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

Procedures and Manual of Joint Sectoral Committee (JSC)

Version: 1

Version	Date	Status	Author
0	31st PPWG Meeting - 2021	Endorsed	ACCSQ-PPWG
1	5th JSC MRA BE Meeting	Agreed	JSC MRA BE

Procedures and Manual of Joint Sectoral Committee (JSC)

Table of Contents

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 5 of the ASEAN MRA specified that the Joint Sectoral Committee (JSC) shall be established and shall be responsible for the effective functioning of this Sectoral MRA. The JSC comprises of one official representative from each Member State's National Drug Regulatory Authority (NDRA).

For effective functioning of this Sectoral MRA, Article 5 specified 6 responsibilities of the JSC which include the establishment of Panel of Expert (PoE) with their competencies and qualification, the establishment of requirements for the competencies and qualifications of independent expert (IE), preparation of requirements and procedures for the listing, verification and removal/de-listing/appeal of BE Centres, providing a forum for discussion on issues that may arise concerning the implementation of this Sectoral MRA, proposing an amendment to this Sectoral MRA, including its annexes and considering any other matters and taking appropriate technical decisions relating to the implementation of this Sectoral MRA.

2. Scope

This document sets out to outline the terms of reference, the procedures, competencies and qualification for the establishment of PoE, the requirements, competencies and qualification for appointment of IEs and the procedures for listing, verification and removal/de-listing/appeal of BE Centres located in ASEAN member states territory.

3. Terms of Reference (ToR) for the Joint Sectoral Committee (JSC)

The content of ToR for the JSC of this MRA is divided into 8 articles as listed below:

Article 1 : Objective
Article 2 : Role of the JSC under the ASEAN Sectoral MRA for BE Study Report of Generic Medicinal Products
Article 3 : Composition of the JSC under the ASEAN Sectoral MRA for BE Study Report of Generic Medicinal Products
Article 4 : Duties and Responsibilities of Chair and co-Chair
Article 5 : Meeting
Article 6 : Terms of Office
Article 7 : Secretary
Article 8 : Rules of Procedures

The detail of the ToR is specified in document **PMOJ.Annex 1**.

4. Establishment of Panel of Expert (PoE)

Article 1 of this ASEAN Sectoral MRA defines a PoE as a group of people with expertise in BE inspection who is appointed by the JSC. The PoE shall comprise the representatives from member states' NDRA.

Article 5 of this ASEAN Sectoral MRA specifies that the JSC shall be responsible for the establishment of PoE with its term of reference including competencies and qualification of individual PoE.

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

There are 2 areas of expertise for BE inspection, Clinical and Bioanalytical. Thus, a registry of PoE will be established for both area of expertise, the processes are summaries as below:

4.1. Each ASEAN Member States may nominate suitable candidates to be included in the PoE Registry.

4.2. The candidates shall submit the application form as in **PMOJ.Annex 2** and **PMOJ.Annex 3** to NDRA for endorsement.

4.3. The NDRA shall forward the endorsed application form to the JSC.

4.4. The JSC shall review the candidates' competency and qualification based on criteria set in Section 5.

4.5. Candidates shall provide the JSC with detailed information relating to their qualifications, technical credentials and experiences, as well as declarations on conflicts of interests and/or financial disclosure (if any) that may influence the outcome of the assessment.

4.6. The decision to include experts in the PoE Registry shall be made by the JSC and minuted. The decision shall be by consensus in the JSC meeting or *ad referendum*.

4.7. If required, the NDRA of the expert may issue an acknowledgement letter to the expert based on the JSC decision.

4.8. ASEAN secretariat shall establish the PoE Registry including the detail of all the selected experts.

4.9. Experts in the PoE Registry shall be required to sign an undertaking for maintaining the confidentiality and abide by the "Statement of Confidentiality and Code of Ethics" that includes the upholding of confidentiality requirements.

