

تعليمات إجازة الاستخدام الطارئ للأدوية**Emergency Use Authorization of Medicinal Product****صادرة بالاستناد لأحكام المادة (٥) من قانون الدواء والصيدلة رقم (١٢) لسنة ٢٠١٣****وتعديلاته وأحكام المادة (٧) من قانون المؤسسة العامة للغذاء والدواء رقم (٤١) لسنة ٢٠٠٨**

المادة ١ :

تسمى هذه التعليمات (تعليمات إجازة الاستخدام الطارئ للأدوية لسنة ٢٠٢١) ويعمل بها من تاريخ نشرها بالجريدة الرسمية .

المادة ٢ :

لغايات تطبيق هذه التعليمات تعتمد التعريفات الواردة في المادة رقم (٢) من أسس تسجيل الدواء وتعديلاتها لسنة ٢٠١٥ السارية المفعول و المادة رقم (٢) من أسس اليقظة الدوائية لسنة ٢٠١٦ السارية المفعول و المادة رقم (٢) من قانون الدواء والصيدلة رقم (١٢) لسنة ٢٠١٣ وتعديلاته بالإضافة إلى تعريف الـ **Emergency use authorization of medicinal product** وهو إجازة الاستخدام الطارئ للأدوية :-

Emergency Use Authorization which is to authorize the emergency use of an unapproved medicinal product or an unapproved use of an approved medicinal product for certain emergency circumstances.

المادة ٣ :

تهدف هذه التعليمات لإجازة استخدام الادوية في الاوضاع الطارئة للعمل على تسهيل توافرها واستخدامها .

المادة ٤ :

يتم تقديم طلب إجازة الاستخدام الطارئ للأدوية بتقديم الوثائق المتوفرة والمرفقات المدعمة وذلك حسب **Medicinal products and Vaccines guidance** المرفق ويتم استيفاء الرسوم وفقاً لنظام الرسوم والمكافآت وتعديلاته السارية .

المادة ٥ :

يتم تقييم ودراسة المرفقات المدعمة لطلب إجازة الاستخدام الطارئ للأدوية من قبل اللجان الفنية المعنية وفي حال استكمال متطلبات الإجازة الطارئة يتم منح الإجازة الطارئة و يستثنى من التحليل لغايات الإجازة فقط.

المادة ٦ :

تكون مدة صلاحية شهادة إجازة الاستخدام الطارئ سنة واحدة من تاريخ الإصدار، وللمدير العام الصلاحية بتمديد فترة إجازة الاستخدام الطارئ لسنة أخرى وبتنسيب من اللجنة العليا للدواء والصيدلة .

المادة ٧ :

يتوجب على مقدم الطلب تقديم جميع وثائق تسجيل الدواء المجاز للاستخدام الطارئ بشكل أصولي خلال ستة اشهر من تاريخ تسجيله أصوليا في بلد المنشأ وبحسب أسس التسجيل سارية المفعول وتعديلاتها .

المادة ٨ :

تمتلك المؤسسة الحق بإلغاء شهادة إجازة الاستخدام الطارئ في الحالات التالية:

- ١- في حال استجبت معلومات علمية حول فعالية و مأمونية الدواء المجاز استخدامه.
- ٢- عند اعلان وزارة الصحة إنتهاء الوضع الطارئ.

المادة ٩ : تمتلك المؤسسة الحق برفض طلب إجازة الاستخدام الطارئ في الحالات المحددة والمذكورة في البند " EUA issuance, EUA request rejection " من الدليل المرفق.

المادة ١٠ : تستثنى الأدوية الحاصلة على إجازة الاستخدام الطارئ من تطبيق أحكام المادة (٦/ب) من أسس تسجيل الدواء لسنة ٢٠١٥ وتعديلاته.

وزير الصحة**رئيس مجلس إدارة مؤسسة الغذاء والدواء****الاستاذ الدكتور فراس إبراهيم الهواري**

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Abbreviations

API: Active Pharmaceutical Ingredient

EMA: European Medicine Agency

EUA: Emergency Use Authorization

FDA: Food and Drug Administration.

