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Ministry of Health Malaysia

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GUIDANCE DOCUMENT
FOREIGN GMP INSPECTION

4th Edition
March 2017

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1.0 INTRODUCTION

A company applying with the National Pharmaceutical Regulatory Division (NPRA) for registration of a medicinal product in Malaysia must provide acceptable evidence to show that the manufacturer of the product follows an internationally accepted standard of Good Manufacturing Practice (GMP) and recognized by the authority in Malaysia.

The Control of Drugs and Cosmetics Regulations 1984 (CDCR) requires that the standard of manufacture and quality control of medicinal products manufactured outside Malaysia be taken into consideration before the products are registered with the authority namely Drug Control Authority (DCA). NPRA as the secretariat to the DCA is responsible for ensuring all manufacturers of registered products in Malaysia are able to provide acceptable evidence that the manufacturing premises conform to current GMP requirements. Hence, foreign manufacturers are also subjected to GMP conformity assessments through acceptable GMP evidence or GMP inspection.

Malaysia became the 26th member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) since 1st January 2002. Hence, the current PIC/S Guide to GMP for Medicinal Products and its Annexes have been adopted as the standard used by NPRA to assess the GMP conformity of manufacturers.

2.0 DEFINITIONS/ABBREVIATIONS

CAPA	Corrective Action and Preventative Action
CDCR	Control of Drugs and Cosmetics Regulations 1984
DCA	Drug Control Authority
GMP	Good Manufacturing Practice
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (Information on ICH can be accessed on the ICH website – www.ich.org)
ICH member country	Japan, Member of the European Union (EU) and the United States of America (USA)
LOC	Letter of Confirmation
MOH	Ministry of Health Malaysia

NDRA	National Drug Regulatory Agency
NPRA	National Pharmaceutical Regulatory Division
PIC/S	Pharmaceutical Inspection Co-operation Scheme (Information on PIC/S Participating Authority can be accessed on the PIC/S website – www.picscheme.org)
PRH	Product Registration Holder
SMF	Site Master File
VMP	Validation Master Plan

3.0 PURPOSE

3.1 The objective of the foreign GMP inspection is to assess the conformance of foreign manufacturers to GMP requirements and ensure quality of products that are registered or in the process of registration/re-registration/change of manufacturing site with DCA of Malaysia and products manufactured for clinical trial purposes (investigational medicinal products). This activity is carried out with a view to strengthen the supervision and administration over imported products and foreign manufacturers as well as ensuring quality and safety of the imported products.

3.2 The purpose of this guidance is:

3.2.1 To provide information on the types of GMP evidence acceptable to the DCA of Malaysia.

3.2.2 To provide the requirements for an on-site inspection of manufacturing facility outside Malaysia where GMP evidence of the premise is not available or acceptable to the DCA of Malaysia.

3.2.3 To provide guidance on how to apply for an on-site foreign GMP inspection.

4.0 SCOPE

4.1 This guidance applies to all manufacturers of medicinal products located outside Malaysia.

5.0 ACCEPTABLE GMP EVIDENCE

5.1 One of the requirements to register an imported medicinal product in Malaysia is submission of acceptable documentary evidence of the GMP compliance of the manufacturer issued by a regulatory authority.

5.2 For pharmaceutical product, the criteria for GMP evidence submission are based on the following directives issued by the Director Pharmaceutical Services:

5.2.1 Bilangan 1 Tahun 2012 – Direktif Mengenai Syarat Pendaftaran Produk Farmaseutikal Dari Luar Negara Berkaitan Keperluan Amalan Perkilangan Baik (APB).

5.2.2 Bilangan 1 Tahun 2016 – Direktif Mengenai Keperluan Pemeriksaan Amalan Perkilangan Baik (APB) Luar Negara Bagi Tujuan Pendaftaran/ Pendaftaran Semula Produk Farmaseutikal Berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD).

5.2.3 Bilangan 11 Tahun 2016 – Direktif Mengenai Penerimaan Pengesahan Pematuhan Amalan Perkilangan Baik (APB) Bagi Tujuan Pendaftaran Semula Produk Farmaseutikal Berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD).

