**AGENDA FOR 110th UAC MEETING (VSEZ UNITS) SCHEDULED AT 1100 A.M ON 25.10.2019 AT 11.00 A.M UNDER THE CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER,VSEZ, SHRI A.RAM MOHAN REDDY, IFS, IN THE CONFERENCE HALL OF ADMINISTRATIVE BUILDING, DUVVADA**

Agenda item No.1.

Ratification of the minutes of the UAC meeting for VSEZ units held on 25.09.2019

Agenda item No.2

**Request of M/s.Reddy's Laboratories Ltd., Formulation unit VII, Plot No. P1 to P9 for inclusion of New product in their LoA – reg.**

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The unit was issued LoA dt.23.03.2005 for manufacture of pharmaceutical tablets, capsules, injections and commenced production w.e.f.22.4.2010 . The unit intends to add new products in their LoA which are as follows:

1. Varenicline Tablets 0.5 mg ITC HS 30049099 at annual capacity of 18.00 lakh for a value of Rs.80.64,000/- ( approximately)

2. Varenicline Tablets 1 mg ITC HS 30049099 at annual capacity of 18.00 lakh for a value of Rs.80,64,000/- ( approximately)
   As per the write up given by the unit the above drug is used for cancer treatment.
   The unit declared that the above products are not in restricted/prohibited list of goods in terms of ITC(HS).

The unit submitted process chart for manufacture of the above drug. The technical write up states that the drug is used as an aid to smoking cessation treatment.

The unit submitted photo-copy of Test Licence dt.04.09.2019 from Drug Control Administration, Govt.of A.P. for the purpose of Examination, Test for chemical and instrumental analysis and not for any commercial use and shall be used for Bio/clinical studies subject to grant of BE/CT permission ofrom the DGG(I) office . The unit also submitted Form-29 wherein it is mentioned that the Licence is valid for 3 years from the date of its issue.

The request of the unit is placed before UAC to consider inclusion of new product in their LoA under broad banding in terms of Rule 19(2) of SEZ Rules, 2006.

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Agenda item No.3

**Request of M/s.Dr.Reddy Laboratories Ltd., Unit IX for inclusion of new products in the LoA – reg.**

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The unit vide their letter dt.12.09.2019 received in the section on 17.9.2019 requested for inclusion of new product " Naloxone Hydrochloride Nasal Spray 4 mg/0.1 ml under ITCHS 30041090 as additional product under broad banding.

The unit submitted Flow chart ( manufacturing process) for the above drug.

The unit submitted copy of permission in CT-14 to manufacture formulation of unapproved active **pharmaceutical** ingredient for test or analysis and not for clinical trial or bioavailability or bioequivalence study only.

The unit's representative attended the UAC meeting held 25.9.2019 and requested UAC to discuss and approve the above said inclusion of additional product. Since there was no agenda placed because the request for inclusion had been received after circulation of agenda and Table Agenda, the matter is being dealt on file as desired in the UAC meeting.

Since the unit has already obtain permission from Central Drugs Standard Control Organization, Hyderabad vide License dt.16.07.2019 , the request of the unit has been dealt on file as per the informal directions on the request of the unit and approved on file under broad banding in terms of Rule 19(2) of SEZ Rules, 2006, and placed the decision for ratification of the UAC.

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