ประกาศสำนักงานคณะกรรมการอาหารและยา

เรื่อง แนวทางในการจัดทำรายงานการศึกษาชีวสมมูลและเตรียมความพร้อมเพื่อรองรับการตรวจตรา
ของศูนย์การศึกษาชีวสมมูลเพื่อขึ้นบัญชีของอาเซียน (ASEAN Listed Bioequivalence Center)

ตามข้อตกลงยอมรับร่วมสำหรับรายงานการศึกษาชีวสมมูลของผลิตภัณฑ์ยาสามัญของอาเซียน (ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products; ASEAN MRA BE) กำหนดให้ประเทศสมาชิกของอาเซียนยอมรับรายงานการศึกษาชีวสมมูลที่ดำเนินการศึกษาในศูนย์การศึกษาชีวสมมูลซึ่งผ่านการรับรองมาตรฐานโดยการตรวจตราของคณะผู้ตรวจตราของอาเซียน (Panel of Experts: PoE) และได้รับการขึ้นบัญชีศูนย์การศึกษาชีวสมมูลของอาเซียน (ASEAN listed BE center) เพื่อนำมาใช้เป็นหนึ่งในเอกสารประกอบการพิจารณาเพื่อขึ้นทะเบียนตำรับยาสามัญ โดยไม่ต้องมีการทำการศึกษาชีวสมมูลหรือตรวจตราการศึกษาชีวสมมูลซ้ำ

เพื่อให้มีความชัดเจนในแนวทางปฏิบัติในการจัดทำรายงานการศึกษาชีวสมมูลและเตรียมความพร้อมรองรับการตรวจตราของศูนย์ศึกษาชีวสมมูลที่มีความประสงค์จะขึ้นบัญชีของอาเซียน รวมถึงสร้างศักยภาพในการแข่งขันของศูนย์ชีวสมมูลของประเทศไทยต่อกลุ่มประเทศอาเซียน ซึ่งเป็นการส่งเสริมภาคอุตสาหกรรมยา และการเข้าถึงยาของประชาชน เลขาธิการคณะกรรมการอาหารและยาจึงออกประกาศดังต่อไปนี้

๑. ในประกาศนี้

"การศึกษาชีวสมมูล" หมายความว่า การศึกษาเปรียบเทียบอัตราเร็วและปริมาณการดูดซึมของตัวยาภายในร่างกายมนุษย์โดยทำการเปรียบเทียบยาสามัญกับยาต้นแบบ ทั้งนี้ การศึกษาทั้งในส่วนคลินิกและส่วนการวิเคราะห์ระดับยาในเลือดต้องดำเนินการภายในประเทศสมาชิกอาเซียน

"รายงานการศึกษาชีวสมมูล" หมายความว่า รายงานการศึกษาชีวสมมูลซึ่งจัดทำขึ้นโดยศูนย์การศึกษาชีวสมมูลที่ได้ขึ้นบัญชีรายชื่อไว้โดยทำตามรูปแบบรายงานการศึกษาชีวสมมูลของอาเซียน

"ศูนย์การศึกษาชีวสมมูล" หมายความว่า องค์กรที่ตั้งอยู่ในอาณาเขตของประเทศสมาชิกอาเซียน ซึ่งเป็นผู้ดำเนินการศึกษาชีวสมมูลและจัดทำรายงานการศึกษาชีวสมมูล

๒. ศูนย์การศึกษาชีวสมมูลที่ประสงค์จะยื่นคำขอเพื่อรับการตรวจตราเพื่อขึ้นบัญชีของอาเซียน ให้ดำเนินการตาม Manual for Application of Bioequivalence (BE) Center to be listed under the ASEAN Mutual Recognition Arrangement (MRA) on BE Study Report ตามแนบท้ายประกาศนี้ (หรือดาวน์โหลดได้จากเว็บไซต์ www.asean.org)

/๓. รายการ...

