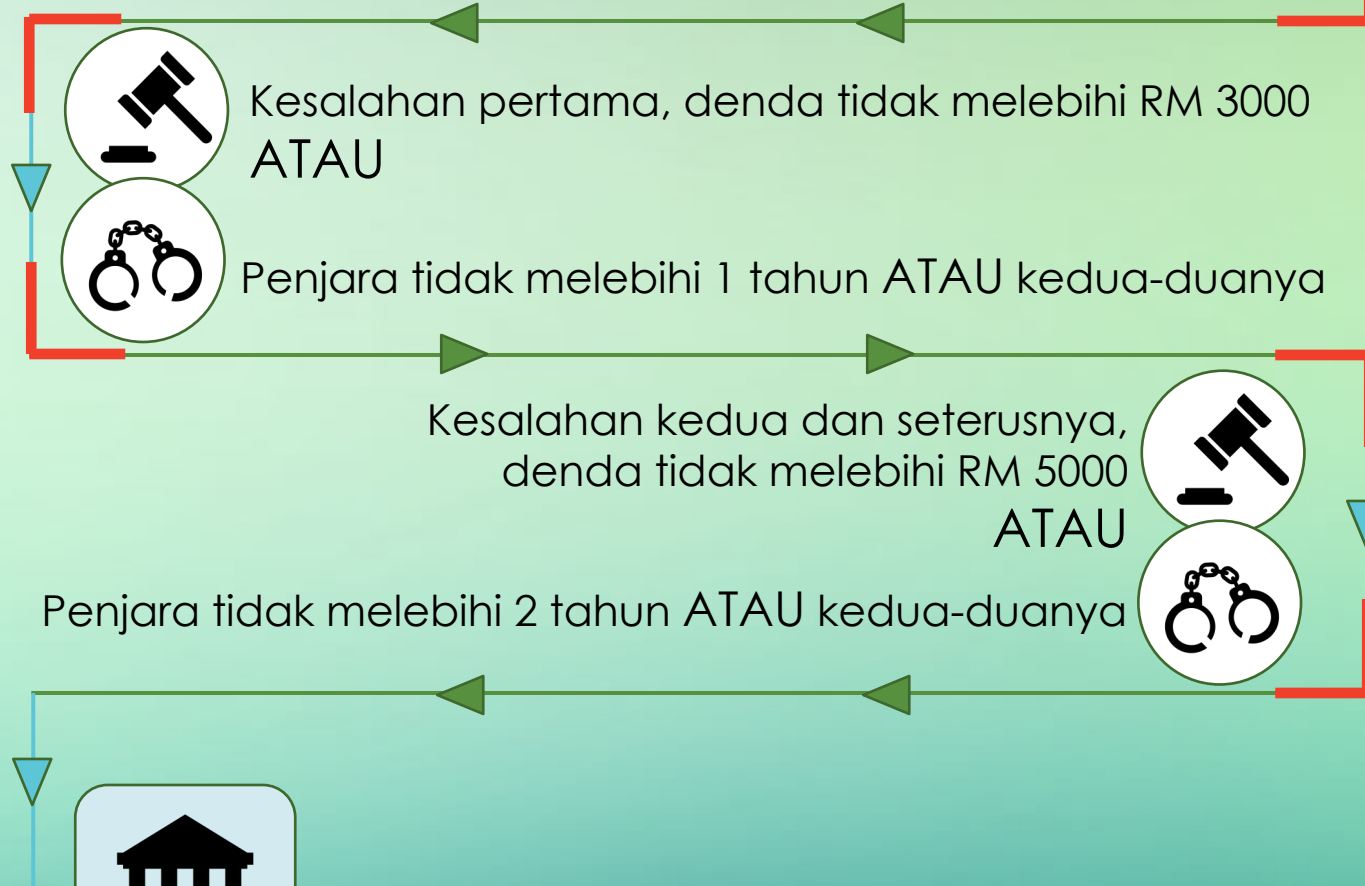
**RM 25,000 Dan/Atau
Penjara 3 Tahun**
(bagi individu)

Menjual atau memiliki produk tidak berdaftar (termasuk online) adalah

MELANGGAR SEKSYEN 12 AKTA JUALAN DADAH 1952!



Hukuman Bagi Kesalahan Di Bawah Akta Ubat(Iklan & Penjualan) 1956





HUKUMAN BAGI KESALAHAN IKLAN DI BAWAH

SEKSYEN 5 (1) AKTA UBAT (IKLAN & PENJUALAN) 1956

KESALAHAN KALI PERTAMA

Didenda maksimum | Dipenjara maksimum
RM 3,000 | 1 TAHUN
Atau kedua-duanya

KESALAHAN BERIKUTNYA

Didenda maksimum | Dipenjara maksimum
RM 5,000 | 2 TAHUN
Atau kedua-duanya



Keperluan Penjualan dan Pembekalan Ubat Veterinar

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



UBAT BERDAFTAR VETERINAR

Ubat berdaftar veterinar mempunyai **nombor pendaftaran MAL** pada label atau pembungkusannya.

NOMBOR PENDAFTARAN MAL

8 DIGIT

MAL20191234[HA/HX]

HA: Ubat Terkawal

HX: Ubat Bukan Racun

Nombor Pendaftaran MAL boleh disemak di laman web : <https://pharmacy.gov.my> atau aplikasi NPRA Malaysia.



Bagi ubat veterinar, hanya **Ubat Terkawal** dan **Ubat Bukan Racun** sahaja yang perlu berdaftar.



Prosedur Pendaftaran Ubat & Ubat Veterinar

Bahagian ini menerangkan dengan lebih lanjut mengenai :



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



PROSEDUR PENDAFTARAN

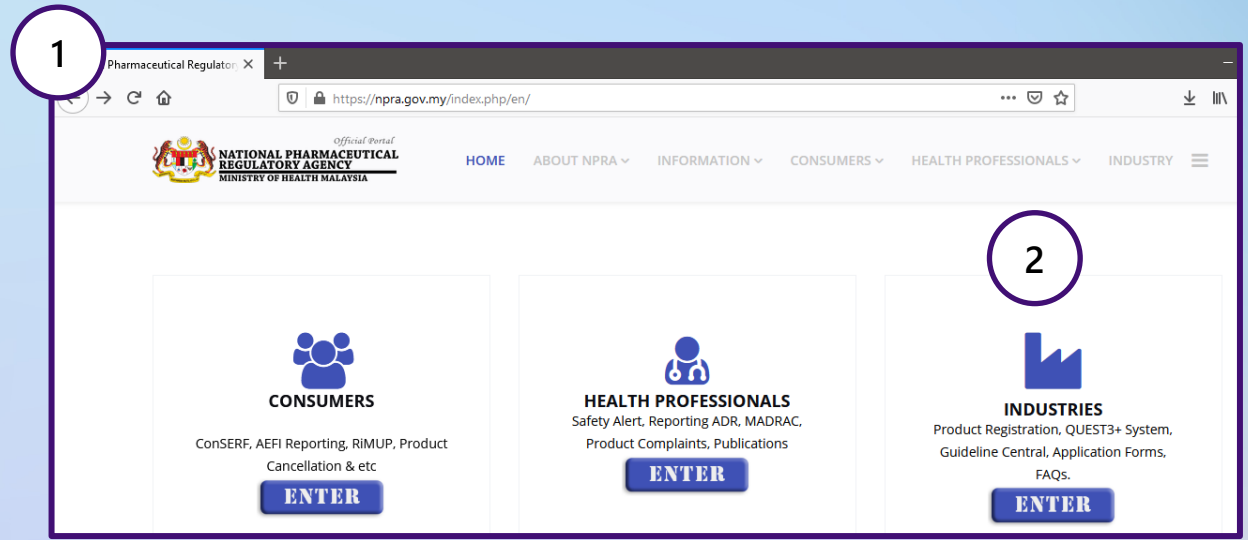
Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



