

Authorization of Covid-19 Vaccines in Turkey: Turkish Market and Licensing Process

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As the coronavirus pandemic has completed its first year, the ongoing vaccination studies in our country and around the world are coming to an end. In this context, whether the vaccine will be compulsory in our country and how the licensing processes will be carried out are issues of concern for vaccine manufacturers.

Although this issue, which directly concerns public health, has been regulated under laws and sub-legislation, these legislations regarding the issue also contain some uncertainties. On the other hand, there is no hesitation on the answer to one aspect of the question: Whether imported or produced domestically, permission of the health administration is mandatory for vaccines. [1]

How Does the Licensing Process Work?

The multipartite structure of health care leads to the variation of licensing rules for medicinal products for human use. In this context, Ministry of Health and Turkish Medicines and Medical Devices Agency ["Agency"] apply different proceedings in terms of licensing medicines and vaccines, conduct of clinical trials and the process of establishing medical product factories. Hence, it is possible to say that no medical product, including vaccines, that are not licensed by the Ministry of Health, can be offered to the market.

In order to license a medicinal product for human use, an application must be made to the Agency. The information and documents that must be submitted for the application are listed in detail in the Regulation. In fact, in order to facilitate the application and to make it uniform with European Union, USA and Japan, the license applications must be submitted in the Common Technical Document ["CTD"] format. Within these countries, license applications are made in this format, so that the applicants do not have to go through trouble of collecting new and different information and documents for each country, and it provides the opportunity to apply to all ICH countries with the same file.

Moreover, in the process of licensing the vaccine, the list of the other countries where a license application has been made for the same product is also requested by the Ministry. In case of the rejection of the license application by one or more of these countries, the rejection and its justification must be notified to the Ministry.

Following the submission of the necessary documents to the Ministry, a pre-assessment is carried out in the first place. The pre-assessment is on controlling if the necessary information and documents are submitted, and as a principle, it should be finalized within 30 days. After the completion of the pre-assessment, an evaluation process is initiated to control whether the licensing conditions are fulfilled.

The criteria and the matters that will be considered during the assessment of the license applications are also regulated in detail in the legislation. The most significant of these is the criterion of being tested in a national laboratory or a laboratory that is approved by the Ministry for this purpose, in order to determine the applicability of the methods used in the control of the product by the manufacturer.

It is imperative for the assessment following the preliminary examination to be completed in 210 days. However, for products that are first in their field for treatment and diagnosis, that are innovative or would greatly reduce the public health expenditure, this time is limited to 180 days. Therefore, it is possible to apply this time limitation of 180 days for coronavirus vaccines. It should also be noted that these time limitations represent the absolute maximum. The administrative authority may finalize the application in a shorter period; in fact, in case of the coronavirus this is a requirement. In addition, in cases like the coronavirus vaccine where it is crucial for public health and also the first in their field, the assessment durations for different applications should be same or similar and the administrative authority should treat every vaccine candidate equally, as the subject is closely connected to individuals' right to access healthcare products and services.

Licensing in Special Cases

In certain cases, the legislation allows the product to be licensed despite its failure to meet certain criteria. This sort of a license can be described as a "temporary license". Taking advantage of this opportunity is only possible when the producer

is carrying out further studies following the issuance of the license and reporting adverse effects related to the medicinal product, along with meeting one of the following criteria: [i] too low therapeutic indications to be proved in detail, [ii] insufficient available scientific data to provide detailed information, or [iii] incompatibility of the collection of such data with accepted ethical principles.

Evidently, issuance of a "temporary license" is bound to the conditions of carrying out further studies and reporting adverse (negative) effects related to the medicinal product, and it is limited to the existence of certain conditions. While the existence of the aforementioned conditions is taken into consideration in the assessment before the "temporary license" is issued; the obligation to carry out further studies and reporting adverse effects are related to the period after the license is granted. However, there is no regulation in the aforementioned legislation regarding how these obligations will be fulfilled in the period following the issuance of the temporary license, and the post-registration process is regulated by the Regulation on the Safety of Medicines. On the other hand, failure to fulfil these requirements can have legal consequences such as suspension and cancellation of the license. In other words, the issuance of the license is not the end of the road; as the vaccine becomes a part of the national healthcare system, it becomes subject to the ongoing supervision and surveillance of the health administration.

