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Review Article

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General requirements for marketing authorization transfers in Thailand, Malaysia, Singapore, Indonesia and Philippines

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ABSTRACT

The review article is only for brief idea about the Marketing Authorization Transfers in few of ASEAN region. Whatever the data here I have been provided is according to my knowledge and study depends on healthy authorities/regulatory authorities sometimes requirements also may change. A Marketing Authorization Transfer is may be necessary to a company selling their product rights to another company it's like acquisition. In Order to transfer any kind of Pharmaceutical Products in ASEAN region from one MAH to other MAH that particular product must have a Marketing Authorization Transfer issued by the competent health/Regulatory Authority. This MAT is issued to a legal entity called MAT. It is a procedure by which the MA is transferred from the Old MAH to New MAH which is a different legal entity. The MA holder is completing responsibility for the life of the pharmaceutical product including all technical development and further alterations. The MAT process outcomes in the original MAH rights and responsibilities concerning the specific pharmaceutical product to be transferred to the New MAH on a specific date on which the transfer is stimulated. According to dossier all the parameters would be present. The expiry date is same and therefore, if applicable, the date by which it has to be renewed in order to remain legal. If any obligations are applicable (post authorization): PSUR, follow-up measures and special commitments.

Keywords: ASEAN (Association of Southeast Asian Nations), Legalization, Marketing Authorization transfers, GMP (Good Manufacturing Practices), Certificate of Pharmaceutical Product and Price certificates.

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1. Introduction

A Marketing Authorization may be transferred from one MAH (Marketing Authorization Holder) (1) to another MAH using a transfer procedure according to the regulatory authorities' approval. An MAT may occur before a product is authorized to a company related to the existing holder or to an unrelated company. Where an authorization is transferred prior authorization, the New MAH must notify to the authority using regulatory guidelines (2).

The MAH recruits the procedure for transfer of MA by a written application submitted to the authority for pharmaceuticals products. This application should be submitted separately for every parameter like strength and dosage form of the drug product on the Current application form for transfer of MA. The application form will be available in countries regulatory authorities website/portal. They are certain conditions must be met to avail of this procedure for transfer after authorization is the new MAH would be the Individual entity, No Change may be made as part of transferring MA and remaining dossier data.

A relationship letter to be provided and also declaration statement as the all right are provided to New MAH for marketing our product in respective country. The New MAH will be required to consequently submit a variation application to add the manufacturing site in order to market the product after transfer has taken place. Any changes to the transfer's authorization/registration like Mock-up's/Leaflet the introduction of the manufacturer must be applied for by a variation application. In order to transfer an MA, the New MAH going to act as a submitter to the agency. Submission

format is different, some countries prefer electronic submissions some other paper/CD format.

Documents which are require to submit the Health Authority are Transfer application forms and signed statements from the Current MAH/applicant and New MAH, Fee Application Form, Proof of Payment, Letter of Authorization, GMP Statement from Site, Pharmacovigilance data, Cover Letter, Product Information leaflet, Mock-up's, COPP, (3) Letter to allow new MAH to refer and use current MAH registered documents and Commitment Letters for any Product recalls (4).

Objectives

- Many companies need ASEAN Data but due to lack of growth and minimum research work much literature is not available.
- To better understand the ASEAN Technical guidelines for MAT
- Assist applicants on the preparation of required data for MAT
- Fully adopt the modular format of the ACTD (ASEAN Common Technical Dossier) and
- To provide Module – 1 data and general requirements

Advantages

The advantages of MAT in ASEAN region is the procedure would be that requirements and timelines could be harmonized for marketing medicinal products, making preparation of a submission (Required documents for submission) and post marketing transfer activities are easier planning for the applicants (5).

Disadvantages

To reach the organization required the agreement of all the investors regarding requirements and time lines (6, 7).

2. Documents Requirements for Marketing Authorization Transfer (8-10)

Malaysia

LOA – Letter of Authorization issued by overseas product holder certified by Notary Public from the country of origin of the product holder; or Malaysia Representative 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 Product Registration Holder (PRH).

c) Complete contact/communication details/mailing 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 head of the company or organization.

f) Full and complete address, email address (if available), telephone and fax number (if available) of the Product Owner.

1. 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.
2. Certified by Commissioner for Oath of the latest document indicating details of Board of director/s and stockholder/s of local product owner; e.g. Form 24 and Form 49.
3. 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
4. Certified by Commissioner for Pledge of the latest document representing details of director/s and shareholder/s of existing PRH; e.g. Form 24 and Form 49.
5. A certified true copy of the Companies Registration Certificate of proposed new PRH; e.g. Form 9 and/ or Form 13.Drug Registration Guidance Document (DRGD) (11)
6. Statement of Acceptance as Product Registration Holder, BPFK-430.5(3) to be completed by proposed new PRH.