FP: Finished Product

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMP: Good Manufacturing Practice

JFDA: Jordan food and drug administration

MOH: Ministry Of Health

PIL: patient information leaflet

PSUR: Periodic Safety Update Reports

RDU: Rational Drug Use Department

RMP: Risk Management Plan

SmPC: Summary of product Characteristics

WHO: World Health Organization

EUDRA: European Union Drug Regulatory Authorities

EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCT GUIDANCE

1- Introduction:

This guidance explains JFDA general recommendations and procedures that are applicable to the authorization of the emergency use of certain medical products to sustain and strengthen national preparedness and response for public health emergencies including emerging infectious disease threats such as pandemic influenza, also, to foster development and availability of medical product for the use in these emergencies.

Medical products include drugs and biological products.

Ministry of Health (MOH) is responsible for the determination of public health emergency or the potential for a public health emergency that has actual or potential effects on the national health security.

After pandemic circumstances declared by MOH, JFD may authorize the emergency use of an unapproved product or unapproved use for an approved product, provided that other statutory criteria are met.

This guidance allows JFDA to facilitate as well as permit the use of medical products in emergencies to diagnose, treat, or prevent life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

This will enable different stockholders such as governmental sponsors, pharmaceutical companies, health entities (hospitals) to be prepared for potential emergencies, collaborate, and participate in supporting public health during pandemic circumstances.

2- Scope of this guidance:

- 1- JFDA unapproved medical products including drugs and biological products.
- 2- JFDA unapproved use for approved medical products medical products including drugs and biological products

3- Criteria for Issuance:

JFDA may issue EUA only if JFDA concludes that the following four statutory criteria for issuance have been met.

- 1- Serious or life-threatening disease or condition
- 2- Evidence of effectiveness

For medical products that might be considered for EUA are those “may be effective” to diagnose, treat, and prevent life-threatening conditions or diseases. The provided evidence for the EUA” may be effective” is with a lower level than the evidence required for the “effective” standard used by the JFDA for regular product approval.

The potential effectiveness of a possible EUA product is intended to be assessed by JFDA based on case-by-case assessment using risk-benefit analysis. JFDA may authorize the emergency use of the product based on the totality of the available scientific evidence that made it reasonable to believe that the product may be effective for that specific use.

3- Risk-benefit analysis

A product may be considered for an EUA if JFDA determines that the known and potential benefit of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks for that product.

JFDA intends to look at the totality of the available scientific evidence to make an overall risk-benefit assessment, to evaluate whether the known and potential benefits outweigh the known and potential risks. These evidence, which could come from a variety of sources, may include (but not limited to):

results of domestic (and)/(or) foreign clinical trials, in vivo efficacy data, and in vitro data that are available for JFDA consideration.

The quality of the available evidence will be assessed by JFDA, taking into consideration the current state of scientific knowledge. The type of scientific evidence that JFDA may consider and should be submitted to support the EUA request is discussed deeply in "Section 5: EUA Request" in this guidance.

4- No alternatives

For EUA issuance by JFDA there must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the emergent disease(s) or condition(s).

If the potential approved alternative(s) are insufficient supplies to fully meet the emergency needs such alternative(s) may be considered as 'unavailable'. And could be considered as 'inadequate', if, for example, a dosage form of an approved product is inappropriate for use in a special population (e.g., a tablet for individuals who cannot swallow pills), or there are contraindicating data for special circumstance or population (e.g., children, immune compromised individuals, or individuals with drug allergy).

4- Pre-EUA activities and submissions

JFDA strongly encourages early engagement and discussion between governmental sponsors or industry and JFDA about the potential EUA products. To facilitate more complete EUA requests and enhance JFDA ability to review and eventually approve the EUA as appropriate.

JFDA strongly encourages the sponsors for the EUA candidate product, particularly one at an advanced stage of development, to ask for scientific advice or any specific directions unique to the EUA request before submission –as described in *JFDA Guidance for applicants seeking scientific advice*–. Which is referred to – in this guidance– as 'pre- EUA 'activities?

In the same way as the requests for EUA issuance, JFDA prioritizes its pre-EUA activities. The extent of and timelines for reviewing such submissions will be determined on a case-by-case basis and will depend on the nature of the submission, the circumstances of the emergency, and the workload of the review staff.