(Directives can be accessed from NPRA website – http://npra.moh.gov.my. For a summary of the directives, refer to *Annex 1 – NPRA Foreign GMP Inspection Directives*)

5.3 Based on 5.2.1, 5.2.2 and 5.2.3,

5.3.1 For pharmaceutical manufacturer located on a site within jurisdiction of a PIC/S Participating Authority or in an ICH member country, GMP evidence issued by the local NDRA is accepted.

5.3.2 For pharmaceutical manufacturer located in an ASEAN member country, GMP evidence issued by the local NDRA is accepted if the NDRA is included in the Listed Inspection Service under the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for GMP Inspection of Manufacturers on Medicinal Products.

5.3.3 For pharmaceutical manufacturer NOT located on a site within jurisdiction of a PIC/S Participating Authority,

5.3.3.1 For **new registration of pharmaceutical product**, starting 1 July 2016, NPRA will conduct an inspection on the foreign manufacturer.

5.3.3.2 Starting 1st January 2017, for **renewal of pharmaceutical product registration**, if the manufacturer has been inspected by NDRA from one

of the 33 reference countries, the GMP evidence issued by the NDRA is accepted. These include:

i. Members of PIC/S that were involved the formation of Pharmaceutical Inspection Convention (PIC) between the year 1970 and 1993.

   Austria, Denmark, Finland, Iceland, Liechestein, Norway, Portugal, Sweden, Switzerland, United Kingdom, Hungary, Ireland, Romania, German, Italy, Belgium, France, Australia

   Total: 18

ii. Members of PIC/S who are also European Union (EU) member states or European Free Trade Association (EFTA) members and have acceded to the European Economic Area (EEA):

   - EU (EEA):
     Austria*, Belgium*, Cyprus, Czech Republic, Slovak Republic, German*, Denmark*, Estonia, Finland*, France*, Hungary*, Ireland*, Italy*, Lithuania, Latvia, Malta, Netherlands, Poland, Portugal*, Romania*, Sweden*, Slovenia, Spain, United Kingdom*, Greece

   - EFTA (EEA):
     Norway*, Liechestein*, Iceland*

     Note:* Countries that also are members of PIC.
     The list of countries under EEA are subject to change.

   Total: 12

iii. NDRA from reference countries stated in the Drug Registration Guidance Document (DRGD) for registration of pharmaceutical products :

   United Kingdom, Sweden, France, USA, Australia, Canada, Japan dan Switzerland

   Note : Countries underlined are PIC or EEA countries.

   Total: 3

iv. Any NDRA that has a cooperation agreement such as Mutual Recognition Agreement (MRA) with PIC/S or any reference countries under para 5.3.3.2 (i) and 5.3.3.2 (ii)

Example: European Medicines Agency (EMA) and PIC/S.

(Refer to Annex 2: Foreign GMP Inspection Tree Decision and Annex 3: List of 33 reference countries)

5.4 Apart from the GMP Evidence's issuing body, the documentary evidence provided must:

5.4.1 Have a validity period that is still current

5.4.2 Provide the correct manufacturer's name and address of manufacturing site

5.4.3 Specify the dosage form class OR the facility used to manufacture the dosage form was covered during the inspection

5.5 The GMP evidence submitted shall be in the format of:

5.5.1 GMP Certificate

5.5.2 GMP Inspection Report

5.6 Where acceptable GMP evidence of the foreign manufacturer is not available or the documentation submitted is insufficient to demonstrate acceptable GMP standard, a GMP inspection shall be conducted by NPRA.

5.7 Submission of acceptable GMP evidence does not guarantee that GMP inspection will not be conducted by NPRA on the foreign manufacturer.

6.0 GENERAL REQUIREMENTS AND PROCEDURES FOR APPLICATION

APPLICATION FOR FOREIGN GMP INSPECTION

6.1 The application for a foreign GMP inspection should be made by a Malaysian registered company (PRH) acting on behalf of the foreign manufacturer.

6.2 The Malaysian registered company (PRH) shall authorize a responsible person (e.g. Chief Executive Officer, Managing Director or Regulatory Manager) to act as the liaison officer with NPRA for all arrangements pertaining to the proposed inspection.

