National Consultation: 3rd Draft of the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for Bioequivalence (BE) Study Reports

03 July 2015
FDA Audio-Visual Room
3/F Annex Building, Alabang
Muntinlupa City
Presentation Outline

• Objectives of the National Consultation
• Backgrounder
  - ASEAN and ASEAN Harmonization
  - ACCSQ-PPWG and its Accomplishments so far
  - ASEAN Sectoral MRA for BE Study Reports
• Timeline in the Development and Finalization of the MRA
• Brief Discussion of the Contents of the MRA (Articles 1 to 18)
• Anticipated Activities Post-MRA Signing
Objectives of the National Consultation
Objectives

• To give the stakeholders an overview of what the ASEAN Sectoral MRA for BE Study Reports is all about and what it intends to achieve, get all relevant parties' perspective on the matter, and present an opportunity for them to comment or provide feedback.

➤ With this in mind, the MRA could be developed into something that is mutually acceptable and beneficial to all.
Backgrounder
What is ASEAN?

Association of Southeast Asian Nations - established in 1967

Original Member States
- Indonesia
- Malaysia
- Philippines
- Singapore
- Thailand

1984
- Brunei Darussalam

1995
- Viet Nam

1997
- Lao PDR
- Myanmar

1999
- Cambodia

Population: 603 million (2011)
GDP (Nominal): US$ 2.4 trillion (2013)
Objectives of ASEAN

1. To accelerate economic growth, social progress, and cultural development
2. To protect regional peace and stability
3. To give opportunities for member states to discuss differences peacefully

1995 – ASEAN Leaders reaffirmed that:

“Cooperative peace and shared prosperity shall be the fundamental goals of ASEAN”
Need for ASEAN Harmonization

10 ASEAN Member States have:

- Very diverse racial, religious, cultural, social, political, economic and geographical background

- Combined market of about 600 million people
**Target**

To create a single market by 2015

**Principle**

Elimination of technical barriers to trade posed by regulations, without compromising the quality, safety and efficacy

**Priority Products**

Agricultural, Fisheries, Wood, Rubber, Automotive, Textiles, Electronics, Tourism, Travel, Logistics, **Healthcare**, e-ASEAN
ASEAN Harmonization in the Pharmaceutical Sector (1)

Timeline:

1992 – Initial efforts towards the harmonization of ASEAN regulations were initiated through the establishment of the ASEAN Consultative Committee on Standards and Quality (ACCSQ).

1999 – To address specific harmonization issues on pharmaceuticals, the ACCSQ Pharmaceutical Product Working Group (PPWG) was formed.
## ASEAN Hierarchy

<table>
<thead>
<tr>
<th>Level</th>
<th>Function</th>
<th>Meeting, Output</th>
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<tbody>
<tr>
<td>President Prime Minister</td>
<td>Highest decision-making body</td>
<td>Annual meeting</td>
</tr>
<tr>
<td>Minister of Economy, Trade,</td>
<td>Coordinate the work of the Association</td>
<td>Joint Ministerial Meeting (JMM)</td>
</tr>
<tr>
<td>Foreign Affairs</td>
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<td>ASEAN Consultative Committee on</td>
<td>Facilitate the objectives of the Free Trade</td>
<td>Harmonized sectors</td>
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<tr>
<td>Standards and Quality</td>
<td>Area / Implement the Mutual Recognition</td>
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<tr>
<td>Pharmaceutical Product Working</td>
<td>Develop harmonization scheme of pharmaceutical</td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>regulations</td>
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</tbody>
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### ASEAN Summit
- President Prime Minister
- Minister of Economy, Trade, Foreign Affairs
- ASEAN Consultative Committee on Standards and Quality
- Pharmaceutical Product Working Group

