



**Turkish Medicines and Medical Devices
Agency-Regulatory and Supervisory Authority:
2nd Information Meeting for Medicines and
Medical Devices Authorities**

**May 07-10, 2018
Ankara / TURKEY**

About Programme

TITCK is organizing this meeting to share experience and knowledge with participating authorities on its organizational structure and practices.

In these four days meeting, modules in fields of human medicines, medical devices, cosmetic products, and pharmacoconomics will be presented by Agency staff expert in his/her field. Participants will also have opportunities of networking and sharing information. In addition, the participating countries will be able to make presentations - not exceeding 15 minutes - on their regulatory policies and practices in a voluntary basis.

Attendance is limited to two representatives for each country. Participation at the meeting is free of charge. Accommodation expenses will be covered by TITCK, apart from that the participants are responsible for other expenses (travel, visa etc.).

Meeting language is English.

About TITCK

TITCK is an affiliated agency of the Ministry of Health. It serves as a supervisory, regulatory and leading authority related to human medicines, medical devices, cosmetic products, traditional herbal medicinal products, advanced therapy products, and medicinal nutrition products.

Currently, over 1000 employees from different professions are working in the Agency. By number, pharmacists, practitioners, engineers, biologists, and chemists are the majority. About 30% of staff have masters or doctorate degree.

How to register?

✉ projeuidb@titck.gov.tr

Places are limited therefore early expression of interest is recommended. Registration form should be sent by February 28, 2018.

Please contact us for your inquiries.

May 7, 2018

09:00 - 09:30 **Registration**

Welcome Speech
Dr. Hakkı GÜRSÖZ
President of TITCK

1. Organizational Structure / 10:00 - 10:45

Moderator: Assoc. Prof. İ. Mert VURAL
Vice President of TITCK

10:00 - 10:45 TITCK as a Regulatory and Supervisory Authority:
Organizational Structure and Practices
Speaker: Eda CİNDÖĞLU, Pharm. M.Sc.
Head of Department

10:45 - 11:00 **Coffee Break**

11:00 - 12:30 Presentation of Participating Countries

12:30 - 13:30 **Lunch**

2. Information Management / 13:30 - 15:00

Moderator: Eray KAPLAN
Vice President of TITCK

13:30 - 15:00 Electronic applications
Restricted Prescription System
Speaker: Ömer Hakan ŞİMŞEK, Pharm. M.Sc.
Head of Department
Pharmaceutical Track and Trace System (İTS)
Speaker: Hasan COŞKUN, Pharm.
Electronic Process Management (ESY)
Speaker: Ahu UZUN, Electrical & Electronics Engineer

15:00 - 15:15 **Coffee Break**

3. Cosmetics / 15:15 - 18:00

Moderator: Recep USLU
Vice President of TITCK

15:15-16:00 Cosmetic Products and Services
Speaker: Yücel DENER
Head of Department

16:00-16:45 Cosmetic Products Inspection
Speaker: Sibel GÜRER, Pharm. M.Sc.
Head of Department

16:45-17:30 Products with Health Declaration and Their Inspections
Speaker from TITCK

17:30-18:00 Analysis and Control Laboratories – Cosmetics
Speaker from TITCK

4. Medicines / 09.30 - 17.00

*Moderator: Dr. Ali ALKAN
Vice President of TITCK*

09:30 - 10:00 Clinical Trials
*Speaker: Nihan BURUL BOZKURT, Pharm. PhD.
Head of Department*

10:00 - 10:45 Marketing Authorization of Medicinal Products for Human Use
*Speaker: Handan ÇELİKEL, Pharm. M.Sc.
Head of Department*

10:45 - 11:20 Marketing Authorization Applications - DEMO
Speaker from TC Health

11:20 - 11:40 Coffee Break

11:40 - 12:30 Analysis and Control Laboratories-Pharmaceuticals
*Speaker: Assoc. Prof. Evren ALĞIN YAPAR
Head of Department*

12:30 - 14:00 Lunch

14:00 - 14:45 Pharmacovigilance and Controlled Substances
*Speaker: Demet AYDINKARAHALİLOĞLU, Pharm. PhD.
Head of Department*

14:45 - 15:15 Herbal and Supportive Products
*Speaker: Aslı CAN AĞCA, Pharm. PhD.
Head of Department*

15:15 - 15:35 Coffee Break

15:35 - 17:00 GXP Inspections
GMP and GCP
GDP and GVP
Handling Counterfeit/Falsified Medicines
*Speaker: Sevil AZAK SUNGUR, Pharm. M.Sc.
Head of Department*

May 9, 2018

5. Pharmacoeconomy / 09.30 - 12.30

*Moderator: Assoc.Prof. İ. Mert VURAL
Vice President of TITCK*

09:30 - 10:15 Turkish Pharmaceuticals Sector and Reimbursement System
Speaker: Dr. Banu BAYAR

Head of Department

10:15 - 11:00 Pharmaceutical Pricing System
Speaker from TITCK

11:00 - 11:20 Coffee Break

11:20 - 12:30 Turkish Pharmaceuticals Sector Umbrella Organizations

12:30 - 14:00 Lunch

6. Pharmaceuticals Analysis and Medical Devices

Laboratory Visit / 14:00 - 17:30

May 10, 2018

7. Medical Devices / 09:30 - 12:30

Moderator: Recep USLU

Vice President of TITCK

09:30 - 10:00 Medical Devices Notified Body and Clinical Trials

Speaker: Asım HOCAOĞLU

Head of Department

10:00 - 10:30 Medical Devices Registration and Coordination

Speaker: Dr. Yalçın SOYSAL

Head of Department

10:30 - 10:50 Coffee Break

10:50 - 11:20 Medical Devices Sectoral Services

Speaker: Dr. Mehmet BAŞ

Head of Department

11:20 - 12:00 Medical Devices Inspection

Speaker: Cengiz YİĞİT

Head of Department

12:00 - 12:30 Analysis and Control Laboratories - Medical Devices

Speaker from TITCK

12:30 - 13:00 Closing Ceremony

13:00 - 14:30 Lunch