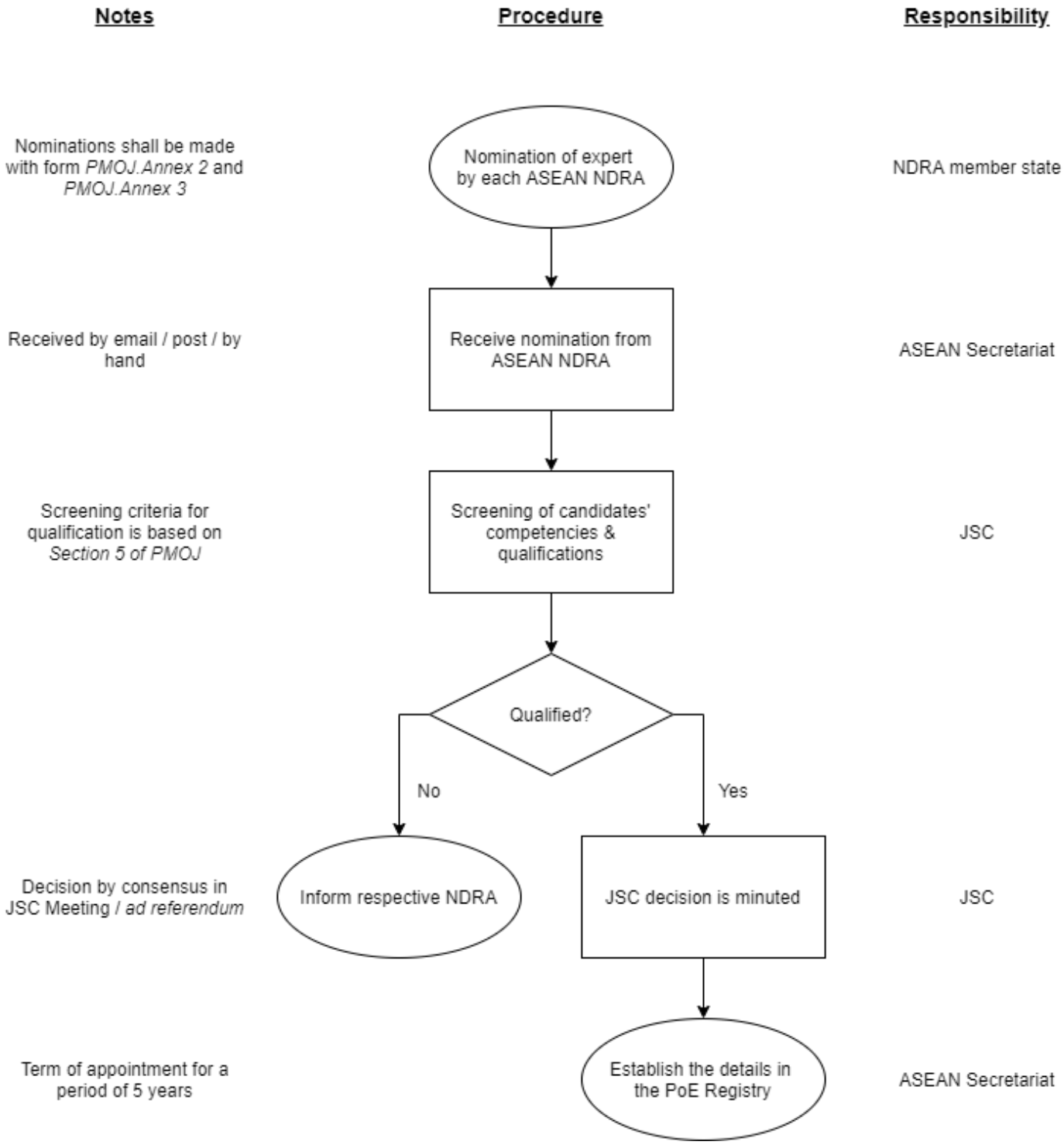
4.10. The terms of appointment as experts in the PoE Registry shall include the duration of an appointment (5 years from the date of appointment), the policy for the reappointment, the disqualification and the resignation.

4.11. Maximum of 3 experts from each NDRA. The experts in the PoE Registry can be replaced and changed based on the NDRA's recommendation. NDRA is recommended to nominate the expert with the expertise of both Clinical and Bioanalytical area.

The procedure for appointment and reappointment expert into the PoE Registry is summarised in **Figure 1**.

Figure 1: Establishment of Panel of Expert (PoE) Registry

Appointment and Reappointment Procedure



5. Competency and Qualification of Panel of Expert (PoE)

Article 5 of this ASEAN Sectoral MRA specifies that the JSC shall be responsible for the establishment of PoE with its term of reference including competencies and qualification of individual PoE.

In order to appoint a qualified expert for BE inspection, specific criteria in term of competency and qualification are established to facilitate the JSC review process. The criteria to be appointed as an expert in Clinical and Bioanalytical area and included into the PoE Registry are specified in Section 5.1 and Section 5.2, respectively. JSC Members may be eligible for appointment as an expert, subject to other criterias listed in this Section.

5.1. The competency and qualification criteria for the selection of Clinical expert are as below:

I. Degree in medicine, pharmacy, health science and relevant degree or higher in qualification.
II. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) training.
III. At least 5 years' GCP inspection experience including at least 10 clinical trials or 5 clinical part of BE studies inspected.
IV. Appointed as a lead inspector for at least 5 inspections to either clinical trials or BE clinical part.
V. The candidate shall be an employee of the NDRA or a designated government agency under the Ministry of Health.
VI. Agreed to sign "Statement of Confidentiality and Code of Ethics".
VII. Able to communicate in English verbally and in writing.

5.2 The competency and qualification criteria for the selection of Bioanalytical expert are as below:

I. Degree in medicine, pharmacy, health science and relevant degree or higher in qualification.
II. Relevant international training in Bioanalytical or Good Laboratory Practice (GLP) inspection principles.

III. At least 5 years' experience as a Bioanalytical or GLP inspector for the respective NDRA including at least 10 Bioanalytical or GLP inspections.
IV. Experience as a Lead Inspector in Bioanalytical or GLP inspections in at least 5 inspections.
V. The candidate shall be an employee of the NDRA or a designated government agency under the Ministry of Health.
VI. Agreed to sign "Statement of Confidentiality and Code of Ethics".
VII. Able to communicate in English verbally and in writing.

6. Roles of Panel of Expert (PoE)

Unless otherwise directed by the JSC, the PoE shall have the following key roles:

6.1 Review, assess and inspect the technical competency of the BE Centres to conduct a full/complete BE study;
6.2 Prepare a report for submission to the JSC on the outcome of the assessment;
6.3 Recommend to the JSC whether the BE Centre meets the criteria to be a Listed BE Centre.

7. Appointment, Competency and Qualification of Independent Expert (IE)

Article 5 of this ASEAN Sectoral MRA specifies that the JSC shall be responsible for establishing requirements for the competencies and qualifications of IE, who shall not be members of the PoE, and who shall be appointed when necessary.

The appointment of IE shall be made by the JSC when necessary based on their competency and qualification. Curriculum vitae (CV) of the IE must be provided to the JSC for verification of the competency and qualification. The appointed IE must fulfil the qualification and competency as listed in Section 7.1.