6.3 The appointed liaison officer responsible for the application is required to submit the completed application form (BPFK 501) with the processing fee of RM 5,000 and these documents:

6.3.1 A copy of Company/Business Registration Certificate (for PRH)

6.3.2 Details of new products to be registered in Malaysia and/or existing registered products of renewal of product registration and/or existing registered products for change of manufacturing site

6.3.3 Site Master File

6.3.4 Validation Master File

6.3.5 Proposed flight route and hotel rate per night

6.3.6 Hotel quotation [Name of hotel, hotel's official website, distance between hotel and manufacturing facility, accommodation during transits (if any)]

6.3.7 Declaration letter from Manufacturer stating that premise is ready to be inspected at any time.

6.3.8 Valid GMP Evidence (preferably GMP certificate/report issued by a PIC/S Participating Authority)

6.4 If the foreign manufacturer is also manufacturing registered products for other PRH, the applicant must ensure that all the other PRH are aware and understand that the outcome of the GMP inspection may affect the registration status of all the products manufactured at this facility.

6.5 Any changes in particulars stated in application form must be notified in writing within one of week of application submission.

6.6 Applicant must ensure that the new products to be registered in Malaysia are licensed/certified for sale in country of manufacture prior to foreign GMP inspection application.

6.7 If the application is successful, NPRA will write to the applicant and announce the proposed date, duration of inspection and estimated cost for inspection.

6.8 Prior to conducting the inspection, a meeting will be organized between the appointed GMP inspectors and the applicant for a preparation of the inspection. Subsequent meetings shall be organized by the lead inspector if necessary.

TRANSPORTATION AND ACCOMMODATION

6.9 Travelling arrangement includes both ground travel and air travel. The applicant is expected to propose a suitable travel itinerary to NPRA (as reference) based on the following criteria:

6.9.1 Preferred airline is Malaysian Airline (MAS);

6.9.2 Flight is normally of the shortest distance from Kuala Lumpur to the point of destination and without transit. If transit is required due to unavailability of routes, the details of the transit destination and duration should be included;

6.9.3 Flight class is Economy Class, with fare structure allowing for change of flight date and time without any penalty or charge;

6.9.4 Arrangement of ground transportation (if any)

6.10 The information on accommodation will be required in the form of an official quotation or similar and satisfy the following criteria:

6.10.1 Hotel details and room category as Standard Room;

6.10.2 Reasonable distance between the hotel and manufacturing facility (Please state the estimated duration to reach the manufacturing facility from the hotel).

PROCESSING FEE, INSPECTION FEE AND INSPECTION EXPENSES

6.11 The payment structure for foreign GMP inspection consist of three parts, in which all shall be borne by the applicant as follows:

6.11.1 Processing Fee

a) Payment of a non-refundable processing fee of **RM 5,000.00** upon application.

6.11.2 Inspection Fee

a) Payment of an inspection fee of **RM 20,000.00** upon issuance of invoice by NPRA.

b) NPRA will issue an invoice to the company **once inspection date is confirmed.**

c) Payment of the inspection fee must be made at least **one month before** the foreign inspection is conducted.

d) The payment shall be made using a banker's cheque payable to:

Name : BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN/ AGENSI REGULATORI FARMASI NEGARA, KEMENTERIAN KESIHATAN MALAYSIA

e) The inspection fee is non-refundable under any circumstances.

6.11.3 Inspection Expenses

a) The inspection expenses will cover all the expenses incurred to conduct the inspection. These include flight ticket, accommodation and other associated expenses (such as allowances, insurance, etc.)

b) NPRA will calculate the inspection expenses using the information obtained from the applicant and inform the applicant accordingly.

c) The inspection expenses costing will be prepared by NPRA based on the eligibility of the inspectors as outlined in the Treasury Circular 3/2003 issued by the Malaysian Ministry of Finance.

d) Payment for the inspection expenses shall be in the form of contribution to a trust fund established under the Malaysian Ministry of Health (MOH) namely *Akaun Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB* (Main Code: 886341, Sub Code: 4001) through a **banker's cheque** made payable to:

Name : KETUA SETIAUSAHA KEMENTERIAN KESIHATAN MALAYSIA

Account No : 21401360003459

e) The expenses for the inspection will be covered using the contribution from the trust fund as mentioned in 6.9.3 (c). NPRA will table the inspection expenses to MOH Trust Fund Committee for approval before the fund is used.

f) The remainder of the contribution will be retained in the trust fund for future purposes as outlined in the *Arahan Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB*.

g) The contribution will also be refunded in the event where foreign GMP inspection cannot be conducted.