1 Layari : <https://www.npra.gov.my/index.php/>

2 Klik pada ikon INDUSTRI / INDUSTRIES

3 Pilih DAFTAR MASUK KALI PERTAMA / FIRST TIME USER





4a Pilih PENGKELASAN PRODUK (Jika Perlu)

4b Pilih REGISTER USB TOKEN bagi pendaftaran AHLI (MEMBERSHIP)

5 Anda akan dibawa ke laman untuk pendaftaran

6 Isi borang berkaitan

4a 1.0 Product Classification

It is important to determine the category of a product that falls within the food-drug interphase (FDI) whether the products are regulated as drug (health supplement or natural product under the NPRA's purview) or, as food (under the FSQ's purview) because different regulatory requirements apply. Therefore, the following flowchart serves only as guide to help you determine the category of the product that falls within the FDI

- Product Classification Guideline (Drug or Food Products)
- Product Classification Guideline (Medical Device-Drug-Cosmetic Interphase Products)
- Product Classification Application Manual (NPRA 300.1)
- Product Classification Form (PDF)
- Product Classification Form (Ms Word)

4b 2.0 QUEST3+ System Basic

THE QUEST 3+ system has been fully utilized from January 2017 for the purpose of registration of medicines and cosmetics and licensing products in Malaysia. As of December 19, 2017, 23,817 drug products and 178,809 cosmetic products have been registered in Malaysia in QUEST 3+.

- Register USB Token
- Token & Java Configuration
- Example of Letter of Authorization for Membership Registration
- Payment Using Personal Account - B2C
- Payment Using Corporate Account - B2B
- Payment Using Credit Card
- User Manual for QUEST Module
- Internet Browser Configuration
- FAQ - MEMBERSHIP & TOKEN
- FAQ - QUEST ONLINE PAYMENT

5 User Registration Process for QUEST3+ Products Registration & Licensing System

POSTED BY JAUZE | 17 JULY 2018 | HITS: 57592

Registration for the QUEST 3+ System is simple, and no regulatory consultation would be required. Refer below for the 5 EASY STEPS to register.

6

5 EASY STEPS to register as a user for the QUEST 3+ System:

1. Go to QUEST3+ System Frontpage [HERE](#)
2. Apply for QUEST 3+ Membership Registration by clicking on [REGISTER HERE](#)
3. Approval email received from Quest 3+ Membership
4. Complete remaining steps at <https://www.msctrustgate.com/mytrustid/enrollment?q=quest3plus>

BIRO PENGAWALAN FARMASEUTIKAL
KEBANGSAAN (BPFK QUEST3+)

TRUSTGATE
SECURE TRANSACTIONS. TRUSTED SECURITY.

New Certificate Enrollment Request

Enrollment for new client digital ID for Biro Pengawalan Farmaseutikal Kebangsaan

- 1 Instructions
- 2 Application Info
- 3 Package & Pricing
- 4 Disclaimer
- 5 Payment
- 6 Complete



7

Membuat bayaran

8

Pengesahan Pengguna Sistem QUEST 3+ akan dihantar melalui emel

9

USB Token boleh diambil secara jumpa terus di MSC Trustgate (sebelum pukul 3 petang) atau secara penghantaran pos (yang akan mengambil masa sehingga 7 hari bekerja)

10

Selepas mendapat token, konfigurasi komputer boleh dibuat berpandukan *QUEST3+ User Manual*

7

products saved in the PAYMENT will be kept up to 30 calendar days only.
 1- To submit your payment, you need to select product that you want to pay.
 2- Once your payment is confirmed, your Cosmetic Notification will be processed by NPCB.
 3- The processing fee for each Cosmetic Notification is RM50.
 4- All payment made for PROCESSING FEE is not refundable.
 5- If payment receipt could not be printed, kindly retrieve the payment receipt from Payment History.

Pay to		
Company Name	National Pharmaceutical Control Bureau	
Address	Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia.	
Telephone No.	+603-7883 5400	

Product Ref #	Product Name	Fee (RM)
201608009020-V	Wet Tissue Sabtu Pagi (vanilla)	50.00
		TOTAL 50.00

Payment Type Personal account (B2C) Corporate Account (B2B) Credit Card

Previous Pay Online NOW

8



10

QUEST User Manual

POSTED BY JAUZE | 13 NOVEMBER 2018 | HITS: 21130

No.	Document Name
1	USER MANUAL QUEST 3+ Digital Certificate (USB Token) Installation, Configuration & Troubleshooting
2	USER MANUAL QUEST 3+ Digital Certificate (USB Token) Using Google Chrome
3	USER MANUAL QUEST 3+ System Module: MEMBERSHIP REGISTRATION
4	USER MANUAL QUEST 3+ System Module: HELPDESK
5	USER MANUAL QUEST 3+ System Module: COSMETIC NOTIFICATION
6	USER MANUAL QUEST 3+ System Module: PRODUCT REGISTRATION
7	USER MANUAL QUEST 3+ System Module: COMPLIANCE & LICENSING
8	USER MANUAL QUEST 3+ System Module: CHANGE OF SITE
9	USER MANUAL QUEST 3+ System Module: CHANGE OF HOLDER & CERTIFICATE OF PHARMA PRODUCTS
10	USER MANUAL QUEST 3+ System Module: VARIATION

9



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LANGKAH – LANGKAH

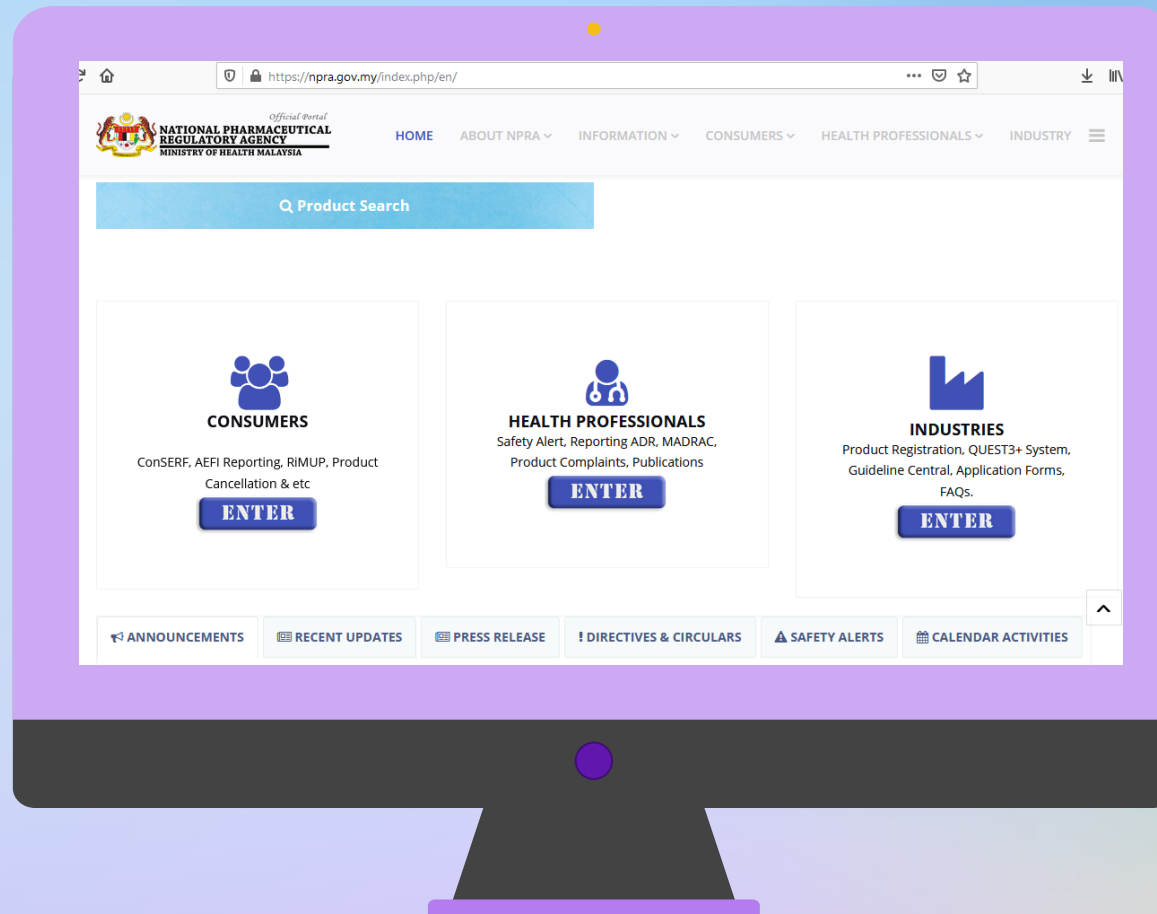
Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



1

Layari laman web :

<https://www.npra.gov.my/index.php/>

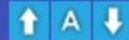


Oleh :
Cawangan Penguatkuasaan
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Bahagian Perkhidmatan Farmasi
Negeri Perlis



Pilihan bahasa boleh dibuat pada bahagian atas laman web :

Directory | Public | QUEST3+ System



Search ...



Official Portal
**NATIONAL PHARMACEUTICAL
REGULATORY AGENCY**
MINISTRY OF HEALTH MALAYSIA

HOME

ABOUT NPRA ▾

INFORMATION ▾

CONSUMERS ▾

HEALTH PROFESSIONALS ▾

INDUSTRY ▮



Bahasa Melayu



Bahasa Inggeris

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



2

Klik pada ikon :



INDUSTRI

Pendaftaran Produk,
Sistem QUEST3+, Garis
Panduan, Borang
Permohonan, FAQs

MASUK

Versi Bahasa Melayu



INDUSTRIES

Product Registration, QUEST3+ System,
Guideline Central, Application Forms,
FAQs.

ENTER

Versi Bahasa Inggeris



3

Pilih :

Industri & Halaman Utama Sistem QUEST3+
Sistem Pendaftaran Produk & Pelesenan

Daftar Masuk Kali Pertama | Log masuk Sistem QUEST3+ | Bantuan Helpdesk

E-Book Panduan Pendaftaran Produk Ubat (DRGD)

FIRST TIME USER

LOG IN QUEST

HELPDESK SUPPORT

DRGD EBOOK

STAFF LOG IN

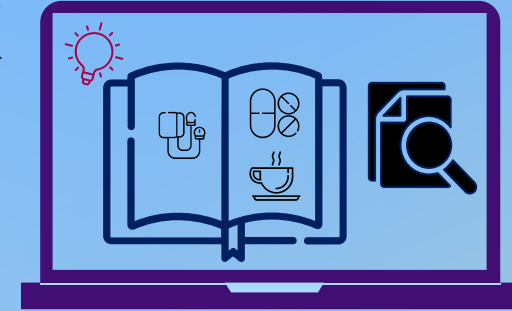
PRODUCT SEARCH

REPORTING ADR



4a

Pilih : PENGKELASAN PRODUK (JIKA PERLU)



1.0 Product Classification

It is important to determine the category of a product that falls within the food-drug interphase (FDI) whether the products are regulated as drug (health supplement or natural product under the NPRA's purview) or, as food (under the FSQ's purview) because different regulatory requirements apply. Therefore, the following flowchart serves only as guide to help you determine the category of the product that falls within the FDI

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Register USB Token

Token & Java Configuration

Example of Letter of Authorization for Membership Registration

Payment Using Personal Account - B2C

Payment Using Corporate Account - B2B

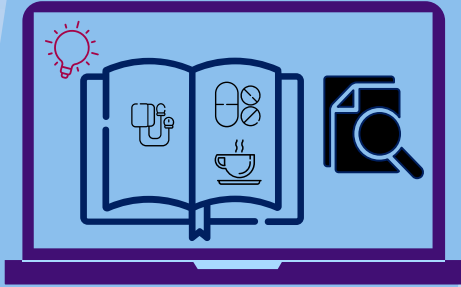
Payment Using Credit Card

User Manual for QUEST Module

Internet Browser Configuration

FAQ - MEMBERSHIP & TOKEN

FAQ - QUEST ONLINE PAYMENT



Pengkelasan Produk boleh dibuat sekiranya *pemohon tidak dapat menentukan* sesuatu produk itu dikategorikan sebagai ubat atau tidak, disebabkan produk tersebut jatuh dalam **salah satu** kategori berikut :

- ✓ Ubat
- ✓ Makanan
- ✓ *Food – Drug Interphase*
- ✓ *Medical Device – Drug Interphase*
- ✓ *Cosmetic – Drug Interphase*



Pengkelasan Produk boleh dilakukan dengan klik pada paparan berkaitan :

Official Portal
NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

HOME ABOUT NPRA ▾

1.0 Product Classification

It is important to determine the category of a product that falls within the food-drug interphase (FDI) whether the products are regulated as drug (health supplement or natural product under the NPRA's purview) or, as food (under the FSQ's purview) because different regulatory requirements apply. Therefore, the following flowchart serves only as guide to help you determine the category of the product that falls within the FDI

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- Product Classification Form (PDF)
- Product Classification Form (Ms Word)

Panduan Mengisi Borang Permohonan Pengkelasan Produk ada disediakan.


Fi pemprosesan adalah **RM300.00 per produk.**



Borang Permohonan Pengkelasan Produk boleh dimuat turun melalui laman web.

Contoh borang :

NPRA 300.1
Kemaskini: Februari 2020



Bahagian Regulatori Farmasi Negara (NPRA)
National Pharmaceutical Regulatory Agency (NPRA)
Lot 36, Jalan Universiti
46200 Petaling Jaya, Selangor.
No. Tel. Tel. No. : 03-78835400 No. Faks. Fax No. : 03-79571200
Laman Sesawang Website : npa.gov.my

PERMOHONAN PENKELASAN PRODUK

PRODUCT CLASSIFICATION APPLICATION

BAHAGIAN I : ARAHAN PART I : INSTRUCTIONS

- Sila isikan borang permohonan ini dengan HURUF BESAR dalam 1 salinan asal berdasarkan **Panduan Mengisi Borang Permohonan Pengkelasan Produk**.
Please fill in this application form in CAPITAL LETTERS in 1 original copy in accordance with the Product Classification Application Manual.
- Borang permohonan ini bersama fi pemrosesan hendaklah dikemukakan di kaunter ataupun melalui pos kepada **Unit Hasil & Kewangan, NPRA** (seperti alamat yang dinyatakan di atas).
The application form together with processing fee should be submitted at the counter or by post to Finance Unit, NPRA (per the above-mentioned address).

BAHAGIAN II : BUTIR-BUTIR PRODUK PART II : DETAILS OF PRODUCT

Nama Produk <i>Product Name</i>	
Bentuk Dos (cth: serbuk/cacair/tablet/tablet lutsiyah/kapsul/uncang teh dll.) <i>Dosage Form (e.g. powder/liquid/tablet/chewable tablet/capsule/tea bag etc.)</i>	
Indikasi/Kegunaan <i>Indication/Usage</i>	
Cara penggunaan <i>Instruction of use</i>	
Cara tindakan (Ustak produk interfasa peranti perubahan-ubat-kosmetik sahaja) <i>Mechanism of action (Applicable for medical device-drug-cosmetic interface products only)</i>	

Formula Lengkap Produk
Complete Product Formulation

(Sila nyatakan kandungan setiap bahan, nama saintifik, bentuk ramuan, bahagian digunakan, fungsi setiap bahan tersebut sama ada sebagai bahan makanan / aktif / eksipien / bahan sampingan seperti pewarna, perasa dan sebagainya, kuantiti dan peratus kompositi)
(Please state each ingredients, scientific names, form of substance, part used, function of each ingredient either as food / active or excipients, quantity and percentage of each ingredients)