### ASEAN Ministry
- Committees
- Product Working Groups
ASEAN Harmonization in the Pharmaceutical Sector

Timeline:
2000-2003

- Key areas on Generics, NCEs, Biologics were harmonized.
- ASEAN Common Technical Dossier (ACTD) format (consisting of Administrative Data, Quality, Safety and Efficacy parts) and ASEAN Common Technical Requirements (ACTR) were developed.
Timeline:

2004-2007
- Trial period of ACTD/ACTR implementation

2009 to the present
- Full ACTD/ACTR implementation
- Development of further ASEAN technical guidelines on Quality, Safety and Efficacy, BA/BE, GMP and Vaccines
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<th>Country</th>
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<td>Target Full: Dec 2014</td>
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<td>Jul 2003</td>
<td>Vietnam</td>
<td>Full: Nov 2009</td>
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ACCSQ-PPWG Accomplishments

1. ASEAN Common Technical Dossier (ACTD)
   - Part I: Administrative Data and Product Information
     - Glossary
     - Organization of Dossier
     - Administrative Data
   - Part II: Quality Document
   - Part III: Nonclinical Document
   - Part IV: Clinical Document
ACCSQ-PPWG Accomplishments (2)

2. ASEAN Common Technical Requirements (ACTR)
   - Bioavailability and Bioequivalence Study
   - Stability
   - Validation of Analytical Procedures
   - Validation of Manufacturing Process
   - Variations
   - Nonclinical (Safety)
   - Clinical (Efficacy)
ACC SQ-PPWG Accomplishments (3)

3. ASEAN Post Market Alert System (PMAS)
4. ASEAN Sectoral Mutual Recognition Arrangement on Good Manufacturing Practice (GMP) Inspection for Manufacturers of Medicinal Products
• Bioavailability/Bioequivalence (BA/BE) Task Force
  – Chair: Indonesia (Badan POM / NADFC)
  – Co-Chair: Malaysia (BPFK / NPCB)
Accomplishments:

- Definition of ASEAN Comparator Product
  - Endorsed at the 13th PPWG Meeting (July 2007)

- Selection Criteria of ASEAN Comparator Product
  - Endorsed at the 13th PPWG Meeting (July 2007)

- ASEAN Inspection Criteria for Bioequivalence Studies
  - 5th draft endorsed at the 19th PPWG Meeting (July 2012)
• **Accomplishments:**
  
  – ASEAN Clinical Part Inspection Checklist for Bioequivalence Study
    
    - 8th draft endorsed at the 22nd PPWG Meeting (March 2015)

  – ASEAN Bioanalytical Part Inspection Checklist for Bioequivalence Study
    
    - 7th draft endorsed at the 22nd PPWG Meeting (March 2015)
• **On-going Discussions:**
  
  – ASEAN Sectoral Mutual Recognition Arrangement for Bioequivalence (BE) Study Reports [3rd draft]
• Technical Working Group on Bioavailability/Bioequivalence (BA/BE) Study Guidelines
  – Chair: Malaysia (BPFK / NPCB)
  – Co-Chair: Indonesia (Badan POM / NADFC)
• **Accomplishments:**

- ASEAN Guidelines for the Conduct of Bioavailability and Bioequivalence Studies (2004) *including* the ASEAN Bioequivalence Study Reporting Format

  ✓ ASEAN Guideline for the Conduct of Bioequivalence Studies (R1) (2015)

  ➢ (R1) is predominantly based on the EMA Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **) that came into effect in August 2010

  ➢ (R1) Draft 4 is considered *Final* as of March 2015
ASEAN Sectoral MRA for BE Study Reports

- Mutual intra-regional acceptance of Reports of BE Studies conducted by Listed BE centers based in ASEAN
- Minimizes the repetition of BE Studies required for marketing authorization from one ASEAN Member State (AMS) to another
  - Reduction of costs for the Pharmaceutical Industry
  - Saves precious (limited) resources of the ASEAN NDRAs as the need for inspections are lessened with the BE Center listing/recognition concept
- Maximizes the capacity of existing ASEAN BE Centers
At the ACCSQ-PPWG level, the ASEAN Sectoral MRA for BE Study Reports is the 2\textsuperscript{nd} MRA initiative undertaken after the ASEAN Sectoral MRA on Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products.
Prerequisites/Conditions:

