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Pharmaceuticals Export Promotion Council of India

(Setup by Ministry of Commerce and Industry, Government of India)

INTERNATIONAL REGULATORS MEET

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

19th -20th September 2019

Hotel Taj Krishna, Hyderabad, India

Time	Day One-19 th September 2019
9:00-9:30 am	Registration
9:30-10:30 am	<p>Inaugural Ceremony</p> <ul style="list-style-type: none">➤ Welcome address by Mr.Uday Bhaskar, Director General, Pharmexcil➤ Opening remarks by Dr.Dinesh Dua, Chairman, Pharmexcil➤ Address by Guest of Honor- Dr.VG Somani, Drug Controller General of India, CDSCO, Govt. of India➤ Address by Chief Guest: Mr.Shyamal Misra, Joint Secretary, Ministry of Commerce & Industry, Govt. of India➤ Vote of Thanks by Mr.Sahil Munjal, Vice Chairman, Pharmexcil
10:30-1:00 pm	<p>Theme Based Discussion on <i>“International Regulatory Convergence to Promote Accessibility and Affordability of Quality Medicines”</i> in two sessions</p> <p>Moderator: Mr.Arun Mishra, Executive Vice President, Regulatory Affairs (Indian Sub-Continent), GSK Consumer Healthcare Ltd</p>
10.30 – 11.30am <i>Panel Discussion- I</i>	<ol style="list-style-type: none">1) Dr.VG Somani, Drug Controller General of India, CDSCO, Govt of India2) Dr.Dinesh Dua, Chairman, Pharmexcil3) Prof Mojisola Adeyeye, Director General, NAFDAC, Nigeria4) Dr. Duncan Ahoube Rachel, Directeur de la DPM MoH, Ivory coast5) Mr. Gustavo Mendes Lima Santos, General Manager for Medicines ANVISA, Brazil6) Mr. Lliousilvero Jorje, National Director, MoH, Paraguay7) Mr.Marlin Cole, Director Guyana Food and Drugs Department (GAFDD)8) Dr. Heba Nabil Mohamad, Head MoH, Egypt9) Mr. T. Silyana Valadislav, Deputy Head MoH, Ukraine10) Mr. Pan Bahadur Kshetry, Act. Director General, DDA, Nepal11) Dr. Myat Moe Kyi, Deputy Director, FDA, Myanmar
11.30-12.00 pm	Tea Break

12.00-1.00 pm <i>Panel Discussion- II</i>	1) Dr.VG Somani , Drug Controller General of India, CDSCO, Govt of India 2) Dr.Dinesh Dua , Chairman, Pharmexcil 3) Mrs.Lisette , Head CECMED, Cuba 4) Mr. Juan Pablo Morales , Acting Chief of National Medicaments Agency, Institute of Public Health (ISP), Chile 5) Mr. Samuel Asante Boateng , Head,Drug Evaluation and Registration Department, Ghana 6) Dr. Eliana Caballero Vedia , Head Department of Marketing Authorization, AGEMED,Bolivia 7) Abduganiev Sh.B ,Director “State Centre for Expertise and Standardization of Medicines, Medical Devices and Medical Equipment”; Republic of Uzbekistan 8) Ms.Nova Emelda ,Head of Sub Directorate of Generic Drugs Registration, NADFC, Indonesia 9) Mr. Willison John. E. DE LUNA , Food-Drug Regulation Officer CDER, Philippines 10) Maj Gen. Md Mahbubur Rahman ,Director-In Charge, DGDA, Bangladesh
1:00 -2:00 pm	Lunch
2:00-4:00 pm	Regulator to Industry Interaction: One to One interaction of Industry representatives with the International Regulators
5.00-6.00 pm	Pharmexcil Annual General Meeting (<i>For Pharmexcil members</i>)
6.00 pm onwards	Export Award ceremony followed by Networking Dinner