Ramuan/ Nama Bahan Ingredient/ Substance	Nama Sainifik Scientific name	*Bentuk ramuan /Bahan Form of ingredient/ substance (e.g.extract, unextracted/ row)	*Bahagian digunakan Part used (e.g. fruit, bark,leaves)	Kegunaan Setiap Ramuan/ Bahan (cth : Bahan makanan / bahan aktif / eksipien / sampingan) Usage of each ingredient/ substance (e.g.Food/Active/Excipient)	Kuantiti / Kekuatan setiap ramuan / bahan (cth: g atau mg) Quantity/Strength of each ingredient /substance (e.g. g or mg)	Peratus setiap Ramuan/Bahan Percentage of each ingredient / substance

* Kolum ini hanya perlu diisi bagi ramuan/bahan dari sumber semulajadi cth: tumbuhan, haiwan, herba dll.
This column to be filled for substance/ingredient derived from natural sources eg: plant, animal, herbal

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



4b

Pilih :

REGISTER USB TOKEN bagi pendaftaran AHLI (MEMBERSHIP)

1.0 Product Classification

It is important to determine the category of a product that falls within the food-drug interphase (FDI) whether the products are regulated as drug (health supplement or natural product under the NPRA's purview) or, as food (under the FSQ's purview) because different regulatory requirements apply. Therefore, the following flowchart serves only as guide to help you determine the category of the product that falls within the FDI

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- Token & Java Configuration
- Example of Letter of Authorization for Membership Registration
- Payment Using Personal Account - B2C
- Payment Using Corporate Account - B2B
- Payment Using Credit Card
- User Manual for QUEST Module
- Internet Browser Configuration
- FAQ - MEMBERSHIP & TOKEN
- FAQ - QUEST ONLINE PAYMENT



5

Anda akan dibawa ke laman untuk pendaftaran

User Registration Process for QUEST3+ Products Registration & Licensing System

POSTED BY JAUZE | 17 JULY 2018 | HITS: 57592

Registration for the QUEST 3+ System is simple, and no regulatory consultant/agent* services should be required. Refer below for the 5 EASY STEPS to register.

5 EASY STEPS to register as a user for the QUEST 3+ System:

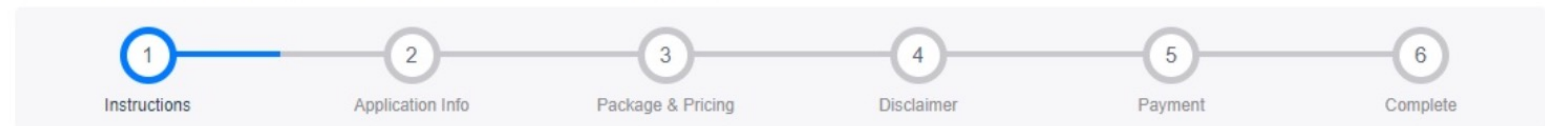
1. Go to QUEST3+ System Frontpage [HERE](#)
2. Apply for QUEST 3+ Membership Registration by clicking on [REGISTER HERE](#)
3. Approval email received from Quest 3+ Membership
4. Complete remaining steps at <https://www.msctrustgate.com/mytrustid/enrollment?q=quest3plus>

BIRO PENGAWALAN FARMASEUTIKAL
KEBANGSAAN (BPFK QUEST₃₊)



New Certificate Enrollment Request

Enrollment for new client digital ID for Biro Pengawalan Farmaseutikal Kebangsaan



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



6

Isi borang berkaitan :

User Registration Process for QUEST3+ Products Registration & Licensing System

POSTED BY JAUZE | 17 JULY 2018 | HITS: 57592

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BIRO PENGAWALAN FARMASEUTIKAL
KEBANGSAAN (BPFK QUEST3+)

TRUSTGATE
SECURE TRANSACTION. TRUSTED BUSINESS

New Certificate Enrollment Request

Enrollment for new client digital ID for Biro Pengawalan Farmaseutikal Kebangsaan

1

Instructions

2

Application Info

3

Package & Pricing

4

Disclaimer

5

Payment

6

Complete



QUEST 3+ Membership Registration

To conduct transactions for product registration, variation, licensing, renewal and other related transactions, you must register your membership and purchase your digital certificate in the form of USB token. Once you have obtained and installed your digital certificate, you will be able to conduct your transactions in QUEST 3+.

Step 1

FILL UP MEMBERSHIP
REGISTRATION FORM

Step 2

SELECT YOUR DIGITAL
CERTIFICATE PACKAGE

Step 3

MAKE PAYMENT TO
MSC TRUSTGATE

Step 4

RECEIVE/COLLECT YOUR
DIGITAL CERTIFICATE

Step 5

READY TO USE QUEST 3+

Please read and understand the Enrollment Instruction below:

- Log on to National Pharmaceutical Control Bureau website.
- Click on "Proceed" button to register your membership. Please take note that the membership registration form requires you to attach scanned images/picture (in JPEG or PDF format, with size below 2MB) as follows:
 - Your Company Registration Form with the Malaysian R.O.C.
 - Company Authorisation Letter (Official letter of authorisation by your company for you to conduct transaction on behalf of the company)
 - Your MyKad / Passport (front & back)
- Payment can be made via Internet payment Gateway (IPG) at MSC Trustgate's portal payment page
- Once your payment is confirmed by MSC Trustgate.com Sdn Bhd, your digital certificate will be couriered to you at the company address given in the membership registration form within 7 working days. You may also choose to self-collect the digital certificate at MSC Trustgate.com Sdn Bhd Head Quarters.

Once you have installed the Digital Certificate, which comes in a USB token, with your Digital Certificate ID, you are ready to conduct your transaction in QUEST 3+. Please follow the installation guide provided with the delivery. In case you require any technical support pertaining to USB Token installation, please contact the telephone number(s) or the email address given in the Installation Guide.

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



Proceed



Isi borang berikut :



QUEST 3+

Online System for
Product Registration, Cosmetic Notification, Licensing & Market Sampling

[Login](#) | [Register](#)

Membership & Digital Certificate Registration Form

COMPANY INFORMATION

Company Registration No. *

- Please use NEW SSM business registration number (e.g. 201901xxxxxx) if available.

201901xxxxxx OR 123456A

Company Name *



Company Registration Date *

Click to select

Business Type *

BERHAD

Office No. *

Example 0361418151

Fax No.

Example 0361418050

Company Address *



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



7

Membuat bayaran

Notes:

- 1- All products saved in the PAYMENT will be kept up to 30 calendar days only.
- 2- To submit your payment, you need to select product that you want to pay.
- 3- Once your payment is confirmed, your Cosmetic Notification will be processed by NPCB.
- 4- The processing fee for each Cosmetic Notification is RM50.
- 5- All payment made for PROCESSING FEE is not refundable.
- 6- If payment receipt could not be printed, kindly retrieve the payment receipt from Payment History.

Pay to

Company Name : National Pharmaceutical Control Bureau
Address : Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia.
Telephone No. : +603-7883 5400

Product Ref #	Product Name	Fee (RM)
2016080009020-V	Wet Tissue Sabtu Pagi (vanilla)	50.00

TOTAL 50.00

Payment Type Personal account (B2C) Corporate Account (B2B) Credit Card

Previous

Pay Online NOW



Cara pembayaran dalam Sistem QUEST 3+

- Register USB Token
- Token & Java Configuration
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3 jenis pembayaran yang boleh dibuat :

Notes:

- 1- All products saved in the PAYMENT will be kept up to 30 calendar days only.
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[Previous](#) [Pay Online NOW](#)



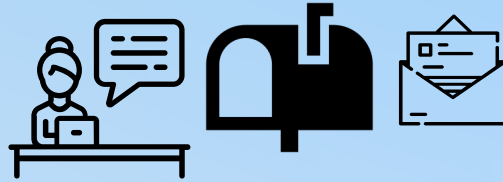
8



Pengesahan Pengguna Sistem QUEST 3+ akan dihantar melalui emel.



