APEX
Pharmaceutical Service

**Under the Patronage
of Her Royal Highness Princess
Sumaya Bint El Hassan**

Track & Trace System

- Securing IDs
- Anti-Counterfeiting
- Secure Point-Of-Sale Information

First MENA Pharmaceutical Track & Trace Conference
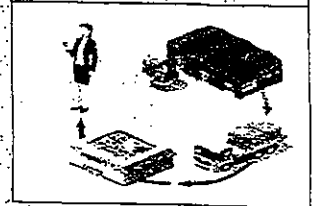## 17th - 18th June, 2014
Le Meridien
Amman-Jordan

Background

Globalization of the pharmaceutical industry presents a regulatory challenge the health regulatory authorities must address to ensure the safety and quality of drug supply chain. Because of this increasing globalization, substandard, falsified, and counterfeit (SFC) drugs present serious threats to global product safety and integrity. Instituting a robust track and trace system for each step of the supply chain would improve the safety and security of the drug supply chain by preventing the introduction of SFC drugs.

In participation with

This conference will focus on bringing a common understanding of what track and trace system is and how it can help assuring the supply chain safety. Regulatory authorities work with manufacturers and other supply chain partners is necessary to successes in implementing such system. The conference program is comprised of two days; the second day will be dedicated to steering committee meetings.

Objectives

- Identify the main pillars that help ensure the safety and quality of the drug supply chain.
- Recognize international initiatives to implement track and trace system in order to safeguard the global supply chain.
- Present examples of regional Track and Trace Systems (focusing on the successful Turkish experience).
- Highlight the necessity for an international tracking system.
- Initiate a steering committee to work on harmonization of an international tracking system in the region.
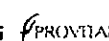
Who Can Attend?

- International and National Regulatory Authorities
- National and International Pharmaceutical Industries
- Regulatory Affairs Experts and Consultants
- Pharmaceutical Distributors and Retailers
- Interested Healthcare Professio

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First MENA Track & Trace Conference
Under the Patronage of HRH Princess Sumaya Bint El Hassan
17th – 18th June 2014

Day One

08:15-08:45	Registration
09:00- 09:30	Opening Ceremony under the Patronage of Her Royal Highness Princess Sumaya Bint El Hassan. • Apex Welcoming Note • H.E Layla Najem - Minister Plenipotentiary – Chairperson of the Committee on Health and Humanitarian Aid (TBC). • H.E. Dr Hayel Obidate, Director General of JFDA
09:30-10:00	Exhibition Opening by Her Royal Highness Princess Sumaya Bint El Hassan Cocktail Reception
10:00-10:15	Conference Overview and Objectives – Dr. Hanan Kakish, Regional Technical and Innovation Director at Apex, Former Medical Research Scientist at U.S. FDA. MENA Office.

Session One: International Initiatives and Implementation Mile Stones
Chaired By: H.E Ambassador Joanna Wronecka Head of EU Delegation to Jordan
Moderated By:

10:30-11:00	WHO Perspective for the Substandard/Spurious/Falsely Labeled/Falsified/Counterfeit (SSFFC) Medical Products – Dr Mohamed Ramzy Ismail, WHO EMRO Representative.
11:05-11:20	IPR and the Fight against Counterfeit Medicines - Brian Grimm, Economic Consular, U.S. Embassy
11:25-11:55	The U.S. FDA's Efforts to Safeguard the Global Supply Chain Emphasizing on the Drug Quality and Safety Act Signed Last November- U.S.FDA Representative
12:00-12:35	The European Approach to Traceability and Governance and The EU Falsified Medicine Directive – Dr. Francois-Xavier LERY, Head of Section for Pharmaceutical Care, Consumer Health Protection and Anti-Counterfeiting- European Directorate for the Quality of Medicines & HealthCare (EDQM)
12:35-13:05	USP chapter <1083> Good Distribution Practices focusing on Supply Chain Integrity and Security and How It Is Linked to The New Drug Quality and Safety Act- Dr. Mary Foster, Chair of the Packaging, Storage and Distribution Committee.
13:05-13:20	Questions and Answers Closing by the moderator
13:20-14:20	Lunch Break

Session Two: Track and Trace Requirements in the Arab World and Future Polices
Chaired By: H.E Dr. Raed Hijazeen – Head of Health and Environment Committee, Jordanian Parliament.
Moderated By: Dr. Hakima Hoseh - Compliance Regulatory Affairs Sr. Manager, Hikma Pharmaceuticals PLC

14:20-14:50	Saudi FDA Perspective -Dr. Abdullah Fahed Almeshal, Manager of Technology Management Department, Drug Sector at SFDA
14:55-15:20	League of Arab State Strategy and Implementation – Dr Lubna Rshaidat, Member in the "Highest Technical Committee for Arab Medicines" – Arab league/Council of Arab Health Ministers.
15:25-15:50	GS1 Standards for Healthcare- Maysaloun (May) Gammouh, Director General of GS1 Jordan
15:55-16:10	Jordan FDA Current and Future Implementation – Amal Abu Al Rob, Pricing Department at JFDA.
16:10-16:30	Questions and Answers Closing by the Moderator

Day Two
Session Three: Case Studies Pros and Cons

Chaired By: Eng. Lina Owis - Deputy General Director- The Jordanian Pharmaceutical Manufacturing Company
Moderated By: Dr. Ikhlas Al Hadidi - Director of Drug Directorate at JFDA
Co-Moderated: Mr. Mohamed Odeh Head of Analysis and Programming Department at JFDA

09:00-09:30	Turkish Implementation-Vice President of the Turkish Medicines and Medical Devices Agency Dr Hakki GÜRSÖZ Track and Trace System Implementation in Turkey- Mr. Taha Yayci, Consultant at Turkish Medicines and Medical Devices Agency.
09:30-09:40	Track and Trace System future aspects in connecting with patient electronic information for establishing electronic pharmacovigilance data base- Mr. Taha Yayci.
09:40-09:50	Current Status of Turkish Pharmaceutical Track & Trace System –Mr. Okan KÖYLÜ, Project Manager of Turkish Pharmaceutical Track & Trace System, Tiga Information Technologies
09:50-10:20	Need and Essentials for Implementation of Track and Trace System – Mr. Harpal Singh, Director Business Development, ACG Inspection Systems
10:20-10:35	Mettler Toledo Representative
10:40-11:15	Questions and Answers Closing by the Moderator
11:15-11:30	Coffee Break
11:30-13:30	Road Mapping and Futuristic Output-Session 1
13:30-14:30	Lunch Break
14:30-16:15	Road Mapping and Futuristic Output-Session 2
16:15 -16:30	Coffee Break
16:30 – 17:00	Closing and Outcomes