DAY TWO, 20th September 2019

Time	Day Two: 20 th September 2019
9.30 am- 10.00 am	<p>Presentation on “Recent developments in the Indian Regulatory system – An overview” by Mr.Ranga Chandrashekhar, DDC(I), CDSCO, Govt of India</p> <p>Question & Answers</p>
10.00 am- 11.00 am	<p>Panel Discussion on “India sourced Generic Drugs - Global Expectations”</p> <p>Moderator: Mr.PBN Prasad, DDC(I), CDSCO, Govt of India</p> <p>Panelists:</p> <ol style="list-style-type: none"> 1) Prof. Mojisola Adeyeye, Director General, NAFDAC, Nigeria 2) Mrs.Lisette, Head, CECMED, Cuba 3) Mr. Pan Bahadur Kshetry, Act. Director General, DDA, Nepal 4) Mrs. Arlene James Ponteen, Director- Secondary Care Services, Ministry of Health, Montserrat. 5) Abduganiev Sh.B, Director “State Centre for Expertise and Standardization of Medicines, Medical Devices and Medical Equipment”; Republic of Uzbekistan 6) Mr.Benjamin Malua Vuanga Ngelesi, Pharmaceutical Advisor, PNAM, Congo 7) Dr.B.Venkateswarlu, JD & Licensing Authority, DCA, Telangana
11.00am - 11.15 am	Tea Break
11.15 am- 12.15 pm	<p>Panel Discussion on “Migrating from Routine to Risk Based Inspections- Optimizing the Human Resources”</p> <p>Moderator: Ms. Visala Annam, DDC(I), CDSCO, Govt of India</p> <p>Panelists:</p> <ol style="list-style-type: none"> 1) Mr. Gustavo Mendes Lima Santos, General Manager for Medicines, ANVISA, Brazil 2) Mr. Samuel Asante Boateng, Head Drug Evaluation and Registration Department. Ghana 3) Ms.Nova Emelda, Head of Sub Directorate of Generic Drugs Registration, NADFC, Indonesia 4) Ms. Sonia Thomas-Gordon, Head (Ag.) Medicines Quality Control and Surveillance Department, Jamaica 5) Mr.Martin Algernon Roberts, President, Antigua & Barbuda Pharmacy Council 6) Mr. T. Silyana Valadislav, Deputy Head, MoH, Ukraine 7) Ms. Jyothi Sardesai, Director, FDA, Goa

12.15pm 1.00 pm	<p>Panel Discussion on “Role of Regulators in the drug procurement policies and Practices- Regulatory preparedness for Healthcare Emergencies”</p> <p>Moderator: Dr.Ramkishan, DDC(I), CDSCO, Govt of India</p> <p>Panelists:</p> <ol style="list-style-type: none"> 1) Mr. Juan Pablo Morales, Acting Chief of National Medicaments Agency, Institute of Public Health (ISP), Chile 2) Dr. Heba Nabil Mohamad, Head, MoH, Egypt 3) Dr. Duncan Ahoube Rachel, Directeur de la DPM, MoH, Ivory coast 4) Maj Gen. Md Mahbubur Rahman Director-In-Charge, DGDA, Bangladesh 5) Mr.Marlin Cole, Director, Guyana Food and Drugs Department (GAFDD) 6) Mr. Anthony Kester Cyrus, Pharmacist, MoH, Social Security and International Business, Grenada.
1.00 pm- 2.00pm	Lunch Break
2.00 pm- 3.00pm	<p>Panel Discussion on “Possible collaborations of Regulatory Agencies to promote access of medicine and new therapies (e.g. Biosimilars, FDCs, Drug-Device Combination etc.)”</p> <p>Moderator: Dr.K.Bangarurajan, JDC(I), CDSCO, Govt of India</p> <p>Panelists:</p> <ol style="list-style-type: none"> 1) Mr. Willison John. E. DE LUNA, Food-Drug Regulation Officer, CDER, Philippines 2) Dr. Eliana Caballero Vedia, Head Department of Marketing Authorization, AGEMED, Bolivia 3) Dr. Myat Moe Kyi, Deputy Directo, FDA, Myanmar 4) Mr. Lliousilvero Jorje, National Director MoH, Paraguay 5) Ms. Astrid Bernice Clair Mondesir, Drug Inspector, Ministry of Health and Wellness, Saint Lucia.
3.00 pm- 3.30 pm	Sum up of Two Days program