The IE shall not be ASEAN NDRA officials or any members of the PoE or any BE Centres.

The IE shall serve in their personal capacity and cannot be represented by an alternate attendee. They shall neither seek nor accept instructions in regard to their performance as IE from any government or other authority external to or within the JSC.

7.1. Competency and qualification of IE:

I. The IE(s) is/are capable to provide an opinion to the JSC on any issue of BE study in term of regulations, applicable law, and standard of conduct and practice;

II. The IE(s) is/are knowledgeable of and have mastered the methods and procedures of an inspection; and

III. Have training and/or experience which may consist of:

- Minimum of five (5) years of experience in the related field;
- Minimum of five (5) years of experience as a clinical or bioanalytical inspector for a BE study or GCP or GLP;
- Knowledge and understanding of;
    - Current technology, computer systems, information technology, data handling and archiving
    - Requirements for laboratory facilities, analytical instrumentation, handling of samples and analyses, pharmacokinetics;
- Evaluation of findings and reporting;

IV. The IE(s) shall agree to sign the declaration of any conflict of interest and financial disclosure.

V. The IE(s) shall agree to sign a declaration of the confidentiality agreement.

VI. The IE(s) shall be able to communicate in English verbally and in writing.

7.2. Application and appointment procedure of IE:

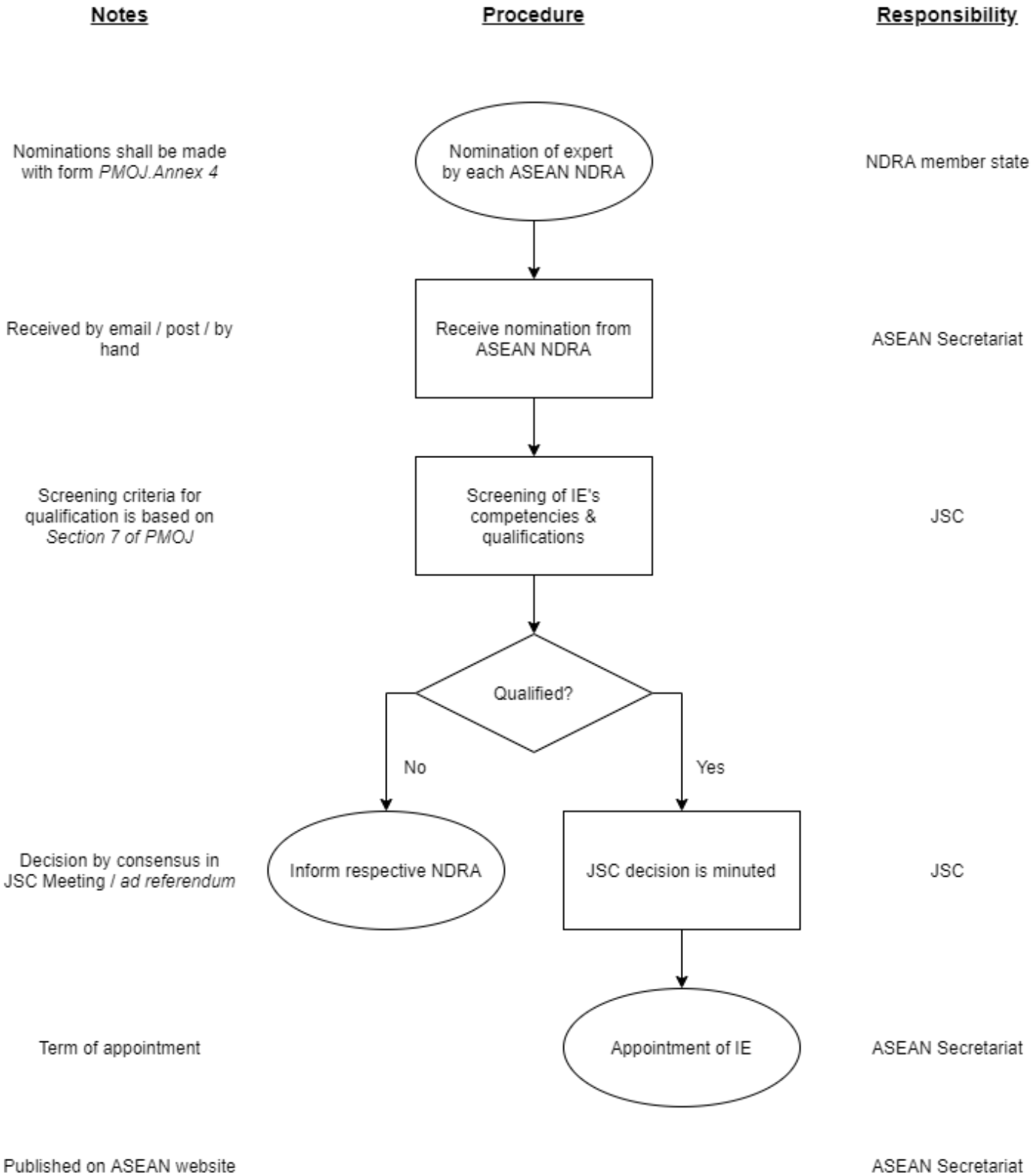
I. The candidate(s) shall submit the application form as in **PMOJ.Annex 4** to the JSC through the NDRA of the ASEAN Member States.

II. The decision to appoint the IE shall be made by the JSC and minuted.

III. If required, the appointed the IE may be issued an acknowledgement letter based on the JSC decision.

The IE appointment procedure is summarised in **Figure 2**.