OUTCOME OF INSPECTION

6.12 The outcome of the GMP inspection will be tabled to the Committee of Evaluation of Inspection on Premises.

6.13 GMP inspection report will be issued to manufacturer through applicant i.e. PRH.

6.14 Manufacturer may be required to submit a Corrective Action and Preventative Action (CAPA) report to NPRA for the non-compliances reported during the inspection within the time frame specified in the GMP report cover letter. The CAPA report will be presented to the Committee of Evaluation of Inspection on Premises for further consideration.

6.15 GMP compliance status will only be concluded as acceptable when the actions outlined in the CAPA are considered satisfactory in addressing the non-compliances and the time

frame needed to close all CAPA is not more than 6 months from the date of inspection report issuance. If more than 6 months is required, the GMP compliance status will be concluded as unacceptable.

6.16 After the GMP compliance status is concluded as acceptable, the applicant may apply for a GMP certificate for the foreign manufacturer. The certificate shall be used administratively for product registration/re-registration/change of manufacturing site purposes with NPRA.

6.17 For inspection with its GMP compliance concluded as unacceptable, the manufacturer is not required to submit a CAPA report as there will be no further consideration or appeal for the GMP compliance status of the manufacturer. Applicant is required to submit a new application in order for NPRA to conduct another inspection on the manufacturing facility.

7.0 REJECTION, TERMINATION OR WITHDRAWAL OF APPLICATION

7.1 NPRA has the right to reject an incomplete application for example an application without supporting documents as mentioned in para 6.3 above.

7.2 The application shall be terminated if payment of inspection fee is not made at least **one month before** the foreign inspection is conducted.

7.3 The date of the inspection will be proposed by NPRA during the evaluation stage, upon receipt of a completed application form (BPFK 501). The applicant and foreign manufacturer are responsible to make sure the premise is fully prepared and not under renovation or any other condition that may affect the GMP inspection conducted.

7.4 The applicant shall submit a written application, explaining the reason, to NPRA if there is a reason for postponing the inspection after the date of inspection has been confirmed.

7.5 NPRA has the authority to terminate the application if the applicant is not able to comply with the proposed date due to unavailability or unpreparedness of facility. Failure to commit to the inspection after confirmed inspection date will result in application rejection and processing fee is not refundable.

7.6 Application which has been terminated or rejected will go through the submission process once again as stated in para 6.0.

7.7 The applicant shall notify NPRA regarding withdrawal of application or any other changes in writing.

7.8 In cases where application is withdrawn/terminated/rejected after contribution has been made to the trust fund, applicant may request for a refund of the contribution. Applicant is advised to request for refund within 30 days of withdrawal.

8.0 ADDITIONAL INFORMATION

8.1 The GMP inspection is subject to final approval by the Ministry of Health Malaysia.

8.2 The applicant shall arrange for a translator to be present during the on-site inspection, at the company's cost, if English or Bahasa Malaysia is not the language used in communication and documentation by the foreign manufacturer.

8.3 The applicant shall assign an individual from the Product Registration Holder to accompany the GMP inspectors during the whole duration of the inspection.

8.4 The manufacturer must ensure that any translated version of the documentation that is provided to the GMP Inspector during the inspection is clear, legible, accurate and in an official manner in line with the manufacturers documentation system.

8.5 The manufacturer shall operate and run production activities as usual during the inspection.

8.6 The number of inspectors appointed and duration of inspection will be decided by NPRA depending on the nature of the products, size of premise and scope of inspection. In most circumstances, the minimum number of the inspectors are 3 and for a minimum duration of 3 days.

