A New Threshold Gate in Turkey for Vaccines: Emergency Use Approval

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While many questions including how the license applications will be assessed, whether the vaccination will be paid and/or obligatory, remained unanswered; the Regulation Amending the Regulation on the Licensing of Medicinal Products for Human Use which is published in the Official Gazette dated December 18th 2020 added a new one to these questions.
According to the new regulation that is introduced by this amendment, in cases where the public health is seriously threatened such as the Covid-19 pandemic that we are going through, under "certain" conditions, the vaccines which there is not adequate data about, may become subject to the Emergency Use Approval (EUA). However, it may increase the legal uncertainties concerning the vaccine manufacturers who seek to enter the market as well as enhancing the preexisting common insecurity of the public opinion regarding the vaccines.

What Is the Difference Between the EUA and the "Licensing in Special Cases"?

The Regulation on the Licensing of Medicinal Products for Human Use (Regulation) allows the licensing of the products in some special cases where certain conditions are not fulfilled. It is possible to consider such a license as a "temporary license"[i], although it depends on special reasons, it constitutes a "license". On the other hand, the EUA does not constitute a license, even a temporary one. Briefly, EUA may be defined as an approval for the use of the vaccines that are/may not be licensed yet. The statements of the administration highlight that EUA is not a license, as well. Nevertheless, the difference(s) between the EUA and the license is not as significant as their names. Hence, EUA and the licensing proceedings lead to the same consequence: allowing the vaccine to be presented in the market.

In addition to that, it is seen that the conditions that the Art. 10 of the Regulation seeks for the temporary license are also sought for the EUA, which is added to the Regulation by Art. 10/A. In other words, the administration bears two different mechanisms that operate under the same conditions and which produce the same results.

Then what are the differences between these mechanisms? In the first place, EUA is a tool which's use is limited by vaccines while a license under Art. 10, which is called the temporary license, may subject all medicinal products for human use, including vaccines.

The second difference is the distinction of the EUA application proceedings (application file, mode of assessment, etc.) from the licensing rules, which is probably the main reason for bringing the EUA. Even though the detailed regulation regarding the EUA is left to the guideline that will be prepared by the Turkish Medicines and Medical Devices Agency (Agency), it is possible to foresee more flexible conditions compared to "licensing in special cases". On the other hand, it may be said that the Agency will assess the benefits and risks for each application with respect to the guideline that will be published. However, it still remains uncertain that how and by which means this assessment will be done.

What Inconveniences Will Come Along with the Uncertainty of the Regulation?

Unlike the recentness of the EUA as a concept in our legislation, similar regulations already exist in legislations of European Union (EU) and United States (US). From this perspective, even though it may be thought as the fulfillment of a lack in our legislation, it is undoubtful that this understanding of "making it along" is not very comforting before the public opinion. Thus, while FDA [US authority] and EMA [EU authority] already accept applications for licensing, even though EUA has been included in Turkish legislation, the guideline on the application and assessment proceedings regarding EUA is not published yet.

Leaving the regulations on that subject to a guideline constitutes a matter of discussion by itself. When it is considered from the legal certainty perspective, it is far from being reassuring regarding that it will not be regulated even by regulation but a guideline which is not named under the hierarchy of norms considering that it would be expected that a practice which affects the healthy living right -which is directly based on the constitution- would have been regulated by law, at least in general terms. Indeed, the Regulation does not even draw a general line regarding the conditions of EUA and assessment proceedings. First and foremost, an environment of legal certainty and stability should be established on such a delicate issue regarding both the manufacturers and individuals, which depends on the regulations that provide legal predictability.

How Does It Work in the EU & USA?

In terms of the USA, the correspondent of the EUA may be deemed as the Emergency Use Authorization (EUA). Even the guideline on the practice has not been published yet, it may be said that the American EUA is the most similar regulation to the EUA in Turkish law. In that order, the main criteria of the assessments of EUA in Turkey will be the "known and potential benefits that are heavier than the known and potential risks".

On the other hand, in the European Union, there is the Conditional Marketing Authorization (CMA) which corresponds to the EUA. In addition, in respect of the EU legislation, for all member states, it is possible to regulate an 'emergency use authorization' which will be valid in their jurisdictions and under the conditions that they have determined. Nevertheless, there are significant differences between these, as well, which firstly appears at the point of responsibility.

As it is revealed in annotation ii [ii]of the European Commission dated December 11, 2020, first and foremost "The emergency use authorization is not an authorization given for the vaccine but temporary use of the vaccine". Unlikely, the Conditional Marketing Authorization grants the same rights and duties with a standard authorization (license), therefore, getting the application and its pursuance are stipulated with more aggravated conditions. In this regard, CMA is more similar to the "licensing in special cases" in Turkish legislation which is discussed above. Nevertheless, when member states grant emergency use authorization through their legislations, in cases where this authorization is given upon government's promotion or request, in respect of the EU legislation, manufacturer or marketing authorization holder should be immunized against any kind of administrative and legal responsibility.

US legislation provides a similar case, as well. Within the scope of the Public Readiness and Emergency Preparedness Act (PREP Act), in emergency cases where public health is threatened, after a notice that will be published by the health ministry, it is possible to deem medication/vaccine manufacturers and distributors immunized against all kinds of responsibility except an intentional violation. This immunization notice regarding the vaccines and medications that will be developed against the Covid-19 has been published in March 2020. This immunity, which is in effect since February 4, 2020, will be pertinent until the end of 2024. Moreover, it is not possible for individuals who are injured by any possible side-reaction of the Covid-19 vaccine to claim any compensation against the administration in respect of US legislation.

Considering the timewise pressure on the vaccine manufacturers and the states' support and promotions on the vaccine development studies the idea behind these immunity regulations may be reasonable. Thus, on the one hand, we have the Covid-19 pandemic, and its negative effects and the need for the vaccine; on the other, vaccines that are presented to market through accelerated scientific research which's risks and benefits may not be observed adequately. In such a case, expecting that the manufacturers who had no chance to test the long-term effects of the vaccines to take risk of conceiving compensation claims which may reach to million dollars. But the rightfulness of this reservation may not correspond with its legality. Hence in Turkey, contrary to the examples of EU and US, there is no legal basis that may provide such immunity to manufacturers and distributors or administration.

[i] Hüseyin Melih Çakır/İ. Selin Nacar Öztürk, "Authorization of Covid-19 Vaccines in Turkey", December 2020
[ii] European Commission, Questions and Answers: Conditional Marketing Authorisation of COVID-19 Vaccines in the EU, Brussels, 11 December 2020

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