Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj. Kami : (3) dlm. BPFK/PPP/07/25
Tarikh : 03 JUN 2013

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984 (PINDAAN 2006) ARAHAN PENGARAH KANAN PERKHIDMATAN FARMASI BILANGAN 4 TAHUN 2013: DIREKTIF UNTUK MEMINDA PROSEDUR PERMOHONAN PERTUKARAN PEMEGANG PENDAFTARAN

Adalah saya merujuk kepada Arahan Bilangan 4 tahun 2013 oleh Pengarah Kanan Perkhidmatan Farmasi.

2. Dimaklumkan bahawa Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia dalam Arahan Bilangan 4 Tahun 2013 telah bersetuju untuk meminda Prosedur Permohonan Pertukaran Pemegang Pendaftaran seperti pada surat arahan Bil. (3) BPFK/PPP/07/25.

3. Pihak pemegang pendaftaran adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

TAN ANN LING
Pengarah Regulatori Farmasi
Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

rn/nb/ppp/bpfk/070513

s.k. Pengarah Amalan dan Perkembangan Farmasi, BPF
Pengarah Penguatkuasa Farmasi, BPF
Timbalan Pengarah Pusat Pendaftaran Produk, BPFK
Timbalan Pengarah Pusat Pasca Pendaftaran Produk, BPFK

Jalan Universiti. P. O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia
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http : //www.bpfk.gov.my

BPFK/PPP/07/25(3)

ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

BILANGAN 4 TAHUN 2013

DIREKTIF UNTUK MEMINDA PROSEDUR PERMOHONAN PERTUKARAN PEMEGANG PENDAFTARAN

TUJUAN

1.1 Arahan ini bertujuan untuk menguatkuasakan pindaan prosedur permohonan pertukaran pemegang pendaftaran.

1.2 Peraturan 29 dalam Peraturan – Peraturan Kawalan Dadah dan Kosmetik 1984 (Pindaan 2006) memberi kuasa kepada Pengarah Kanan Perkhidmatan Farmasi untuk mengeluarkan arahan ini.

LATAR BELAKANG

2.1 Berdasarkan asas bahawa pemegang pendaftaran adalah bertanggungjawab selaku pemegang pendaftaran untuk menguruskan segala urusan pendaftaran dan pemasaran produk, Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuaratnya kali ke **263** pada **29 April 2013** telah bersetuju untuk meminda prosedur permohonan pertukaran pemegang pendaftaran (rujukan *Drug Registration Guidance Document,* 16.3 *Change of Product Registration Holder*) yang melibatkan permohonan untuk pertukaran pemegang pendaftaran di mana permohonan perlu dikemukakan oleh pemegang pendaftaran sediaada produk berkenaan.

PELAKSANAAN

3.1 Permohonan pertukaran pemegang pendaftaran perlu dikemukakan oleh **pemegang pendaftaran sediaada.**

3.2 Pendaftaran produk boleh dibatalkan oleh PBKD sekiranya pemilik produk membatalkan pelantikan pemegang pendaftaran sediaada dengan mengemukakan *Letter of Termination (LOT)*. Ini kerana syarat pendaftaran di bawah Peraturan 8(1), Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984 tidak lagi dipenuhi iaitu tiada pemegang pendaftaran yang sah.

3.3 Pemilik produk perlu mengemukakan pendaftaran baru sekiranya ingin meneruskan pendaftaran produk yang sama tetapi melalui pemegang pendaftaran yang baru.

3.4 Prosedur baru permohonan pertukaran pemegang pendaftaran adalah seperti di Lampiran I.

3.5 Tarikh pelaksanaan bagi prosedur baru permohonan pertukaran pemegang pendaftaran berkuatkuasa mulai pada **3 April 2013**.

"BERKHIDMAT UNTUK NEGARA"

DATO' EISAH A. RAHMAN
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia.

s.k.:
Pengarah Amalan dan Perkembangan Farmasi
Pengarah Penguatkuasa Farmasi
Pengarah Regulatori Farmasi

16.3 CHANGE OF PRODUCT REGISTRATION HOLDER

16.3.1 INTRODUCTION

A transfer procedure shall be used where a product registration for the purpose of marketing authorization to be transferred from the existing product registration holder (PRH) to another holder. This procedure allows the same product to maintain the same registration number.

Upon receipt of complete application, the application shall be processed within forty-five (45) working days.