๓. รายการหลักเกณฑ์แนวทางอ้างอิงสำหรับการศึกษาชีวสมมูล การจัดทำรายงานการศึกษาชีวสมมูล และการตรวจตราศูนย์การศึกษาชีวสมมูลเพื่อขึ้นบัญชีของอาเซียน (List of References for BE Inspection) ปรากฏตามแนบท้ายประกาศนี้

ทั้งนี้ นับตั้งแต่บัดนี้เป็นต้นไป

ประกาศ ณ วันที่ ๒๕ ธันวาคม พ.ศ. ๒๕๖๔

(นายสุรโชค ต่างวิวัฒน์)
รองเลขาธิการ ปฏิบัติราชการแทน
เลขาธิการคณะกรรมการอาหารและยา

ภาคผนวก ก

Manual for Application of Bioequivalence (BE) Center to be listed under the ASEAN Mutual Recognition Arrangement (MRA) on BE Study Report

ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products

Manual for Application of Bioequivalence (BE) Centre to be listed under the ASEAN Mutual Recognition Arrangement (MRA) on BE Study Report

Version: 0

Version	Date	Status	Author
0	31st PPWG Meeting - 2021	Endorsed	ACCSQ-PPWG

Manual for Application of BE Centre to be listed under ASEAN MRA on BE Study Report

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Annexes

1. Introduction

An *ASEAN Mutual Recognition Arrangement (MRA) for Bioequivalence (BE) Study Reports of Generic Medicinal Products* was signed on 2nd November 2017 in Manila, Philippines by Ministers of the 10 ASEAN Member States.

Article 1 of this ASEAN Sectoral MRA defines a BE Centre as any independent organisation located in the territory of the Member State which conducts BE studies and issues BE study reports.

Article 8 of this ASEAN Sectoral MRA specifies that an application for listing of BE Centre shall be submitted to the JSC, by the National Drug Regulatory Authority (NDRA) where the BE Centre is located.

2. Scope

This document sets out to outline the process for listing of BE Centres, which includes application procedures, decision process, appeal and complaint procedures as guidance for BE Centres in ASEAN to be listed under the MRA for BE Study Report. The current scope of the MRA on BE study Report will cover immediate release, oral, solid dosage forms with systemic actions only.

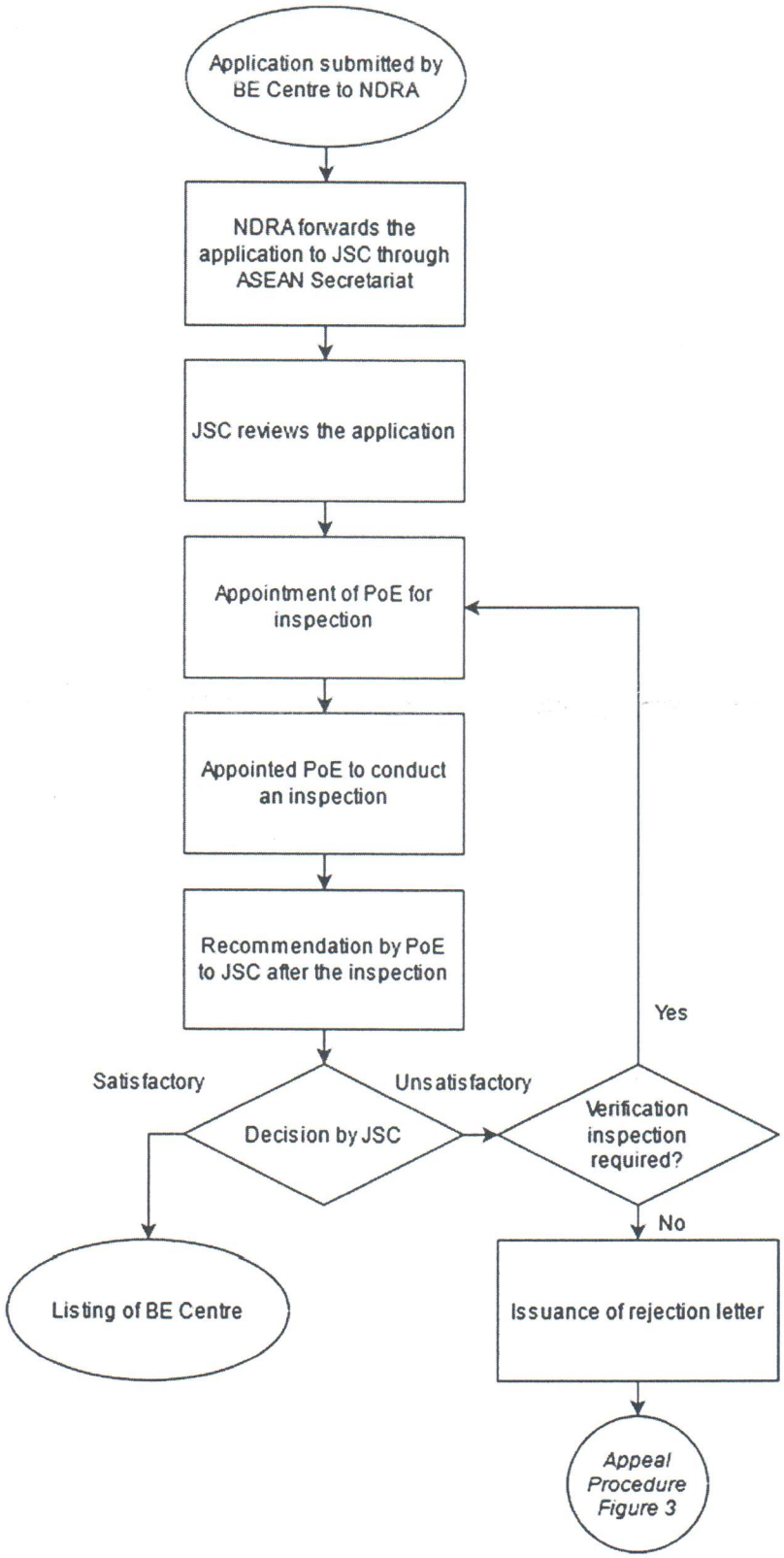
3. Process for Listing of Bioequivalence (BE) Centre

