

**Turkish Medicines and Medical Devices Agency-Regulatory
and Supervisory Authority:**

**Information Meeting for Medicines and Medical Devices
Authorities**

**06-09 November 2017
Ankara, TURKEY**

About Programme

We, as Turkish Medicines and Medical Devices Agency (TITCK), are organizing this meeting for countries requesting information particularly about our organizational structure and implementations.

In the meeting, modules we prepared in fields of medicine, medical device, cosmetics and pharmacoconomics will be presented by Agency personnel competent in his/her field.

In these four days participants will be able to come together with TITCK staff and share information about issues related to functioning of the Agency. In addition, the participating countries will be able to make presentations, not exceeding 15 minutes, on medicines, cosmetics and medical devices policies and regulations in their own countries, if they wish.

Registration to meeting is free of charge and at most two participants from each country are allowed. Accommodation and travel expenses will be covered by participants themselves.

Meeting language is English.

About TITCK

Turkish Medicines and Medical Devices Agency is the sole national authority responsible from developing and implementing regulatory, supervisory, and steering policies for medicines, medical devices and cosmetics.

In the agency mainly pharmacists, doctors, chemists and biologists and 1000 employees from different occupations are working and 30% of workers have masters and doctorate degree.

Our Agency, which has a vision to be pioneer and reference in its working fields and in geography it lies, aims to share experience and gains obtained through this training meeting with authorized agencies of participating countries.

How to register?

You can have detailed information about the meeting in website:

<http://www.titck.gov.tr/2017TITCK>

Registration form available in the link above should be sent to projeuidb@titck.gov.tr

For your inquiries, please contact us at projeuidb@titck.gov.tr

Latest Registration Date: 20 October 2017

08:30 – 09:00 Registration

09:00 – 09:30 Opening Ceremony

Dr. Hakkı GÜRSÖZ

President of Turkish Medicines and Medical Devices Agency

09:30–10:15 **General Information on Turkey**

10:15-10:30 Coffee Break

1. Organizational Structure / 10:30 – 11:15

Moderator: *Assoc. Prof. İ. Mert VURAL*

Vice President of TITCK

10:30-11:15 TITCK as a Regulatory and Supervisory Authority: Organizational Structure and Practices, Organizational Structure, Turkish Pharmaceuticals Market, General Legislation

Speaker: Eda CİNDÖĞLU, Pharm. M.Sc.

Head of Department

11:15-12:30 Presentation of Participating Countries

12:30–14:00 Lunch

14:00-16:30 Presentation of Participating Countries

16.30–16:50 Coffee Break

2. Information Management / 16 :50-18:00

Moderator: *Eray KAPLAN*

Vice President of TITCK

16:50-18:00 Electronic applications

Pharmaceutical Track and Trace System (İTS)

Speaker from TITCK

Electronic Process Management (ESY)

Speaker from TITCK

Restricted Prescription System

Speaker from TITCK

3. Processes on Pharmaceuticals / 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
Speaker: Hacer COŞKUN ÇETİNTAŞ, 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: Yücel DENER
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: Sibel GÜRER, Pharm. M.Sc.
Head of Department

PARALLEL SESSION

4. Processes on 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

12:30-14:00 Lunch

5. Processes on Cosmetics / 14.00-17.00

Moderator: *Recep USLU*
Vice President of TITCK

14:00-14:45 Cosmetic Products and Services

Speaker: Assoc. Prof. Evren ALĞIN YAPAR
Head of Department

14:45-15:30 Cosmetic Products Inspection

Speaker: Sevil AZAK SUNGUR, Pharm. M.Sc.
Head of Department

15:30 -15:50 Coffee break

15:50-16:35 Products with Health Declaration and Their Inspections

Speaker from TITCK

16:35-17:00 Analysis and Control Laboratories – Cosmetics

Speaker from TITCK

6. Pharmacoeconomy / 09.30 – 12.30

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

09:30-10:15 Pricing System

Speaker: Dr. Banu BAYAR
Head of Department

10:15-11:00 Turkish Pharmaceuticals Sector and Reimbursement System

Speaker from TITCK

11:00-12:30 Turkish Pharmaceuticals Sector Umbrella Organizations

Speaker from IEIS

12:30-14:00 Lunch

7. Pharmaceuticals Analysis and Medical Devices

Laboratories Visit / 14:00 -18:00

PARALLEL SESSIONS

Workshop on Pharmaceuticals /

09:30–12:30

*Moderator: Hacer COŞKUN ÇETİNTAŞ, Pharm.M.Sc.
Head of Department*

Workshop on Pharmacoeconomy /

09:30–12:30

*Moderator: Dr. Banu BAYAR
Head of Department*

12:30-13:00 Closing Ceremony

13:00-14:30 Lunch