What Are the Recent Decisions and Announcements Made by Government Health Institutions?

The outbreak of coronavirus (COVID-19), which has been declared as pandemic by the World Health Organization, has led to widespread measures being taken around the world. The coronavirus, first seen in Wuhan, China, in December 2019, has been detected in almost 28 Million cases in 215 countries as of today, creating a global crisis with a death toll of over 900.000.

The number of cases and deaths started to rise rapidly after the announcement of the first case detection in Turkey with a press release made by the Minister of Health on 11 March 2020. Currently, approximately 300,000 cases have been detected in Turkey. Turkey has halted flights to countries where the disease has been seen since the virus began to appear abroad and has closed land border crossings.

As of mid-March, due to the spread of the virus in Turkey, stricter measures were taken, such as limiting the street access for people over 65 and people with chronic disease, turning student dormitories into quarantine zones, closing all public resting and entertainment places and providing takeaway services only.

As a result of the measures taken, the normalization process was initiated as of June with the decrease in the number of cases, but unfortunately, the number of cases began to rise again rapidly as a result of both the bending of the measures and the more imprudent behavior of the public in the summer. The Ministry of Health, that predicts that the second wave will begin in October, plans to re-imply the restrictions, taking into account the current situation.

The Ministry of Health ("MoH"), the Turkish Medicines and Medical Devices Agency ("TMMDA") and the Social Security Institution ("SSI") have also taken the following measures so far in order to combat coronavirus:

MoH:

- As of 20.03.2020, visitor entrance to the MoH building is not

- In order to fight with Covid-19, The MoH launched the Corona information website where citizens can question the risk of disease online. The application which was previously offered via 184 line is now will also be available on koronaonlem.saglik.gov.tr.
- Health Minister Fahrettin Koca, stated that "Hayat Eve Sığar" is a facilitator, free and easily downloadable mobile application, informing about possible risks and guiding against risk, and reported that as of today, its users has exceeded 10 million.Turkish Council Scientific Health Board Vaccine Workshop has been started in Izmir with the participation of Deputy Minister of Health Prof. Dr. Emine Alp Oak, Secretary General of the council Baghdad Amrayev, Ambassador of Kazakhstan to Ankara Abzal Saparbekuli, representatives of member countries and scientists.

TMDDA:

- A regulation regarding the purchase of respiratory insulator masks by prescription and in return of payment from the pharmacies, has been made. Patients with a health report on the use of a filtered mask may obtain their masks from pharmacies by presenting their reports.
- Considering measures that have been taken in order to prevent the outbreak of COVID-19, it has been announced that visits that will be performed in accordance with the product promotion activities of pharmaceutical companies' product promotion representatives to physicians, dentists and pharmacists in all types of healthcare institutions/authorities, including pharmacies are suspended until a second notice. In the meantime, the promotional activities of product promotion representatives can be conducted electronically (by e-mail, video conferencing).
- However, due to the "normalization process" in Turkey that has begun due to the decreasing number of new COVID-19 cases, the Medicines and Medical Devices Agency published an announcement on 5 June 2020 to amend the precautions for promotion representatives that had been put in place. Within this scope, from 8 June 2020, product promotion representatives have been able to engage in product promotion activities in person in primary healthcare institutions that

provide diagnosis and treatment services. In terms of these activities; visiting days and hours should be determined by the authorities of these centers, during the visits, product promotion representatives should use masks and comply with social distance and hygiene rules, the promotion materials and printed promotional materials should not be distributed during the visits, the visits should be completed as soon as possible, the information regarding the physician, dentist and pharmacist visited by the product promotion representative must be recorded. from 15 June 2020, product promotion representatives have been in theory able to visit physicians, dentists and pharmacists working in other hospitals except the hospitals treating patients diagnosed with COVID-19. In addition to the listed rules above, in these visits; the visits shall not be made in inpatient services, if a decision to restrict the visit has been taken by the hospital itself, this decision should be complied.

- Guidelines for Scientific Meetings and Educational Activities to be Held Within the Scope of the Regulation on Medical Device Sales, Advertising and Promotion has been amended by adding provisions on web-based meetings.
- Under the measures taken by the MoH due to COVID-19, temporary measures have been taken regarding the red, green and regular prescription medicines which are subject to monitoring as well as purple and orange prescription medicines in order to ease patients' access to medicines that they are use chronically.
- Considering that the COVID-19 pandemic may have an effect on clinical research conducted in Turkey; a document has been published regarding the measures to be taken regarding temporary interruption or early termination of clinical research if necessary, identification of authorized body that shall apply the emergency security measures to be taken after notifying the Ethics Board of these situations, whether violations of the protocol under COVID-19 should be reported to the ethics board, actions necessary to keep the product stock more than usual against possible custom barriers and how to conduct Ethics Board’s meetings.