Article 1 of this ASEAN Sectoral MRA defines a BE Centre as any independent organisation located in the territory of the Member State which conducts BE studies and issues BE study reports.

Article 8 of this ASEAN Sectoral MRA specifies that an application for listing of BE Centre shall be submitted to the JSC, by an NDRA where the BE Centre is located. The inspection of BE centre shall be conducted by the Panel of Expert (PoE). The JSC will make its decision for the listing of BE centre based on the recommendations from the PoE. The ASEAN Secretariat shall update and maintain the list of BE Centres and publish it in the ASEAN website.

The listing of BE Centre process is summarised in **Figure 1**:

Figure 1: Process for Listing of Bioequivalence (BE) Centres



4. Application for Listing of Bioequivalence (BE) Centre

Article 1 of this ASEAN Sectoral MRA defines a BE Centre as any independent organisation located in the territory of the Member State which conducts BE studies and issues BE study reports.

Article 7 of this ASEAN Sectoral MRA specifies that the NDRA of each Member State shall be responsible for ensuring that any BE Centre within its jurisdiction that requests to be listed under this sectoral MRA complies with all the requirements for listing before submitting the application to the JSC.

Article 8 of this ASEAN Sectoral MRA specifies that an application for listing of BE Centre shall be submitted to the JSC, by the NDRA where the BE Centre is located.

The listing of BE centres is a voluntary scheme. Any BE Centre located in the territory of the ASEAN Member State is eligible to apply for the BE Centre inspection. The inspection will cover all sites and components which include the clinical site, bioanalytical site as well as the pharmacokinetic and statistical analyses components of BE studies. However, only one clinical site and one bioanalytical site are allowed in the first inspection. Additional clinical or bioanalytical sites will be considered after successful listing of the BE Centre under the *ASEAN MRA for BE Study Reports of Generic Medicinal Products*.

The BE centre shall be listed under the MRA on the ASEAN website only after the BE Centre has been recognised by the JSC.

4.1. General requirements and procedures:

The application for BE Centre Inspection shall be made by an applicant representing the company using application form as in **MoA.Annex 1**. The BE Centre shall appoint an Authorised Person (e.g. Director/Manager/Senior Executive) to act as the liaison officer with the JSC for all arrangements on the proposed inspection. The completed application form should be submitted to JSC through the NDRA of the host country. The NDRA shall endorse the application before forwarding it to the JSC.

4.2. Inspection Fee:

An inspection fee of **USD 500 per man-day** with a maximum of USD 2,500 per expert for a 5-day inspection will be incurred for each expert appointed as the PoE for the inspection. The inspection fee will only be calculated based on the number of inspection day(s) excluding travelling days. Payment shall be made directly to the PoE's country of origin according to the procedure specified in **MoA.Annex 2**.

