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Pharmaceuticals Export Promotion Council of India
(Setup by Ministry of Commerce and Industry, Government of India)

GLOBAL REGULATORS CONCLAVE

“International Regulatory Convergence to Promote Accessibility and Affordability of Quality Medicines”

(21 – 23 September 2022, IEML Knowledge Park, Greater Noida)

DRAFT AGENDA

Day 1: 21 September 2022, Wednesday

9.30 – 12.00 hrs	Inauguration Ceremony
11.30 – 12.30 hrs	Visit to Exhibition / Networking
12.30 – 14.00 hrs	Lunch Break
Session 1 14.00 – 15.45 hrs	<p style="text-align: center;">Thematic Discussion</p> <p style="text-align: center;">“International Regulatory Convergence to Promote Accessibility and Affordability of Quality Medicines”</p> <p>Welcome Address by Mr.Udaya Bhaskar, DG-Pharmexcil Key Note Address by Chairperson of Conclave: Dr.V.G.Somani, DCG(I), Special address:</p> <ol style="list-style-type: none"> 1. Prof Mojisola Christianah Adeyeye, DG-NAFDAC, Nigeria 2. Mr.Vladislav Shestakov, Director of FSI «SID and GP» (FSI «State Institute of Drugs and Good Practices» (FSI «SID & GP»), Russia 3. Dr.Kang Seogyoun, DG- MFDS, South Korea 4. Dr. Mátyás BÉLA Szentiványi MD PhD, DG- OGYÉI (National Institute of Pharmacy and Nutrition), Hungary 5. Ms.Olga Lidia Jacobo Casanueva, DG-CECMED, Cuba 6. Dr.Maryam Aljalahma, CEO, NHRA (National Health Regulatory Authority), Bahrain
1545 – 1600 hrs	Tea / Coffee Break
Session-2 15.45 – 17.00 hrs	<p>Industry expectation from regulators to achieve common goal of Mutual Reliance Mechanism for facilitated Access of Medical products</p> <p><u>Session Chair : Mr.Sahil Munjal, Chairman-Pharmexcil</u></p> <ol style="list-style-type: none"> 1. Mr.Sudersahan Jain, Secretary General, Indian Pharma Alliance (IPA) 2. Dr.Viranchi Shah, National President, Indian Drug Manufacturers Association (IDMA) 3. Mr.R.K.Agrawal, President, Bulk Drug Manufacturers Association (BDMA) 4. Dr.Harshavardhan, Executive Secretary, Indian Vaccine Manufacturers Association (IVMA) 5. Association of Biotechnology Led Enterprises (ABLE) Representative

* To be confirmed

Day 2: 22 September 2022, Thursday

Session 3 1000 – 1130 hrs	<p>Panel Session on Learnings From COVID-19 Pandemic</p> <p>The Session would discuss the following:</p> <ul style="list-style-type: none"> • <i>Regulatory Enablers for fast track approvals</i> • <i>Supply Chain Resiliency</i> • <i>Regulatory preparedness for Healthcare Emergencies</i> <p>Moderator: Ms.Lakshmi Prasanna, Director-Regulatory Affairs, Pharmexcil</p> <ol style="list-style-type: none"> 1. CDSCO Official (to be nominated by DCG(I)) 2. Dr. Mátyás BÉLA Szentiványi MD PhD, DG- OGYÉI, Hungary 3. Ms Luz Maria Hederra, Head(s)-Medicine Regulatory Agency, Public Health Institute(ISP) of Chile 4. Mr Leandro Jose Villanueva, Vice minister of Public Health and General Director of DIGEMAPS (General Directorate of Medicines, Food and Health Products) Dominican Republic 5. Ms Heran Gerba Borta, Director General, EFDA, Ethiopia 6. Dr Vijitha Ranasinghe Gunasekera, CEO, National Medicines Regulatory Authority, Sri Lanka 7. Ms. Fatima Murad Rahim, Deputy Director, Drug Administration - Health Regulation Sector of UAE
1130 – 1145 hrs	Tea / Coffee Break
Session 4 1145 – 1315 hrs	<p>Panel Session on</p> <p>“Migrating from Routine to Risk Based Inspections- Optimizing the Human Resources in Post Pandemic”</p> <p><u>Session Chair: Dr.H.G.Khoshia, Commissioner, FDA-Gujarat</u></p> <ol style="list-style-type: none"> 1. CDSCO official (to be nominated by DCG(I)) 2. Mr Vladimir Smirnov, Chief Technology Officer For GLP,(FSI «SID & GP» (FSI «State Institute of Drugs and Good Practices» (FSI «SID & GP»)), Russia 3. Mr Aziz Dusmatov, Director Of The Sue Center GXP (SUE "State Center For Expertise And Standardization Of Medicines, Medical Devices And Medical Equipment"), Uzbekistan 4. Ms Maria Aba Lovelace-Johnson, Director of Inspectorate, FDA-Ghana 5. Dr Furaha Godfrey Nyunza, Drugs Inspector, TMDA (Tanzania Medicines And Medical Devices Authority) 6. Dr.Keohavong Bounxou, DG- Food and Drug Department, Laos 7. Mr Armando Victorino Andino Gimenez, Director General of Health Assessment And Registration, National Directorate of Health Surveillance – DINAVISA, Paraguay 8. Mr Alfred Rudyard Athill, Director of Pharmaceutical Services, Ministry of Health, Wellness & the Environment, Antigua & Barbuda

