APPENDIX 8: CHANGE OF PRODUCT REGISTRATION HOLDER

INTRODUCTION

A transfer procedure for the purpose of changing the existing product registration holder (PRH) that is authorized to market a registered product in Malaysia to another holder. This procedure allows the registered product to maintain the same registration number.
Once NPRA deems the application is complete, the outcome of the change of PRH application shall be decided by the Drug Control Authority within forty five (45) working days.

CONDITIONS

The application is subjected to the following conditions:

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 Regulatory Agency (NPRA).
3) The registered product intended to be transferred to a new PRH shall have a remaining registration validity period of at least six (6) months. If the registration validity is less than six (6) months, the existing PRH shall first apply for the renewal of this registered product.
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.
5) In the interim, the existing PRH shall still bear the marketing authorization responsibility of the said registered product.
6) The transfer shall come into effect on the day the DCA makes a decision on the outcome of the Change of PRH 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 then bear responsibility for the said product.
7) However, the existing PRH is allowed to deplete the stocks and will still be held liable should any pharmacovigilance issues or quality defects associated with the product arise during the interim of the transfer.
8) The existing PRH or newly approved PRH shall submit a written request to deplete the existing stocks after DCA approval has been obtained for the transfer. The PRH that submits the request shall be held responsible for the

batches and quantity requested in the event any pharmacovigilance issues or quality defects associated with those product batches arise.

9) Application may be rejected if the applicant fails to provide satisfactory required documents within 30 working days starting from the first date of correspondence by the evaluator.

APPLICATION

The existing PRH shall submit the following documents and payment via the online Quest system:

1. Fill and submit application online via the current QUEST system
2. Processing Fee
3. Original Supporting Documents

PROCESSING FEE

1. NON-REFUNDABLE processing fee.
   - For Poison/ Non-Poison product : RM 1,000.00
2. The processing fee shall be paid online via QUEST immediately after the change of PRH application has been submitted.
3. Foreign currency is not accepted.

SUPPORTING DOCUMENTS

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

   LIST OF REQUIRED SUPPORTING DOCUMENTS:

   i) Letter of Authorization (LOA) issued by the Product Owner. If the Product Owner is an entity registered outside of Malaysia then the LOA must be certified by the Notary Public from the country of origin of said Product Owner. However, if the Product Owner is a Malaysian registered entity then the LOA must be certified by a local Commissioner for Oaths The LOA shall consist 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 as registered in QUEST.
   c. Company name, business registration number and address of the existing PRH as registered in QUEST.

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 name, address, email address (if available), telephone and fax number (if available) of the Product Owner as registered in QUEST.
g. The Product Owner name and address in the LOA must be identical to the information of the Product Owner registered in QUEST for the product(s) concerned.
h. The LOA must be submitted in the Product Owner's official letterhead.

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

ii) Resolution by the Company Board of Directors of local Product Owner verifying that ALL the Board of Directors/ Partners have given their consent to the Change of PRH. This resolution must be signed by ALL the Board of Directors/ Partners. If the Product Owner is not a local entity, please omit.

iii) Latest document indicating details of director/s and shareholder/s of local Product Owner (e.g. Corporate Information, Summary of Share Capital, Directors/Officers, Shareholders/Members from the MyData SSM website). These documents must be certified by the Commissioner for Oaths (i.e. Statutory Declaration). If the Product Owner is not a local entity, please omit.

iv) Resolution by the Company Board of Directors of existing PRH verifying that ALL the Board of Directors/ Partners have given their consent to the Change of PRH. This resolution must be signed by ALL the Board of Directors/ Partners.

v) Latest document indicating details of director/s and shareholder/s of existing PRH (e.g. Corporate Information, Summary of Share Capital, Directors/Officers, Shareholders/Members from the MyData SSM website). These documents must be certified by the Commissioner for Oaths (i.e. Statutory Declaration).

vi) The Company/ Business Registration Certificate of the proposed new PRH certified true copy by a MAICSA accredited company secretary or

by the Companies Commission of Malaysia (e.g. Form 9 and/ or Form 13).

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

2. The ORIGINAL documents listed above shall be submitted to the Centre of Product Registration, NPRA once payment for the application has been made. Photocopies of documents will not be accepted.
3. Date of the documents including date of stamps/signatures of certifying bodies must be recent, i.e. not exceeding six (6) months from the date of application.
4. Each page of attachment of product list (if any) must be endorsed by the signatory.
5. 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.

SUPPORTING DOCUMENT FORMAT EXAMPLE

Suggested format example for the Letter of Authorization.

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 Regulatory Agency 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/ Position*
Company stamp

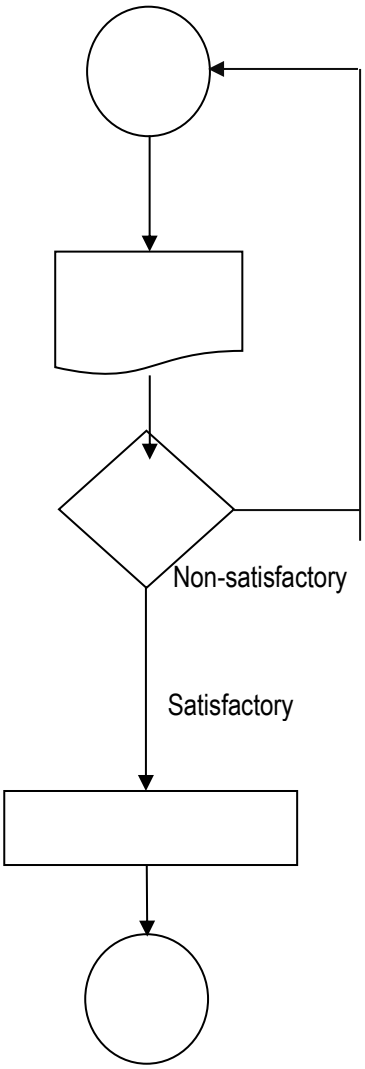
***Certified by Notary Public/ Commissioner for Oath*

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.*

FLOWCHART FOR THE CHANGE OF PRODUCT REGISTRATION HOLDER



Company (Existing PRH)

Submit completed application to NPRA as below;

1. Fill and submit application online via QUEST system.
2. Processing Fee
3. Submit original supporting documents to Centre for Product Registration.

Secretariat

Receive and evaluate application and original documents.

Secretariat

Processing of evaluated application

1. Satisfactory:
   a) Table to DCA meeting for approval
2. Non-satisfactory:
   b) 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