GUIDELINE ON TRANSFER AUTHORIZATION HOLDER ~~FROM EXISTING MARKET AUTHORIZATION HOLDER~~ (MAH)

Introduction

Transfer of Marketing Authorisation Holder (MAH) is the procedure by which the MAH is transferred from the currently approved Marketing Authorisation Holder (MAH) to a new MAH which is a different company/ business partnership / person/legal entity. This procedure is formally known as "agency transfer".

Such a Transfer may result from the MAH's commercial decision to divest the MA or be needed in anticipation of the MAH ceasing to exist as a legal entity and MA being taken over by another legal entity.

A change of name and/or address of the MAH is not a MA Transfer if the holder remains the same person/legal entity. Such change should be notified as a variation application (Refer variation guidelines of NMRA).

The National Medicines Regulatory Authority (The Authority) may permit such a transfer of MA of ~~grant permission to appoint a new Market Authorization holder in place of existing MAH~~ medicines, medical device, borderline products and cosmetics for the purpose of continuation of availability of said products as ensuring availability is one of the objectives of NMRA.

> ***Section 3, NMRA Act-*** *The objects of the Authority shall be to –*
> *(a) ensure the availability of efficacious, safe and good quality medicines, efficacious, safe and good quality medical devices and efficacious, safe and good quality borderline products to the general public at affordable prices;*

Purpose

Transfer of Marketing Authorisation Holder (MAH) of a particular manufacturer in place of existing MAH for the purpose of market continuation of the medicine / medical device / Borderline product / cosmetic in the Sri Lankan market.

A Transfer of a MA can only be initiated once a MA has been granted. In case there is a need to change the proposed MAH during the initial Marketing Authorization , the applicant who initially applied for the MA is advised to contact NMRA.

This guideline is applicable for transfer of a product or a number of products from the same manufacturer to a new MAH from the previous MAH. ~~or to more than one MAHs.~~

The MAH of the MA to be transferred is termed the Transferor.

The company/ business partnership / person/legal entity to whom the Transfer is to be granted is termed the Transferee.

Scope

Such authority may be granted on a request made by the ~~proposed MAH(s).~~ Transferee.

Procedure

A Transfer of a MAH ~~Appointment of a new of a particular manufacturer in place of existing MAH for the purpose of market continuation~~ must be carried out as per the procedure described in standard operating procedure (SOP) No…….. of NMRA. ~~for the purpose, approved by the Authority.~~

The Transferee should submit a written application(s) in accordance with the application form available in the Authority website / web portal, alone with documents listed in annexure as (A) to the authority.

The authenticity of the "Letter of authorization (LOA)" issued by the manufacturer appointing the new MAH, the "NO Objection Letter" issued by the Transferor agreeing the transfer and all other relevant documents shall be confirmed from the relevant parties by the Authority before a decision is taken on the transfer.

In situations where a "No Objection Letter (NOL)" from the Transferor ~~current MAH~~ is not available, details of the appointment of Transferee ~~new MAH~~ should be informed to Transferor ~~current MAH(s)~~ by the Authority for comments and explanations. Transferor ~~objections and they~~ should submit their objections, if any, within 14 days of letter of receiving the letter.

Once receiving the both confirmation (Manufacturer & Transferor ~~Present MAH~~) the Authority shall proceed the appointment of the Transferee ~~New MAH~~.

In situations where the Transferor ~~current MAH(s)~~ object the appointment of the Transferee ~~New MAH~~ with reasons, the Authority ~~has an authority to~~ decides whether the objection could be considered or not.

If the Transferor ~~they~~ submit valid reason in writing justifying the objections and if there is a valid pending registration before the Authority, the Authority shall ~~notify~~ inform the manufacture to resolve that problem with the Transferor ~~present MAH.~~ The Authority shall proceed the procedure of appointment of the Transferee ~~New MAH~~ after resolving the said problem.