Figure 2: Procedure for Appointment of Independent Expert (IE)



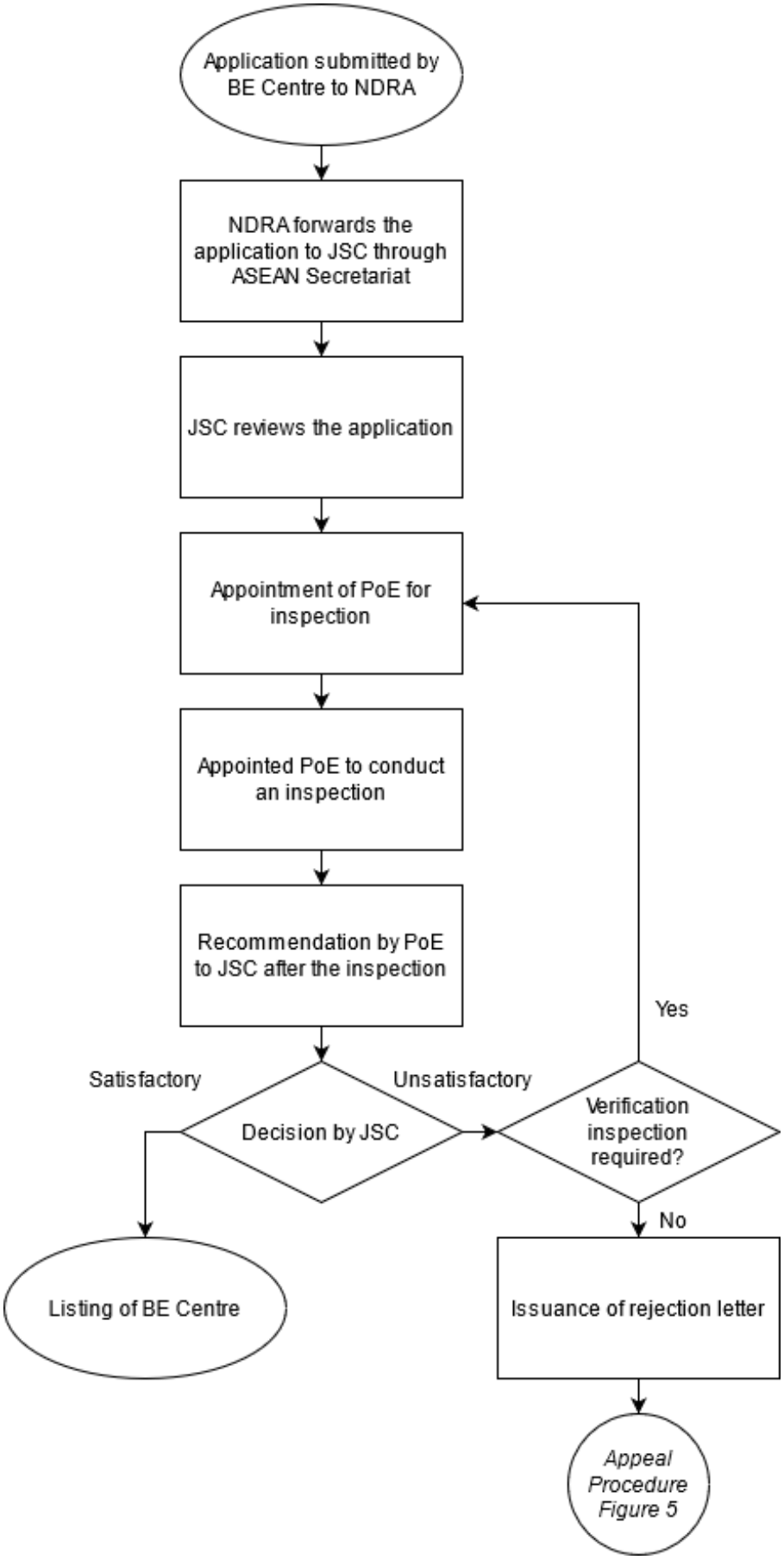
8. Process for Listing of Bioequivalence (BE) Centre

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 the BE study and issues BE study report.

Article 8 of this ASEAN Sectoral MRA specified 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 the BE centre shall be conducted by the appointed 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 Listed BE Centre and publish it on the ASEAN website.

The listing of BE Centre process is summarised in **Figure 3**.

Figure 3: Process for Listing of Bioequivalence (BE) Centres



9. 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 specified that the NDRA of each Member States shall be responsible for ensuring that any BE Centre within its jurisdiction that request 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 specified that an application for listing of BE Centre shall be submitted to the JSC, by an 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 sites either clinical or bioanalytical 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.

9.1. General requirement and procedure:

The application for BE Centre Inspection shall be made by an applicant representing the company using application form as in ***MoA.Annex 1*** of ***Manual for Application of BE Centre to be listed under the ASEAN MRA on BE Study Report***. The BE Centre shall appoint an Authorized 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.

9.2. 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 expert's country of origin according to the procedure specified in ***MoA.Annex 2*** of ***Manual for Application of BE Centre to be listed under the ASEAN MRA on BE Study Report***.

9.3. 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*** of ***Manual for Application of BE Centre to be listed under the ASEAN MRA on BE Study Report***. All inspection related costs incurred over the course of the inspection by the appointed experts shall be borne by the BE Centre under assessment.

All inspection fee and funding issues shall be addressed and resolved before the PoE embarks on the inspection.