4.3. Funding for the PoE:

Details of expenditures such as airfare, daily subsistence allowance, transportation, travel insurance and others along with the payment procedure are specified in **MoA.Annex 2.** All inspection related costs incurred over the course of the inspection by the appointed experts shall be borne by the BE Centre under assessment.

In each inspection, a minimum of three (3) experts and a maximum of four (4) experts will be appointed by the JSC to cover the clinical and bioanalytical sites as well as the pharmacokinetic and statistical analyses components of BE studies. From the appointed experts, a Rapporteur get in touch with the contact listed in the application form for further arrangements on the inspection.

Refund of inspection fees and inspection costs are subject to country specific requirements of each appointed expert. Additional information on the inspection fee, PoE funding and refunds are specified in **MoA.Annex 2**. All inspection fee and funding issues shall be addressed and resolved before the PoE embarks on the inspection.

5. Decision for Listing of Bioequivalence (BE) Centre

Article 1 of this ASEAN Sectoral MRA defines a Listed BE Centre as a BE Centre which has been recognised by the JSC.

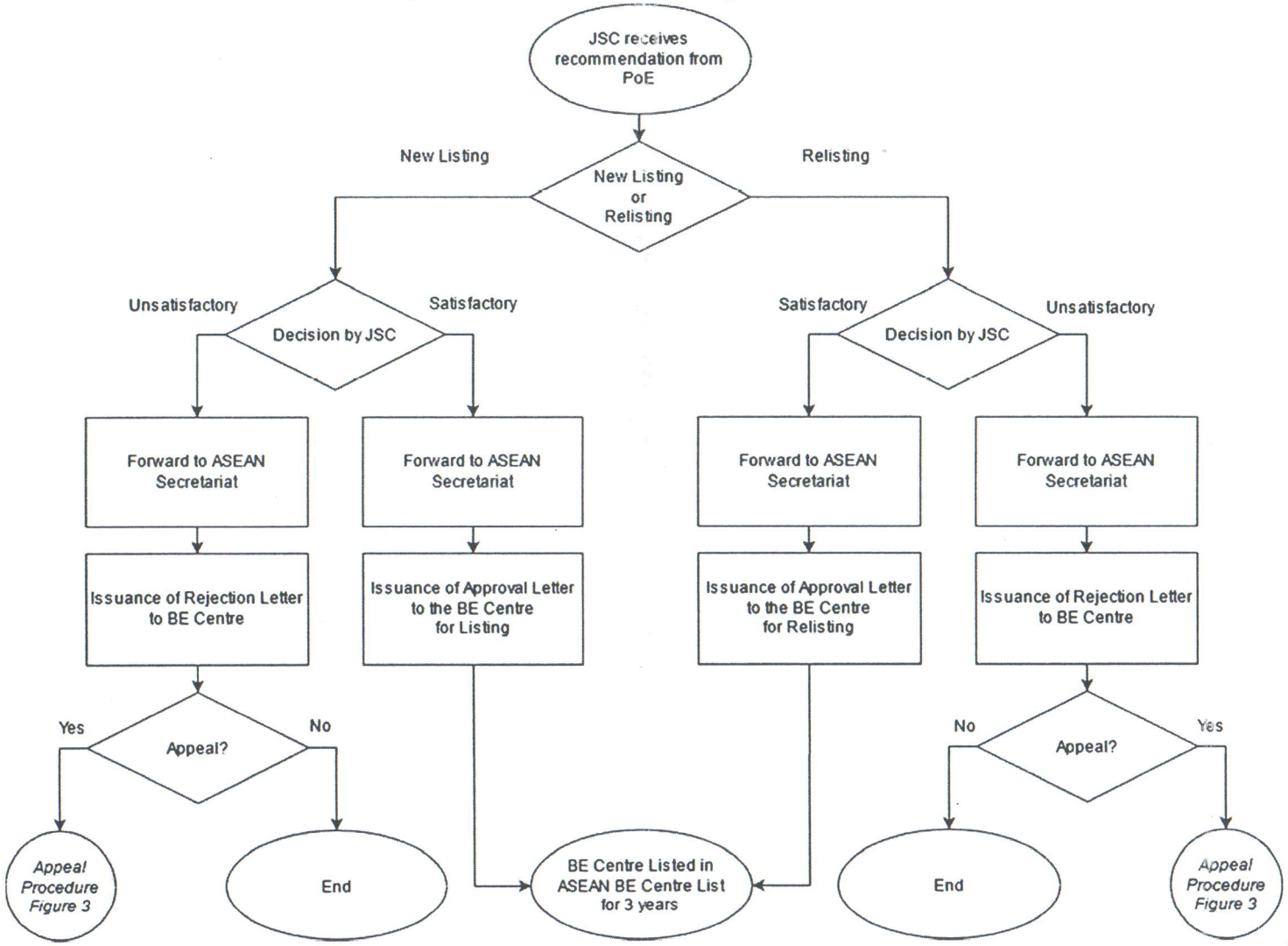
Article 8 of the ASEAN Sectoral MRA states that the inspection of BE centre shall be conducted by the appointed PoE and the JSC will make its decision on the listing of BE centre based on the recommendations from said PoE.