8.7 Inspections are limited to one inspection per site for either sterile or non-sterile facility. Inspections of multiple sites or to both sterile and non-sterile or to both biologics [drug product (DP) and drug substance (DS)] facilities will require separate applications.

8.8 NPRA adopts the PIC/S Guide to GMP for Medicinal Products and its annexes for the GMP inspection.

8.9 NPRA reserves the right to invalidate the GMP certificate issued to the manufacturer when evidence exists (such as product complaints, serious adverse events, etc.) or have reason to believe that the manufacturer is not complying with the GMP guidelines/requirements.

8.10 The same GMP certificate may be used by the same applicant for other product registration applications if the scope of manufacture is the same, provided the validity date of the GMP certificate is still current.

8.11 An acceptable GMP compliance of a manufacturer does not guarantee the manufactured product will be approved for registration in Malaysia.

8.12 Inquiries relating to foreign GMP inspection may be directed to the following contact:

Centre for Compliance and Licensing
National Pharmaceutical Regulatory Division

Ministry of Health Malaysia
Lot 36, Jalan Universiti,
46200 Petaling Jaya, Selangor.

Tel : (60)-378018557
Fax : (60)-379571200

9.0 FORM

BPFK 501 - Foreign GMP Inspection Application Form *(downloadable NPRA website – http://npra.moh.gov.my.)*