16.3.2 CONDITIONS

The conditions for the PRH transfer procedure are as follows:

1. An application to transfer the marketing authorization of a product shall be submitted by the **existing PRH**.
2. The new PRH shall be a registered company/ business with Companies Commissioner of Malaysia and a registered QUEST user with National Pharmaceutical Control Bureau (NPCB).
3. The existing product registration shall have a remaining validity **period of at least six (6) months**. If the period is less than six (6) months, product registration renewal shall be made before the transfer application is submitted.
4. No change/s can be made to the technical data or approved pharmaceutical / pharmacological information, including the texts of the product label and leaflet, **except** the name and address of the approved PRH, unless made through variation procedure.
5. In the interim, the existing PRH is still vested with the marketing authorization of the said registered product.
6. The transfer shall come into effect on the day the DCA makes its decision on the application. Upon the transfer of product registration to the new PRH, the authorization issued to the previous PRH will be cancelled as the product cannot be marketed simultaneously by two different PRHs. The new PRH shall bear responsibility for the said product.
7. However, the existing PRH is allowed to deplete the stocks and still holds the responsibility in the event of pharmacovigilance issues or quality defects associated with the product arises during the interim transfer period.

8. The existing PRH or new approved PRH shall submit a written request to deplete existing stocks after DCA approval for the transfer. The PRH who submitted the request shall hold the responsibility in the event of pharmacovigilance issues or quality defects associated with the product.
9. Application shall be rejected if the applicant fails to provide satisfactory required documents within 30 working days starting from the first correspondence date.

16.3.3 APPLICATION

The existing PRH shall submit the following documents and payment to NPCB:

1. Application Form BPFK-430.5
2. *Borang Penyerahan Permohonan* BPFK-001
3. Processing Fee (refer 16.3.4)
4. Original Supporting Documents (refer 16.3.5)

16.3.4 PROCESSING FEE

1. NON-REFUNDABLE processing fee.
   - Traditional Product : RM 500.00
   - Poison/ Non-Poison product : RM 1,000.00
2. The processing fee shall be paid in the form of a bank draft/ money order/ postal order, made payable to "Biro Pengawalan Farmaseutikal Kebangsaan".
3. Application/s without correct processing fee will not be accepted for processing. Foreign currencies are not acceptable.

16.3.5 SUPPORTING DOCUMENTS

1. All supporting documents shall be produced in ORIGINAL copies as listed below:

LIST OF REQUIRED SUPPORTING DOCUMENTS:

i) Letter of Authorisation (LOA) issued by overseas product owner **certified by Notary Public from the country of origin of the product owner; or**

Malaysia Commissioner for Oath for local product owner and **shall consists** of the following information:

a. The registered name and registration number of the product(s) concerned.
b. Company name, business registration number and address of the proposed new PRH.
c. Company name, business registration number and address of the existing PRH.
d. Effective date of the appointment and termination given by the product owner. If the effective date is not mentioned, the date of the LOA issued will be considered as the effective date.
e. Signature of the Managing Director/ Director/ President/ Chief Executive Officer/ General Manager who has overall responsibility for the company or organization.
f. Full and complete address, email address (if available), telephone and fax number (if available) of the Product Owner.

**Note:* LOA format example (Please refer 16.3.6 Supporting Document Format Example)

ii) Resolution by Company Board of Directors of **local product owner** to verify that ALL Board of Directors/ Partners have given their consent to the Change of PRH.

iii) Certified by Commissioner for Oath of the latest document indicating details of director/s and shareholder/s of **local product owner**; e.g. Form 24 and Form 49.

iv) Resolution by Company Board of Directors of **existing PRH** to verify that ALL Board of Directors/ Partners have given their consent to the Change of PRH.

v) Certified by Commissioner for Oath of the latest document indicating details of director/s and shareholder/s of **existing PRH**; e.g. Form 24 and Form 49.

vi) A certified true copy of the Company/ Business Registration Certificate of proposed new PRH; e.g. Form 9 and/ or Form 13.

vii) Statement of Acceptance as Product Registration Holder, BPFK-430.5(3) to be completed by proposed new PRH.

2. Date of the documents must be recent, i.e. not exceeding six (6) months from the date of application.

3. Each page of attachment of product list (if any) must be endorsed by the signatory.

4. The Secretariat, if necessary, has the right to request for further supplementary information or documentation. Failure to do so may result in the rejection of the transfer application.

16.3.6 SUPPORTING DOCUMENT FORMAT EXAMPLE

This format example is suggested for the applicant in order to produce the required supporting document i.e. Letter of Authorisation (LOA).

PRODUCT OWNER Letter Head (full and complete address, email address, telephone and fax number)

(Please state) Date of LOA (the existing PRH shall submit an application within 6 months from this date)

Drug Control Authority,
Lot 36, Jalan Universiti,
46200 Petaling Jaya,
Selangor, Malaysia.

Dear Sir/ Madam,

LETTER OF AUTHORIZATION FOR TRANSFER OF PRODUCT REGISTRATION HOLDER

The above subject matter is referred.

Due to *(please state) reason of the transfer*,

2. We, *Name of registered Product Owner*, the undersigned as the product owner for the said product(s) listed below:

Name of Product(s)	**Registration Number**
(If number of product > 10, endorsed attachment is allowed.)	

hereby authorize
Company name with business registration number and full address of the proposed new PRH
to be the Product Registration Holder and to act on our behalf/ responsible for all matters pertaining to the registration of the listed product(s) including obtaining approval for any subsequent product variation and maintenance of the product(s) registration.

