GUIDANCE AND REQUIREMENTS ON CONDITIONAL REGISTRATION OF PHARMACEUTICAL PRODUCTS DURING DISASTER

Revision 1 – July 2021

This guidance is adapted from:

1. WHO Emergency Use Listing Procedure (January 2020)
2. WHO Considerations for Evaluation of COVID-19 Vaccines (24 September 2020)
3. WHO Use of Emergency Use Listing Procedure for Vaccines against COVID-19: Q&A
4. WHO Q&A for Guidelines on Emergency Use Listing Procedure (July 2020)
5. WHO: Coronavirus Update 37 – What We Know About COVID-19 Vaccine Development
6. US FDA Emergency Use Authorization for Vaccines to Prevent COVID-19 (Oct 2020)
7. ASEAN Guideline on Submission of Manufacturing Process Validation Data for Drug Registration
8. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E5(R1): Ethnic Factors in the Acceptability of Foreign Clinical Data
9. Regulation 8 of Control of Drug and Cosmetics Regulations 1984

In the event of any discrepancy with Guideline on Conditional Registration for New Chemical Entities and Biologics in Malaysia, this Guidance Document shall prevail for conditional registration of pharmaceutical products during disaster.

Revision 1 – July 2021

ACKNOWLEDGEMENT

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Bahagian Regulatori Farmasi Negara (NPRA), Ministry of Health Malaysia would like to express sincerest gratitude to the stakeholders and individuals for their contribution and assistance in establishing and finalising this guidance document. Your commitment in preparing this guidance document will bring a change to the pharmaceutical industry towards providing expedited access towards better health outcomes for the nation.

CONTENT

ABBREVIATIONS

ADR	Adverse Drug Reaction
AEFI	Adverse Events Following Immunization
DCA	Drug Control Authority
DRGD	Drug Registration Guidance Document
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
MOH	Ministry of Health Malaysia
NCL	National Control Laboratory
NDRA	National Drug Regulatory Authority
NPRA	*Bahagian Regulatori Farmasi Negara* (NPRA)
OECD	Organisation for Economic Co-operation and Development
PBRER	Periodic Benefit Risk Evaluation Report
PIC/S PA	Pharmaceutical Inspection Cooperation Scheme (PIC/S) Participating Authorities
PKKK	Centre for Compliance and Quality Control
PKPF	Senior Director of Pharmaceutical Services
PKPSR	Centre for Regulatory Coordination and Strategic Planning
PPPK	Centre for Product and Cosmetic Evaluation
PRH	Product Registration Holder
RMP	Risk Management Plan
TTSP	Time and Temperature Sensitive Products
WHO	World Health Organization

1. BACKGROUND

Bahagian Regulatori Farmasi Negara (NPRA) developed this document in response to the current COVID-19 outbreak that has affected the lives and livelihood of Malaysians and everyone around the globe.

NPRA identified the need for this guidance as most pharmaceutical products (including vaccines) have yet to complete their Phase III clinical studies and may not be able to fully register the products in Malaysia due to the lack of data.

2. OBJECTIVES

a) To provide expedited access to pharmaceutical products for treatment or prevention during disasters without compromising aspects of quality, safety and efficacy using a risk-based approach.
b) As a guide or reference for all relevant stakeholders including healthcare professionals.

3. DEFINITION

Disaster (*Bencana*):
In accordance with the Directive No. 20, National Security Council, disaster is defined as an incident that occurs in a sudden manner and complex in its nature and that causes losses of lives, damages to property or natural environment and bring a deep effect to local activities. Such incident needs a management that involves extensive, resources, equipment, skills and work force from many agencies with an effective coordination, which is possibly demanding a complex action and would take a long time.

In Malaysia, the declaration of a disaster is done by authorities that are given the jurisdiction. For example, the COVID-19 pandemic is under the purview of Prevention and Control of Infectious Diseases Act 1988 (Act 342).

4. SCOPE

New pharmaceutical products (including vaccines) for use during a disaster.