- Conducted by a Listed BE Center based in ASEAN
- The same comparator product is recognized by the NDRA of the AMS where the BE Study was conducted and the NDRA of the AMS where the BE Study Report is to be submitted.
- Approval of the BE Study Report by the NDRA of the AMS where the BE Study was conducted does not guarantee the approval by the NDRA of the AMS where the BE Study Report is to be submitted.
- The BE Study Report is consistent in form and substance with the ASEAN BE Study Reporting Format.
As the finalization of the MRA was identified as one of the AEC Key Deliverables for 2015, ACCSQ-PPWG has committed to expedite the development of the MRA in order to meet the deadline.

- In this context, finalized means the stage where the ACCSQ-PPWG has completed the necessary negotiations and the document is ready for legal scrubbing process by the AMS and the ASEAN Secretariat.
Timeline in the Development and Finalization of the MRA
MRA Development and Finalization Timeline (1)

- 1st Workshop on the Development of an MRA for BE Study Reports, October 2014 in Jakarta
  - Organized under the ASEAN Regional Integration Support from the European Union (ARISE) Programme
  - Discussion of the results of ASEAN-wide survey to determine the feasibility of having an MRA for BE Study Reports and identify its scope
MRA Development and Finalization Timeline (2)

• Inter-sessional BA/BE Task Force Meeting, October 2014 in Jakarta
  – Crafting and discussion of the initial draft of the MRA
  – For circulation to AMS for inputs/comments and come-up with the 2\textsuperscript{nd} draft

• 11\textsuperscript{th} BA/BE Task Force Meeting (back-to-back with the 22\textsuperscript{nd} ACCSQ-PPWG Meeting), March 2015 in Vientiane
  – Discussion of the 2\textsuperscript{nd} draft and (after further inputs) finalization of the 3\textsuperscript{rd} draft of the MRA
MRA Development and Finalization Timeline (3)

• 43rd ACCSQ Leaders Meeting, April 2015 in Manila
  – Reporting of progress in the development of the MRA by the Co-Chair of ACCSQ-PPWG

• April to June/July 2015
  – AMS to carry out national consultation on the 3rd draft of the MRA and submit inputs/comments to the ASEAN Secretariat

• July 2015
  – ASEAN Secretariat to circulate the compilation of inputs/comments to AMS
MRA Development and Finalization Timeline (4)

- 2\textsuperscript{nd} Workshop on the Development of an MRA for BE Study Reports, August 2015 in Jakarta
  - Organized under the ARISE Programme
  - AMS to discuss and review all comments from the national consultation process and provide recommendations for the draft MRA

- Inter-sessional BA/BE Task Force Meeting, August 2015 in Jakarta
  - AMS to study recommendations from the ARISE Workshop and consider finalization of the 4\textsuperscript{th} draft of the MRA
MRA Development and Finalization Timeline (5)

• December 2015 (in line with the AEC Key Deliverables for 2015)
  – 4th draft of the MRA finalized and endorsed by ACCSQ-PPWG and ready for legal scrubbing process

• January to February 2016
  – Legal review at the national level

• 12th BA/BE Task Force Meeting, March 2016 in Cambodia (to be confirmed)
  – Legal scrubbing with the ASEAN Secretariat Legal Services and Agreements Division (LSAD)
MRA Development and Finalization Timeline

- April 2016 (to be confirmed)
  - Submission of the MRA to ACCSQ and subsequently to SEOM for endorsement
- June to July 2016 (to be confirmed)
  - Domestic process to have Letter of Full Power for ASEAN Economic Minister to sign the MRA
- 2nd half of 2016 (to be confirmed)
  - Signing by AEM
Contents of the MRA (Articles 1 to 18)
Article I: Definitions (1)