Article 7 of ASEAN Sectoral MRA states that the NDRA of each Member States shall be responsible for monitoring the performance of its Listed BE Centres and shall notify the JSC of any non-compliance that it observes.

The decision tree to list or relist a BE Centre is summarised in the **Figure 2**.

Once the BE Centre had been recognised by the JSC, the BE Centre will be listed in ASEAN BE Centre List for 3 years. Relisting is required every 3 years. For BE Centres found to be unsatisfactory for listing or relisting, the BE Centre may initiate the appeal process which is specified in Section 6.

Figure 2: Decision for Listing of BE Centre

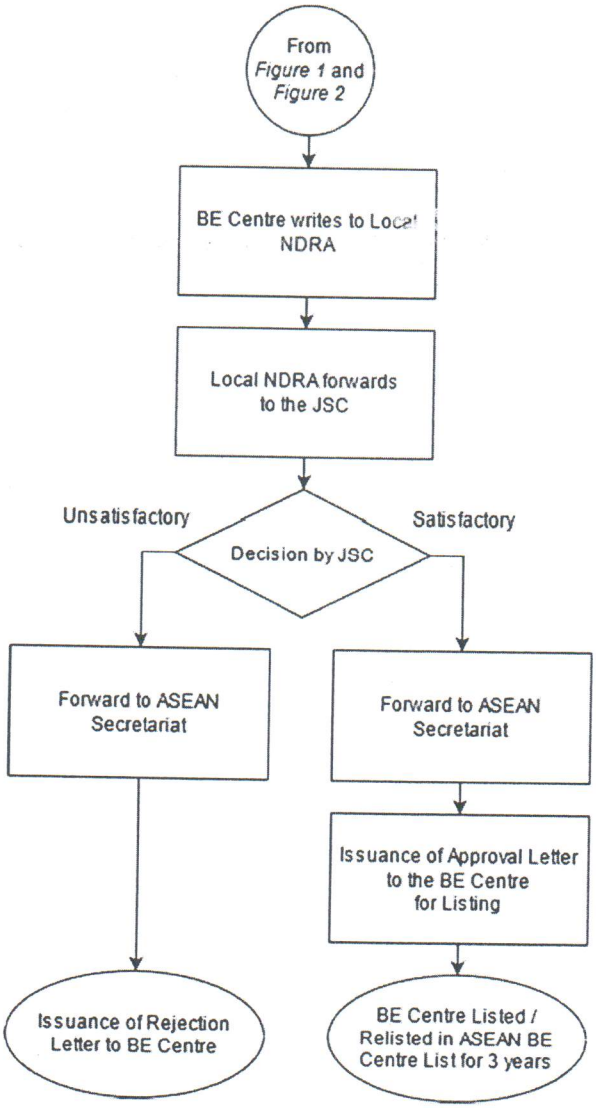


6. Handling of Appeal

The BE Centre aggrieved by any decision of the JSC may make a written appeal with justification to the JSC through the NDRA within 60 calendar days from the time the decision is made known to the BE Centre.

The JSC will discuss the appeal in the next JSC meeting or *ad referendum* where the JSC may seek advice from other experts in the PoE Registry with or without an independent expert (IE) before making any decision. Procedure for the appointment of IE shall be used for requesting any advice from IE. Any decision of the JSC made on the appeal shall be final. The appeal process is summarised in **Figure 3**.

Figure 3: Appeal Process



7. Handling of Complaints

Any disagreements or differences of opinion arising during the inspection normally shall be resolved during the inspection or at the closing meeting of said inspection. However, where problems and disagreements persist and a resolution is unattainable, the BE centre may raise a complaint against the issue(s) within 60 calendar days after the inspection report has been issued. Such complaints must be addressed in writing to the JSC through local NDRA.

