Brief Report

1) **Name of the Event**: INTERNATIONAL REGULATORY MEET, HYDERABAD

2) **Purpose of the Event**: The purpose of organising this Regulatory Meet is to establish convergence and harmonisation through deliberations for a greater market access to affordable quality medicines. This is the theme with which deliberations took off and interestingly the officials present were so vocal leading to the discussions beyond the theme emphasizing on health care budget, dependency, innovation, green channel and also on the diseases vs patients' access without having any borders.

3) **Country** : INDIA

4) **Date of Event**: 19th – 20th September, 2019

5) **EC approval (in brief)**: This event was approved under MAI scheme.
K-11020/88/2019-E&MDA dated: 28th May, 2019

6) a) Approved : Rs. 80,00,000/-
b) Release of 1st installment (in Rs.) : Rs.40,00,000/-
c) 2nd installment, if any (in Rs.) : NIL
d) Remaining amount pending for release (in Rs.) : Rs.5,54,057 /-

7) **Brief description of the event**: Pharmexcil with the support of Ministry of Commerce & Industry, Government of India and Central Drugs Standards Control Organization (CDSCO), Ministry of Health & Family Welfare, organised two-day International Regulatory Meet, which was attended by 30 Regulators from 22 countries. Dr.VG Somani, Drugs Controller General of India graced the occasion as the Chief Guest and about 20 State and Central Regulators from different States participated in the two-day meet.

Regulators Industry interaction is another important activity organized during this event and it is delighted to see large participation from the industry and focused interactions with the regulatory officials for more than three hours which would have definitely gained them an insight of the regulatory practices and changes therefore. The event had participation of 280 delegates representing 165 companies.

8) **Details of Indian Participants**:
   i) Number of Participants : 162
   ii) Brief profile of each participants : Details Enclosed
   iii) Participants response : Good

9) **Details of Buyers/Visitors :**
   i) Number of Overseas buyers : 36
   ii) Number of Visitors : Not Applicale

iii) Visitors feedback : Not Applicable

10) **Business generated**:

i) No. of enquiries : Not Applicable
ii) No. of MOUs Signed : Not Applicable
iii) On spot Orders Booked : Not Applicable
iv) Total Business generated : Not Applicable

11) **Brief note on export potential of the country/product:** *Not applicable*

12) **Outcome analysis by Council**: The two-day International Regulatory Meet organized during 19-20th Sep.2019 have had extensive discussions on the challenges faced by the Regulatory authorities and steps being taken to improve the quality standards and manufacturing facilities. The cooperation is sought from India on the possible convergence and mutual recognition of standards.

- The Meet has created awareness to the industry on the regulatory practices being followed by each country and the approach/criteria by the authorities while sanctioning the product approvals.

- It has provided a platform for the industry and is a great networking opportunity for industry to interact with the Chiefs of various regulatory authorities and also for the Regulatory officials to have rapport with regulatory officials from India and overseas.

- It is evident from the discussions that the dependency on either API or Finished Dosage formulations is unavoidable and in the process of the dependency every country has few challenges in terms of sourcing the quality raw material, prices of drugs, availability, and accessibility to the pre-approved products of SRA countries. Availability of affordable quality drugs is the key and India is among the top five global generic manufacturers.

- Many countries are gearing up for exclusive pharmaceutical SEZ/parks and promoting investments into their country and also strengthening the concept of indigenous manufacturing. Countries including Nigeria, Egypt, Indonesia and Bangladesh have invited India Pharma industries to set up facilities and explore possible collaborations.

- The thought process of the regulatory authorities has been patient centric and legislations/enactments are made keeping in view of the people's perspective with the motto "Patient Fist" and reduced health care expenses. For instance, Europe and Japan are moving towards reduction of their healthcare budgets and looking

towards generic medicines which widens the scope and opportunity for generics from India.

- We are hopeful that in future some of these countries come together and join hands with CDSCO, in addressing the issues of mutual interest by signing MoU/ mutual agreements similar to that of EU and USA. This will facilitate recognition of product approvals, inspections and audits, IP recognition and reduction in timelines.

- The forum discussed on the opportunities present for the India pharma industry and areas of cooperation country wise, which are the key take away of the International regulatory Meet.

Photographs:


pharmexcil
Pharmaceuticals Export Promotion Council of India
(Set up by Ministry of Commerce & Industry, Govt. of India)
INTERNATIONAL REGULATORS MEET
AL REGULATORY CONVERGENCE TO PROMOTE ACCESSIBILITY AND AFFORDABILITY OF QUALITY MEDICINES"
15TH AGM & EXPORT AWARDS
INDIA
MR. ARUN MISHRA
DR. SIYAT MOE KYI