5. ELIGIBILITY CONDITIONS

a) The disease for which the product is intended is serious or immediately life threatening, has the potential of causing an outbreak, epidemic or pandemic; AND
b) Existing products have not been successful in eradicating the disease or preventing outbreaks; AND
c) The product should be at least in an on-going Phase III clinical study that have preliminary data on safety and efficacy based on at least one well-planned Phase III clinical study that clearly demonstrates the safety and efficacy of the product; AND
d) The product must have at least be given authorization for use (via emergency use approval or any pathway equivalent to it) or have obtained marketing authorization from national regulatory authorities of country of origin OR any DCA reference agencies OR by World Health Organization (WHO).

6. TIMELINE FOR CONDITIONAL REGISTRATION PROCESS

All registration applications for pharmaceutical products during disaster that fulfills the condition will be given **priority review** status which is **120 working days** from the date the complete application is received.

If the product has been conditionally approved or given emergency use authorization or listing by any DCA reference countries or WHO (hereby referred as Recognition Pathway), the time taken for reviewing process would be significantly shorten.

7. VALIDITY OF CONDITIONAL REGISTRATION

A conditional registration is valid for one (1) year. Thereafter, the conditional registration may be renewed two (2) times (with the possibility of 2 extensions of 1 year each).

8. ESSENTIAL DATA / DOCUMENTS REQUIRED

8.1 Chemistry, Manufacturing and Control (CMC)

In general, a complete quality program will be expected at the point of submission. The application needs to be submitted with detailed information on chemical, manufacturing and controls; manufacturing site(s) where the product, if registered, is or would be manufactured and the current status of the manufacturing site(s) with respect to current Good Manufacturing Practice (cGMP) requirements and relevant information regarding the product supply chain. Such information will assist NPRA in evaluating the availability of the product to the recipients and whether the anticipated storage condition and distribution will affect the safety and efficacy of the product. Any quality documents which are not available should be justified and subjected to the review of NPRA.

8.1.1 Manufacturing

a) Vaccine products

Sufficient data to support the manufacturing of drug substance as well as drug product to ensure quality and consistency of the vaccine manufactured. Generally, validation data on three (3) batches are required from each manufacturing facility would be sufficient to support the consistency of vaccine quality.

b) Non-vaccine products

- Generally, validation data on three (3) batches are required. If there is no validation data on the three (3) production batches, Option 2 or 3 from ASEAN Guideline on Submission of Manufacturing Process Validation Data for Drug Registration can be applied.
- Validation process (based on quality risk assessment) that can indicate that the supplied batch could be produced consistently.

8.1.2 Control of Active Ingredient and Finished Product

a) Vaccine products

- Full characterization of cell banks according to WHO Technical Report Series (TRS) 978 and any subsequent.
- Full characterization of master and working seed organism(s), based on reference to the most appropriate WHO TRS.
- Process validation (based on quality risk assessment for the development stage) and demonstration of consistency of production at the production scale used for the lots to be distributed.
- An evaluation and mitigation plan for potential adventitious agents
- Data to demonstrate that the DS is sufficiently characterized in order to identify and understand the critical properties that impact performance and stability.
- Justified specifications for starting material, intermediates, excipients and final products.
- A detailed description of the quality control system for all stages of manufacturing, including the testing program for in-process/intermediate product quality and DS and DP quality for release.
- The DS and DP development history and manufacturing changes introduced in Phase 1, 2, 3 and lots used during the said emergency, including analytical comparability of DS lots with these changes.
- Analytical methods and qualification/validation data for all quality-indicating assays. Validation data for assays used to evaluate critical vaccine qualities such as purity, identity, and potency are expected. Quality release data and supplementary characterization tests to assess the impact of the changes on the DS quality attributes should be provided.
- A tabular listing of all clinical studies and DP lot numbers used in each study including DS lot genealogy, manufacturing processes used, and the manufacturing site, as well as the Certificates of Analysis (CoAs) for all clinical lots used in clinical studies and information on any lots that were initiated but not accepted for release.
- Analytical methods and qualification/validation data for all quality-indicating assays. Validation data for assays used to evaluate critical vaccine qualities such as purity, identity, and potency are expected.
- Aseptic-process information, including the appropriate validation studies.
- A description of sterile filtration and sterilization processes, as well as validation studies. Depyrogenation of container-closure systems, if applicable, should also be provided.

