Turkey – Pharmacovigilance
COVID-19 Treatment and Vaccines

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History of Pharmacovigilance

- Turkey became the 27th member of WHO Programme for International Drug Monitoring in 1987.
- Publication of the first regulation in 2005.
  - Clearly defines that ADR reporting is the responsibility of all healthcare professionals.
- More functional and active structure with TUFAM (Turkish Pharmacovigilance Center) since 2005
  - Certification training for pharmacovigilance contact person (not active currently)
  - All hospitals with >50 inpatient beds and pharmaceutical companies have to assign a Pharmacovigilance Contact Person

https://www.titck.gov.tr/faaliyetalanlari/ilac/18

How TÜFAM Works?

- Who reports: All healthcare professionals, pharmaceutical companies
- Online form, fax, email ….
- Following causality assesment report is sent to Uppsala Monitoring Center

- What to report?
  - Serious adverse drug reactions
  - Pharmaceuticals marked with ▼
  - Reaction that is not included in the SpC
  - Not sure whether to report or not

ADR Reporting Numbers

- ADR reporting rate in Turkey is **2 reports per one million inhabitants per year**
- Below the average of ADR reporting of similar-income countries

Aagaard L, Strandell J, Melskens L, et al. Global patterns of adverse drug reactions over a decade: analyses of spontaneous reports to VigiBaseTM. Drug Saf. 2012;35:1171–1182.
Ozcan G, Aykac E, Kasap Y, et al. Adverse drug reaction reporting pattern in Turkey: analysis of the national database in the context of the first pharmacovigilance legislation. Drugs Real World Outcomes. 2016;3:33–43.

Reasons of Low Reporting Numbers

- Lack of knowledge (not being sure if it is an AE, not knowing how and where to report etc.)
- HCPs with better knowledge of pharmacovigilance and ADR reporting practices reported more.
- HCPs did not know the essentials of pharmacovigilance and ADR reporting system in Turkey, and they were not aware of their role in this system.

Güner MD, Ekmekci PE. Healthcare professionals' pharmacovigilance knowledge and adverse drug reaction reporting behavior and factors determining the reporting rates. *J Drug Assess*. 2019;8(1):13-20. doi:10.1080/21556660.2019.1566137

Pharmacovigilance in Education

- Curricula of medical schools were evaluated
  - 41 (65.1%) provide pharmacovigilance course for 0.5–2 hours, during the 3rd year.
  - Not sufficient for the students to acquire satisfactory knowledge on ADR and to influence their attitudes as physicians in the future.
- Realization of the centrality of pharmacovigilance to public health and its ethical importance is the first step to improve the **quality and quantity of pharmacovigilance** activities.
- Adding a **comprehensive pharmacovigilance curriculum** both to graduate and professional continuing education of all healthcare professionals.

Güner MD, Ekmekci PE Is Medical Schools, Curricula Content of Pharmacovigilance and Rational Pharmacotherapy- Related Subjects Sufficient for Future Physicians? Turkish Clinics J Med Ethics, 2019; 27(3)186-95.
Guner M D. Ekmekci P E. Incentives to Increase Pharmacovigilance Practices from an Educational and Ethical Point of View. J of Pharmacol & Clin Res. 2017; 3(5): 555624. DOI: 10.19080/JPCR.2017.03.555624

Vaccine Specific Pharmacovigilance Activities

- None…

- Mentioned in general information
- The importance of adding serial number of the vaccine underlined

COVID-19 Specific Pharmacovigilance Activities

- Unfortunately, none…

COVID -19 Treatment Specific Adverse Reaction Reporting Form

The names of the pharmacuetical products put currently used for the treatment of COVID- 19

T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

COVID-19 Tedavisine Yönelik Advers Reaksiyon Bildirim Formu

Bu raporu e-posta ile tufam@titck.gov.tr adresine veya 0312 218 35 99 no'lu faksa gönderiniz.

TÜRKİYE FARMAKOVİJİLANS MERKEZİ 2005

Hasta Adı ve Soyadının Baş Harfleri	Doğum Tarihi / Yaşı	Cinsiyeti
		☐ Erkek ☐ Kadın

Şüpheli İlacın Adı *(İşaretleyiniz)*	Doz	İlaca Başlama Tarihi *(gün/ay/yıl)*	İlacın Bitiş Tarihi *(gün/ay/yıl)*
☐ Oseltamivir			
☐ Hidroksiklorokin			
☐ Azitromisin			
☐ Favipravir			
☐ Lopinavir / Ritonavir			
☐ Tosilizumab			

Eş Zamanlı Kullanılan Diğer İlaçlar	Veriliş Yolu	Doz	İlaca Başlama Tarihi *(gün/ay/yıl)*	İlacın Bitiş Tarihi *(gün/ay/yıl)*

Turkey COVID Vaccination

- Only one product : Sinovac.
- 2.5% of the population received 2 doses
  - Healthcare professionals
  - Age > 65
  - Limited explanation about vaccine during vaccination; postvaccine observation for 15-30 mins.
  - Questionary send by short message, mobile application, evaluating only 24 hours after vaccination.
  - No printed document providing information on efficacy and safety of the vaccine.

- Clinical trials of Sinovac and Pfizer Biontech are being conducted in Turkey in several centers.