- It has been announced that the period of approval for non-indication or foreign medicines use given by TMMDA on a patient basis has been extended to 30.06.2020, noting that the decision on the use of the related medicines in treatment being at the initiative of Physicians.
- It has been announced that TMMDA may grant temporary marketing authorization for 3 months to the companies applying in order to meet the need for sanitizer in direct contact with the human body (excluding its use in health institutions and organizations). The marketing authorizations of the products that do not submit the results of the effectiveness test, accelerated stability test and irritation test to the authority within one month and do not meet all of the specified requirements will be cancelled.
- Until a new announcement is publiched, registration applications requiring physical documents of the types of EC certificate and declaration of conformity, where Apostille or embassy/consular approval procedures cannot be completed due to the COVID-19 outbreak, will also be accepted without apostile approval or embassy/consular approval. The documents in question will be given a 60-day extension without requiring an application for a period extension by undertaking pursuant to announcement 2020/KK-1, and another 60-day extension may be granted if an application for a period extension is made. In addition, registration of documents that do not require physical documents in the types of Quality Management System (ISO 13485) certificate and authorized distributorship certificate, that do not have Apostille approval or embassy/consular approval due to the covid-19 outbreak, will also be accepted until a new announcement on the matter is
- Unit dose monitoring for 6 drugs used in hospitals has been started through Medicine Tracking System in the process of combating the pandemic.
- Considering that the readability tests are conducted face-to-face and the risk of covid-19 contamination that will occur during the carrying out of these tests, readability tests that must be submitted for the completion of MA procedures for medicinal products for human use for

which a MA application will be made and/or the application process is ongoing, may be submitted before the sales permission application until further notice in order to prevent delays in MA

- Considering that the applications to the Pharmaceutical Product Certification Unit have been made physically, examination will be carried on the certificates submitted electronically via ESY and only the approval process will be carried out physically in order to minimize the contact of the
- Web-based meetings that all participants can access from their own computers, organized/supported by MA/permit holders, are not considered within the scope of meetings postponed due to COVID-19. For all meetings to be organized/supported by MA/permit holders on a web basis, applications must be made in accordance with the provisions of the Regulation on The Promotion Activities of Medicinal Products For Human Use.
- Due to COVID-19, some measures related to medicine use of chronic patients have been taken by the Agency with the announcement dated 16.03.2020. However, due to the risks of medicines being monitored (medicines that used with the Medicine Safety Monitoring Form and that distributed on a limited basis), a second announcement was issued regarding the medicines in question and the supply of these medicines.
- Due to the Covid-19 outbreak, green and red prescriptions belongs to March 2020 will be delivered to the Provincial Health Directorates along with prescriptions for April 2020. In addition, the prescriptions registered within the scope of "non-prescription medicine supply in chronic diseases " are counted within the scope of electronic prescription in the system.
- An official letter was issued regarding registry of medicine requests of inpatients and prescriptions of outpatients who are receiving COVID-19 treatment through My e- Pulse Prescription system (recetem.enabiz.gov.tr) by physicians working in health facilities.
- In order to prevent the supply problem of imported special medicinal foods (medical foods and enteral nutrition products), the validity periods

of control certificates for these products which will expire within April May and June has been extended by 3 months from the date of expiry.

- As is known, due to the outbreak of Covid-19, pre-approval processes were initiated in the export and import of some products. A guide has been prepared by the Agency in order to perform the pre-approval application processes correctly.
- In order to effectively combat Coronavirus (2019-nCoV), which is defined as a pandemic by the World Health Organization (WHO), to maximize the availability of masks, gloves, gowns and other medical supplies, Turkish Standards Institute (TSE) made number of European standards and ISO/IEC standards for medical devices and personal protective equipment available free of charge to interested parties on the web to support efforts to combat the pandemic, in cooperation with European standardization organizations CEN and CENELEC and ISO and IEC .
- Requirements for initiating clinical trials in the COVID-19 vaccine were published by TMMDA, underlining that studies must be conducted in accordance with international guidelines and applicable legislation in order for candidate vaccines to move on with the implementation on human stage (clinical trial phase). In this context, it was announced that quality file preparation, toxicity, farmokodynamics, pharmacokinetics studies and local tolerance and additional studies should be completed.

SSI:

- As the possibility of catching infectious diseases with more severe symptoms is higher in terms of people whose immunity is negatively affected depending on chronic disease, regulations have been made on the supply of medicines and medical supplies in order to prevent disruption of these people' access to health care and decrease the possibility of infection as reducing the application of these individuals to health care providers as much as possible is important for fighting against Coronavirus disease (COVID-19).
- It has been announced that the application of electronic retrieval of medical market, optician institutions, hearing centers and pharmacies'

invoice annex documents will be made mandatory in prescriptions and invoices issued as of 01.03.2020.