- Storage conditions, including the container-closure integrity, should be validated and this information should be provided.
- Stability plan/ data (with stability indicating test) for the vaccine produced at the scale produced for the lots to be supplied to Malaysia. The stability data is to support expiry of the vaccine and to provide a guide on storage during logistic activities (transport and distribution) and also in the end users. This should also include any in-use data if available.

b) Non-vaccine products

- Information on active ingredient and finished products related including characterization (including known and potential impurities), composition, preparation, controls (specifications, analytical methods and their validation).
- Stability data (long-term and accelerated) generated on at least three (3) batches on a batch scale to be supplied to Malaysia.

8.1.3 Quality Control Data on Finished Product

a) Protocol of analysis (POA)
b) Certificate of Analysis (COA)
c) Analytical method validation data

8.1.4 Labelling (minimum requirement in English)

a) Package insert containing information for healthcare providers
b) Patient Information Leaflet (in both English and Bahasa Malaysia)
c) Inner and Outer carton labels
d) A plan to help assure that prospective recipients and healthcare providers are adequately informed about the uncertainties regarding both the potential benefits and risks. A fact sheet to contain the following:
    - This has been registered for emergency use in Malaysia
    - Describe the significant known and potential benefit and risks of the use of this product (the extent to which such benefits and risks are unknown)
    - Recipients have the option to accept or refuse the administration as this is purely voluntary

8.1.5 Good Manufacturing Practice (GMP) Requirements

a) Documentary evidence of manufacturer's GMP compliance e.g., GMP Certificate and GMP inspection report issued by Pharmaceutical Inspection Co-operation Scheme Participating Authorities (PIC/S PA); OR
b) Evidence of listing in WHO Prequalified Lists (if (a) is not available); OR
c) GMP Certificate and GMP inspection report issued by National Drug Regulatory Authority (NDRA) of country of origin, manufacturer's declaration of GMP compliance, pre-recorded site tour on manufacturing facilities and other documents deemed relevant (if (a) and (b) are not available)

8.1.6 Requirement on supply chain

Registered products in Malaysia can only be handled by importers/wholesalers with valid Import License and/or Wholesaler's License issued by NPRA. All licensed importers and wholesalers are required to comply with the principles of current Good Distribution Practice (GDP). The importers and/or wholesalers are also fully responsible in ensuring all parties involved in the supply chain of the products comply with the requirement of GDP, including Annex 1: Management of Time and Temperature Sensitive Products (TTSP) at all times until it reached the users (if TTSP is involved) :

Under the circumstances where the importers and/or wholesalers are not licensed by NPRA:

a) The company shall submit an application to NPRA to obtain license as only licensed importers/wholesalers are allowed to import/distribute registered products in Malaysia.
b) For handling of TTSP, the company shall submit an application of GDP inspection to NPRA in order to verify the suitability of the premise in handling TTSP.

8.1.7 Good Distribution Practice (GDP) Requirements

a) Valid Import License/Wholesaler's License
b) License Condition stating that the company is allowed to import and/or distribute cold chain products (if TTSP is involved)

c) Valid supporting documents (contract, agreement, appointment letter etc.) that declare and confirm the name and address of assigned party who is involved in storage, distribution and supply of the product (if applicable).

8.1.8 Risk management plan

The applicant must submit a Risk Management Plan (RMP) document including all information on the latest risks pertaining to the product and other information as follows:

a) Summary of the Safety Specifications, which include the important identified risks, important potential risks and important missing information on the product

b) Summary of the pharmacovigilance plans (routine or additional plans) proposed based on the product risks. These include any planned, ongoing and completed studies or trials.

c) Summary of any Risk Minimisation Measures (routine or additional) based on the identified and potential risks of the product. These include any amendments to the product labelling, preparation of any educational brochures and guidelines or information for healthcare providers, pharmacists and patients.

d) A Malaysia-specific annex that highlight local safety concerns in the local population, local pharmacovigilance plan and local risk minimization activities planned to address the specific safety concerns.