• “Accept”
  – means the use of bioequivalence study reports from listed Bioequivalence Centers as part of the requirement for the registration of generic medicinal products by the National Drug Regulatory Authority of an ASEAN Member State taking into consideration that the review and assessment is under the jurisdiction of the respective Member States.
Article I: Definitions (2)

• “Bioequivalence (BE) Center”
  – means any independent organization located in ASEAN Member States which conducts the BE Study and issues the BE Study Report. Both clinical and bioanalytical parts of the study must be conducted in ASEAN Member States.

• “Bioequivalence Study”
  – means a comparative bioavailability study designed to establish equivalence between a generic medicinal product and comparator product.
Article I: Definitions

• “Bioequivalence Study Report”
  – means a report of the BE Study issued by a Listed BE Center according to the ASEAN BE Study Reporting Format.

• “ASEAN Comparator Product”
  – means a pharmaceutical product selected based on the Selection Criteria of ASEAN Comparator Product with which the generic medicinal product is intended to be interchangeable in clinical practice, and does not refer to a harmonized list of comparator products.
Article I: Definitions

• “ASEAN Comparator Product” (Continued)

  – Selection Criteria of ASEAN Comparator Product (1)
    ▪ Innovator product, and multiple manufacturing sites of the same innovator registered in the country
    ▪ If the innovator product used as comparator is not registered in the country, justification is required from the generic company to prove its interchangeability with the registered innovator (*in vitro* or *in vivo*)
Article I: Definitions (5)

• “ASEAN Comparator Product” (Continued)

– Selection Criteria of ASEAN Comparator Product (2)

  ▪ If the innovator product cannot be identified, the choice of comparator must be made carefully and be comprehensively justified by the applicant. The selection criteria of a comparator in order of preference are:
    ➢ Approval in ICH and associated countries
    ➢ Pre-qualified by WHO
Article I: Definitions

• “Generic Medicinal Product”
  – means a pharmaceutical product which has the same qualitative and quantitative composition in active substance(s) and the same pharmaceutical form as the comparator product, and whose bioequivalence with the comparator product has been demonstrated by appropriate bioavailability studies.
Article I: Definitions

• “Listed Bioequivalence Center”
  – means a BE Center which has been recognized by the Joint Sectoral Committee.

• “National Drug Regulatory Authority (NDRA)”
  – in relation to each Party, means the regulatory authority or entity of that Party which exercises a legal right to control the import, manufacture, export, distribution, transfer, use and sale of medicinal products within that Party’s jurisdiction and which may take regulatory action to ensure that the products marketed within its jurisdiction comply with regulatory requirements.
Article I: Definitions

• “Panel of Experts (PoE)”
  – means a group of people with expertise in BE inspection who are appointed by the Joint Sectoral Committee. The PoE shall comprise the representatives from ASEAN NDRAs.

• “Party/Parties”
  – means ASEAN Member State/s that is/are participating in the Sectoral MRA.
Article 2: Objective

• To facilitate the mutual recognition of BE Study Reports of generic medicinal products, issued by Listed BE Centers located in the territories of ASEAN Member States
Article 3: General Provisions

- All ASEAN Member States shall be eligible to participate in the Sectoral MRA.
- Parties to the Sectoral MRA shall ensure that only the reports of BE Studies conducted as per the latest version of the ASEAN Guideline for the Conduct of BE Studies are accepted for review.
- Each Party shall establish a list of comparator products as guided by the ASEAN Guideline for the Conduct of BE Studies, wherever possible. Each Party is encouraged to publish this list on its website.
Article 4: Scope

• The Sectoral MRA applies to BE Study Reports of generic medicinal products as defined in Annex A of this Sectoral MRA, from those Listed BE Centers located in ASEAN Member States.