9

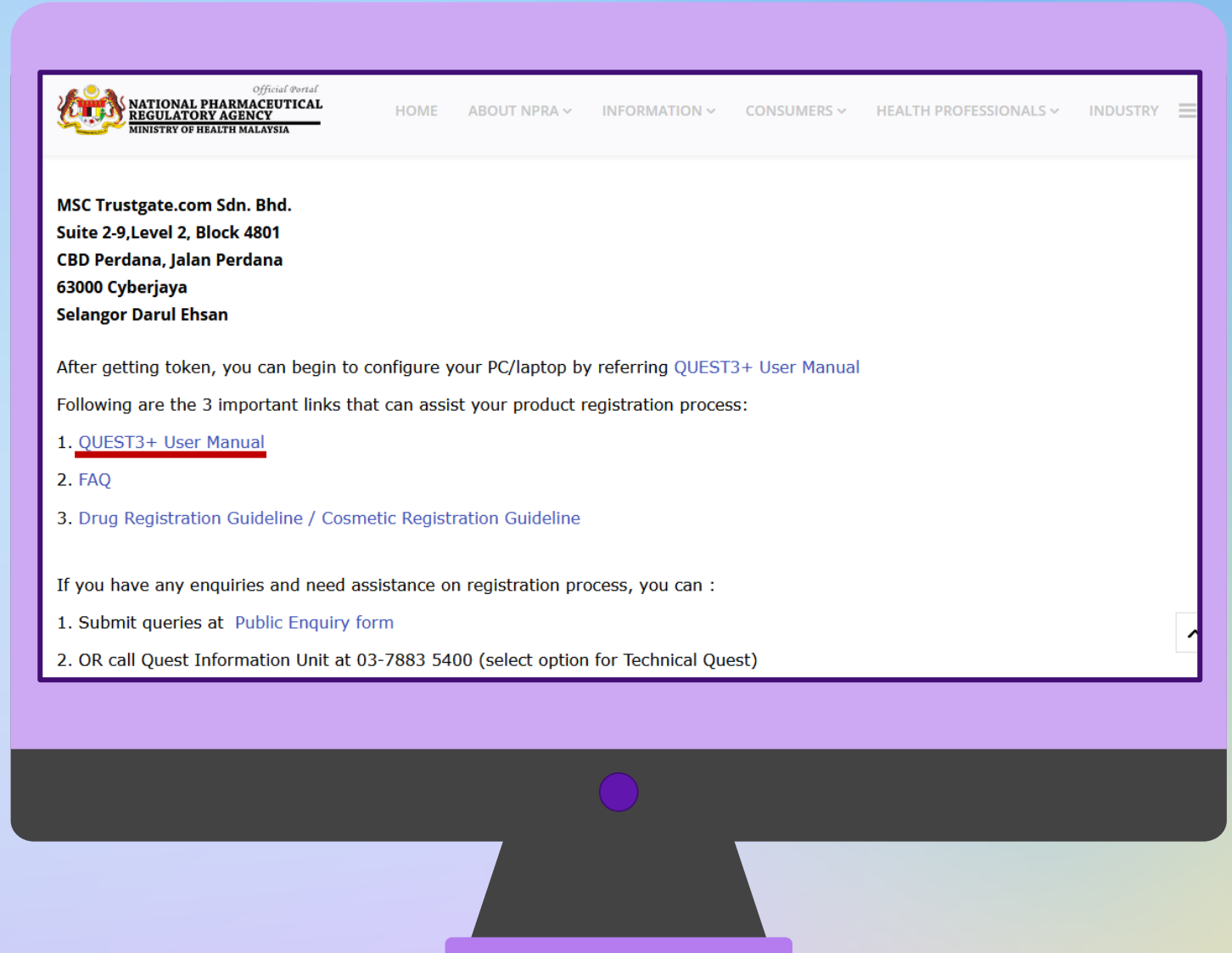


USB Token boleh diambil secara jumpa terus di MSC Trustgate (sebelum pukul 3 petang) atau secara penghantaran pos (yang akan mengambil masa sehingga 7 hari bekerja)



10

Selepas mendapat token, konfigurasi komputer boleh dibuat berpandukan *QUEST3+ User Manual*



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



QUEST3+ *User Manual* ini disediakan dengan penerangan setiap langkah yang dilengkapi *screenshot* daripada laman web beserta penjelasan.

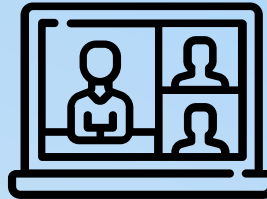
QUEST User Manual

POSTED BY JAUZE | 13 NOVEMBER 2018 | HITS: 21130

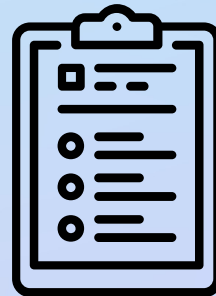
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10	USER MANUAL QUEST 3+ System Module: VARIATION



Maklumat yang boleh diperolehi di laman web NPRA



Kenalpasti pengilang berlesen, pemborong berlesen, pengimport atau pengilang kosmetik sekiranya perlu.



Maklumat Pendaftaran Produk



Maklumat pada paparan seterusnya adalah **ringkasan** daripada *Drug Registration Guidance Document (DRGD)*, Third Edition, January 2021 yang boleh dimuat turun dari laman web NPRA

Bil	Kategori Produk	Dokumen yang Diperlukan	Bayaran Pemprosesan (RM)	Bayaran Analisa (Bahan : RM)	Jumlah Bayaran (RM)	Tempoh Penilaian (Hari Bekerja)
1	Produk Ubat Baru	1. Paten / Status <i>Data Exclusivity</i> 2. <i>Registration Dossier</i> dalam format ICH CTD / ASEAN CTD 3. Sijil GMP 4. Sijil CPP (produk import) 5. Maklumat berkaitan <i>Active Pharmaceutical Ingredient</i> 6. <i>Process Validation Report</i> 7. <i>Analytical Validation Report</i>	1000	1 bahan aktif: 3000 2 / > bahan aktif: 4000	4000 5000	245 (NCE) 210 (Hybrid)



Bil	Kategori Produk	Dokumen yang Diperlukan	Bayaran Pemprosesan (RM)	Bayaran Analisa (Bahan : RM)	Jumlah Bayaran (RM)	Tempoh Penilaian (Hari Bekerja)
2	Biologik	1. Paten / Status Data Exclusivity 2. Registration Dossier dalam format ICH CTD / ASEAN CTD 3. Sijil GMP 4. Sijil CPP (produk import) 5. Maklumat berkaitan <i>Active Pharmaceutical Ingredient</i> 6. <i>Process Validation Report</i> 7. <i>Analytical Validation Report</i>	1000	1 bahan aktif: 3000 2 / > bahan aktif: 4000	4000 5000	245



Bil	Kategori Produk	Dokumen yang Diperlukan	Bayaran Pemprosesan (RM)	Bayaran Analisa (Bahan : RM)	Jumlah Bayaran (RM)	Tempoh Penilaian (Hari Bekerja)
3	Generik (Racun Berjadual)	<ol style="list-style-type: none"> 1. Paten / Status Data Exclusivity 2. Registration Dossier dalam format ICH CTD / ASEAN CTD 3. Sijil GMP 4. Sijil CPP (produk import) 5. Maklumat berkaitan Active Pharmaceutical Ingredient 6. Stability Data 7. Process Validation Report 8. Analytical Validation Report 9. Bioequivalence Study Report 	1000	1 bahan aktif: 1200 2 / > bahan aktif: 2000	2200 3000	210



Bil	Kategori Produk	Dokumen yang Diperlukan	Bayaran Pemprosesan (RM)	Bayaran Analisa (Bahan : RM)	Jumlah Bayaran (RM)	Tempoh Penilaian (Hari Bekerja)
4	Generik (Racun Tidak Berjadual)	1. Paten / Status Data Exclusivity 2. Registration Dossier dalam format ICH CTD / ASEAN CTD 3. Sijil GMP 4. Sijil CPP (produk import) 5. Maklumat berkaitan Active Pharmaceutical Ingredient 6. Stability Data 7. Process Validation Report 8. Analytical Validation Report 9. Bioequivalence Study Report	1000	1 bahan aktif : 1200 2 / > bahan : 2000	2200 3000	Penilaian Penuh : 210 Penilaian Ringkas : 116 Penilaian Penuh : 210 Penilaian Ringkas : 136