8.1.9 Pharmacovigilance System Summary (PVSS)

Brief description of the company's pharmacovigilance system (Pharmacovigilance System Summary (PVSS) including the Adverse Drug Reaction (ADR) reports management procedures and safety risks assessment and management.

8.2 Safety and Efficacy Data

Bioassays for assessment of clinical endpoints

The diagnostic bioassays that were used to assess study endpoints of clinical studies supportive of the emergency request should be identified. Standard Operating Procedures (SOP) and validation reports for the final assay methods, and a list of all laboratories where the clinical samples have been tested, should be submitted to support the request.

8.2.1 Clinical Data

a) Vaccine products

- Clinical data demonstrating the appropriate dose to be used and initial acceptable safety and immunogenicity in the Malaysian* population in which the vaccine will be used in the context of a disaster.
- Clinical data must include at least completed Phase I and II clinical trials which shows compelling data/results.
- All safety data (compiled) accumulated from phase 1 and 2 studies conducted with the vaccine, with focus on serious adverse events, adverse events of special interest, and cases of severe COVID-19 among study subjects.
- The vaccine must be currently undergoing a well-designed Phase III clinical trial(s) with interim data of efficacy (including immunogenicity) and safety with a median follow-up duration of at least two months after completion of the full vaccination regimen to help provide adequate information to assess a vaccine's benefit-risk profile, including: adverse events; cases of severe COVID-19 disease among study subjects; and cases of COVID-19 occurring during the timeframe when adaptive (rather than innate) and memory immune responses to the vaccine would be responsible for a protective effect.
- Safety data from Phase III clinical trial that includes :
  a. Local and systemic solicited adverse reactions collected for the protocol-defined duration of follow-up in an adequate number of subjects to characterize reactogenicity in each protocol-defined age cohort participating in the trial
  b. All safety data collected up to the point at which the database is locked to prepare the submission of the emergency request, including a high proportion of enrolled subjects (numbering well over 3,000 vaccine recipients) followed for serious adverse events (SAEs) and adverse events of special interest for at least one month after completion of the full vaccination regimen; and
  c. Sufficient cases of severe COVID-19 among study subjects to support low risk for vaccine-induced ERD (a total of 5 or more severe COVID-19 cases in the placebo group would generally be sufficient to assess whether the severe COVID-19 case split between vaccine vs. placebo groups supports a favorable benefit-risk profile or conversely raises a concern about ERD).

- Vaccine safety and COVID-19 outcomes in individuals with prior SARS-CoV-2 infection, who might have been asymptomatic, are important to examine because screening for prior infection is unlikely to occur prior to administration of COVID-19 vaccines under emergency use. An emergency request should therefore include subgroup analyses of safety and efficacy endpoints stratified by prior infection status at study entry, as determined by pre-vaccination serology or medical history.

  * In the event that the Phase III clinical trials are not conducted in Malaysia, the applicant should provide a bridging report to show that the population (subject) that is being used in the said clinical trials can be applied to the Malaysian population. Refer to ICH E5 (R1) as follow:

  ❖ ETHNIC FACTORS IN THE ACCEPTABILITY OF FOREIGN CLINICAL DATA E5 (R1) (https://database.ich.org/sites/default/files/E5_R1_Guideline.pdf)

  ❖ E5 IMPLEMENTATION WORKING GROUP QUESTIONS & ANSWERS (R1) (https://database.ich.org/sites/default/files/E5_Q%26As_R1_Q%26As.pdf)

b) Non-vaccine products

- Clinical data demonstrating the appropriate dose to be used as well as acceptable safety and efficacy that can be used by the population in Malaysia* in the context of a disaster
- Clinical data should include at least completed Phase I and II clinical studies demonstrating encouraging data.
- Products must at least be undergoing Phase III clinical study that have preliminary data on safety and efficacy based on at least one well-planned Phase III clinical study that clearly demonstrates the safety and effectiveness of the product.