The JSC will discuss the complaints in the JSC meeting or *ad referendum* in which the JSC will then take appropriate steps through communication, dialogue, consultation and cooperation to achieve a mutually acceptable resolution. The JSC may seek advice from other experts in the PoE Registry with or without an IE when necessary. Procedure for the appointment of IE shall be used if advice from IE is required. Any decision on the complaint(s) will be made in consensus among the JSC members. The JSC's decision in response to the complaint will be done in writing to the BE centre.

APPLICATION FORM
INSPECTION FOR LISTING OF BIOEQUIVALENCE CENTRE
ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products

Parts 1-2 to be completed by BE centre. Please submit the completed application form to respective National Drug Regulatory Authority (NDRA).

1. Details of Bioequivalence (BE) Centre

Name			
Address			
Country			
Phone		**Fax**	
Email (General)			
Contact Person			
Designation			
Phone		**Fax**	
Email			

NOTE 1: Please make sure all information above is correct and written in FULL. The same information will be published in the ASEAN website when the centre has been successfully listed in the ASEAN BE Centre List.

	Clinical Site	Bioanalytical Site
Name		
Address		
Country		
Phone		
Fax		
Contact Person		
Designation		
Email		

NOTE 2: Only one clinical site and one bioanalytical site are allowed in the first inspection. Additional clinical or bioanalytical sites will be considered after successful listing of the centre under the MRA BE Study Reports of Generic Medicinal Products.

2. Details of Authorised Person as Liaison Officer for Inspection

Name			
Designation			
Phone		**Fax**	
Email			

3. Authorized Person's Declaration

By submitting this application, I declare:

a. I am hereby authorised by the company to make this application.
b. I have read and agree to all requirements of the ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products Procedures and Manual of Joint Sectoral Committee (JSC).
c. I hereby declare that details furnished in this form are true, accurate and complete; the supporting documents are authentic or true copies.
d. I undertake to pay all required inspection fee and estimated cost expenditure including flight ticket, daily subsistence allowance, and other associated expenses (such as per diem, insurance, etc.) as guided by *ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products Procedures* and Annex 2 of *Manual for Application of Bioequivalence (BE) Centre to be listed under ASEAN Mutual Recognition Arrangement (MRA) on BE Study Report* (MoA.Annex 2).
e. I undertake to add more contribution if the expenditure for the inspection is more than expected. I understand that in the event where the inspection cannot be conducted, the contribution will be refunded subject to the procedures outlined under MoA.Annex 2
f. I hereby confirm that the BE centre has agreed and is ready to be inspected.
g. I undertake to ensure the availability of an English translator in case the inspection team is not familiar with the local language.

Signature			
Name		**Date**	
Position			
Stamp			

4. For Office Use Only (to be completed by NDRA)

Received Date			
NDRA			
Contact point of NDRA for this application			
Name			
Designation			
Phone		**Fax**	
Email			
Institutional clearance: Director of NDRA			
Name			
Signature		**Date**	
Email		**Phone**	
Stamp			
Date of Forwarding to Joint Sectoral Committee (JSC)			

5. For Office Use Only (to be completed by JSC)

Date of Receipt			
List of experts appointed for this inspection	**Name**	**Area of Inspection**	**Country**
Reference Number			
Rapporteur			
Co-Rapporteur			
Date of Inspection			
Date of Decision Made			
Signature		**Date**	

List of Documents to Support the Application
(To Be Submitted in English)

For both clinical and bioanalytical sites,

1) Organization Chart

2) List of Personnel Involved in BE Study

3) Facility Floor Plan

4) List of Standard Operation Procedures

5) List of Equipment Used in BE Study

6) List of BE Studies Conducted over the Past 2 Years

All supporting documents must be in English language and softcopy in Optical Character Recognition Portable Document Format (OCR PDF) with the search function enabled.

Payment Procedure for ASEAN Inspection for Listing of Bioequivalence Centre

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Section 1: Inspection Fee and Cost

According to *Manual for Application of Bioequivalence (BE) Centre to be listed under ASEAN Mutual Recognition Arrangement (MRA) on BE Study Report*, 2 types of payments shall be made to the NDRA of each appointed expert who will participate in the inspection;

1. Inspection fee:

   Professional fee of **USD 500 per man-day** (Calculated based on the number of inspection day(s) excluding travelling days) with a maximum of USD 2,500 per expert for 5 days inspections.