Bil	Kategori Produk	Dokumen yang Diperlukan	Bayaran Pemprosesan (RM)	Bayaran Analisa (Bahan : RM)	Jumlah Bayaran (RM)	Tempoh Penilaian (Hari Bekerja)
5	Suplemen Kesihatan a) Tuntutan am atau pemakanan	1. Sijil GMP 2. Sijil CFS 3. Sijil CPP (produk import)	1000	1 bahan aktif: 1200	2200	116
	b) Tuntutan berfungsi (Sederhana)			2 / > bahan aktif: 2000	3000	136
	c) Tuntutan pengurangan risiko (Tinggi)					245



Bil	Kategori Produk	Dokumen yang Diperlukan	Bayaran Pemprosesan (RM)	Bayaran Analisa (Bahan : RM)	Jumlah Bayaran (RM)	Tempoh Penilaian (Hari Bekerja)
6	Produk Semulajadi	1. Sijil GMP 2. Sijil CFS 3. Sijil CPP (produk import) 4. Sijil Analisa (Certificate of Analysis)	500	700	1200	1 bahan aktif: 116
	Produk Semulajadi dengan Tuntutan Terapeutik		1000	1 bahan aktif: 3000	4000	2 / > bahan: 136
				2 / > bahan aktif: 4000	5000	245



Bil	Kategori Produk	Dokumen yang Diperlukan	Bayaran (RM)	Tempoh Penilaian (Hari Bekerja)
7	Produk Veterinar a) Produk Innovator / NCE	1. Registration Dossiers dalam format CTD / ASEAN CTD 2. Sijil GMP 3. Sijil CPP (produk import) 4. Drug Master File atau Sijil CEP 5. Stability data 6. Process Validation Report 7. Analytical Validation Report	1500	225
	b) Generik (Racun Berjadual)		1500 (Untuk eksport sahaja: 500)	190
	c) Generik (Racun Tidak Berjadual / OTC)		1500 (Untuk eksport sahaja: 500)	190



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Muka surat ini sengaja dibiarkan kosong



Prosedur Notifikasi Kosmetik

Bahagian ini menerangkan dengan lebih lanjut mengenai :

Prosedur Notifikasi



Maklumat Notifikasi



Yuran Pemprosesan



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis

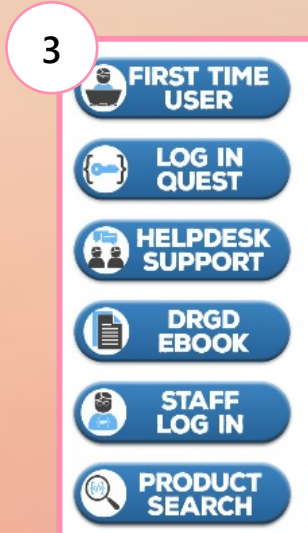
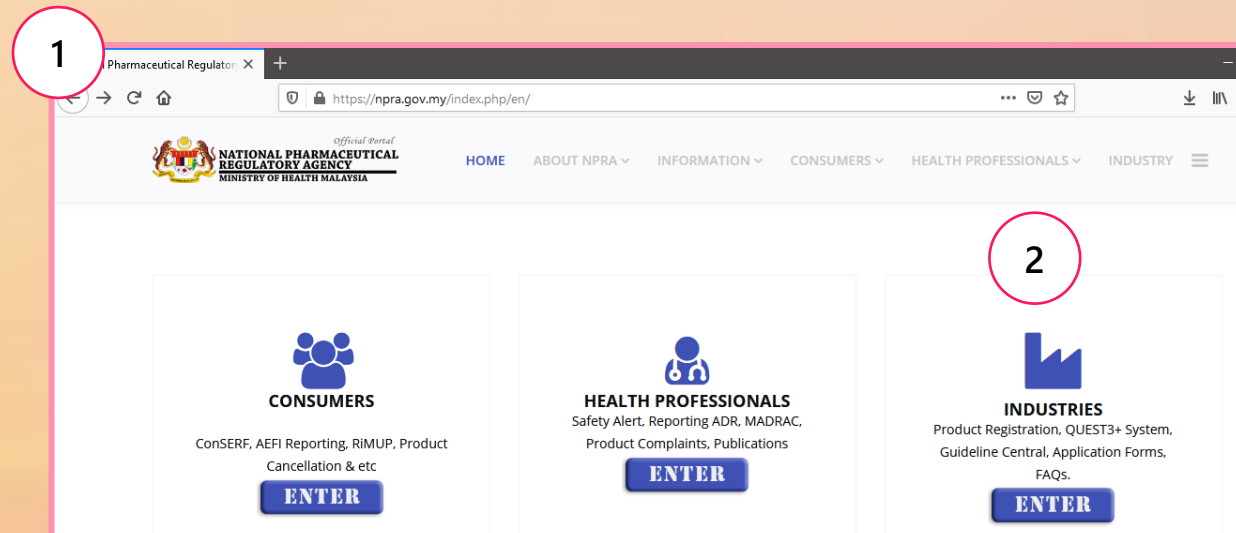


PROSEDUR NOTIFIKASI

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



- 1 Layari : <https://www.npra.gov.my/index.php/>
- 2 Klik pada ikon INDUSTRI / INDUSTRIES
- 3 Pilih DAFTAR MASUK KALI PERTAMA / FIRST TIME USER



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



4 Pilih REGISTER USB TOKEN bagi pendaftaran AHLI (MEMBERSHIP)

5 Anda akan dibawa ke laman untuk pendaftaran

6 Isi borang berkaitan

4

1.0 Product Classification

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5

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POSTED BY JAUZE | 17 JULY 2018 | HITS: 57592

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BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN (BPFK QUEST3+)

TRUSTGATE
SECURE TRANSACTIONS. TRUSTED SECURITY.

New Certificate Enrollment Request

Enrollment for new client digital ID for Biro Pengawalan Farmaseutikal Kebangsaan

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



7

Membuat bayaran

8

Pengesahan Pengguna Sistem QUEST 3+ akan dihantar melalui emel

9

USB Token boleh diambil secara jumpa terus di MSC Trustgate (sebelum pukul 3 petang) atau secara penghantaran pos (yang akan mengambil masa sehingga 7 hari bekerja)

10

Selepas mendapat token, konfigurasi komputer boleh dibuat berpandukan *QUEST3+ User Manual*

7

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Telephone No.	:	+603-7883 5400

Product Ref #	Product Name	Fee (RM)
201608009020-V	Wet Tissue Sabtu Pagi (vanilla)	50.00
		TOTAL 50.00

Payment Type Personal account (B2C) Corporate Account (B2B) Credit Card

[Previous](#) [Pay Online NOW](#)

8



10

QUEST User Manual

POSTED BY JAUZE | 13 NOVEMBER 2018 | HITS: 21130

No.	Document Name
1	USER MANUAL QUEST 3+ Digital Certificate (USB Token) Installation, Configuration & Troubleshooting
2	USER MANUAL QUEST 3+ Digital Certificate (USB Token) Using Google Chrome
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9	USER MANUAL QUEST 3+ System Module: CHANGE OF HOLDER & CERTIFICATE OF PHARMA PRODUCTS
10	USER MANUAL QUEST 3+ System Module: VARIATION