8.2.2 Non-clinical Data

a) Vaccine products

A list of non-clinical data demonstrating acceptable safety (e.g., characterization of markers associated with enhanced disease, biodistribution, shedding and attenuation), immunogenicity and efficacy in the most appropriate animal model. The applicant must justify the choice of animal model.

b) Non-vaccine products

Non-clinical data demonstrating acceptable safety and efficacy in the most appropriate animal model. The choice of animal model shall be justified.

8.2.3 Good Laboratory Practice (GLP) requirements

Below are the supporting documents to be submitted to ensure non-clinical safety studies are being conducted in accordance with Good Laboratory Practice (GLP) (Note: If the safety non-clinical safety studies were not conducted in Organisation for Economic Co-operation and Development (OECD) member countries or countries adherent to Mutual Acceptance (MAD) system):

a) GLP Compliance Statement
b) Inspection report issued by Compliance Monitoring Authority (CMA) of Organisation for Economic Co-operation and Development (OECD) or full adherent to Mutual Acceptance of Data (MAD) system.
c) In the circumstances where (b) is not available and no GLP inspection can be conducted due to any unforeseen circumstances, inspection report issued by the national CMA of the respective country can be considered.

8.3 Assessment Report(s)

If the product has been given conditional registration or emergency use authorization or emergency use listing from any of DCA's reference countries or WHO, a recognition procedure could be used (**Refer 9. RECOGNITION PROCEDURE**). The PRH is then required to submit all assessment reports and Q&A (between the manufacturer and the respective regulatory agency, if applicable) (in English) that have been issued by these regulatory authorities or agencies.

9. RECOGNITION PROCEDURE

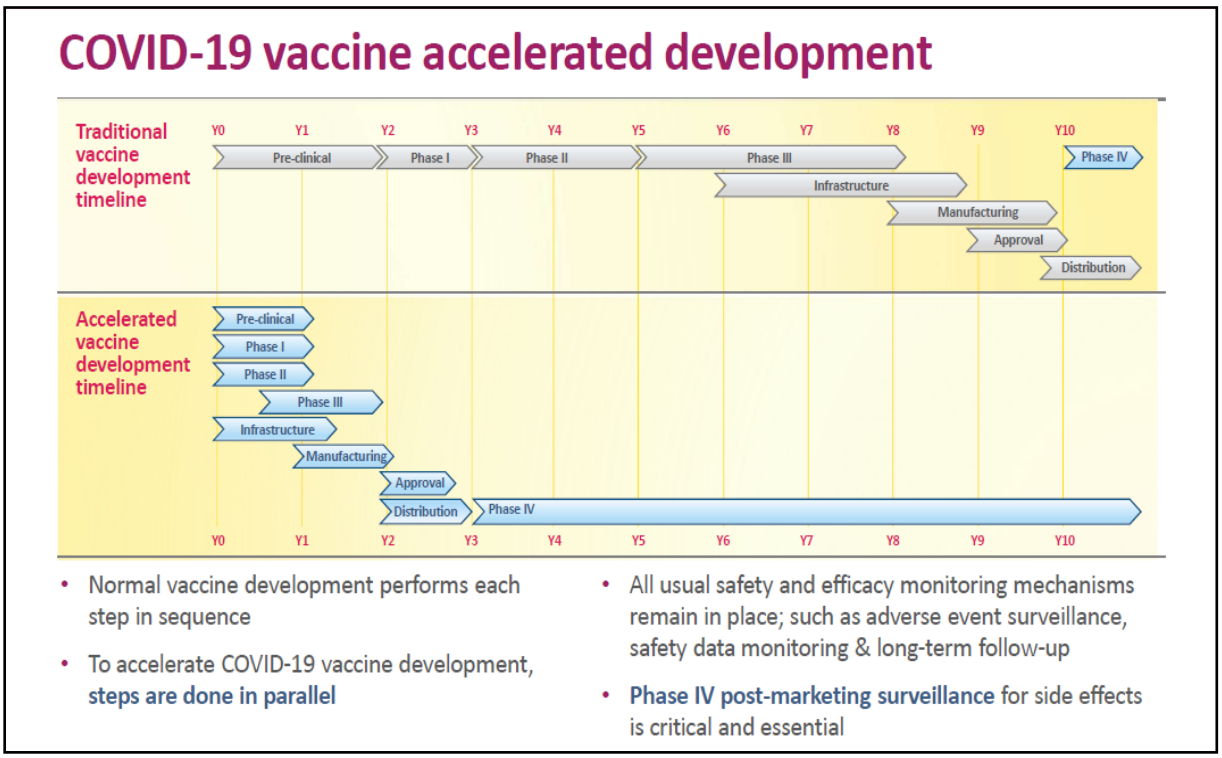
The recognition procedure is the acceptance of the regulatory decision of another regulator or other trusted institution. Recognition should be based on evidence of conformity that the regulatory requirements of the reference regulatory authority is sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement. – WHO Good Reliance Practices in Regulatory Decision-Making: High Level Principles and Recommendations (Draft, June 2020)