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

b) Each page of addition of product list must be endorsed by the signatory.

c) 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. (12).

Thailand (13-15)

a) Cover letter

b) Application form

c) Summary of Product Characteristics, PI, Labelling and Package Leaflet

d) Proof of Payment

e) Completed local registration application form

f) Completed local form regarding registration transfer

g) Statement to confirm that the label and PI of the drug are the same as the registered ones (except license holder's name, company's logo)

h) Copy of the company's import license for drugs

i) Letter to allow new MAH to refer and use current MAH registered documents (one letter per one product license)

j) Letter to cancel the product license of Current MAH attached with the original product license (one letter per one product license)

k) Pending variation at Thai FDA

l) Product registration certificates

m) Commitment letter for Recalls

n) Copy of company's import license for drugs

Indonesia (16, 17)

a) Old MA certificate

b) Packaging & labeling artwork

c) Statement letter of no objection from old MAH

d) Quality document, if required by Health authority

e) No objection letter

f) Divestment letter and Agreement

g) Existing approval's for all products from NADFC which will be transferred to the new company name

h) New labeling and product information

i) Complete ICH CTD Module 3 for each product

j) Manufacturing License

k) CPP (Note: copy of current CPP is acceptable for submission. However, new CPP shall be provided during review or upon MA approval)

l) GMP Certificate of DS and DP manufacturer

m) Latest inspection report

Philippines

a) Cover Letter

b) Overall ASEAN Common Technical Dossier Table of Contents

c) Application Form

d) Product Information and Labelling

e) Patient Information Leaflet

f) Proof of fee payment

g) License to Operate (LTO) of New MAH

h) Legalized Agreement between the manufacturer and the new MAH

i) Legalized GMP certificate of the manufacturer

j) Termination of Contract/Deed of Assignment

k) (*In the case of buy-out, document to prove ownership of New MAH.)

l) Draft complete labelling materials reflecting the new MAH.

m) Notarized Letter of Authorisation

n) Mock-up

Singapore (15)

a) Cover Letter

b) Application Form

c) LOA Letter of Authorization

d) Confirming Letter

e) Statement of understanding

f) Commitment Letter for revised PI and labeling

g) Declaration Letters of Product ownership transfer

Annexures

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

ANNEXURE1: COVER LETTER (18)

Date

To

Ministry of Health

Subject: Transfer of Marketing Authorisation (MA) from Current MAH to New MAH

The purpose of this application is to transfer the Marketing authorisation in Name of the Country from Current MAH to New MAH for the following pharmaceutical product.

List of Products

Please find the below enclosed documents.

Yours Sincerely,

…….. (Date)

ANNEXURE 2: LETTER FOR POST-APPROVAL CHANGE (19)

To the Health Authority,

XXXXXX

Center for Drug Regulation and Research

Sir/Madam,

We would like to submit our application for Post-approval Change/s, (*type of Post Approval Change as per AVG or Country-specific requirements*) for the following product/s:

List of Products

Yours faithfully,

Company representative name and signature

Position

ANNEXURE 3: NO OBJECTION LETTER (20)

Date:

To whom it may concern

We, ----------as the Current Marketing Authorisation holder in (Country Name) for the below listed products hereby declare that we does not have any objections regarding the transfer of Marketing Authorisations of the below mentioned products to New MAH

List of Products

Yours faithfully,

…… (Current MAH)

…….. (Date)

…….

Name

Title

…… (New MAH)

…….. (Date)

…….

Name

Title

ANNEXURE 4: LETTER OF AUTHORIZATION

Date:

To whom it may concern

We would like to inform you that Current MAH is the manufacturer for the below mentioned products for Country Name

List of Products

In accordance with Asset Sales and Purchase Agreement, effective ---------- between, Current MAH and New MAH, the above mentioned Products had be acquired and Authorized by New MAH.

Yours faithfully,

ANNEXURE 5: MARKETING AUTHORIZATION TRANSFER AGREEMENT (21)

To,

Ministry of Health

XXX

It is hereby agreed that the Marketing Authorisations/Certificates of Product Registration in the Name of the Country for the below pharmaceutical products will be transferred from Current MAH to New MAH.