2. Inspection cost:

   The following should be borne by the BE Centre for each expert who has been selected to conduct the inspection;

   a. Round-trip flight ticket in Y Class (i.e. full-fare economy-class ticket) with flight insurance included in the airfare,
   b. Travel insurance for each expert capped at USD 100. The selected experts will arrange for their travel insurance,
   c. Local transportation capped at USD 100. The local transportation covers the cost of transportation for experts in the country of origin,
   d. Daily Subsistence Allowance (DSA) will be based on the United Nations (UN) DSA rate. The DSA rate covers accommodations, meals and

incidental costs, such as laundry, personal phone charges and other miscellaneous expenses.

e. For ground transport, the BE Centre should arrange for suitable ground transportation for the experts. The ground transport will cover the cost of transportation for experts in the destination country and borne by the BE Centre.

f. Other administrative costs to be borne by BE Centre:

   i. On force majeure case (including but not limited to war, riot, fire, flood, hurricane/typhoon, earthquake, lightning, explosion, strikes, lockouts, and acts of state or governmental action prohibiting or impeding travel), the cost incurred will be borne by BE Centre.

   ii. Conversion and transfer fees of payment will be done at the point of transaction and borne by the BE Centre. This will be based on the regulations in each ASEAN Member State (AMS) on processing the payment.

Refunds of the inspection fee and inspection costs are subject to country specific requirements. Kindly confirm with the appointed experts for the inspection on the refund policy prior to initiating payment.

Section 2: Country Specific Payment Procedures

Each AMS have their procedure for payment. Thus, BE Centre need to pay according to the relevant AMS' procedure as specified below;

Brunei Darussalam

1. Inspection fee & Inspection cost:

a. Payment shall be made:

- by the BE centre to the Government bank account:

Bank:	Bank Islam Brunei Darussalam
Account Name:	Government of Brunei Darussalam
Account No:	00-001-01-8000089

- In Brunei Dollar currency only
- at least 2 weeks before the inspection date.

b. If inspection cost is insufficient, additional inspection cost will be requested according to the shortage.

c. If the inspection is cancelled, the balance cost that is not used will be reimbursed to the BE centre.

d. All costs are non-refundable if there is surplus from the cost after the inspection.

Cambodia

Indonesia

Detail payment not yet available as Indonesia need to revise the related regulation.

Lao PDR

Malaysia (Draft - still subject to approval from Ministry of Health Level)

1. Inspection fee:

a. Payment shall be made;

- by an appointed agent in Malaysia (Official representative of the BE Centre in Malaysia),
- in "Malaysia Ringgit (RM)" currency. The foreign currency exchange rate

from USD to RM will be based on the published rate by "Accountant General's Department of Malaysia",

- using bank draft to "*Biro Pengawalan Farmaseutikal Kebangsaan*",
- at least 2 weeks before the inspection date.

b. The process is summarised as below;

- BE Centre appoint an agent in Malaysia (BE Centre representative in Malaysia) to liaise with NPRA

↓

- The selected expert(s) from Malaysia who is/are responsible for the inspection will issue the inspection fee invoice in "Malaysia Ringgit (RM)" based on the published foreign exchange rate by "Accountant General's Department of Malaysia"
- The rate will be based on the month of payment

↓

- Payment shall be made at least 2 weeks before the inspection date to NPRA according to the requirement above.

2. <u>Inspection cost:</u>

a. Expected cost expenditure with "Terms and Conditions" for contribution will be issued by the selected expert(s) at least 2 months prior to the Ministry of Health Malaysia Trust Fund Meeting. The estimation will usually be determined around 1 year before the inspection date.

b. The expected inspection cost is depending on the inspection location and will be estimated based on the criteria in Section 1.

c. The contribution shall be made;

- by an appointed agent in Malaysia (Official representative of the BE Centre in Malaysia),
- in "*Malaysia Ringgit* (RM)" currency,

- via bank draft to "*Akaun Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB*" via NPRA (Attention: *Ketua Setiausaha Kementerian Kesihatan Malaysia*) by the date stated in the invoice.