If the product has been given conditional registration or emergency use authorization or emergency use listing from any of DCA's reference countries or WHO, the above recognition procedure could be used. PRH who wishes to use this route should provide a declaration letter from manufacturer that the dossier submitted to NPRA is the same as the one submitted to the authority that has given the said authorization. Assessments reports as per para 8.3 should be submitted and subjected to the acceptance by NPRA.

However, local requirements such as labeling, good distribution practice, pharmacovigilance and lot release procedures are to be ensured in place before the start of immunization in Malaysia.

10. MONITORING OF QUALITY, SAFETY AND EFFICACY DATA POST-REGISTRATION

In reference to the document *WHO: Coronavirus Update 37 – What we know about COVID-19 vaccine development,* all pre-clinical studies, Phase I, II, III clinical studies, manufacturing, regulatory approvals as well as distribution of vaccines are shortened from 10 years to 3 years. Meanwhile, the duration of the Phase IV post-marketing surveillance clinical study is extended as monitoring of adverse events following immunization is very crucial and critical.



Hence, the same concept is proposed for this conditional registration where all post-registration activities will be strengthened as below:

10.1 Compliance to Lot Release requirements (for vaccine and plasma derived medicinal products only)

Vaccines and plasma derived medicinal products which is conditionally registered will be subjected to the Lot Release requirement before the imported batch could be distributed in Malaysia. This is to ensure each of the batches was consistently produced according to the required quality, safety and efficacy.

The requirements for Lot Release are as follows:

a) To provide batch release certificate from NDRA/NCL of country of origin. If the document is not available, evaluation on Lot Summary Protocol for each imported batch is mandatory
b) Cold chain inspection will be conducted in the warehouse upon the vaccine/plasma products arrival in Malaysia
c) Physical testing will be conducted on injectables vaccine/plasma products

10.2 Safety Surveillance

At the point of application, some clinical trials results may still be pending and safety information particularly in certain groups of patients for example pregnant and nursing mothers, children and the elderly is limited. Thus, post-listing safety surveillance is crucial. The company shall be committed to implement the risk management plans (RMP) and other responsibilities as follows:

a) Submit the Pharmacovigilance System Master File (PSMF) which include complete information on the company's pharmacovigilance system and safety risks management within 6 months of the registration date.
b) As part of the listing conditions, conduct enhanced surveillance on adverse drug reactions (ADR) or adverse events following immunization (AEFI) for a specified time period.
c) Submit the Safety Summary Report monthly after listing (which covers the line listing and summary tabulation of the adverse reactions, a review of ongoing clinical study and interim analysis of safety information) and *Periodic Benefit Risk Evaluation Report* (PBRER) approved by the reference country every six months or once it is available.
d) Submit the updated Risk Management Plan (RMP) that contains the latest safety information including any amendments to the pharmacovigilance plans and the risk minimization measures to manage any new emerging safety risks. The submission shall be made every 3 months or periodically when new information becomes available.
e) Notify the NPRA in writing within 24 hours of becoming aware of any new emerging safety issues outside the country, which involve withdrawal/ suspension of registration or listing of the product, and no later than three (3) calendar days of other safety issues. The notification shall include all information on regulatory actions taken and/ or new directives issued by these other regulatory agencies.

