Notice to Applicant

Procedures of scientific advice for biological products

Year 2024

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I. Introduction

Scientific advice is a service established to provide guidance to applicants of biological products.

Scientific advice service is managed within Biological and innovative products and clinical studies central administration (BioInn) in the general administration of biological products independently by development and advice (DA) unit where regulators approached to scientific advice are not assessing the file during its formal submission to grant MA.

II. Scope

This document provides assistance to the applicants in the scientific advice process.

III. Benefits of scientific advice

- Early identification of potential issues or challenges.
- Optimization of development plans.
- Streamlining regulatory submissions.
- Enhancing the likelihood of regulatory approval.
- Enhancing good submission practice for registration of new biological products by applicants which enables fostering good review practice.

IV. Conditions for scientific advice

- Bio Inn gives scientific advice by **responding to specific questions** posed by the applicant on the development of a particular biological product.
- The applicant presents the way it plans to develop its product and identifies questions and possible solutions. Bio INN then gives advice on the applicant's proposals.
- Scientific advice is prospective in nature. DA unit **does not evaluate** the results of the studies and in no way concludes on whether the benefits outweigh the risks.
- Scientific advice from Bio INN is not legally binding on EDA or on the applicant with regard to any future marketing authorization applications, however complying with scientific advice increases the chances of receiving marketing authorization but it does not guarantee it.
- During the formal submission of the file ,if the applicant doesn't align to the outcome of the scientific advice ,Justification should be submitted

V. When applicant can seek scientific advice

- Local applicants can seek advice at any stage of development for guidance or direction from BioInn on the best methods and study designs to generate robust information to support the marketing authorization application.
- Scientific advice may be useful in case no or insufficient relevant details in EDA published guidelines, or in pharmacopoeia monographs.
- Scientific advice for screening of CTD is not accepted in case the file is already submitted to registration administration.

VI. Phases and scope of scientific advice

- **Developmental phase**

  Scientific advice helps to ensure that local applicants perform the **appropriate tests and studies**, so that no major objections regarding the design of the tests are likely to be raised during the evaluation of the marketing authorization application. The scope of developmental phase may include:

  - Developmental issues (regarding the production for locally produced products).
  - Similarity issues.

- **Pre-authorization phase**

  This phase is mainly concerned by the applicants who seek information to accelerate the process of marketing authorization, such as:

  - Laboratory testing issues (including the determination of number of samples and reagents needed for the marketing authorization analysis).
  - CTD screening (quality, non-clinical, clinical)
  - Regulatory related questions (e.g. different registration pathway, reliance conditions, …etc)

- **Post authorization phase**

  This phase is concerned by any raised questions during lot release or post approval changes (e.g. categorization, required documents, grouping,…etc) before the official submission.

VII. Scientific advice procedures

1- The applicant must fill the scientific advice application form (Annex I) then send it to the following e-mail (biots.da@edaegypt.gov.eg).
2- DA unit verify the eligibility of the scientific advice request for scientific advice within **2WDs**.
3- In case of acceptance, the applicant is notified to send the required documents along with the fees payment receipt.
4- A preparatory meeting can be organized if needed, in particular for first users of scientific advice or for complex products.
5- In case any clarification needed from the applicant on the scientific advice report, a follow up can be requested by sending mail to DA unit.

VIII. Required documents and timeframe

1- For laboratory testing issues the applicant should submit: detailed SOPs (for all QC tests that were mentioned in the COA of drug product as well as any related/referred SOPs as cell retrieving SOP, specific dilutions ,etc), detailed method validations of drug product, justification of specification of drug product, CoA of drug product, specification sheet of drug product, and reference materials CoAs. The scientific advice letter will be issued within **10 WDs** after the submission of all the required documents.
2- For CTD (quality, preclinical & clinical) screening, complete & updated CTD, SmPC, and CPP must be submitted. The scientific advice letter will be issued within **20 WDs** after the submission of all the required documents.
3- For development issues, the applicant shall submit developmental proposal along with all supportive documents. The scientific advice letter will be issued within **40 WDs** after the submission of all the required documents.
4- For regulatory related questions & similarity issues, the applicant shall submit the supportive documents. The scientific advice letter will be issued within **20 WDs** after the submission of all the required documents.
5- For Post marketing issues such post approval changes issues the applicant shall submit the supportive documents. The scientific advice letter will be issued within **10 WDs.**
6- In case not completing the required documents within 30 days, the request will be considered cancelled and the applicant shall submit a new one.

IX. Abbreviations

ATMP	Advanced Therapy Medicinal Products
Bio INN	Central Administration of biological and innovative products and clinical studies
CoA	Certificate of Analysis
CPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
DA	Development & Advice
EDA	Egyptian Drug Authority
MA	Marketing Authorization
QC	Quality Control
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
WDs	Working Days

X. Annexes

Annex I: Application Form for Scientific Advice

Annex I: Application Form for Scientific Advice

Product Name	
Product type	☐ Recombinant DNA derived products ☐ Vaccine ☐ Plasma derived product ☐ Extract ☐ ATMP ☐ Others ……
Active substance	
Presentation / Volume	
Applicant	
Manufacturer	
Marketing Authorization holder	
Batch release site	
Intended indication	
Manufacturer status	☐ Local ☐ Imported
Contact person	
Contact Number	

Contact e-mail	
Submission date	
Scope of scientific advice	☐ Laboratory testing issues ☐ Quality ☐ Clinical / non clinical ☐ Development issues ☐ Similarity issues ☐ Regulatory related questions ☐ Post approval change issues ☐ Lot release issues ☐ Others ……
Regulatory status	☐ Pre-authorization ☐ Post-authorization ☐ Submitted to registration directorate (specify at which step……..)
Post change approval Scientific advice request is related to	☐ Administrative changes ☐ Quality changes ☐ Product Labelling information changes (pack/insert) ☐ Safety changes ☐ Regulations of variations ☐ Analysis issues
Required scientific advice pre-	☐ No
	☐ Yes ……

submission meeting	
Questions	…… …… …… N.B Questions should be Clear and Concise
List of Attachments	- Documents - Payment receipt - Annexes include any information potentially relevant to the Questions

☐ **The Company commits that the submitted documents are in the same version as that will be submitted during marketing authorization process and any deviation will be properly communicated and justified.**

Notes:

- **Scientific advice is independent from the submission route**
- **Does not substitute for the industry's responsibility for the development of their products**

Authorization company representative:
Signature:
Date:
Stamp: