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دولة ارتريا وزارة الصحة

NATIONAL MEDICINES AND FOOD ADMINISTRATION

Date: 25-Mar-2022 **Ref:** SR/2022/0003

To: Ipca Laboratories Limited

street/plot number: Mum1256

region/state: Indi countrysss: India

Subject: Queries to Applicant - for the Registration Application of Insane, INJECTION POWDER FOR SOLUTION, Subcutaneous

Dear Applicant -

Reference is made to the application for registration dated [date/month/year]: of the following product:

S.No	Product Name	Application Number
1	Insane,INJECTION POWDER FOR SOLUTION , Subcutaneous	NMFA/AR/2022/0002

This is to kindly inform you that evaluation of Insane,INJECTION POWDER FOR SOLUTION, Subcutaneous has been completed. In this regard, we are attaching herewith the queries for your reference and to respond not later than [Month(text) date, year]. Failure to respond by this date, the authority, at its discretion, will proceed to make a decision on the product for re-application of marketing authorization.

Best regards,

lyassu Bahta Director, National Medicines and Food Administration Ministry of Health Asmara, Eritrea

Queries to Applicant - for the Registration of Insane, INJECTION POWDER FOR SOLUTION, Subcutaneous

Upon evaluation of the dossier for the registration of Insane,INJECTION POWDER FOR SOLUTION, Subcutaneous, the following queries have been raised. Therefore, please address the following questions with the respect to the submitted product dossier.

Module 1

<Section title> (<Page number>)

<insert your comments on the respective section of Module 1 here>

Module 2

<Section title> (<Page number>)

<insert your comments on the respective section of Module 2 here>

Module 3

<Section title> (<Page number>)

<insert your comments on the respective section of Module 3 here>

ቴሌ/Tel. +291-1-125525 +291-1-125393 **4ክስ/**Fax +291-1-122899 4.4.7./P.O.Box 212



ص.ب ۲۱۲

تلفون ١٢٥٥٥١ - ١ - ٢٩١ فاكس ١٢٨٩٩ - ١ - ٢٩١ 791-1-170898