10.3 Quality monitoring of product

Product quality monitoring will be conducted based on report received from company or health facilities or consumers. The company is responsible to submit product quality report to NPRA within 48 hours upon receipt of the report.

10.4 Product updates post-registration

a) The applicant must promptly inform NPRA of all changes regarding formulation, manufacturing process, testing methods, specifications, facilities and any other aspects that might result in a :
   - change of the safety and/or efficacy and/or performance of the product
   - change the basis for the conditional registration

b) Product that has been conditionally registered will be listed in NPRA's website through Product Search.

c) If the data for Phase III clinical trial has been completed, a full application for product registration can be submitted through QUEST3+ system. Refer to the Drug Registration Guidance Document (DRGD) for more information.

FURTHER INFORMATION

Please contact the respective department as listed below:

ENQUIRY ON EVALUATION OF CONDITIONAL REGISTRATION:

a) Biologics Section,
Centre for Product and Cosmetic Evaluation (PPPK)
Bahagian Regulatori Farmasi Negara (NPRA)
Tel : 03-7883 5571
Fax : 03-7956 7075
E-mail : azizahag@npra.gov.my

b) New Chemical Entity Section,
Centre for Product and Cosmetic Evaluation (PPPK)
Bahagian Regulatori Farmasi Negara (NPRA)
Tel : 03-7883 5569
Fax : 03-7956 7075
E-mail : rosliza@npra.gov.my

ENQUIRY ON VACCINE/ PLASMA PRODUCT LOT RELEASE REQUIREMENT FOR IMPORTED BATCH:

Product and Cosmetic Testing Section (Lot Release)
Centre for Compliance and Quality Control (PKKK)
Bahagian Regulatori Farmasi Negara (NPRA)
Tel : 03-7801 8472
Fax : 03-7956 7075
E-mail : vaccinecqc@npra.gov.my

ADVERSE DRUG REACTION (ADR) REPORTING / PRODUCT QUALITY REPORTING:

Centre for Compliance and Quality Control (PKKK)
Bahagian Regulatori Farmasi Negara (NPRA)
E-mail :
a) fv@npra.gov.my (ADR reporting)
b) qpr@npra.gov.my (Product Quality reporting)

APPENDIX I: CHECKLIST FOR CONDITIONAL REGISTRATION DURING DISASTER

Since the expectation is that the manufacturing/quality control and clinical development of the product submitted for conditional registration will continue to full product registration, the dossier submission of pharmaceutical products (including vaccines) should follow the ASEAN Common Technical Dossier (CTD) format or CTD format.

No.	Documents	Yes	No
1. Manufacturing & Quality Control			
1.1	Process validation data for drug substance (3 batches)		
1.2	Process validation data for drug product (3 batches)		
1.3	Full characterization of cell banks, master and working seed organism(s)		
1.4	Full characterization of drug substance		
1.5	Justified specifications for starting material, intermediates, excipients and final products		
1.6	Validation of potency tests and other critical assays		
1.7	Stability data for Drug substance and Drug Product		
1.8	Lot summary protocol		
1.9	Protocol Analysis and Analytical Method Validation		
1.10	Certificate of Analysis for drug substance (2 batches)		
1.11	Certificate of Analysis for drug product (2 batches)		
2. Labelling requirements (minimal requirement: in English)			
2.1	Package Insert		
2.2	Patient information leaflet (in both English and Bahasa Malaysia)		
2.3	Inner and Outer Carton Labels		
2.4	A plan to help assure that prospective recipients and healthcare providers are adequately informed about the uncertainties regarding both the potential benefits and risks. A fact sheet to contain the following: a) This has been registered for emergency use in Malaysia b) Describe the significant known and potential benefit and risks of the use of this product (the extent to which such benefits and risks are unknown) Recipients have the option to accept or refuse the administration as this is purely voluntary		
3. Good Manufacturing Practice (GMP) requirements			
3.1	Documentary evidence of manufacturer's GMP compliance		
	a) GMP Certificate and Inspection Report issued by PIC/S PA		
	b) Evidence of listing in WHO Prequalified Lists (if (a) is not available)		

Since the expectation is that the manufacturing/quality control and clinical development of the product submitted for conditional registration will continue to full product registration, the dossier submission of pharmaceutical products (including vaccines) should follow the ASEAN Common Technical Dossier (CTD) format or CTD format.			
No.	**Documents**	**Yes**	**No**
	c) GMP Certificate and GMP inspection Report issued by National Drug Regulatory Authority of country of origin, manufacturer's declaration of GMP compliance, pre-recorded site tour on manufacturing facilities and other documents deemed relevant (if (a) and (b) is not available)		
4. Good Distribution Practice (GDP) & supply chain requirement			
4.1	Information on the logistic/transportation provider involved in the distribution of product		
4.2	Evidence of GDP compliance of storage facilities involved in storage and distribution of product		
5. Safety / Pharmacovigilance			
5.1	Benefit Risk Assessment Report		
5.2	Risk Management Plan (RMP) including Malaysia-specific annex		
5.2	Summary of Pharmacovigilance System including contact details of Responsible Person for Pharmacovigilance (RPPV)		
6. Clinical data			
6.1	The conduct of any clinical trials should be in accordance to Good Clinical Practice (GCP)		
6.2	Clinical study reports (efficacy and safety)		
6.3	Bridging report (Reference: ICH E5(R1) - Ethnic Factors in the Acceptability of Foreign Clinical Data)		
6.4	Additional information on ongoing clinical trials (Phase III)		
7. Non-clinical data & Good Laboratory Practice (GLP) requirement			
7.1	Documentary evidence indicating that non-clinical safety studies are being conducted based on Good Laboratory Practice (GLP):		
	a) GLP Compliance statement		
	b) Inspection report issued by Compliance Monitoring Authority (CMA) of Organisation for Economic Co-operation and Development (OECD) or full adherent to Mutual Acceptance of Data (MAD) system.		
	c) In the circumstances where (b) is not available and no GLP inspection can be conducted due to any unforeseen circumstances, inspection report issued by the national CMA of the respective country can be considered.		
7.2	Non clinical study reports		

Since the expectation is that the manufacturing/quality control and clinical development of the product submitted for conditional registration will continue to full product registration, the dossier submission of pharmaceutical products (including vaccines) should follow the ASEAN Common Technical Dossier (CTD) format or CTD format.			
No.	**Documents**	**Yes**	**No**
8. Lot Release requirement (for vaccine and plasma derived medicinal product ONLY)			
8.1	Packaging and shipping validation data report/document		
8.2	Able to provide Summary Lot Protocol for each imported lot before distribution in Malaysia		
8.3	Able to provide Batch Release Certificate from Regulatory Authority from Country of Origin for each imported lot before distribution in Malaysia		
9. Other supporting documents			
9.1	Letter of authorization from manufacturer		
9.2	Summary basis for the conditional registration from responsible NRA (if applicable)		
9.3	Type A License for importers (Poisons Act 1952)		
9.4	Companies Commission of Malaysia (SSM) certificate		
9.5	Import Licence/Wholesaler's Licence (including attachment of Licence Condition/ 'Syarat Lesen')		
9.6	Application Letter for Cold Chain Facilities Verification Inspection		
9.7	All assessment reports (applicable to Recognition Procedure only)		
9.8	Declaration letter from manufacturer (applicable to Recognition Procedure only)		
9.9	Q&A (between the manufacturer and the respective regulatory agency, if applicable) (in English) that have been issued by these regulatory authorities or agencies		