List of Product

Yours Truly,

ANNEXURE 6: CERTIFICATE OF PHARMACEUTICAL PRODUCT (3)

No. of certificate:

Validity:

Exporting (certifying) Country:

Importing (requesting) Country:

1. Name and dosage form of the product:

1.1 Active ingredient(s)[2] and amounts per unit dose3

For complete composition including excipients see attached4:

Is this product licensed to be placed on the market for use in the exporting country? 5 Yes

Is this product actually on the market in the exporting country? If answer to 1.2 is ~ continue with the section2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B6

2. A.1. Number of product licence7 and date of issue:

2. A.2. Product License Holder (name and address):

2. A.3. Status of License Holders:

2. A.3.1 For categories band c the name and address of the manufacturer producing the dosage form is9:

2. AA. Is summary basis of approval appended? 10:

2. A.5. Is the attached, product information complete & Consonant with the license? II

2. A.6. Applicant for certificate, if different from the License Holder (name and address) 12:

2. B.I Applicant for Certificate (name and address):

2. B.2. Status of Applicant: 2.B.2.IFor categories band c the name and address of the manufacturer producing the dosage form is9:

Why is marketing authorization lacking? Not required not requested/Under consideration/refused

Remarks13

3. Does the certifying authority arrange for periodic inspection of Manufacturing Plant in which the Dosage form is produced?

Periodicity of routine inspections (years):

Has the manufacture of this type of dosage form been inspected?

Do the facilities and operations conform to GMP as recommended by the World Health Organization? 15

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the Manufacture of the product? 16 (Key in appropriate)

Address of certifying authority:

Telephone:

Fax no:

Name of the authorized person:

Signature:

Stamp & Date:

ANNEXURE 7: PRODUCT INFORMATION LEAFLET (22)

COMPOSITION:

Clinical particulars:

Therapeutic indications

Posology and method of administration

Contraindications

Pregnancy and lactation

Pregnancy:

Breast-feeding

Over Dosage:

Pharmacological properties:

Pharmacokinetic Properties:

Absorption

Distribution

Biotransformation

Elimination

Adverse Reactions:

Nature and contents of the container:

Al/Al blisters:

Pack sizes:

Special precautions for disposal and other handling:

STORAGE:

Presentation:

Manufactured by (Address

3. Conclusion

Regulatory Affairs plays a vital role in MAT. It is a heart of success, the acute rate regulating step in any trade endeavor where products and Pharmaceutical companies are bought and sold their entity. This article indicates the general requirements for Marketing Authorization Transfers in ASEAN Countries. Requirements are not

same to Country to country it may vary in country specific like in Legalization/Notarization/Apostillation. The Regulatory Strategy is completely different compared to normal Drug Registration process. In some ASEAN States they may require Legalization/Notarization/Apostillation for COPP/GMP and some other documents. Marketing Authorization Transfers are not easy to perform in this so many issues are involved. A careful balance needs to be struck between the stock levels, submission timings and the expiry or transfer of the license, to ensure continued commercial supply to the market and full regulatory compliance. There is a requirement for involvement with many different functions between the companies involved, not just Regulatory but Manufacturing, Quality, Pharmacovigilance, Legal part, Mock-Up's, Logistics and Commercial. The old MAH and New MAH should work in combining way with each other for ensuring the MAT is actioned correctly. Once the submission done and gets the approvals from the health authority the new MAH have a right to sell the products in that particular country.

Abbreviations

- ASEAN - Association of Southeast Asian Nations
- MAH - Marketing Authorization Holder
- MAT - Moving Annual Total
- PSUR - Periodic Safety Update Reports
- GMP - Good Manufacturing Practice
- COPP - Certificate Of Pharmaceutical Product
- ACTD - ASEAN Common Technical Dossier
- LOA - Letter Of Authorization
- PRH - Product Registration Holder
- DRGD - Drug Registration Guidance Document
- CTD - Common Technical Dossier
- NADFC -National Agency Of Drug And Food Control

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Conflict of interest

The authors declare that there are no conflicts of interest.

References

1. Marketing Authorization Holder – Legal Obligations [Internet]. PHARMALEX; 2018 [cited 2018 Jan 20]. Available from: https://mcgeepharma.com/eur/legal-obligations-of-the-marketing-authorisation-holder/
2. Definition of Marketing Authorization Transfer [Internet]. Wikipedia; 2018 [cited 2018 Jan 11]. Available from: https://en.wikipedia.org/wiki/Marketing_authorization_transfer
3. Certificate of pharmaceutical product [Internet]. Genpact Pharmalink; 2018 [cited 2018 Jan 14]. Available from: http://www.pharmalinkconsulting.com/blog/blog/certificates-of-pharmaceutical-product-cpps/
4. Member Countries. Association of Southeast Asian nations [Internet]. Aseansec [cited 2018 Jan 04]. Available from: http://www.aseansec.org/74.htm
5. The ASEAN advantage [Internet].Canada ASEAN business council; 2012 [Cited 2017/07]. [cited 2018 Jan 25]. Available from: https://www.canasean.com/wp-content/uploads/2017/07/The-ASEAN-Advantage.pdf
6. Marketing Authorization Holder – Legal Obligations [Internet]. Pharmalex; 2018 [cited 2018 Feb 21]. Available from: https://mcgeepharma.com/eur/legal-obligations-of-the-marketing-authorisation-holder/
7. A critical review of the current marketing authorization transfer procedure in Europe [Internet]. Europe: 2013 [cited 2018 Feb 02]. Available from: https://dgra.de/media/pdf/studium/masterthesis/master_gordon_g.pdf
8. Medicinal products. Transfer of Marketing Authorisation [Internet]. Croatia: Halmed [cited 2018 Jan 08]. Available from: http://www.halmed.hr/en/Lijekovi/Upute-za-podnositelje-zahtjeva/Prijenos-odobrenja
9. Applications regarding new marketing authorization holder [Internet]. Danish Medicines agency [cited 2018 Jan 14]. Available from: http://laegemiddelstyrelsen.dk/en/topics/authorisation-and-supervision/licensing-of-medicines/variations/guideline.
10. Updated Marketing Authorization Holder (MAH) Procedures [Internet]. Malaysia: 2005 May 02 [cited 2018 Jan 09]. Available from: https://www.pacificbridgemedical.com/news-brief/malaysia-updated-marketing-authorization-holder-mah-procedures/
11. Drug registration guidance document (DRGD) [Internet]. Malaysia: Ministry of Health; 2016 Jan [updated 2016 Jan; cited 2018 Jan 12]. Available from: http://npra.moh.gov.my/images/Drug-Registration-GuidanceDocument/2016/Jan2016/Complete_DRGD_JAN_2016.pdf
12. Kadian N, Saini M, Tandon M. Registration Procedure of marketing authorization of Medicinal Products in Malaysia [Internet]. India [cited 2018 Jan 20]. Available from: https://www.scribd.com/document/317850003/Registration-Procedure-of-Marketing Authorization-of-Medicinal-Product-in-Malaysia
13. Guideline on Procedural Aspects Regarding Marketing Authorization of Vaccines in Thailand. Pharmaceutical Bureau [Internet]. FDA, Ministry of Public Health; 2016 [cited 2018 Feb 22]. Available from: http://www.fda.moph.go.th/sites/drug/Shared%20Documents/Vaccine/Procedural_%20_Vaccine_final_sep_08.pdf
14. Adcock A, Rungpry S, Homhuan A, Tilleke & Gibbins. Distribution and marketing of drugs in Thailand: overview [Internet].Thomsonreuters [cited 2018 Feb 23]. Available from:

https://uk.practicallaw.thomsonreuters.com/0-618-6841?transitionType=Default&contextData=(sc.Default) &first Page=true&bhcp=1
15. Jain A, P. V, Reddy.G R, T.M. P. Regulatory Requirements & Marketing Authorization of Generic Drugs in Singapore & Thailand. International Journal of Drug Regulatory Affairs [Internet]. 2018 Feb 13 [cited 2018 Feb 24];3(1):62-4. Available from: http://ijdra.com/index.php/journal/article/view/158
16. Distribution and Marketing of Drugs in Indonesia [Internet]. Thomsonreuters; 2018 Apr 01 [cited 2018 Apr 23]. Available from: https://uk.practicallaw.thomsonreuters.com/2-618-5567?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1
17. NADFC [Internet]. Wikipedia; 2018 [cited 2018 Jan 16]. Available from: https://en.wikipedia.org/wiki/National_Agency_of_Drug_and_Food_Control of Repulic of Indonesia
18. Transfer of Marketing Authorization (MA) from Current MAH to New MAH [Internet].DGRA;2018 [cited 2018 Jan 18]. Available from: https://dgra.de/media/pdf/studium/masterthesis/master_gordon_g.pd
19. Centre for drug regulation and research [Internet].Philippines: FDA; 2018 [cited 2018 Jan 17]. Available from: https://ww2.fda.gov.ph/fda-corner//center-for-drug-regulation-research
20. No Objection Letter [Internet]. CDSCO; 2014 [cited 2018 Feb 11]. Available from: http://www.cdsco.nic.in/writereaddata/2014check_noc_form_29.pdf
21. Application form for the transfer of a marketing authorization holder for an authorized product [Internet]. Malta: Medicines Authority [cited 2018 Feb 12]. Available from: https://gov.mt/en/Services-And-Information/eforms/Documents/eForms%20PDF/MFEI/MA/Transfer_of_a_marketing_authorisation_holder_for_an_authorised_product_application.pdf
22. Product-information templates [Internet]. EMEA; 2018 [cited 2018 Jan 20]. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&mid=WC0b01ac0580022c59