10. Appointment of Panel of Expert (PoE) for Inspection

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

10.1. Arrangement of Inspection

The JSC will determine the number of experts for each area of expertise that will be involved for each inspection based on:

I. Location and number of sites to be inspected

II. Scope of inspection: System, facility and study audit (recommended to audit minimum of 2 studies)

III. Area to be inspected: Clinical, Bioanalytical, Pharmacokinetics and Statistical Analysis

10.2. Appointment of the PoE for inspection

Based on the criteria below, the JSC will appoint the PoE for each inspection from list of experts in the PoE Registry. General criteria as below shall be followed;

I. The expert from the country to be inspected shall not be involved in the inspection;

II. A minimum of three (3) experts and a maximum of four (4) experts shall be appointed from three (3) different Member States for each inspection, if possible.

III. The inspection team shall be comprised of experts from at least 2 Member States if point II is not achievable.

IV. In the event of point II and III cannot be achieved, the JSC will have the final decision based on the justification and consensus by all members.

V. The role of Rapporteur and Co-Rapporteur will be assigned to the appointed experts for the inspection.

VI. To avoid conflict of interest, such expert who also serves as JSC MRA BE Member shall not be involved in the evaluation and decision-making process of the outcome assessment that is made by the approved expert him/herself, in the JSC MRA BE Meeting.

Procedure for inspection by the PoE is specified in the ***OMOP.Operation Manual of PoE***.

11. Decision for Listing of Bioequivalence (BE) Centre

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

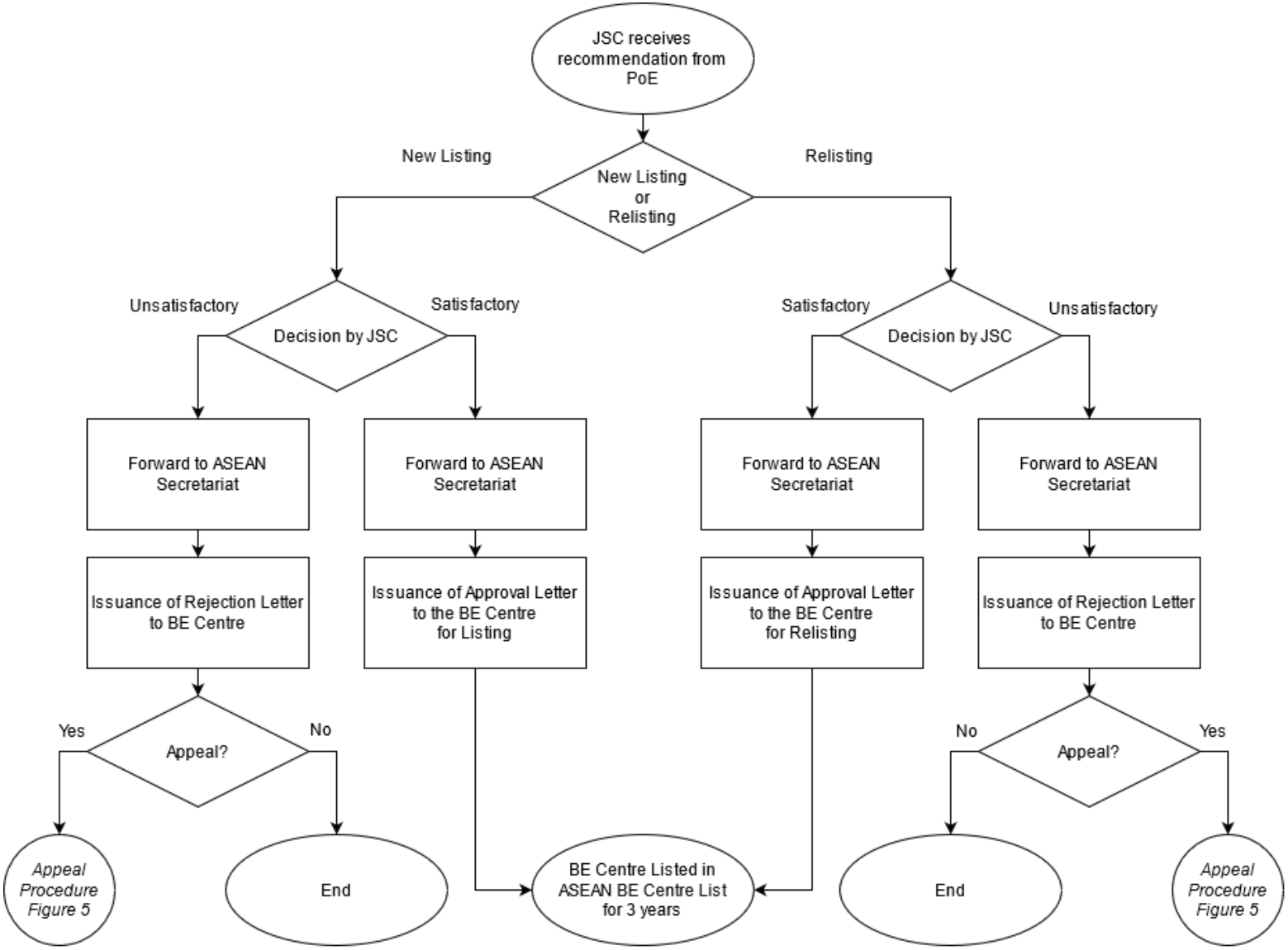
Article 8 of ASEAN Sectoral MRA states that the inspection of BE centre shall be conducted by the appointed PoE and the JSC will make its decision for the listing of BE centre based on the recommendations from said PoE.

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 **Figure 4**.

