



**TURKISH MEDICINES AND MEDICAL DEVICES  
AGENCY-REGULATORY AND SUPERVISORY  
AUTHORITY:**

**3<sup>RD</sup> INFORMATION MEETING FOR MEDICINES  
AND MEDICAL DEVICES AUTHORITIES**

**June 11-13, 2019  
Ankara / TURKEY**

## About Programme

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

In this three-day meeting, modules on human medicines, medical devices, 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](mailto:projeuidb@titck.gov.tr)

Places are limited therefore early expression of interest is recommended. Registration form should be sent by March 01, 2019.

Please contact us for your inquiries.

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**June 11, 2019**

**09:00 - 09:30**    *Registration and Welcome Coffee*

**09:30 - 10:00**    *Official Welcome and Opening Remarks*

**INTRODUCTION TO THE TITCK REGULATORY FRAMEWORK**

**10:00 - 10:15**    TITCK as a Regulatory and Supervisory Authority:  
Organizational Structure and Practices

**10:15 - 10:30**    TITCK and International Cooperations

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	<b>MODULE I*. MEDICINES [PARALLEL SESSION]</b>	<b>MODULE II*. MEDICAL DEVICES [PARALLEL SESSION]</b>
<b>10:30 - 11:00</b>	Clinical Trials	Medical Devices Notified Body and Clinical Trials
<b>11:00 - 11:30</b>	Marketing Authorization of Medicinal Products for Human Use <ul style="list-style-type: none"><li>- Generics</li><li>- Biosimilars</li></ul>	Medical Devices Registration and Coordination
<b>11:30 - 11:45</b>	<i>Coffee Break</i>	<i>Coffee Break</i>
<b>11:45 - 12:15</b>	Marketing Authorization of Herbal and Supportive Products	Medical Devices Sectoral Services
<b>12:15 - 12:45</b>	Pharmacovigilance	Medical Devices Inspection
<b>12:45 - 14:00</b>	<i>Lunch</i>	<i>Lunch</i>
<b>14:00 - 14:30</b>	Analysis and Controls	Analysis and Controls
<b>14:30 - 15:30</b>	Good Practice and Inspections GMP and GCP GDP and GVP	

*\*Module I and Module II will be carried out as parallel sessions.*

**15:30 - 15:45**    *Coffee Break*

**15:45 - 17:00**    Presentations of Participating Countries

**17:00 - 20:00**    *Group Photo and Networking Event*

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**June 12, 2019**

**MODULE III. INFORMATION MANAGEMENT**

<b>10:00 - 10:30</b>	E-Prescription System
<b>10:30 - 11:00</b>	Pharmaceutical Track and Trace System (İTS) Republic of Turkey Medical Devices and Drugs Database (TİTUBB) Product Tracking System (ÜTS)
<b>11:00 - 11:30</b>	Support to Innovation Health Industries Transformation and Research Platform (SEDAP)
<b>11:30 - 12:30</b>	Presentations of Participating Countries
<b>12:30 - 14:00</b>	<i>Lunch</i>
<b>14:00 - 17:30</b>	<b>PHARMACEUTICALS ANALYSIS AND MEDICAL DEVICES LABORATORY VISIT</b>

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**June 13, 2019**

**MODULE IV. PHARMACOECONOMY**

<b>10:00 - 10:30</b>	Framework of Pharmaceutical Pricing and Reimbursement System
<b>10:30 - 11:00</b>	Access to Medicines
<b>11:00- 11:30</b>	Turkish Pharmaceutical Sector : An Overview [Speaker from Turkish Pharmaceuticals Sector Umbrella Organizations]
<b>11:30 - 12:00</b>	<i>Closing Ceremony</i>
<b>12:00 - 13:30</b>	<i>Lunch</i>
<b>13:30 - 17:00</b>	<b>SITE VISIT</b>

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