It is impossible to foresee the approach the Authority will choose to take regarding the scope of the license [Normal License-Temporary License] that will be granted to the prospective vaccines. The existence of conditions for the issuance of a "temporary license" will be assessed separately in each case. Although there is no concrete data on the interpretation of the conditions in the article specifically for Covid-19 vaccines, considering that the proceedings for the vaccines in question progress much faster than usual vaccine development processes and also that there is a global urgency, it would be more appropriate to regard these applications within the scope of 'temporary license'.

On the other hand, if the license is granted within the scope of this regulation, the packaging and the usage instructions for the product is obliged to state that the product had yet to meet certain criteria. When this obligation is considered in conjunction with the doubtful approach of individuals to vaccination, it is also possible for the licenses for coronavirus vaccines to be subject to the normal license procedure instead of the temporary license.

Which Means to Pursue in Case of Rejection of the License Application?

In the case of rejection of the application, the reasoned decision will be notified to the applicant. In such case, the applicant has the right to object the decision within 30 days. Although it is regulated that the objection will be evaluated and finalized within 90 days, considering that this period is quite long for the Covid-19 vaccine, it should be finalized promptly, within a shorter period than the Regulation provides.

On the other hand, it is possible to directly file a case in administrative jurisdiction instead of filing an administrative objection, which is not obligatory. However, a such case is not subject to the urgent procedure that is regulated under the Law No. 2577 on Administrative Procedure. In addition, the administrative court cannot decide without having an expert's report. In this respect, -considering the benefits sought and the characteristic of the sector- judicial remedy may fail to provide the rapid response expected by the applicant.

Could Covid-19 Vaccines Become Mandatory?

Whilst it is a matter of interest for public opinion, whether the vaccination will be obligatory is a critical question for suppliers in order to assess the capacity of the market. It is possible to approach this question from two different angles. Firstly, can government mandate the vaccination; secondly, can private persons make the vaccine imperative for benefit from certain services.

The Constitutional Court has put an end to the discussion on the possibility of compulsory vaccination by stating that it is out of the question unless it becomes a requirement by law [Constitutional Court, 11.11.2015, Application No:2013/1789][2]. In this context, Covid-19 vaccine is not stated in the General Hygiene Law No. 1593, in which the mandatory vaccinations mentioned in the decision are regulated. Therefore, in terms of the current legal order, it does not seem possible for the administration to make the vaccine mandatory for the whole society.

The situation is relatively different for private persons. Within the scope of freedom of contract, regarding private persons such as airline companies or shopping malls, in principle, there is no obstacle to require vaccination to let people benefit from the service they offer. However, at this point, it is important to note that public services provided by both public and private sector are out of scope of these evaluation since it is not possible to make vaccination obligatory to benefit from public services unless it is regulated by law. Accordingly, there is no legal obstacle to seek the obligation to be vaccinated to benefit

from the services offered by private sector –apart from the aforementioned public services, and such obligation may encourage and even practically force people to get vaccinated.

In conclusion, considering that the vaccine concerns public health, it might be regarded as an acceptable precaution for private sector agents to bring the vaccination requirement for environments where people gather in large numbers. In addition, the fact that the administration may not render the vaccination obligatory and that the vaccination will be considered as a preventive health service, people should be able to choose not only whether or not to be vaccinated but also to which vaccine to receive.[3] As a result of this requirement, the administration is under the responsibility of assessing the license applications that fulfil the medical requirements in an objective, transparent and swift way. The implementation of this responsibility can be demanded by individuals under the right to access medical goods and services, and by those who apply for a license within the scope of the freedom of enterprise and property rights.

[1] Pharmaceutical and Medical Preparations Law, art.3

[2] Halime Sare Aysal, B. No.2013/1789, 11.11.2015

[3] See also: Hüseyin Melih Çakır, Sağlık Hizmetlerinin Özel Hukuk Kişileri Tarafından Yürütülmesi, İstanbul, 2015

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