5- EUA request

Regulatory Documents:

A- Summary of recommended information:

Generally, JFDA recommends that a request for an EUA should include a well-organized summary of the available scientific evidence concerning the product's safety and efficacy, risks (including an adverse event profile) and benefits, and any available, approved alternatives to the product. The exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency or threat of emergency and the nature of the candidate product. JFDA may seek additional data and information on a case-by-case base to ensure that the statutory criteria for issuance of an EUA are met.

JFDA recommends that the following information to be submitted in any request for an EUA:

- A description of the product and its intended use (e.g., identification of the serious or life-threatening disease or condition for which the product may be effective; where, when, and how the product is anticipated to be used; and/or the population for which the product may be used)
- A description of the product's regulatory status:
 - JFDA approval status (e.g., whether the product is unapproved or whether it is approved but the EUA is for its unapproved use).

- If the product or the intended use is under investigational application.
- Whether the product is approved by other regulatory agencies and clarification regarding world-wide registration status, for either the proposed use or another use
- Information on the use of the medical product by either a foreign country or an international organization (e.g., the World Health Organisation WHO)
- Available safety and efficacy information for the product (fully discussed in section 5.B);
- Information and data in the EUA request should be comparable and supportive to the summary of product characteristics (SmPC) and patient information leaflet (PIL), a draft of the 'fact sheet' to be provided to the health care professional, authorized dispensers, and patients.
- Mock up and Labeling.
- Health authority approval of the latest Plasma master file (if the product contain plasma derivatives).
- If Certificate of Pharmaceutical product (CPP) can't be provided, any documents prove the product status in the country of origin (registered and / or marketed) with commitment to provide it once it's available.
- For the Quality part; information on chemistry (as applicable), active pharmaceutical ingredient (API) and finished product (FP) characterization and identification (as applicable given the nature of the product), manufacturing process and controls , the available stability Data ; a list of production site (manufacturing site (s) or would be manufacturing site (s)) starting from API to the FP along with their JFDA approval status, and current GMP (s) If it is (are) not accredited,

- request for accreditation along with :
- GMP.
- SMF.
- Remote inspection report/ accreditation / registration of the site / the product by reference country or any international references accepted by JFDA / prequalification By WHO / EUDRA GMP , should be submitted to JFDA, .
- Additionally a declaration or/and clarification concerning manufacturing process(s) similarities/differences and their impact on the FP quality and safety.
- Information about composition of the product and their source and the related certificates (*TSE CEP*).
- Information about the available FP quantity and the capabilities of the manufacturing site(s).
- A discussion of risks and benefits, including the available information concerning the threats posed by the intended medicinal products (*discussed in more details in section 5.E*).
- Any other reference JFDA can rely upon, as applicable

B. Recommended Safety Information

B.1-Generally:

In general, the exact amount and type of the recommended safety information that should be submitted to JFDA as part of EUA request will vary depending on several factors, including: if the product is approved for another indication and, the stage of development in the case of an unapproved product. For some products, JFDA expects that data from controlled clinical trials will be available. While, for others, JFDA anticipates to consider clinical experience from other than a controlled trial if the circumstances warrant.

JFDA expects the submission of the available safety information interpretation concerning the seriousness of the clinical condition, alternative diagnostic, or (if any) alternative therapies, and the specific circumstances of the emergent

situation or emergent threat. JFDA encourages early discussion about the nature and type of safety data that might be suitable for submission between any sponsor of a candidate product and JFDA (even before a determination of actual or potential emergency).

B.2– Unapproved Uses of Approved Products

If the new indication uses a similar dose, duration, route of administration, or mechanism of action (as appropriate given the nature of the product), and the intended patient population is similar, to that for which the product is approved. JFDA recommends that the request for an EUA will reference the approved application, including the right of reference as applicable.

If the new use may cause a different risk to the patient population (e.g., suggesting the possibility of increased toxicity). JFDA recommends providing any information from relevant in vitro studies, animal toxicology studies, and (if available) human clinical data and experience, to support that use.

B.3– Unapproved Products

Knowing that, the range of available data for unapproved products will differ widely. JFDA recommends that any EUA request would include the available preclinical testing data, such as in vitro and animal toxicology data. JFDA also encourages that human safety information from clinical trials and individual patient experience to be provided, if available. Data submitted in the request should attempt to link the likely exposure to the product to any relevant, existing preclinical data. When animal data are used, sufficient information should be provided to link the results of these data to expected exposures of the product when use in humans for the proposed indication. Any safety information associated with use in humans of that product or related compounds of a similar design should also be submitted.