1315 – 1415 hrs	Lunch Break
Session 5 1415 – 1545 hrs	<p>Panel Session on “Accessibility, Affordability & Equitable distribution for COVID-19 Vaccines & Therapeutics”</p> <p><u>Session Chair: Prof Mojisola Christianah Adeyeye, DG-NAFDAC, Nigeria</u></p> <ol style="list-style-type: none"> 1. Dr.Medhat Al-Ghobashy, Scientific Advisor to Chairman, EDA, Egypt 2. Prof Khin Zaw, DG- Department of Food And Drug Administration, Myanmar 3. Dr.Pablo Sánchez Gastélum, Secretary of Health, The State of Guanajuato, Mexico 4. Dr.Yuri Werner Quisbert Aruquipa, Executive Director General, State Agency For Medicines & Health Technologies (AGEMED), Bolivia 5. Mr Makomani Siyanga, Acting Director-General, Zambia Medicines Regulatory Authority 6. Dr Dansou Alfred, Additional DG, SOBAPS (Beninese Company For The Supply Of Health Products), Benin 7. Mr. Sai Prasad, Chairman of the Developing Countries Vaccine Manufacturers Network (DCVMN) & Executive Director of Bharat Biotech Intl Ltd
1545 – 1600 hrs	Tea / Coffee Break
Session 6 1600 – 1730 hrs	<p>Closed door Roundtable Discussion among the Regulators on How to achieve common goal of Mutual Recognition (Industry participation is restricted)</p>

* To be confirmed

Day 3: 23 September 2022, Friday

Session 7 1000 – 1130 hrs	<p>Panel Session on “India sourced Generic Drugs - Global Expectations”</p> <p><u>Session Chair: Dr.Chava Satyanarayna, Chairman-iPHEX & CEO – M/s.Laurus Labs</u></p> <ol style="list-style-type: none"> 1. Mr. Benjamin Calinisan De Los Santos, CEO, Philippine Pharma Procurement Inc, Philippines 2. Mr Rafael Adolfo Perez De Leon, Director General, Promesecal, Dominican Republic 3. Dr Juan Nacer Ledezma, Executive Director General, Health Supply and Supply Center (CEASS), Bolivia 4. Mrs Ana Karina Ramirez, Executive Director of ARCSA, (National Agency For Regulation, Control And Sanitary Surveillance), Ecuador 5. Mrs Alma Nubia Lacayo Castillo, Director General Medical Supplies Division, Ministry of Health of Nicaragua 6. Mr Mphatso Kawaye, DG- Pharmacy & Medicines Regulatory Authority, Malawi 7. Mrs. Fanjalalaina, Domoina Rajaonarivony, Director of Procurement and Stock, SALAMA, Madagascar, 8. Mr Oumar Douhe Bah, DG-National Directorate Of Pharmacies and Medicines (DNPM), Guinea 9. Representative from WHO India office*
1130 – 1145 hrs	Tea / Coffee Break
Session 8 1145 – 1245 hrs	<p>Panel Session on “Effective Use of Pharmacopoeias”</p> <p>Moderator: Shri S V Veerramani, Vice Chairman- Pharmexcil</p> <p><u>Session Chair: Dr.Rajeev Raghuvamshi, Secretary-cum-Scientific Director of the Indian Pharmacopoeia Commission</u></p> <ol style="list-style-type: none"> 1. Representative of USP 2. Mr Samuel Asante-Boateng, Director-Drugs & Herbal Medicines Registration, FDA, Ghana 3. Dr Toure Kourouma Aisseta, Deputy Director, National Public Health Laboratory Ivory Coast 4. Ms Amreeta Mangatha, Registrar of the Pharmacy Board, Mauritius 5. Mr.Yakhyaev Ulugbek - Deputy Chairman of the Pharmacopoeia Committee, Uzbekistan 6. Mrs Nik Shamsiah Nik Salleh, Senior Principal Assistant Director, National Pharmaceutical Regulatory Agency, Malaysia 7. Mr Alberto Jequicene Chambe, Administrator of Operations and Pharmaceutical Research, ANARME (National Medicines Regulatory Authority), Mozambique
1245-1300	Bio-Break

Session-9 1300-1330	Summary of the Conclave Concluding Address by CDSCO Vote of Thanks
1330 – 1430 hrs	Lunch Break

* To be confirmed