

## Health Industry Regulations in the New Presidential Government

As a result of the referendum, held on April 16, 2017, an amendment has been made on Constitution and transition has been made to Presidential Government System. The most fundamental feature of this system is; the transfer of all executive authorities to the President with the annulment of the office of Prime Ministry. The President has become both the head of state and the head of executive power. On the other hand, although TBMM is still the fundamental legislative body, it shares this authority with the President and the President, relying on authority, directly derived from the Constitution, is authorized to issue Presidential Decrees (PD), without the need to adoption of an authorization law by the National Assembly (limited to economic, social and cultural rights fields).

On the other hand, since the head of execution is determined as the President alone; the Council of Ministers have been annulled and the Presidential Cabinet have assumed the office of Council of Ministers. Indeed, the provisional article 21 of the Constitution regulates this matter as follows:

*F) The Decree-laws, By-laws, Regulations and other regulatory acts issued by the Prime Ministry and the Council of Ministers in force at the time of the entry into force of this Law [the Constitution numbered 2709] shall remain in force until their abolishment. The application of Article 152 and 153 [Articles of the Constitution titled as Claim of unconstitutionality before other courts and Constitutional Court Decisions] regarding the Decree-Laws in force shall continue.*

*G) The powers given to the Prime Ministry and the Council of Ministers by laws and other legislation shall be used by the President until amendments are made to the relevant legislation.*

With the effective date of the new system, first of all, under the Decree Law, numbered 703, the laws concerning organization and duties of certain ministries and duties, have been annulled and the organizations of certain ministries have been merged. Accordingly:

- With the revision on the organizational laws of Ministry of Family and Social Policies and Ministry of Labour and Social Security, the two ministries have been merged as, "Ministry of Family, Labour and Social Services."

- Ministry of Finance has been merged with Undersecretariat of Treasury under the name, "Ministry of Treasury and Finance".
- Ministry of Transportation, Maritime and Communication, has been named as Ministry of Transportation and Infrastructure.
- Ministry of Customs and Commerce and Ministry of Economy have merged to create Ministry of Commerce.
- Ministry of Development has been annulled and most of the duties and authorities of this Ministry have been transferred to Presidency of Strategy and Budget and some have been granted to Ministry of Industry and Technology.

Other than this, various state organizations have been annulled and re-organized with PDs and Decree Laws. The revisions, made with PDs and Decree Laws, are essentially changes made for compliance with the Government regime change in Constitution, consisting of changes to reflect changes in the affiliated Ministries of these institutions or the transfer of the authority, previously granted to Cabinet of Ministers to Presidency.

### **The impact of the new system on the industry**

When we examine the PD, numbered 1 and the Decree Law, numbered 663, we see that the authorities and duties of the Ministry of Health have remained basically the same. There are no essential changes concerning this issue. Here, the most important change, in compliance with new system, is the specification that the rules and procedures for determination of pharmaceutical prices, would be determined by the President, not by Cabinet of Ministers.

Currently, the fundamental legislation concerning determination of pharmaceutical prices, is the Decree concerning Pricing of Human Medicinal Products, dated February 24, 2017 (Pricing Decree) by the Cabinet of Ministers and this Decree will remain valid until a new legislation is introduced according to the above-mentioned temporary article 21 of the Constitution.

*The duties and authorities of the President of the Turkish Medicines and Medical Devices Agency, established under the Ministry of Health have been regulated in greater detail and on the other hand, the Agency has been authorized to order construction of service building and healthcare facility, encouragement of the use of medical products and services, establishment of foreign healthcare service units and encouragement of the use of medical products and services.*

The powers given to the Agency are considered to be in line with the prioritization to the local manufacture prominent in the recent years.

Social Security Institution has been re-organized with PD, numbered 4, yet no changes have been made in its organizational structure and function. The name of the Ministry, to which SSI is attached, has been changed as "Ministry of Labour, Social Services and Family," yet it still preserves its public legal entity and is financially autonomous. No changes has been made in the service units of the Institution.

Many duties of Ministry of Development have been transferred to Presidency of Strategy and Budget and the duties on the preparation and follow-ups of development plans in line with the fundamental objectives, principles and purposes determined by the President will be performed by this Presidency. Within this context, it can be said that the Presidency of Strategy and Budget will play an important role in government's pharmaceutical purchases and expenditures and investments to be made to new technologies in the health industry. The new duties of the Ministry of Industry and Technology are as follows:

- Incentives to regulate the operations of the private industry and foreign capital activities in compliance with plan targets and objectives
- To prepare development programs in regional or industrial basis
- To provide coordination of development agencies and to conduct the works and procedures concerning the same,
- To prepare policies, targets and strategies for information society, in this field, to provide coordination between public institutions and establishments, non-governmental organizations and private industry and to effectively manage the implementation.

In addition to the work of the above-mentioned ministries and the regulations to be amended, it is foreseen that the activities of the Policy Boards will be shaping the health industry.

With Presidential Decree, numbered 1, Policy Boards on certain issues have been established to collaborate with the President and to fulfil the directives of President and their fundamental duties have been determined as to provide opinions to public institutions and establishments for issues within their own field of duty and by obtaining the opinions of Ministries, institutions and establishment, civil society and industry representatives, experts in the field and other related persons, to monitor the applied policies and developments and to provide report to the President in studies.

Among the Presidential Board, important ones are "Science, Technology and Innovation Policies Board," "Health and Foodstuffs Policies Board" and "Economic Policies Board." It is expected that these Policy Boards contribute during the regulation preparation of Ministries in order to fulfil the objectives of the President.

### Next steps

Since, all these legislations have not been adapted to this new system, within this transitional period, it is contemplated that there may be certain delays with respect to processes, involving Ministries. However, it is stated that the legislation will be made compliant with new system by the end of the year.



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