C. Recommended Effectiveness Information

Its well-recognized by JFDA that comprehensive effectiveness data are unlikely to be available for every EUA candidate product, and the information necessary to authorize emergency use of a product will also depends on the circumstances of the declared emergency. In addition to the available knowledge about the product's safety profile. The sufficiency of efficacy data as well as the risk-benefit profile of each EUA candidate product. Will be assessed by JFDA on a case-by-case basis.

JFDA recommends that requests for consideration for EUA's include any available relevant scientific evidence regarding the following:

- Product's mechanism(s) of action to diagnose, treat, or prevent the disease or condition underlying the request.
- For drugs, preclinical testing data, such as in vitro evidence of the effect of the product in preventing or reducing the toxicity of the specified agent.
- Data on activity or effectiveness in animals that would contribute to understanding potential effects in humans (*Sufficient data should be provided to correlate and predict the expected human exposure*), including but not limited to any animal efficacy studies available for products during development.
- Evidence from human experience relevant to assessing activity, effectiveness, and dosing (e.g., in published case reports, uncontrolled trials, controlled trials, and any other relevant human use experience).
- For drugs, data to support the proposed dosage for the intended use (including pharmacokinetics and pharmacodynamics data, and for vaccines or antibody therapies, immunogenicity and/or achievement of protective levels of relevant parameters of immunity).

D. Other Data Considerations

JFDA recommends that a request for any EUA includes the following types of data, as appropriate and to the extent feasible:

- Well-organized study reports that provide a complete assessment and analysis, including any statistical analyses, of available safety and efficacy data and an interpretation of the findings. If final study reports are not yet available, any available interim study reports should be provided and clearly identified as such.
- Any statistical analyses, of available safety and efficacy data and an interpretation of the findings. If final study reports are not completed yet, any available interim study reports should be provided and identified as such.
- Source data for clinical studies, nonclinical laboratory studies, and any animal studies that contribute to assessing product activity or efficacy in the treatment of the underlying disease or condition or a closely related disease or condition. Such as tabular listing for key studies, case report forms for all patients who withdrawn from clinical studies due to an adverse event, and for patients who died during clinical studies, regardless of the causality; relevant published literature, taking into consideration translations for non-English source data.
- Statements on whether the nonclinical laboratory studies were conducted in compliance with applicable Good Laboratory Practice for Nonclinical Laboratory Studies (GLP) and whether the clinical studies were conducted in compliance with applicable Good Clinical Practice standards (GCP). *As described in JFDA Bioequivalence and bio waiver guidance.*
- For any animal studies not performed under GLP but submitted in support of an EUA, the method and quality systems used to ensure the quality and integrity of these data should be specified.

- Data from any ongoing testing and/or studies (e.g., ongoing long term stability data, any appropriately controlled clinical trials conducted in parallel with the EUA during the emergency response) or any other data or information that may change JFDA's evaluation of the product's safety or efficacy and that become available during the period of review or the term of the EUA. Such data should be submitted to JFDA when it becomes available.

E. Discussion of Risks and Benefits

JFDA recommends that discussion of the candidate product's known and potential risks and benefits to be included within EUA request. Which involves a synthesis of the data and information requested above, including:

- Measures taken to reduce risk or optimize benefit.
- Limitations, uncertainty, and data gaps.
- A description of circumstances, if any, under which the product should not be used (e.g., contraindications).
- To the extent known, information concerning the actual or potential threats posed by the product involved, and anticipated response and operational considerations that may be relevant to an assessment of risks and benefits

6- Format of Submissions

Each EUA submission should include:

- Cover letter
- Well organized contents in a reviewable and sufficiently complete form to permit substantive review.
- Submissions may be provided in an electronic or paper format (all formats are applicable)

In rapidly developing emergency circumstances, or when previously unanticipated or unavailable medical products are being considered, JFDA recognize that it may not be possible for a sponsor to provide all the requested data or to provide it in the format suggested promptly. Therefore, JFDA will accept and evaluate the EUA request based on data which the sponsor can submit. On the other hand, a request that is missing data, poorly documented, or incomplete will make determination of whether the product's benefits outweigh its risks more difficult and could result in JFDA request for additional information, the need for a longer time for review, or a decision not to authorize emergency use of the candidate product. Therefore, JFDA recommends sponsor to seek for scientific advice unique to the submission before submission as described *in JFDA Guidance for applicants seeking scientific advice*.