d. If there is surplus from the cost expenditure after the inspection, it will be retained in the fund for government use according to the directive of "*Arahan Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB.*"

e. If the contribution is insufficient, an additional contribution will be requested according to the shortage.

f. If the inspection is cancelled, the balance cost that is not used will be reimbursed to the appointed agent in Malaysia.

g. The invoice for inspection cost will be issued by the selected expert(s) from Malaysia who is/are responsible for the inspection.

h. The process is summarised as below;

- BE Centre appoint an agent in Malaysia (BE Centre representative in Malaysia) to liaise with NPRA

↓

- The selected expert(s) from Malaysia who is/are responsible for the inspection will issue the estimation inspection cost with "Terms and Conditions" for contribution.

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- BE Centre representative in Malaysia agrees with the cost estimation and "Terms and Conditions" for contribution.

↓

- The selected expert(s) from Malaysia who is/are responsible for the inspection will issue the invoice for contribution.

↓

- Payment shall be made by the date stated in the invoice.

All payment and contribution shall be made via the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia as the National Drug Regulatory Agency (NDRA) in Malaysia. Any question regarding the payment method, please contact the selected expert(s) from Malaysia for further clarification.

Myanmar

Philippines

Singapore

1. **Inspection fee & inspection cost payment mechanism:**

   a. Account Payee details:

Vendor\Company name:	Health Sciences Authority
Bank Name:	DBS
Bank Address: Wef 30 Jul 2012	12 Marina Boulevard
	#45-00 DBS Asia Central @ Marina Bay Financial Centre Tower 3
	Singapore 018982
Beneficiary Name:	Health Sciences Authority
Bank Code:	7171
Branch Code:	001
Account No	001-900112-9
SWIFT Code	DBSSSGSG

   b. Currency of payment: Singapore Dollars (SGD)
   c. Mode of payment: Telegraphic transfer and bank charges (both agent and beneficiary banks) relating to the transfer should be borne by inspectee.
   d. Timelines for payment: 3 working days before BE inspection.
   e. A tax invoice may be issued if requested by the inspectee.
   f. All costs incurred by HSA should be fully reimbursed.
   g. Any specific requirements for: Minimally, all cost incurred by HSA should be fully reimbursed.
   h. Contact information: HSA_CT@hsa.gov.sg

Thailand
All payment shall be made via Thai Food and Drug Administration's bank account. The details of the bank account will be notified later. Wire transfer and bank charges (both agent and beneficiary banks) relating to the transfer should be borne by inspectee. Currency of payment: Thai Baht Payment at least 2 months before the inspection dates (for the exchange rate please refer to Bank of Thailand website: https://www.bot.or.th/English/Pages/default.aspx)
Viet Nam

ภาคผนวก ข

รายการหลักเกณฑ์แนวทางอ้างอิง (List of Reference Guidelines) ในการจัดทำรายงานการศึกษาชีวสมมูลและการเตรียมความพร้อมรองรับการตรวจตราของศูนย์ศึกษาชีวสมมูลเพื่อขึ้นบัญชีของอาเซียน (ASEAN listed Bioequivalence center) สามารถดำเนินการตามหลักเกณฑ์ดังต่อไปนี้

๑. ASEAN Guideline for the Conduct of Bioequivalence Studies, March 2015

๒. Integrated Addendum To ICH E6 (R1): Guideline For Good Clinical Practice E6 (R2), November 2016

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๒. Annex I: To Procedure for Conducting GCP Inspections Requested by The EMEA: Investigator Site, September 2007, (Procedure no.: INS/GCP/3/I, EMEA/INS/GCP/197219/2005)

๓. Annex II: To Procedure for Conducting GCP Inspections Requested by The EMEA: Clinical Laboratories, September 2007, (Procedure no: INS/GCP/3/II, EMEA/INS/GCP/197220/2005)

๔. Annex III: To Procedure for Conducting GCP Inspections Requested by The EMEA: Computer Systems, November 2007, (Procedure no: INS/GCP/3/III-Rev 1, EMEA/INS/GCP/444656/2007 Corr*)

๕. Annex VII: To Procedure for Conducting GCP Inspections Requested by the EMEA: Bioanalytical Part, Pharmacokinetic and Statistical Analyses of Bioequivalence Trials, May 2008, (Procedure no.: INS/GCP/3/VII, EMEA/INS/GCP/97987/2008)