Once the BE Centre had been recognised by the JSC, the BE Centre will be listed in ASEAN BE Centre List for 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. Relisting is required every 3 years.

Figure 4: Decision for Listing of BE Centre



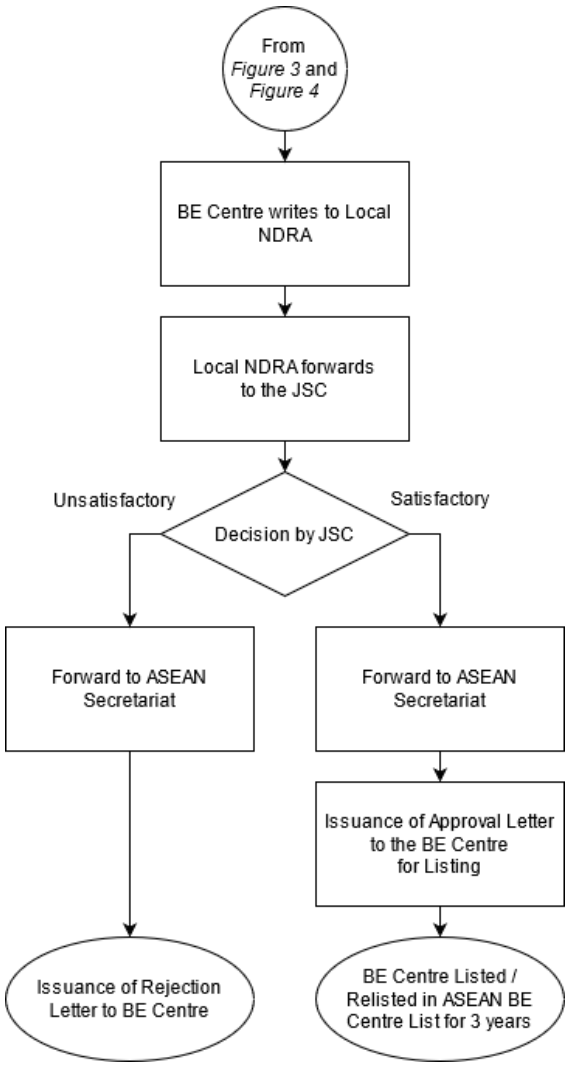
12. Handling of Appeal

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

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 5**.

Figure 5: Appeal Process



13. Handling of Complaint

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.

14. Documentation and Documents Control

There are two categories of documentation to be archived, namely JSC related documents and BE inspections related documents. ASEAN Secretariat shall maintain the JSC related documents while respective ASEAN NDRA shall maintain BE inspection related documents.

All JSC related documents shall be maintained for a minimum period of 6 years from the date of issuance of the documents. The list of JSC related documents should be filed and archived include, but not limited to:

No.	Documents	Responsibility
I.	The constitution (MRA), TOR, Annexes and procedures	ASEAN Secretariat
II.	The curriculum vitae of all PoE	ASEAN Secretariat
III.	The curriculum vitae of all appointed IE	ASEAN Secretariat
IV.	The agenda of JSC meetings	ASEAN Secretariat

V.	The minutes of JSC meetings	ASEAN Secretariat
VI.	A copy of all materials submitted by the applicant	ASEAN Secretariat
VII.	A copy of the decision as recorded in the JSC minutes	ASEAN Secretariat
VIII.	Appointment of PoE for individual BE inspection	ASEAN Secretariat
IX.	Listing of BE centre/ approval letter	ASEAN Secretariat

All BE inspection related documents shall be maintained for a minimum period of 6 years following completion of an inspection. The list of BE inspection related documents should be filed and archived include, but not limited to:

No.	Documents	Responsibility
I.	Announcement letter	Respective NDRA
II.	Requested document	Respective NDRA
III.	Documents and records that were taken during the inspection	Respective NDRA
IV.	The final inspection report, addendum 1 and addendum 2 which include the recommendation from PoE to JSC	Respective NDRA
V.	All written documentation (include Corrective and Preventive Action (CAPA)) received during the response of inspection report	Respective NDRA
VI.	Correspondences by JSC, PoEs and applicants regarding the application, decision and follow-up	Respective NDRA

All PoEs participated in each inspection shall maintain all documents related to the inspection. After the completion of the inspection, the Rapporteur of each inspection shall ensure all confidential documents to be sent and archived by the respective NDRA within 60 calendar days from the listing date. The NDRA shall index all the BE inspection related documents before archive.

NDRA shall maintain the document distribution list. Any required hard copy documents are distributed according to an established list to ensure availability at the location where the activity will be performed prior to commencement of work.

Terms of Reference (ToR) for the Joint Sectoral Committee (JSC) Under The ASEAN Sectoral Mutual Recognition Arrangement (MRA) for Bioequivalence (BE) Study Report of Generic Medicinal Products

Background

As required by the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for Bioequivalence (BE) study report, specifically under Article 5 thereof, a Joint Sectoral Committee (JSC) shall be established upon signing of the Sectoral MRA, which shall be responsible for the effective functioning of this Sectoral MRA.

JSC should be established to monitor the implementation of the ASEAN Sectoral MRA for BE Study Report of Generic Medicinal Products and report the status of its implementation to the PPWG. The Pharmaceutical Product Working Group (PPWG) would monitor the overall implementation of the MRA. However, noting that there are other deliverables for the PPWG which are still under discussion and there is a need to have a technical group to carry out the necessary activities for the implementation of the MRA, the ASEAN Consultative Committee on Standards and Quality (ACCSQ) recommended the establishment of a sub-group under the PPWG to carry out the detailed implementation of the MRA and report the status of its implementation to the PPWG.

Article 1: Objective

1. To monitor and ensure the effective implementation of the ASEAN Sectoral MRA for BE Study Report of Generic Medicinal Products upon signing of the MRA.

Article 2: Role of the JSC under the ASEAN Sectoral MRA for BE Study Report of Generic Medicinal Products

2. The JSC shall be responsible for:
   - 2.1. Establishing a Panel of Expert (PoE), that shall consist of the National Drug Regulatory Authority (NDRA) officials, and establishing its terms of reference including the competencies and qualification of individuals in the PoE;
   - 2.2. Establishing requirements for the competencies and qualifications of independent experts, who shall not be members of the PoE, and who shall be appointed when necessary;
   - 2.3. Preparing the requirements and procedures for the listing, verification and removal/de-listing/appeal of BE Centres in accordance with this Sectoral MRA;
   - 2.4. Providing a forum for discussion of issues that may arise concerning the implementation of this Sectoral MRA;
   - 2.5. Proposing an amendment to this Sectoral MRA, including its annexes; and proposing additional annexes when necessary; and
   - 2.6. Considering any other matters and taking appropriate technical decisions relating to the implementation of this Sectoral MRA.

Article 3: Composition of the JSC under the ASEAN Sectoral MRA for BE Study Report of Generic Medicinal Products

3. The JSC shall comprise:
   3.1 One official representative from each Member State's NDRA. The representative may be accompanied by his/her delegation at meetings of the JSC. For the purpose of membership of the JSC, a Member State shall notify the ASEAN Secretariat of the name of the official representative or his/her official designate.
   3.2 The Chair and the Co-Chair shall be appointed from the members of JSC.

A list of the JSC members is found in **Appendix 1**.

Article 4: Duties and Responsibilities of Chair and co-Chair

4.1 The Chair shall be present at every meeting of the JSC and ensure that all decisions made are based on consensus. For those member states who are absent, decisions shall be obtained through email (ad ref).
4.2 In the absence of the Chair, the co-Chair shall assume the duties and responsibilities of the Chair.
4.3 Prior to any of its Meetings, the Chair will consult with the members of the JSC on the agenda to be covered during the Meetings.
4.4 The Chair shall report to the PPWG on the proceedings and the decisions made during the JSC Meetings for endorsement by PPWG.

Article 5: Meeting

5.1 The JSC shall meet at least once a year and when required, in order to discharge its duties and determine its own rules of procedures.
5.2 All meetings of the JSC shall be convened by the Chair and/or the Co-Chair.
5.3 Every decision of the JSC shall be reached by consensus of the members. Any disagreement amongst the JSC shall be settled in accordance with Article 15 (Settlement of Disputes) of the Sectoral MRA.
5.4 Notices of Meetings and Meeting Agendas shall be dispatched to all Members of the JSC by the ASEAN Secretariat at least 60 days before the meeting date.
5.5 The Meeting should have at least 6 Member States present for a meeting to be convened.
5.6 The report of the meeting should be circulated to all Member States. For absent Member State(s), they will be given 2 weeks period for endorsement of the meeting report.

Article 6: Terms of Office

6. The terms of office for the Chair and Co-Chair of the JSC shall be for a 3 year period and may be considered for re-election.

Article 7: Secretary

7. The Secretary shall be an officer of the ASEAN Secretariat appointed under the authority of the Secretary-General. The Secretary shall be responsible for maintaining records of membership, meetings and proceedings of the JSC. This shall include records of Panel of Experts, requirements and procedures for the listing, verification and removal/de-listing of BE Centres and decisions made.

Article 8: Rules of Procedures

8. The JSC may determine its own rules of procedures. These rules of procedure and changes shall be notified to the PPWG.

Chair of JSC

(……..…….)

APPENDIX 1

Members of the JSC

Brunei Darussalam	Name and contact details
Cambodia	Name and contact details
Indonesia	Name and contact details
Lao PDR	Name and contact details
Malaysia	Name and contact details
Myanmar	Name and contact details
Philippines	Name and contact details
Singapore	Name and contact details
Thailand	Name and contact details
Viet Nam	Name and contact details

APPLICATION FORM
PANEL OF EXPERT
CLINICAL
ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products

1. Personal Information

Title			<Candidate's Photo>
First name			
Last name			
Gender			
Date of birth			
Nationality			
Position			
Name of institution			
Full professional mailing address including city/country			
Contact details (including international and area codes)	Tel: Fax:	Mobile phone: Email:	
Job title and description			

2. Academic Qualifications

Name of school/institution	Degree/ Master/PhD	Years of attendance

3. Language Proficiency

Language/ Written	Oral (state: fair, good, excellent)	Written (state: fair, good, excellent)
English		

4. Participation in International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) training

Name of institution	Title of training	Location	Date of attendance

5. Professional Background (List last three positions held)

Name of institution	Position held	Date of employment (from/to)	Brief description of work

6. Knowledge and experience

(Please rate your experience by putting 'X' in relevant options)

Inspection Experience	Less than 5	5 – 10	More than 10	Comments
Number of years GCP inspection experience				
Number of GCP inspections				
Number of GCP inspections (BE clinical part)				
Number of times appointed as a lead inspector (BE/non BE study)				

Other knowledge and experience in GCP Inspection:

Required attachments

(Your application form will not be accepted without the attachments listed below)

☐ Curriculum vitae or resume

☐ Please provide a copy of your relevant training certificates

Please note:

- *Answer all questions on the application form*
- *Type or print legibly*
- *Agree to sign a confidentiality agreement for each inspection appointed by the JSC*