7- EUA Request JFDA Processing and Prioritization

Generally, JFDA intends to determine priorities for its review of requests for EUA issuance based on a different of factors. Which include?

- The JFDA will prioritize the Vaccines/ medicinal product EUA requests and it will gain the benefit of Fast track request if it's authorized by astringent regulatory authority such as EMA and/or USFDA.
- The seriousness and incidence of the clinical disease or condition and the urgency of the treatment need.
- The public health need for the product and the potential role in ensuring national health security.
- The availability and adequacy of the information supporting the possibility that the product may be safe and effective in preventing, treating, or diagnosing the emergent condition or disease.
- Whether the request from MOH (e.g., Jordanian Epidemiology Committee).

- The availability of the product (e.g., the quantity and manufacturing capacity).

8- Review of EUA Requests

A formal request to issue an EUA generally should not be submitted until the MOH has issued an emergency declaration. MOH must first declare that circumstances exist justifying such an authorization for an actual emergency. JFDA typically coordinate with MOH throughout the EUA process starting from pre-EUA activities till EUA issuance.

Each EUA request will be reviewed and evaluated by the relevant registration committee based on the type of candidate medicinal product (originator drugs, generic drugs, or vaccines and sera committees).

9- EUA issuance, EUA request rejection

When the circumstances necessitate and when adequate information has been available through “pre-EUA activities”. JFDA is prepared to issue EUAs expeditiously. JFDA will determine the timelines for reviewing and acting on any EUA request to EUA issuance on a case-by-case basis.

JFDA may reject to review or issue an EUA based on different factors. If:

- The candidate product may fail to meet the necessary criteria identified and discussed in this guidance.
- The candidate product may fail to meet any one of the factors given the circumstances of the emergency or threat of emergency.

Under such circumstances, the relevant registration committee will officially notify the applicant/sponsor that JFDA rejects the EUA request and issuance.

10- CONDITIONS OF AUTHORIZATION

JFDA may establish conditions on an EUA necessary or appropriate to protect the public health as following:

Information relating to authorized product**A- Information for Health Care Professionals or Authorized Dispensers:**

For an unapproved product and for an unapproved use of an approved product, JFDA must (to the extent practicable given the circumstances of the emergency) establish conditions to ensure that health care professionals who administer the EUA product are informed:

- That JFDA has authorized the emergency use of the product (including the product name, dose, dosage form, and an explanation of its intended use).
- The significant known and potential benefits and risks of the emergency use of the product, and the extent to which such benefits and risks are unknown.
- The available alternatives and their benefits and risks (if present).

Hence, JFDA recommends that a "Fact Sheet" for health care professionals or authorized dispensers should be included in a request for an EUA. This fact sheet includes essential information about the product.

In addition to the previously mentioned information in this section, Fact Sheets should include also:

- A description of the disease/condition.
- Any contraindications or warnings.
- Dosing information (if applicable), including any specific instructions for special populations.

- JFDA contact information for reporting adverse events

JFDA anticipated that “the fact sheets” typically will be brief (few pages) since health care professionals or authorized dispensers will likely have limited time to review fact sheets during an emergency. *JFDA may consider making fact sheets for Emergency authorized products published on the JFDA web site.*

B- Information for patients:

To ensure that patients are informed about the EUA product, JFDA recommends that a ‘Summary information’ for patients should be included within the EUA request. These essential pieces of information about the product are:

- That JFDA has authorized emergency use of the product.
- Product name, dosage form, justification of the intended use, and dosing frequency.
- The significant known and potential benefits and risks associated with the emergency use of the product, and of the extent to which such benefits and risks are unknown.
- That they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product.
- JFDA contact information for reporting adverse events.

11- Monitoring and Reporting of Adverse Events

Any perceived side effect should be reported to the Rational Drug use Department (RDU) in JFDA using the online JFDA Adverse Incident Reporting Forms demonstrated in *JFDA pharmacovigilance guidance.*

12- Risk management plan (RMP) & periodic safety update reports (PSUR)**Submission**

For unapproved use of an approved product PSUR and RMP should be included (as applicable) within EUA request. For unapproved product sponsors should provide JFDA with any new safety information and post authorization safety study (if applicable) as described in (*JFDA pharmacovigilance guidance*).

