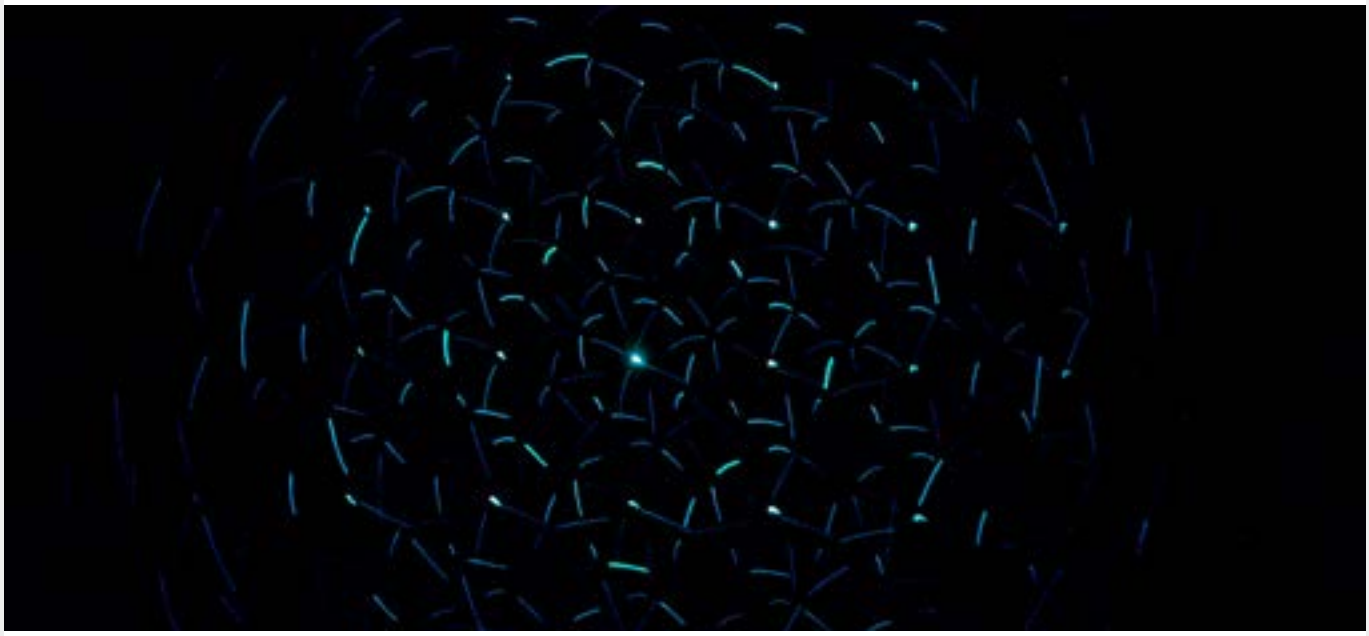
Actions Taken by the Ministry of Health and the Turkish Pharmaceutical and Medical Device Institution in relation to COVID-19

March 2020



Dear Colleagues, Clients and Friends,

Coronavirus ("**COVID-19**"), which has been declared as "pandemic" by the World Health Organisation first emerged in Wuhan, China on 31 December 2019, and rapidly became a major topic by spreading across the globe. The first case in Turkey was seen on 11 March 2020, following which the Ministry of Health (the "**Ministry**") and the Turkish Pharmaceutical and Medical Device Institution (the "**Institution**") have taken various actions and steps to prevent the spread of the virus, protect the public health and ensure the market order. Some of the significant actions taken to date are as follows:

- ***Restrictions on promotional activities.*** According to the Institution's announcement dated 19 March 2020, visits paid by product promotion representatives to all health institutions and organizations including pharmacies, doctors, dentists and pharmacists have been suspended until a further announcement. However, within this period, product promotion representatives can carry out promotional activities electronically (via e-mail or video conference).

- ***Export license requirement for medicinal products used against COVID-19.*** As per the "Communiqué Amending the Communiqué Regarding Products Subject to Export Prohibition

and Pre-Authorization (Export:96/31)" published in the Official Gazette numbered 31058 dated 4 March 2020, export of protective masks (masks with gas, dust and radioactive dust filter), jump suits (protective work-clothes), liquid-proof aprons (protective aprons used against chemicals), goggles (protective goggles) supplied to the market within the scope of the Regulation on Personal Protective Equipment; as well as medical and surgery masks, and medical sterilized/ non-sterilized gloves supplied to the market within the scope of the Regulation on Medical Devices became subject to the pre-authorization of the Institution. Additionally, under the Amending Communiqué published in the Official Gazette numbered 31080 dated 26 March 2020, ventilators, oxygen concentrators, ventilation consumables, patient circuits, cannulas, intubation tubes and intensive care monitors have also been made subject to export pre-authorization. Information and documents required for obtaining export authorization from the Institution of the relevant products are indicated in the announcements of the Institution dated 5 March 2020 and 6 March 2020. On the other hand, no authorization is required for products, export declarations of which have been registered with the relevant Ministry before 4 March 2020.

- ***Temporary license to produce disinfectants.*** Pursuant to the Circular numbered 2020/1 dated 19 March 2020, which regulates the procedures and principles regarding processes and operations related to biocidal products that are in direct contact with human body, temporary license may be issued for a period of three months whereby pharmacies can be allowed to produce hand sanitizers using the formula determined by the Institution, for purposes of meeting the need for disinfectants due to the state of emergency caused by the COVID-19 outbreak.

- ***Measures regarding clinical researches.*** Measures to be applied to clinical researches in connection with COVID-19 have been determined with the announcement dated 20 March 2020. Firstly, sponsors have been reminded of the need to regularly conduct risk assessments by observing priorities and urgencies due to COVID-19 and to carry out and update research organizations on this basis. In terms of such risk assessments; protection of the safety of volunteers, reducing the workload of research centres and ensuring compliance with social isolation rules are essential. Pursuant to the regulation; (i) clinical researches may be temporarily suspended or terminated early if deemed necessary considering the nature of the research, (ii) in cases giving rise to safety concerns, emergency safety measures can be implemented without being subject to the approval of ethics committee and the Institution, (iii) in case of deviation/breach of the protocol due to COVID-19 measures, such deviation or breach will not be required to be notified to the ethics committee and the Institution, (iv) postponing or re-scheduling of monitoring of clinical researches will be initial preference, but in case continuing of such monitoring activity is necessary due to the nature of the research, then timing of the visits will be coordinated with the research centre; (v) if monitoring at the research centre is not possible due to circumstances such as quarantine or isolation, clinical researches may be remotely monitored in accordance with the Law on Protection of Personal Data and confidentiality principles applicable to clinical researches, (vi) products subject to clinical researches may be stocked up more than usual in order to ensure the sufficient amount of stock due to any potential quarantine or customs restrictions, (vii) research meetings will only be held online within this period and (viii) trainings and meetings regarding good clinical practices and clinical researches to be held face to face will not be allowed.

- ***Postponement of scientific organisations.*** Based on the Circular numbered 2020/3 published in the Official Gazette numbered 31074 dated 20 March 2020, all national and international scientific, cultural, artistic and similar meetings or organizations to be held at open or closed spaces have been postponed until the end of April 2020.

Please do not hesitate to contact us for any further information on this briefing.

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