  ➢ Covers immediate-release oral solid dosage forms with systemic action
Article 5: Joint Sectoral Committee (JSC) (1)

• A JSC shall be established upon signing of the Sectoral MRA, which shall be responsible for the effective functioning of the Sectoral MRA.

• The JSC shall comprise the Head of the NDRA of each Party or his/her official designate. For the purpose of membership to the JSC, a Member State shall, upon becoming a Party to this Sectoral MRA, notify the ASEAN Secretariat of the name of the Head of its NDRA or his/her official designate.
Article 5: Joint Sectoral Committee (JSC) (2)

- The JSC shall be responsible for:
  - Establishing a Panel of Experts (PoE), which shall consist of officers from the NDRA of each Party, and its terms of reference (ToR) which include competency and qualifications of the PoE. The JSC member may also become a PoE member;
  - Establishing standards and training programs to ascertain the competency of persons nominated to be a member of the PoE;
Article 5: Joint Sectoral Committee (JSC) (3)

- The JSC shall be responsible for: (continued)
  - Preparing a procedure for the listing of BE Centers as well as the removal/delisting of those that have already been listed;
  - Providing a forum for discussion of issues that may arise concerning the implementation of the Sectoral MRA;
  - Establishing, reviewing and amending any annexes referenced to the Sectoral MRA; and
Article 5: Joint Sectoral Committee (JSC) (4)

- The JSC shall be responsible for: (continued)
  - Considering any other matters and taking appropriate technical decisions relating to the implementation of the Sectoral MRA.

- The JSC shall meet at least once a year as and when required, to discharge its duties, determine its own rules of procedures, and make its decision by consensus. Any disagreement shall be settled in accordance with Article 15.
Article 6: Mutual Recognition Obligations

- Parties to the Sectoral MRA shall accept the BE Study Reports for review by respective NDRA from those Listed BE Centers.
- Assessment of the BE Study Report remains within the jurisdiction of a Member State’s NDRA.
Article 7: National Drug Regulatory Authority (NDRA) (1)

- The NDRA shall be designated by each Party for the implementation of the obligations of the Sectoral MRA.
- All Parties shall notify the ASEAN Secretariat of the name, address, contact details and name of the Head of their NDRA and update of any changes.
- All Parties shall ensure that the NDRA is authorized to implement the provisions of this Sectoral MRA as per obligations of this Sectoral MRA.
Article 7: National Drug Regulatory Authority (NDRA) (2)

- The NDRA shall be responsible in monitoring the performance of its Listed BE Centers. It shall notify the JSC of any non-compliances that it observes.
- The NDRA shall be responsible in ensuring that any BE Center within its jurisdiction that requests to be listed under the Sectoral MRA complies with all the requirements for the listing of a BE Center before submitting the application to the JSC.
Article 8: Listing of BE Centers

• Applications for the listing of BE Centers shall be submitted by any NDRA to the JSC.
• The inspection of the BE Center will be conducted by PoE whereas the JSC will recognize and list the BE Center based on recommendation from PoE.
• The removal of any listed BE Centers shall be in accordance with the procedure established by the JSC.
• The ASEAN Secretariat shall update and maintain the list of BE Centers and publish it on the ASEAN website.
Article 9: Transparency

• Each Party shall designate the contact point(s) for exchange of information. A list of contact points shall be forwarded to the ASEAN Secretariat, which shall establish, update and maintain the list of contact points for each Party participating in the Sectoral MRA.

• All Parties are encouraged to publish the BE Centers which are listed in their respective territories.