Candidate's Signature

Signature			
Name		**Date**	
Position			

To be completed by NDRA of the candidate

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

FOR OFFICE USE ONLY (to be completed by the JSC)

Received Date			
Name of ASEAN Secretariat			
Signature		**Date**	

APPLICATION FORM
PANEL OF EXPERT
BIOANALYTICAL
ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products

1. Personal Information

Title		<Candidate's Photo>
First name		
Last name		
Gender		
Date of birth		
Nationality		
Position		
Name of institution		
Full professional mailing address including city/country		
Contact details (including international and area codes)	Tel: Fax:	Mobile phone: Email:
Job title and description		

2. Academic Qualifications

Name of school/institution	Degree/ Master/PhD	Years of attendance

3. Language Proficiency

Language/ Written	Oral (state: fair, good, excellent)	Written (state: fair, good, excellent)
English		

4. Participation in relevant international training on Bioanalytical or GLP

Name of institution	Title of training	Location	Date of attendance

5. Professional Background (List last three positions held)

Name of institution	Position held	Date of employment (from/to)	Brief description of work

6. Knowledge and experience

(Please rate your experience by putting 'X' in relevant options)

Inspection Experience	Less than 5	5 – 10	More than 10	Comments
Number of years Bioanalytical/GLP inspection experience				
Number of Bioanalytical/GLP inspections				
Number of times appointed as a lead inspector (BE Bioanalytical/GLP inspection)				

Other knowledge and experience in Bioanalytical/GLP Inspection:

Required attachments

(Your application form will not be accepted without the attachments listed below)

☐ Curriculum vitae or resume

☐ Please provide a copy of your relevant training certificates

Please note:

- *Answer all questions on the application form*
- *Type or print legibly*
- *Agree to sign a confidentiality agreement for each inspection appointed by the JSC*

Candidate's Signature

Signature			
Name		**Date**	
Position			

To be completed by NDRA of candidate

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

FOR OFFICE USE ONLY (to be completed by the JSC)

Received Date			
Name of ASEAN Secretariat			
Signature		**Date**	

APPLICATION FORM
INDEPENDENT EXPERT
ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products

1. Personal Information

Title			<Candidate's Photo>
First name			
Last name			
Gender			
Date of birth			
Nationality			
Position			
Name of institution			
Full professional mailing address including city/country			
Contact details (including international and area codes)	Tel: Fax:	Mobile phone: Email:	
Job title and description			

Briefly describe how your job relates to this application

2. Academic Qualifications

Name of school/institution	Degree/ Master/PhD	Years of attendance

3. Language Proficiency

Language/ Written	Oral (state: fair, good, excellent)	Written (state: fair, good, excellent)
English		

4. Participation in relevant international training on the related field and GCP/ BE/Bioanalytical/ GLP

Name of institution	Title of training	Location	Date of attendance

5. Professional Background (List last three positions held)

Name of institution	Position held	Date of employment (from/to)	Brief description of work

Please provide information on your professional background related to work experience in NDRA (number of years working, type of activities you have been involved, etc)

6. Area of Expertise

a.	
b.	
c.	
d.	
e	

7. Knowledge and experience

a. Number years of experience in related field: _____

Related fields (e.g. Computerised System)	**Comments**

b. Inspection experience

(Please rate your experience by putting 'X' in relevant options)

Inspection Experience	**Less than 5**	**5 – 10**	**More than 10**	**Comments**
Number of years in clinical part for BE study inspection				
Number of years in Bioanalytical for BE study inspection				

8. Alternative professional experience

Please supply relevant details of experience you consider as an alternative to the competence requirements set out in Section 7 of Procedures and Manual of Joint Sectoral Committee (JSC), ASEAN MRA for BE Study Reports of Generic Medicinal Products.

Experience	**Number of years**	**Dates : (from-to)**

Required attachments

(Your application form will not be accepted without the attachments listed below)

☐ Curriculum vitae or resume

☐ Please provide a copy of your relevant training or related field certificate

Please note:

- *Answer all questions on the application form*
- *Type or print legibly*

9. Declaration

By submitting this application form, I declare;

- All information provided above is true and complete.
- To produce on request, documents to support my expression of interest and accept that failure to do so may invalidate my application.
- To confirm that I am willing to commit to act independently in the public interest and to make complete declarations of any direct or indirect interests that might be considered prejudicial to my independence.
- To serve in my personal capacity and I shall not represent by an alternate attendee. I shall neither seek nor accept instructions in regard to my performance as IE from any government or other authority external to or within the JSC.
- To take reasonable measures to protect the Confidential Information; subject to applicable national legislation, not to disclose the Confidential Information to any person(s); not to use the Confidential Information for any purpose outside the mandate, and in particular, in a manner which would result in a benefit to myself or any third party; destroy or return to respective NDRA, all copies of Confidential Information after use; and to return all Confidential Information (including any minutes or notes I have made as part of my duties as IE) to respective NDRA upon the termination of my functions as IE.
- That I have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements) in the subject matter or materials discussed during the performance of my duties as IE.

Candidate's Declaration

Signature			
Name		**Date**	
Position			

To be completed by NDRA

Received Date			
NDRA clearance: Director of NDRA			
NDRA			
Name			
Designation			
Phone		**Fax**	
Email			
Signature		**Date**	
Stamp			
Date of Forwarding to Joint Sectoral Committee (JSC)			

FOR OFFICE USE ONLY (to be completed by JSC)

Date of Receipt			
Name of Reviewer			
Signature		**Date**	