10.0 ANNEXES

Annex 1: NPRA Foreign GMP Inspection Directives

Annex 2: Foreign GMP Inspection Tree Decision

Annex 3: List of 33 reference countries

11.0 END OF DOCUMENT

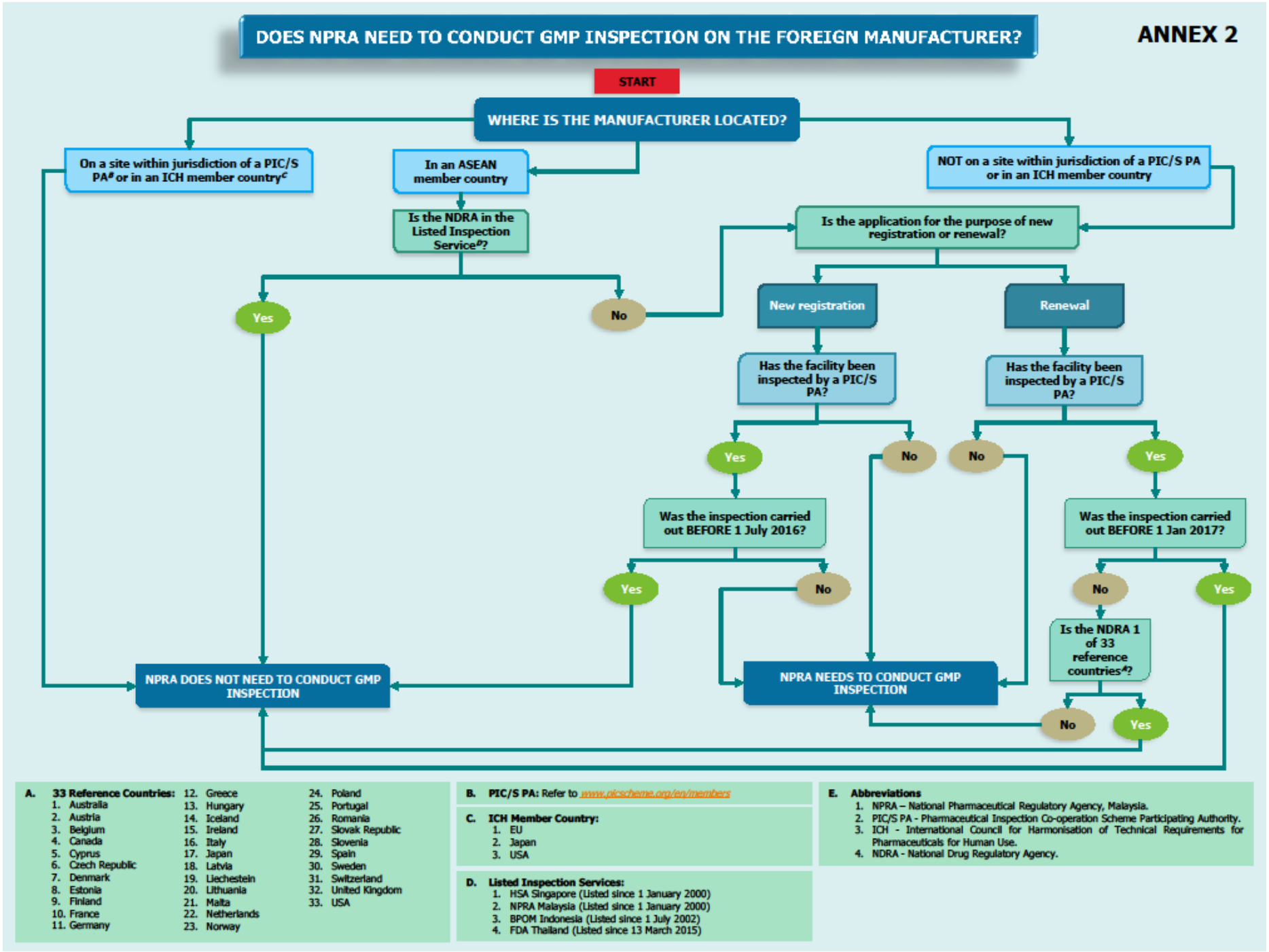
NPRA FOREIGN GMP INSPECTION DIRECTIVES

ANNEX 1

	Directive 1/2012 Direktif Mengenai Syarat Pendaftaran Produk Farmaseutikal Dari Luar Negara Berkaitan Keperluan Amalan Perkilangan Baik (APB). (Tarikh Kuat Kuasa 28 Disember 2012)	**Directive 1/2016** Direktif Mengenai Keperluan Pemeriksaan Amalan Perkilangan Baik (APB) Luar Negara ***Bagi Tujuan Pendaftaran/ Pendaftaran Semula*** Produk Farmaseutikal Berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD). (Tarikh Kuat Kuasa 22 Januari 2016)	**Directive 11/2016** Direktif Mengenai Penerimaan Pengesahan Pematuhan Amalan Perkilangan Baik (APB) ***Bagi Tujuan Pendaftaran Semula*** Produk Farmaseutikal Berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD). (Tarikh Kuat Kuasa 30 Jun 2016)
Location of Pharmaceutical Manufacturer On a site within jurisdiction of a PIC/S Participating Authority or in an ICH member country[1].	**New Registration and Renewal of Registration** *Para. 3.1.1a* GMP evidence issued by the local NDRA is accepted • New Registration - effective 01/07/2012. • Renewal of Registration – effective 01/01/2014.	New Registration and Renewal of Registration Para. 3.1.1a of Directive 1/2012 is still applicable.	New Registration and Renewal of Registration Para. 3.1.1a of Directive 1/2012 is still applicable.
Location of Pharmaceutical Manufacturer ***NOT*** located on a site within jurisdiction of a PIC/S Participating Authority or in an ASEAN member country.	**New Registration and Renewal of Registration** *Para. 3.1.1b* GMP evidence issued by any PIC/S Participating Authority or ICH member is accepted. • New Registration - effective 01/07/2012. • Renewal of Registration – effective 01/01/2014.	**New Registration and Renewal of Registration** *Para. 1*[2] Only GMP evidence by NPRA is accepted. • New Registration - effective 01/07/2016[3]. • Renewal of Registration – effective 01/01/2017.	New Registration Para.1 of Directive 1/2016 is still applicable. **Renewal of Registration** *Para. 2.1*[4] Only GMP evidence by the 34 reference countries[5] is accepted. • Renewal of Registration - effective 01/01/2017[6]
Location of Pharmaceutical Manufacturer In an ASEAN member country.	**New Registration and Renewal of Registration** *Para. 3.1.1c* GMP evidence issued by the local NDRA is accepted if the NDRA is included in the Listed Inspection Service[7] under the ASEAN Sectoral MRA for GMP Inspection of Manufacturers on Medicinal Products • New Registration - effective 01/07/2012. • Renewal of Registration – effective 01/01/2014.	New Registration and Renewal of Registration Para. 3.1.1c of Directive 1/2012 is still applicable.	New Registration and Renewal of Registration Para. 3.1.1c of Directive 1/2012 is still applicable.