~~If the Transferor refuses to issue a NOL for the purpose without giving a valid reason and if their objection is based on the commercial issue between both parties, the Authority shall not consider such objections since commercial disputes do not come under the purview of the Authority.~~ Not agree with this statement

See this way

In the event where the Transferor refuses to issue a NOL for the transfer of MAH without giving a valid reason within the given period, the Authority shall consider that there is no objection for the same.

When the objection for the transfer of MAH is based on the commercial issue between the Transferor and Transferee, the Authority shall proceed the transfer in situations where need and continuous availability of the products are of National interest.

In situations where there are no business transactions with Transferor ~~current MAH~~ and the manufacturer for last 2 years and the manufacturer can provide evidence in that regard, the Authority has powers to appoint new MAH for the entire agency (for all the products of the manufacturer) or relevant number of products. ~~certain pharmaceutical product(s).~~

If all documents and requirements are fulfilled, the Authority shall issue the payment(s) invoice according to the regulation relevant to the fees for the appointment of a Transferee ~~new MAH~~.

The Authority shall issue a letter the to the Transferee appointing Transferee as the MAH for the entire agency (for all the products of the manufacturer) or relevant number of products as after payment of relevant fee. This letter is considered as the appointment letter of the MAH.

Annexure A

Documents Requirements for Marketing Authorization Transfer

Put Numbers; not dots.

Re- organize the order of docs.

- Application form Transferee alone with request letter.
- Copy of the company profile approval letter (in case of medicines)
- Copy of business registration with the board of directors of Transferee.
- Copy of the certificate of importer/ wholesale license.

- Original Letter of authorization (LOA) addressed to Chairman / Chief Executive Officer (CEO) – the Authority issued by the manufacturer.
  (This letter should include the name and address of the manufacturing site. If any contract manufacturing activities are available, those detail also should be mentioned in the letter.
  If the manufacturer wish to appoint more than one MAH in Sri Lanka, name and address of each MAH and their respective pharmaceutical products should be clearly indicated in the letter.
  This authorization letter should be signed by the top level management of the manufacturing facility such as Chairman / CEO / General Manager (GM) / Director / Legal Officer / Regulatory Officer. In this letter name and designation of the authorized officer should be displayed and it should be dated and stamped by the authorized officer. It should be copied to current MAH, the Authority and proposed MAH.)
- Where applicable, a copy of the letter of termination to current MAH issued by the manufacturer. This letter should also be copied to the Chairman / CEO – the Authority and proposed MAH.
- Original "No Objection Letter" (NOL) from the Transferor ~~current MAH~~ Transferor agreeing to the transfer
  (This letter should address to Chairman / CEO – the Authority and signed by the top level management of the current MAH such as Chairman / CEO / General Manager (GM) / Director / Legal Officer / Regulatory Officer.)
- List of products where applicable.
  (This letter should be included official INN / Generic / approved names with brand names.
- Agreement between the manufacturer and the Transferor
- Agreement between the manufacturer and proposed local agent
- Declaration letter mentioning the Authorized Signatories (Full Name, ID Number, Company Seal, Director Seal, and Signature) for the letters sent to the Authority. This should be Authorized officer and the CEO

Annexures

Below given Forms are drafted templates as per Regulatory Authority and New MAH prepares and submits in requested format:

ANNEXURE1: REQUEST LETTER

Date

To
National Medicines Regulatory Authority

Subject: Appointment of Transfer of Marketing Authorization (MA) from Current Market Authorization Holder (MAH) to New MAH

The purpose of this application is to transfer the Marketing authorization from Current MAH to New MAH.

1. Name and address of the manufacturing site:
2. Details of the contract manufacturing (if applicable):
3. Name(s) and address(es) of the current MAH(s):
4. Type of the transfer: Entire agency / Product wise
5. Name(s) and address(es) of the proposed MAH(s):
6. List of Product(s) against proposed MAH(s) (Please use the separate annexure)

Yours Sincerely,

……..Signature (Proposed MAH)

……. (Date)

…….(stamp)

Name:

Title: