"Industry expectation from Regulators to achieve common goal of Mutual Reliance Mechanism for facilitated Access of Medical products"

IPHEX & Global Regulators Conclave

21-23 September 2022, India Expo Centre, Greater Noida.

Dr. G. V. J. A. Harshavardhan
Executive Secretary, Indian Vaccine Manufacturers Association

Indian Vaccine Manufacturers Association

- Vaccine Manufacturers Association (IVMA) (No.86 of 2010) was registered with the Registrar of Societies, Hyderabad, on 3rd February 2010. Dr. Cyrus S. Poonawalla, Chairman of Serum Institute of India was the First President.
- We requested the Registrar of Societies to amend the name as Indian Vaccine Manufacturers Association (IVMA).
- In 2017, the Association took a major step to engage with the Union Ministry of Health and Family, Delhi through the intervention of Confederation of Indian Industry. The Association submitted to the Government a White Paper prepared by Sathguru Management Consultants, Hyderabad, on the discussions held with the Officials of the Ministry.

Regus Business Centre, Office Nos. 135 & 137, Level 1, Midtown Building, Road No.1, Banjara Hills, Opp. Jalagam Vengal Rao Park, Hyderabad, Telangana 500034, India. contact@ivma.in

Bye Laws and Rules of IVMA

- IVMA resolved to assist the Indian private sector human vaccine manufacturers to represent their concerns to the Government related to the progress and profitability of the industry.
- To represent the Members in matters related to audit and inspections of their facilities with the Union Ministry of Health and Family Welfare, Drugs Controller General (India) and the Central Drugs Laboratory.
- To assist India to become self-sufficient in the development and manufacture of all the necessary human vaccines of quality at affordable cost.

Bye Laws and Rules of IVMA

- To participate in the harmonization of regulatory pathways across the continents through active dialogue with WHO, UNICEF, PAHO, GAVI and CEPI for equitable availability of vaccines across the nations

- To support advocacy of vaccines and immunization efforts of the Government and Non-Governmental agencies.

Regulatory Requirements

- The Drugs and Cosmetics Act (1940) of India was a pre-independence legislation enacted by the Indian Central Legislative Assembly. Review of obsolete laws and updating of the existing laws is a continuing process to accommodate changed requirements and adaptation of new technology.
- The work of review and updating of Drugs and Cosmetics Rules (1945) was vigorously taken up from the year 2016. The Government has time and again emphasized the need to review obsolete laws and to periodically repeal and amend laws.

CDSCO

- The Central Drugs Standard Control Organization (CDSCO) under the Director General of Health Services, Union Ministry of Health and Family Welfare is the National Regulatory Authority (NRA). DCG(I) is the Head of CDSCO.

- National Single Window System has access to over 100 Central Level Approvals and State Single Window Systems of 14 States/UTs with one user id and password. Online licensing portal Sugam was set up in January 2016.

- New Drugs and Clinical Trials Rules, 2019.
- CDSCO Industry Guidelines are effective from 01 April 2020.

New Drugs, Medical Devices and Cosmetics Bill 2022

- IVMA is grateful to the Government of India for the timely effort initiated to introduce the New Drugs Medical Devices and Cosmetics Bill 2022 before the Parliament in order to keep pace with changing needs, times and technology.
- Government expects the related pharmaceutical and biotech industries to submit their comments and suggestions on the Bill by 22 August 2022.
- I was a keen observer of the functioning of the Indian Regulatory Authorities from 1964 till date, with reference to human vaccines.

Regus Business Centre, Office Nos. 135 & 137, Level 1, Midtown Building, Road No.1, Banjara Hills, Opp. Jalagam Vengal Rao Park, Hyderabad, Telangana 500034, India. contact@ivma.in

Harmonization of CTD/CMC

- During the years 2011-2012, as the Vice-President of the Developing Countries Vaccine Manufacturers Network (DCVMN), I successfully negotiated with Gates Foundation to support projects on harmonization of CTD/CMC, availing of specific expert advice by member organizations and, preparation of a Catalogue of Consultancy Agencies.

- IVMA proposes to continue work on harmonization of vaccine dossiers for prompt registration by other importing countries.

Impact and disruption by Covid –19 pandemic

Covid-19 pandemic exposed the unpreparedness of the Manufacturers and Regulators of the vaccine manufacturing countries:

- In the rapid development of appropriate vaccines in quantities that could be shared with other developing countries.
- In the amendment of Regulatory pathways for prompt Batch Release Certification of new pandemic vaccines.
- In prioritization specific age groups for emergency vaccination and Safe-guarding of national interests.

India - Global Vaccine Hub

- Undoubtedly, India is the epicentre for vaccine manufacturing in the world. With many top vaccine manufacturers supplying basic and advanced vaccines to nearly 170 countries, India over the years, emerged as the global vaccine hub. India is the global in vaccines with over one-third share of the total vaccine market. Indian manufacturers account for 65% of vaccine supplies made to UNICEF.

- Indian vaccine industry with many state-of-the-art manufacturing facilities earned India the recognition of having the largest global capacity for WHO prequalified vaccine manufacturing.

Regus Business Centre, Office Nos. 135 & 137, Level 1, Midtown Building, Road No.1, Banjara Hills, Opp. Jalagam Vengal Rao Park, Hyderabad, Telangana 500034, India. contact@ivma.in

KEY FACTORS AND IVMA SUPPORT

- Increased public awareness about vaccination, public immunization programs, coupled with government support to develop new vaccines, are the key factors that drive India's vaccine industry.

- The current President of IVMA is Mr. Adar C. Poonawalla of Serum Institute of India. IVMA assures that once the harmonization of Regulatory Pathways become operational, it would enable IVMA member organizations to continue to promptly provide quality vaccines to the Developing Countries in required quantities.

THANK YOU

Regus Business Centre, Office Nos. 135 & 137, Level 1, Midtown Building, Road No.1, Banjara Hills, Opp. Jalagam Vengal Rao Park,
Hyderabad, Telangana 500034, India. contact@ivma.in