Current Measures from Healthcare Regulators Regarding COVID-19 in Turkey

Authors: Gönenç Gürkaynak, Esq., Ceren Yıldız and Nazlı Gürün, ELIG Attorneys-at-Law

As a result of the pandemic of Coronavirus (COVID-19), taking into consideration the rate of contagion and cases in countries all around the world, governments are taking new measures almost every day in order to respond to the crisis as rapidly as possible. Similarly, since the first detected case in Turkey on March 11, 2020, Turkish government has been doing more tests, taking the necessary precautions and measures to prevent further spread of coronavirus and to protect its citizens.

To date, several governmental institutions have taken various measures in order to tackle the spread and control of coronavirus. The Ministry of Health was no exception, with multiple measures from a regulatory perspective. Below is the summary of the regulatory arrangements made by the Presidency and the Ministry of Health and Turkish Medicine and Medical Devices Agency with regards to COVID-19:

- Turkish Medicine and Medical Devices Agency ("***Agency***") issued amendments to the procedures of clinical trials and measures to be taken during clinical trials in relation to COVID-19. These measures include, (i) suspension and early termination of clinical trials if and when necessary, (ii) emergency safety measures to ensure volunteer protection without the ethics committee's approval or Agency's authorization, (iii) changes (postponing or rescheduling) in monitoring activities during clinical trials, and (vi) stocks of investigational products and clinical trial supplies in larger quantities in case of scenarios such as quarantine and import restrictions.

- The Ministry of Health issued a new circular consisting of 12 articles of measures for healthcare staff and hospitals. The circular requires both public and private hospitals to follow the necessary procedures to accept and treat patients until their COVID-19 diagnosis becomes certain. All hospitals that have at least two specialists of inflectional diseases, clinical microbiology, thoracic diseases or internal medicines, and level 3 intensive care beds are now considered "pandemic hospitals".

- The Agency announced that activities of product promotion representatives that are done through visiting health institutions, doctors, dentists and pharmacies are suspended until further notice. According to the announcement, representatives may carry out their promotional activities through electronical means (e-mails, video conferences).

- Exports of (i) protective masks filtered against gas, dust and radioactive dust, protective bodysuits, liquid tight aprons used for protection against chemicals, protective glasses (for personal protective gear) and (ii) medical and surgical masks and medical

sterilized or non-sterilized gloves (put into market through Medical Device Regulation), are now subject to pre-authorization of the Agency.

- Exports of (i) ethyl alcohol, (ii) cologne, (iii) disinfectant, (iv) hydrogen peroxide and (v) melt blown fabric are now subject to pre-authorization of the Agency.

- The Agency announced the guidance measures to be taken by pharmacies with regard to their personnel, pharmacy environment and patients in relation to COVID-19. The Agency also ordered through its related letter sent to governorships dated March 26, 2020 that, (i) pharmacies should frequently check and follow the Ministry of Health's regularly updated "COVID-19 Guide", (ii) the relevant governorship should be immediately notified in the event a pharmacy owner or personnel gets infected, (iii) the pharmacy should be disinfected and a responsible manager should be assigned, if necessary, in the event the pharmacy owner or its responsible manager gets infected, and (iv) a supervisor or responsible manager should be assigned if requested by pharmacy owners who are 65 years of age or older, or who have a chronic disease.

- The Agency announced that as of March 26, unit dosage of pharmaceuticals used in treatment of COVID-19 will be tracked through Pharmaceuticals Track & Trace System. The list of pharmaceuticals used in treatment is provided together with the announcement.

- The Agency issued further guidance on obtaining chronic illness medications that are tracked due to their risks, providing guidance for each medicine type.

- The Agency made an announcement requiring companies to fill out the table attached to the announcement, in order for the companies to provide information on the status, results and updates of their research and development studies on COVID-19.

- The Agency announced that all medical doctors are required to prescribe medication to COVID-19 patients through the electronic prescription system ("e-Nabız Reçetem") in order to enable the Ministry of Health and the Agency to generate an integrated data pool for COVID-19 patient treatment protocols.

Article contact: Gönenç Gürkaynak, Esq. Email: gonenc.gurkaynak@elig.com

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