• Each Party may request for information regarding the Listed BE Center from the respective Party where the BE Center is located.
Article 10: Implementation

• This Sectoral MRA is a multilateral arrangement in which all ASEAN Member States are parties to.
• A Party which does not require BE Study Reports for marketing authorization of generic medicinal products or does not have any listed BE Centers within its territory shall not be prevented from participating in the Sectoral MRA.
• Notwithstanding paragraph 1 of this article, a party whose NDRA has not listed any BE Centers shall accept BE Study Reports from those Listed BE Centers under the Sectoral MRA for review.
Article 11: Annexes to the Sectoral MRA (1)

• The Parties shall adhere to the following, but not limited to, Annexes of this Sectoral MRA:

A. Scope of application of the Sectoral MRA
   ➢ Text to be further developed by Singapore

B. ASEAN Guideline for the Conduct of BE Studies, including Selection Criteria of ASEAN Comparator Product, and ASEAN BE Study Reporting Format
   ➢ (R1) Draft 4 considered Final as of March 2015

C. ASEAN Inspection Criteria for BE Studies
Article 11: Annexes to the Sectoral MRA (2)

• A list and text of the latest version of the Annexes, indicating effective dates for implementation, shall be maintained on the ASEAN website.
Subject to the provisions of the Sectoral MRA, nothing in it shall be construed to limit the authority of a Party to determine, through its legislative and administrative measures, the level of protection it considers appropriate for the safety and protection of the health of persons in its territory.
Article 12: Preservation of Regulatory Authority (2)

• Nothing in the Sectoral MRA shall be construed to limit the authority of the NDRA to take any appropriate immediate measures whenever it ascertains that a generic medicinal product may:
  – compromise the health and safety of persons in its territory, or
  – fail to satisfy a requirement within the scope of the Sectoral MRA
Article 13: Confidence Building

- Parties shall, through their contact points, strengthen and enhance existing cooperation through information exchange on regulatory requirements, conformity assessment procedures and regimes, and through confidence building measures.
Article 14: Confidentiality

• Parties shall maintain, to the extent permitted under their laws and regulations, the confidentiality of information exchanged under the Sectoral MRA.

• Parties shall take all precautions reasonably necessary to protect information exchanged under the Sectoral MRA from unauthorized disclosure.
Article 15: Settlement of Disputes

The Parties shall at all times endeavor to agree on the Sectoral MRA’s interpretation and application, and shall make any attempt through communication, dialogue, consultation and cooperation to arrive at a mutually satisfactory resolution of any matter that might affect the Sectoral MRA’s implementation.
Article 15: Settlement of Disputes

• The provisions of the ASEAN Protocol on Enhanced Dispute Settlement Mechanism, and amendments thereto, shall apply to disputes concerning the interpretation, implementation and/or application of any of the provisions under the Sectoral MRA.
Article 16: Rights and Obligations under Existing International Agreements and Conventions

• The Sectoral MRA or any actions thereto shall not affect the rights and obligations of any party under any existing international agreements or conventions to which it is also a signatory or party to.
Article 17: Deferral of Implementation

- Proposed by the ASEAN Secretariat LSAD to be omitted and instead be incorporated in Article 6: Mutual Recognition Obligations
Article 18: Final Provisions

- The provisions the Sectoral MRA may be reviewed or amended by agreement of all Parties.
- Parties shall undertake appropriate measures to fulfill the agreed obligations.
- Parties shall make no reservations with respect to any of the provisions.
- The Sectoral MRA shall be deposited with the ASEAN Secretary General, a certified copy of which shall be promptly furnished to each party.
Article 18: Final Provisions

- The Sectoral MRA shall enter into force upon the date of its signature.
Anticipated Activities
Post-MRA Signing
Post-MRA Signing

• Creation of the Joint Sectoral Committee (JSC) and the corresponding appointment of the Panel of Experts (PoE)
  – Representatives from individual AMS
• Comprehensive Training of ASEAN BE Inspectors
  – Objective is to have uniform understanding and implementation of the requirements in the inspection of BE Centers in ASEAN for listing/recognition purposes
Post-MRA Signing (2)

- Listing/Recognition of ASEAN BE Centers
  - Following an application process, inspection of BE Centers based in ASEAN shall be undertaken.