13- Termination of an EUA Declaration:

JFDA will periodically review the circumstances and appropriateness of an EUA, including circumstances that might warrant withdrawal of the EUA. The review will include regular assessment based on any additional information provided by the applicant, any new safety and efficacy information based on domestic and/or international data.

Generally, EUA certificate will be valid for one year from the date of issuance unless it is extended by JFDA based on the emergent situation or it is early terminated by JFDA if:

- 1- MOH Declared that the emergent situation and circumstances that precipitated in the authorization have ended
- 2- There is a change in the approval status of the product such as:
 - A- new additional information regarding the authorized product safety and efficacy indicating that the product is no longer “may effective” as described previously in this guidance, or
 - B- The authorized use(s) for the JFDA approve product or the authorized product for JFDA unapproved product are no longer unapproved. When the product or/and indication is later approved by JFDA. If the sponsor provides JFDA with data supporting product safety and efficacy meet to the “effective” standards. (*According to JFDA registration guidance*)

14- PUBLICATION JFDA

Publication on JFDA web site could be considered.

15- Reference:

**Emergency Use Authorization of Medical Products and Related Authorities
Guidance for Industry and Other Stakeholders, January 2017**

Annex I**Emergency Use Authorization for Vaccines (Specific documents)**

- JFDA will prioritize the Vaccines EUA requests and it will gain the benefit of Fast track request if it's authorized by astringent regulatory authority such as EMA and/or USFDA.
- Any vaccines EUA request should have the following documents in addition to the previously mentioned regulatory requirements in this guidance:
 - 1- Sponsors should include plan for active follow-up and collection for safety data (including deaths and hospitalization, and other serious or clinically significant adverse events) among individuals administered the vaccines under EUA in order to inform ongoing benefit risk-determinations to support the continuation of the EUA.
 - 2- Safety and efficacy data (Module 4 and 5) the available data should be submitted to JFDA according to" Section C at USFDA Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry October 2020" requirements. Taking in to consideration that the provided phase III studies should include at least 3000 volunteers at the vaccine group.

- 3- The sponsors should provide JFDA with any new results of the ongoing clinical studies (interventional (phase III) and non-interventional (phase IV)) within one week in addition to the interim report on monthly basis or according to its Time line of issuance , including all the safety information regarding all the critical adverse reactions of the vaccine.
- When the authorized vaccines are imported to the Jordanian market:
- 1- JFDA will Prioritize and accelerate the process
 - 2- Summary of production and quality control protocol, vaccine certificate of analysis, and batch release certificate form country of origin should be submitted to the JFDA.
 - 3- Cold chain should be maintained and submit all the need documents to the JFDA.
 - 4- The required Lab testing after EUA will be determined based on case-by-case assessment

- في حال قيام منظمة الصحة العالمية بتقديم الدواء أو المطعوم لإجازة الاستخدام الطارئ يجب ان يكون من خلال مستودع ادوية (وكيل للشركة مالكة حق تسويق المطعوم / الدواء) أو الشركة نفسها مع الالتزام بجميع المتطلبات المذكورة في هذه التعليمات ويجب تحديد المسؤوليات بشكل واضح من الـ WHO او الشركة نفسها او الجهة المستخدمة للمطعوم / الدواء ، وان تكون هناك جهة مسؤولة عن متابعة الـ Pharmacovigilance وشريطة ضمان سلسلة التبريد cold chain و ضمان التخزين لدى الجهات المعنية مع التأكيد على ضمان أهمية سلامة سلسلة الامداد و التخزين للمطاعيم

Reference:

USFDA Emergency Use Authorization for Vaccines to Prevent COVID-19
Guidance for Industry October 2020.

Annex II

Summary of recommended information:

- Well organized contents in a reviewable and sufficiently complete form to permit substantive review.
- Submissions may be provided in an electronic or paper format (all formats are applicable)

Module 1

- Cover letter
- Description of the product and its intended use.
- Description of the product's regulatory status:
 - JFDA approval status (e.g., whether the product is unapproved or whether it is approved but the EUA is for its unapproved use).
 - If the product or the intended use is under investigational application.
 - Whether the product is approved by other regulatory agencies and clarification regarding world-wide registration status, for either the proposed use or another use
 - Information about the use of the medical product by either a foreign country or an international organization (e.g., the World Health Organisation WHO).
- Mockup and Labeling
- Summary of product characteristics (SmPC) and patient information leaflet (PIL). “ it should contain JFDA side effect reporting address”.
- A draft of the ‘fact sheet’ to be provided to the health care professional, authorized despisers, and patients. “ it should contain JFDA side effect reporting address”.
- Health authority approval of the latest Plasma master file (if the product contain plasma derivatives).

- If Certificate of Pharmaceutical product (CPP) can't be provided, any documents prove the product status in the country of origin (registered and / or marketed) with commitment to provide it once it's available.
 - RMP if applicable
 - Information about composition of the product and their source and the related certificates (*TSE CEP*).
 - A list of production site (manufacturing site (s) or would be manufacturing site (s)) starting from API to the FP along with their JFDA approval status, and current GMP (s), If it is (are) not accredited, request for accreditation along with
 - GMP.
 - SMF.
 - Remote inspection report/ accreditation / registration of the site / the product by reference country or any international references accepted by JFDA / prequalification by WHO / EUDRA GMP , should be submitted to JFDA.
- يتم تقديم الدواء أو المطعوم للمؤسسة لإجازة الاستخدام الطارئ من خلال مستودع ادوية (وكيل للشركة مالكة حق تسويق المطعوم / الدواء) والالتزام بجميع المتطلبات المذكورة في هذه التعليمات
- وفي حال عدم وجود مستودع ادوية (وكيل للشركة مالكة حق تسويق المطعوم أو الدواء) يمكن تقديم الملف من قبل الشركة نفسها ويجب تحديد المسؤوليات بشكل واضح من الشركة .
- في حال قيام منظمة الصحة العالمية بتقديم الدواء أو المطعوم لإجازة الاستخدام الطارئ يجب تحديد المسؤوليات بشكل واضح من المنظمة نفسها (WHO) او الجهة المستخدمة للمطعوم / الدواء .
- بخصوص المطاعيم ضرورة وجود جهة مسؤولة عن متابعة Pharmacovigilance الـ
- و ضمان سلسلة التبريد cold chain والتخزين لدى الجهات المعنية مع التأكيد على ضمان أهمية سلامة سلسلة الامداد و التخزين للمطاعيم .

Module 3 (as applicable)**S-part:**

- **API general information.**
- **Manufacturer(s) “a declaration or/and clarification concerning manufacturing process(s) similarities/differences”**
- **Characterization and identification (as applicable given the nature of the product)**
- **Impurity.**
- **Specification / justification of specification.**
- **Manufacturing process and controls.**
- **The available stability data in addition to commitment to provide JFDA within the result of the ongoing stability study.**

P-part

- **Composition.**
- **Manufacturer(s) “a declaration or/and clarification concerning manufacturing process(s) similarities/differences and their impact on the FP quality and safety”.**
- **Characterization and identification (as applicable given the nature of the product).**
- **Impurity.**
- **Specification / justification of specification.**
- **Manufacturing process and controls.**
- **Container closure system.**
- **The available stability data in addition to commitment to provide JFDA within the result of the ongoing stability study.**
- **Information about the available FP quantity and the capabilities of the manufacturing site(s).**

Module 4 & 5 “ The available data & it will be assessed as a case-by-case “

- A discussion of risks and benefits, including the available information concerning the threats posed by the intended medicinal products.
- For medicinal products: The available data about safety and efficacy data should be submitted to JFDA .
- For vaccines: safety and efficacy data should be submitted based on “ *Section C in USFDA Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry October 2020*” requirements. Taking into consideration that the provided phase III studies should include at least 3000 volunteers at the vaccine group.
- PSUR “ if available “.
- Commitment to provide JFDA with the result of any ongoing clinical trials (Phase III or Phase IV) once its available (Within one week for the authorized vaccines) .
- Commitment to provide JFDA with the interim report on monthly basis or according to its Time-line of issuance.
- plan for active follow-up and collection for safety data (including deaths and hospitalization, and other serious or clinically significant adverse events) among individuals administered the vaccines/drugs under EUA in order to inform ongoing benefit risk-determinations to support the continuation of the EUA.