9



Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis

Muka surat ini sengaja dibiarkan kosong



LANGKAH – LANGKAH

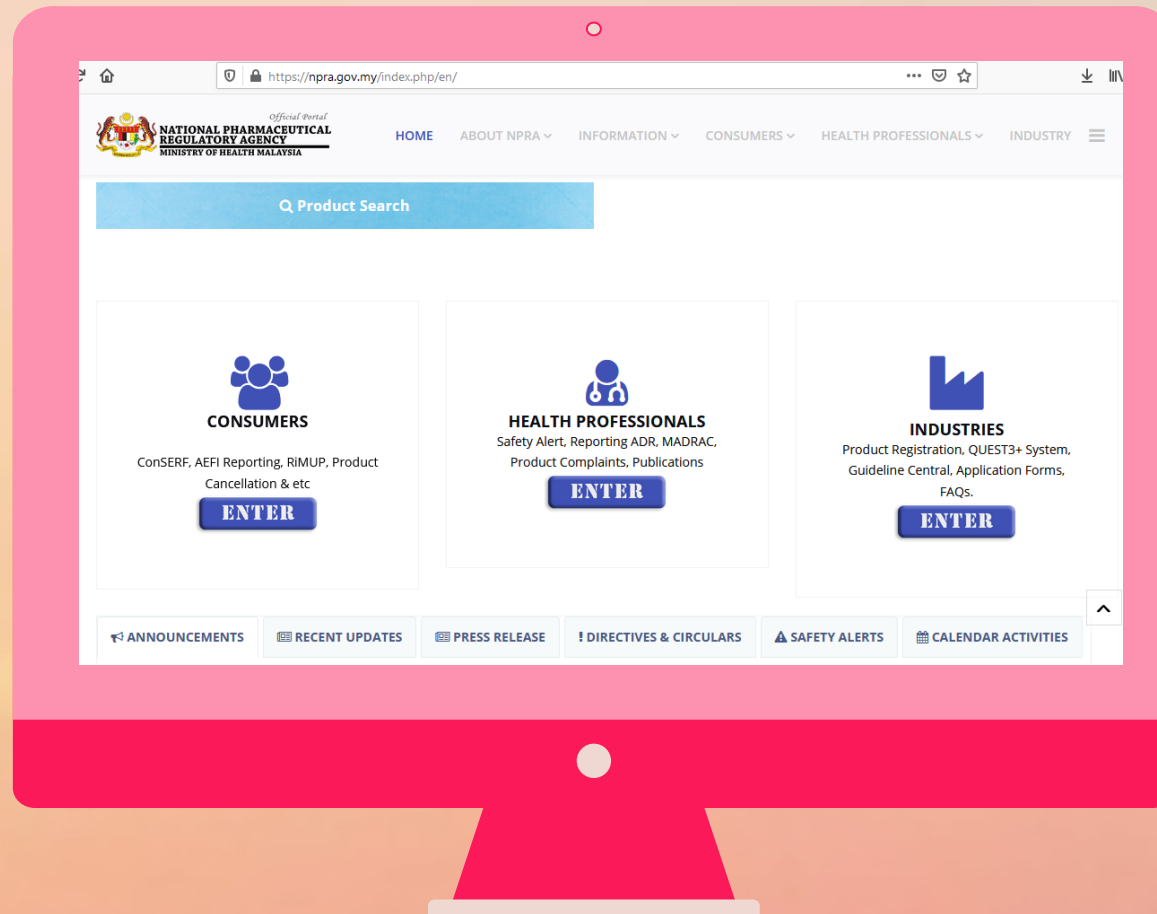
Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



1

Layari laman web :

<https://www.npra.gov.my/index.php/>

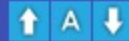


Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



Pilihan bahasa boleh dibuat pada bahagian atas laman web :

Directory | Public | QUEST3+ System



Search ...



Official Portal
**NATIONAL PHARMACEUTICAL
REGULATORY AGENCY**
MINISTRY OF HEALTH MALAYSIA

HOME

ABOUT NPRA ▾

INFORMATION ▾

CONSUMERS ▾

HEALTH PROFESSIONALS ▾

INDUSTRY ▮



Bahasa Melayu



Bahasa Inggeris

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



2

Klik pada ikon :



INDUSTRI

Pendaftaran Produk,
Sistem QUEST3+, Garis
Panduan, Borang
Permohonan, FAQs

MASUK

versi Bahasa
Melayu



INDUSTRIES

Product Registration, QUEST3+ System,
Guideline Central, Application Forms,
FAQs.

ENTER

versi Bahasa
Inggeris



3

Pilih :

Industri & Halaman Utama Sistem QUEST3+
Sistem Pendaftaran Produk & Pelesenan

Daftar Masuk Kali Pertama | Log masuk Sistem QUEST3+ | Bantuan Helpdesk

E-Book Panduan Pendaftaran Produk Ubat (DRGD)

FIRST TIME USER

LOG IN QUEST

HELPDESK SUPPORT

DRGD EBOOK

STAFF LOG IN

PRODUCT SEARCH

REPORTING ADR

Oleh :
Cawangan Penguatkuasaan
Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



4

Pilih :

REGISTER USB TOKEN bagi pendaftaran AHLI (MEMBERSHIP)

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- FAQ - MEMBERSHIP & TOKEN
- FAQ - QUEST ONLINE PAYMENT



5

Anda akan dibawa ke laman untuk pendaftaran

User Registration Process for QUEST3+ Products Registration & Licensing System

POSTED BY JAUZE | 17 JULY 2018 | HITS: 57592

Registration for the QUEST 3+ System is simple, and no regulatory consultant/agent* services should be required. Refer below for the 5 EASY STEPS to register.

5 EASY STEPS to register as a user for the QUEST 3+ System:

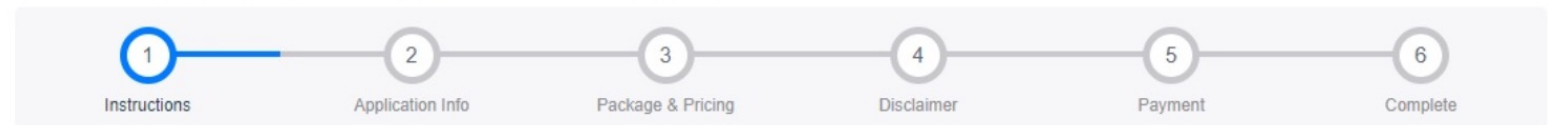
1. Go to QUEST3+ System Frontpage [HERE](#)
2. Apply for QUEST 3+ Membership Registration by clicking on [REGISTER HERE](#)
3. Approval email received from Quest 3+ Membership
4. Complete remaining steps at <https://www.msctrustgate.com/mytrustid/enrollment?q=quest3plus>

BIRO PENGAWALAN FARMASEUTIKAL
KEBANGSAAN (BPFK QUEST3+)



New Certificate Enrollment Request

Enrollment for new client digital ID for Biro Pengawalan Farmaseutikal Kebangsaan



Oleh :
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Farmasi (CPF)
Bahagian Perkhidmatan Farmasi
Negeri Perlis



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Isi borang berkaitan :

User Registration Process for QUEST3+ Products Registration & Licensing System

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BIRO PENGAWALAN FARMASEUTIKAL
KEBANGSAAN (BPFK QUEST3+)

TRUSTGATE
SECURE TRANSACTION. TRUSTED BUSINESS

New Certificate Enrollment Request

Enrollment for new client digital ID for Biro Pengawalan Farmaseutikal Kebangsaan

1

Instructions

2

Application Info

3

Package & Pricing

4

Disclaimer

5

Payment

6

Complete



QUEST 3+ Membership Registration

To conduct transactions for product registration, variation, licensing, renewal and other related transactions, you must register your membership and purchase your digital certificate in the form of USB token. Once you have obtained and installed your digital certificate, you will be able to conduct your transactions in QUEST 3+.

Step 1

FILL UP MEMBERSHIP
REGISTRATION FORM

Step 2

SELECT YOUR DIGITAL
CERTIFICATE PACKAGE

Step 3

MAKE PAYMENT TO
MSC TRUSTGATE

Step 4

RECEIVE/COLLECT YOUR
DIGITAL CERTIFICATE

Step 5

READY TO USE QUEST 3+

Please read and understand the Enrollment Instruction below:

- Log on to National Pharmaceutical Control Bureau website.
- Click on "Proceed" button to register your membership. Please take note that the membership registration form requires you to attach scanned images/picture (in JPEG or PDF format, with size below 2MB) as follows:
 - Your Company Registration Form with the Malaysian R.O.C.
 - Company Authorisation Letter (Official letter of authorisation by your company for you to conduct transaction on behalf of the company)
 - Your MyKad / Passport (front & back)
- Payment can be made via Internet payment Gateway (IPG) at MSC Trustgate's portal payment page
- Once your payment is confirmed by MSC Trustgate.com Sdn Bhd, your digital certificate will be couriered to you at the company address given in the membership registration form within 7 working days. You may also choose to self-collect the digital certificate at MSC Trustgate.com Sdn Bhd Head Quarters.