[1] ICH Member Countries are EU, Japan and US.
[2] Para. 3.1.1b of Directive 1/2012 was nullified by Para. 1 of Directive 1/2016.
[3] For new product registration, GMP evidence issued by any PIC/S Participating Authority or ICH member is accepted if the inspection was conducted before 01/07/2016. After 01/07/2016, inspection by NPRA is necessary.
[4] Para. 1 of Directive 1/2016 for the purpose of renewal of product registration was nullified by Para 2.1 of Directive 11/2016.
[5] Australia, Austria, Belgium, Canada (Kanada), Cyprus, Czech Republic (Republic Czech), Denmark, Estonia, Finland, France (Perancis), Germany (Jerman), Greece, Hungary, Iceland, Ireland, Italy (Itali), Japan (Jepun), Latvia, Liechestein, Lithuania, Malta, Netherlands (Netherland), Norway, Poland, Portugal, Romania, Slovak Republic (Republik Slovak), Slovenia, Spain (Sepanyol), Sweden, Switzerland, United Kingdom, USA (Amerika Syarikat).
[6] For renewal of product registration, GMP evidence issued by any PIC/S Participating Authority or ICH member is accepted if the inspection was conducted before 01/01/2017. After 01/01/2017, inspection by NPRA is necessary unless the manufacturer has been inspected by any of the 34 reference countries.
[7] HSA Singapore (Listed since 1 January 2000), NPRA Malaysia (Listed since 1 January 2000), BPOM Indonesia (Listed since 1 July 2002) and FDA Thailand (Listed since 13 March 2015).

ANNEX 2



A. 33 Reference Countries:

1. Australia
2. Austria
3. Belgium
4. Canada
5. Cyprus
6. Czech Republic
7. Denmark
8. Estonia
9. Finland
10. France
11. Germany
12. Greece
13. Hungary
14. Iceland
15. Ireland
16. Italy
17. Japan
18. Latvia
19. Liechestein
20. Lithuania
21. Malta
22. Netherlands
23. Norway
24. Poland
25. Portugal
26. Romania
27. Slovak Republic
28. Slovenia
29. Spain
30. Sweden
31. Switzerland
32. United Kingdom
33. USA

B. PIC/S PA: Refer to www.picscheme.org/en/members

C. ICH Member Country:

1. EU
2. Japan
3. USA

D. Listed Inspection Services:

1. HSA Singapore (Listed since 1 January 2000)
2. NPRA Malaysia (Listed since 1 January 2000)
3. BPOM Indonesia (Listed since 1 July 2002)
4. FDA Thailand (Listed since 13 March 2015)

E. Abbreviations

1. NPRA – National Pharmaceutical Regulatory Agency, Malaysia.
2. PIC/S PA - Pharmaceutical Inspection Co-operation Scheme Participating Authority.
3. ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
4. NDRA - National Drug Regulatory Agency.

ANNEX 3

LIST OF 33 REFERENCE COUNTRIES

1. Australia
2. Austria
3. Belgium
4. Canada (Kanada)
5. Cyprus
6. Czech Republic (Republic Czech)
7. Denmark
8. Estonia
9. Finland
10. France (Perancis)
11. Germany (Jerman)
12. Greece
13. Hungary
14. Iceland
15. Ireland
16. Italy (Itali)
17. Japan (Jepun)
18. Latvia
19. Liechestein
20. Lithuania
21. Malta
22. Netherlands (Netherland)
23. Norway
24. Poland
25. Portugal
26. Romania
27. Slovak Republic (Republik Slovak)
28. Slovenia
29. Spain (Sepanyol)
30. Sweden
31. Switzerland
32. United Kingdom
33. USA (Amerika Syarikat)