3. Therefore, we hereby terminate marketing authorization of the existing Product Registration Holder
Company name with business registration number and full address of the existing PRH
for the listed product(s) effectively on *date of authorization / termination.*

4. We shall confirm that the entire dossier of the listed product(s) includes all the data in support of the original application, together with all correspondence with the Drug Control Authority (DCA)/ National Pharmaceutical Control Bureau concerning the listed product(s), to be transferred from *Company name of the existing PRH* to *Company name of the proposed new PRH* upon the approval from DCA.

Thank you.

Sincerely,

**Company officer's signature(s)*
**Full name & Title/ Positition*
Company stamp

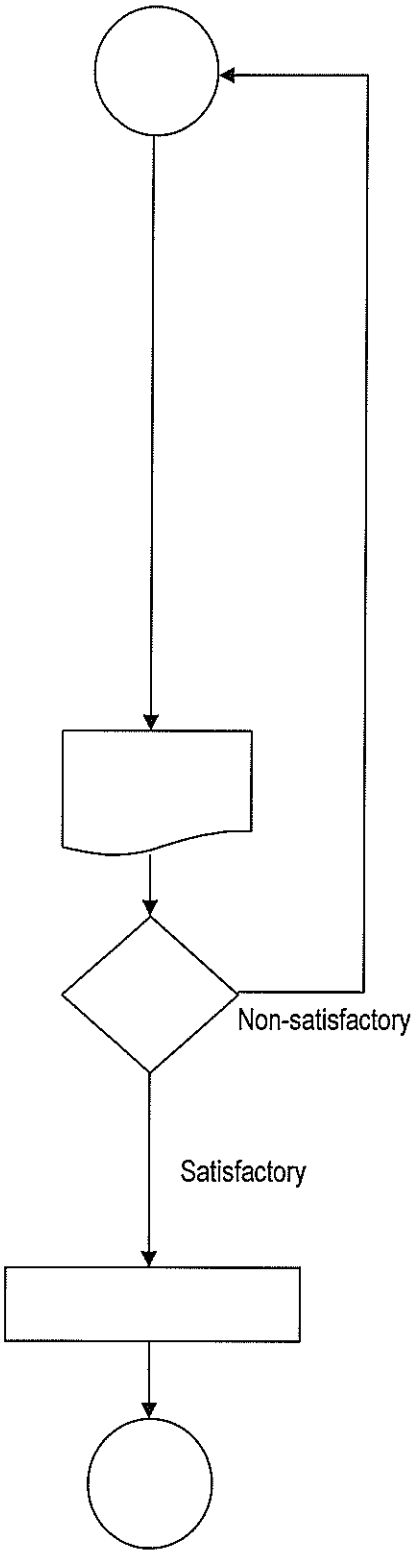
***Certified by Notary Public/ Commissioner for Oath*

cc: *Company of proposed new PRH*
Company of existing PRH
Product Manufacturer
} *(A copy of LOA shall be sent to these companies by the Product Owner)*

IMPORTANT NOTICE:

1. **LOA shall be signed by Managing Director/ Director/ President/ Chief Executive Officer/ General Manager who has overall responsibility for the company or organization.*
2. ***LOA shall be certified by Notary Public of the country of origin for overseas company or Malaysia Commissioner for Oath for local company.*

16.3.7 FLOWCHART FOR THE CHANGE OF PRODUCT REGISTRATION HOLDER



Company (Existing PRH)

Submit completed application to NPCB as below;

1. Application Form BPFK-430.5
2. *Borang Penyerahan Permohonan* BPFK-001
3. Processing Fee
4. Original Supporting Documents consisting of;
   - LOA from product owner certified by Notary Public for overseas company or Commissioner For Oath for local company
   - Resolution by Company Board of Directors of local product owner
   - The latest Form 24 and Form 49 of local product owner certified by Commissioner for Oath
   - Resolution by Company Board of Directors of existing PRH
   - The latest Form 24 and Form 49 of existing PRH certified by Commissioner for Oath
   - Company/ Business Registration Certificate of proposed new PRH
   - Statement of Acceptance As Product Registration Holder; BPFK-430.5(3) completed by proposed new PRH

Secretariat

Receive documentations and evaluation of application

Secretariat

Processing of evaluated application

1. Satisfactory:
   - Table to DCA meeting for approval
2. Non-satisfactory:
   - Table to DCA meeting for rejection (processing fee is NON REFUNDABLE in the event that application is being rejected)

DCA Meeting

Secretariat

Processing of DCA meeting outcome

1. Notification of transfer approval to new proposed PRH and termination notification to existing PRH for approved application; OR
2. Notification of transfer rejection to existing PRH for rejected application