- Sectoral MRA expected to be fully implemented five years after signing
Question & Answer

Portion
Question

- If a BE Study Report from a Listed BE Center has been accepted by an ASEAN NDRA in fulfillment of one of the requirements in generic drug registration, does this mean that this same BE Study Report should no longer be reviewed and assessed if this is to be submitted to another ASEAN NDRA?
Answer

- Taking certain factors into consideration (e.g. the varying technical capacities of AMS on BE Studies) the detailed review and assessment of a BE Study Report remains under the jurisdiction of individual AMS.
Question

• If the conduct of the BE Study of my product was undertaken by 2 facilities (i.e., 1 each for the clinical and bioanalytical phases) and one of this 2 phases was conducted by a BE Center outside of ASEAN, can I participate in the MRA?
Answer

• To be able to participate in the MRA, both the clinical and bioanalytical phases of a BE Study should be conducted by a Listed BE Center located in ASEAN.
Question

• Will the ASEAN BA/BE Task Force come-up with a harmonized list of comparator products?
The ASEAN BA/BE Task Force does not intend to come-up with a harmonized list of comparator products, as the Selection Criteria of ASEAN Comparator Product has already been established.

- Innovator product, and multiple manufacturing sites of the same innovator registered in the country
- If the innovator product used as comparator is not registered in the country, justification is required from the generic company to prove its interchangeability with the registered innovator (in vitro or in vivo)
- If the innovator product cannot be identified, the choice of comparator must be made carefully and be comprehensively justified by the applicant. The selection criteria of a comparator in order of preference are:
  - Approval in ICH and associated countries
  - Pre-qualified by WHO
What products would be covered in the MRA?
Answer

• The ASEAN Sectoral MRA for BE Study Reports shall apply only to immediate-release oral solid dosage forms with systemic action.

• The coverage may be expanded in the future as agreed upon by the JSC.
Question

• Will FDA PHL require existing registered products with prior satisfactory BE Study or Biowaiver to repeat this once the MRA is implemented?
Answer

• For local marketing purposes, the BE Study or Biowaiver need not be repeated.
• However, if the manufacturer/MAH in the Philippines intends to have the product exported to other AMS, the conditions of the MRA should be fulfilled (e.g. conduct, reporting format, choice of comparator product and BE center, etc.)
Question

• Will FDA PHL still accept reports of BE Studies conducted outside of ASEAN?
• As it is not the objective of the MRA to impose that all BE Studies be conducted within ASEAN, it remains the prerogative of individual AMS to continue accepting BE Studies done outside ASEAN subject to prevailing local regulations.
Question

- If my product is being manufactured outside of ASEAN, will I still be able to participate in the MRA?
Answer

- Regardless of country of manufacture, to be able to participate in the MRA, the BE Study should be conducted by (a) Listed BE Center(s) within ASEAN. Other provisions of the MRA should also be taken into consideration.
Question

• How can our testing facility be a Listed BE Center?
Answer

• A procedure shall be developed by the still-to-be-formed JSC for BE Center listing (as well as delisting). Prior to the listing process, the PoE needs to be in place, the members of which have to be appropriately trained to ascertain competency prior to actual inspection.

• Documents that could be used as basis in the listing process include:
  - ASEAN Inspection Criteria for Bioequivalence Studies
  - ASEAN Clinical and Bioanalytical Part Inspection Checklists for Bioequivalence Study
Answer

• On behalf of the local BE Center, FDA PHL shall submit the application for listing to the JSC.
Closing Insight

“As the national drug regulatory authority, the road ahead for the Food and Drug Administration Philippines may be difficult and challenging. However, with the strengthening of FDA’s institutional foundation in-line with its mandate, coupled with the cooperation and shared commitment of all its stakeholders and partners, the ultimate goal of ensuring that only safe, effective and quality generic medicines are made available to the Filipinos, the ASEAN region and the rest of the world is not a far-fetched one.”
THANK YOU!

Balancing Innovation and Sound Regulation