Once you have installed the Digital Certificate, which comes in a USB token, with your Digital Certificate ID, you are ready to conduct your transaction in QUEST 3+. Please follow the installation guide provided with the delivery. In case you require any technical support pertaining to USB Token installation, please contact the telephone number(s) or the email address given in the Installation Guide.



Proceed



Isi borang berikut :



QUEST 3+

Online System for
Product Registration, Cosmetic Notification, Licensing & Market Sampling

[Login](#) | [Register](#)

Membership & Digital Certificate Registration Form

COMPANY INFORMATION

Company Registration No. *

- Please use NEW SSM business registration number (e.g. 201901xxxxxx) if available.

201901xxxxxx OR 123456A

Company Name *



Company Registration Date *

Click to select

Business Type *

BERHAD

Office No. *

Example 0361418151

Fax No.

Example 0361418050

Company Address *



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Membuat bayaran

Notes:

- 1- All products saved in the PAYMENT will be kept up to 30 calendar days only.
- 2- To submit your payment, you need to select product that you want to pay.
- 3- Once your payment is confirmed, your Cosmetic Notification will be processed by NPCB.
- 4- The processing fee for each Cosmetic Notification is RM50.
- 5- All payment made for PROCESSING FEE is not refundable.
- 6- If payment receipt could not be printed, kindly retrieve the payment receipt from Payment History.

Pay to

Company Name : National Pharmaceutical Control Bureau
Address : Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia.
Telephone No. : +603-7883 5400

Product Ref #	Product Name	Fee (RM)
2016080009020-V	Wet Tissue Sabtu Pagi (vanilla)	50.00

TOTAL 50.00

Payment Type Personal account (B2C) Corporate Account (B2B) Credit Card

Previous

Pay Online NOW



Cara pembayaran dalam Sistem QUEST 3+

- Register USB Token
- Token & Java Configuration
- Example of Letter of Authorization for Membership Registration
- Payment Using Personal Account - B2C
- Payment Using Corporate Account - B2B
- Payment Using Credit Card
- User Manual for QUEST Module
- Internet Browser Configuration
- FAQ - MEMBERSHIP & TOKEN
- FAQ - QUEST ONLINE PAYMENT



3 jenis pembayaran yang boleh dibuat :

Notes:

- 1- All products saved in the PAYMENT will be kept up to 30 calendar days only.
- 2- To submit your payment, you need to select product that you want to pay.
- 3- Once your payment is confirmed, your Cosmetic Notification will be processed by NPCB.
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Previous

Pay Online NOW



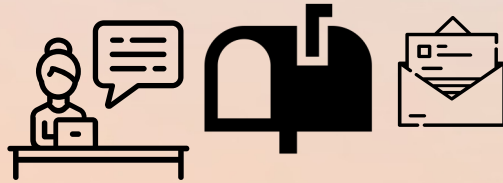
8



Pengesahan Pengguna Sistem QUEST 3+ akan dihantar melalui emel.



9



USB Token boleh diambil secara jumpa terus di MSC Trustgate (sebelum pukul 3 petang) atau secara penghantaran pos (yang akan mengambil masa sehingga 7 hari bekerja)



10

Selepas mendapat token, konfigurasi komputer boleh dibuat berpandukan *QUEST3+ User Manual*

Official Portal
NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

HOME ABOUT NPRA INFORMATION CONSUMERS HEALTH PROFESSIONALS INDUSTRY

MSC Trustgate.com Sdn. Bhd.
Suite 2-9, Level 2, Block 4801
CBD Perdana, Jalan Perdana
63000 Cyberjaya
Selangor Darul Ehsan

After getting token, you can begin to configure your PC/laptop by referring [QUEST3+ User Manual](#)

Following are the 3 important links that can assist your product registration process:

1. [QUEST3+ User Manual](#)
2. [FAQ](#)
3. [Drug Registration Guideline / Cosmetic Registration Guideline](#)

If you have any enquiries and need assistance on registration process, you can :

1. Submit queries at [Public Enquiry form](#)
2. OR call Quest Information Unit at 03-7883 5400 (select option for Technical Quest)

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QUEST3+ *User Manual* ini disediakan dengan penerangan setiap langkah yang dilengkapi *screenshot* daripada laman web beserta penjelasan.

QUEST User Manual

POSTED BY JAUZE | 13 NOVEMBER 2018 | HITS: 21130

No.	Document Name
1	USER MANUAL QUEST 3+ Digital Certificate (USB Token) Installation, Configuration & Troubleshooting
2	USER MANUAL QUEST 3+ Digital Certificate (USB Token) Using Google Chrome
3	USER MANUAL QUEST 3+ System Module: MEMBERSHIP REGISTRATION
4	USER MANUAL QUEST 3+ System Module: HELPDESK
5	USER MANUAL QUEST 3+ System Module: COSMETIC NOTIFICATION
6	USER MANUAL QUEST 3+ System Module: PRODUCT REGISTRATION
7	USER MANUAL QUEST 3+ System Module: COMPLIANCE & LICENSING
8	USER MANUAL QUEST 3+ System Module: CHANGE OF SITE
9	USER MANUAL QUEST 3+ System Module: CHANGE OF HOLDER & CERTIFICATE OF PHARMA PRODUCTS
10	USER MANUAL QUEST 3+ System Module: VARIATION

Muka surat ini sengaja dibiarkan kosong



MAKLUMAT NOTIFIKASI

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Buka laman web :

<https://www.npra.gov.my/index.php/en/>



Official Portal
NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

HOME ABOUT NPRA INFORMATION CONSUMERS HEALTH PROFESSIONALS **INDUSTRY**

Product Categories

Browse Guidelines, Directives, Circulars, Announcements and Application Forms according to Product Categories

 COSMETICS Any preparation intended to be placed in...	 NATURAL PRODUCTS Traditional (General) &	 GENERIC MEDICINES Bioequivalence (BE), Prescription (Full) Non-	 BIOLOGICS Biological/Biotech/Biosimilar, Vaccines, Blood
---	--	---	--

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Tempoh Validiti Notifikasi : 2 tahun

Pembaharuan perlu dilakukan tidak kurang dari **satu (1) bulan** tarikh luput notifikasi

Sebarang perubahan pada produk yang telah dinotifikasi perlu dihantar ke NPRA.

Terdapat 2 jenis pindaan iaitu:

Jenis Perkara	1	2
Keterangan	Pindaan yang masih mengekalkan nombor notifikasi semasa	Pindaan yang memerlukan nombor notifikasi baru
Bayaran	Tiada	RM50 (yuran pemprosesan)

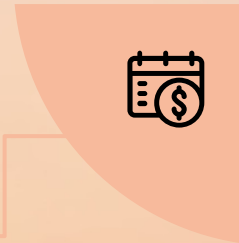


Nombor Notifikasi

Nombor notifikasi adalah unik bagi setiap produk dan variant(jika ada) seperti di dalam format berikut :

NOTyymmxxxxxK

(y: year, m: month, x: serial number)



Yuran

Yuran pemprosesan :

RM50.00 bagi setiap produk kosmetik (dan variant jika ada)

Yuran pemprosesan **pembaharuan** notifikasi bagi setiap satu produk kosmetik (dan variant jika ada) RM50.00

Setiap pembayaran **TIDAK** akan dipulangkan sekiranya permohonan telah dihantar dan bayaran telah dilakukan.



Untuk penjelasan yang lebih lanjut, pengguna boleh muat turun :



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<https://www.npra.gov.my/index.php/en/cosmetic-main-page.html>



**Cawangan Penguatkuasaan Farmasi (CPF)
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