

Turkey Introduces New Rules for Drug Procurement, Tobacco Packaging and Food-related Health Declarations

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Turkey has introduced new regulations for procurement of licensed or unlicensed drugs (which are not available in the Turkish market), plain packaging rules for tobacco, as well as a new requirement to obtain permission for food-related health declarations.

The Law Amending Certain Laws and Decree Laws Regarding Support of Public Health ("**Law**") was published in Official Gazette number 7151 on 5 December 2018, entering into effect on the same date.

Drug procurement scheme extended

Previously, only the Turkish Pharmacists' Association ("**TPA**") could procure unlicensed drugs, or licensed drugs which were not available in Turkey, from abroad. The Law extends this power to the Social Security Institution ("**SSI**") and the other authorized institutions (not yet announced).

In 2017, the Ministry of Health decided that the SSI could import these drugs and the Turkish Post General Directorate could carry them directly to patients, or to hospital pharmacies (where the patient is being treated).

The Ministry of Health's decision was criticized on the basis that the standard post service could not provide the special transport conditions, which most drugs require. Rather, critics argued that to ensure patient safety, drugs should only be provided by pharmacies.

Accordingly, the Law establishes a legal basis for the Ministry of Health's 2017 decision. It enables unlicensed or licensed drugs which cannot be found in the Turkish market to be procured by the SSI, TPA or other institutions/organizations which the Ministry of Health deems appropriate. The drugs must be procured for personal use.

It is expected the other institutions/organizations will be in line with related legislation, such as the:

- Pharmaceuticals and Medical Preparations Law, and
- Regulation on Human Medicinal Products Licensing.

Permission/license owners for these drugs must apply for a license within three years of entering the foreign drugs list, then obtain a license within two years of the application. If they fail to make a license application (or a license cannot be obtained), the President can decide whether procurement of these drugs can continue or not.

Plain packaging for tobacco products

The Law states that tobacco products must be sold in a standardized plain packaging, preventing advertisement, promotion and sponsorship.

The amendments include:

- The packaging area dedicated to written and illustrated warnings are increased from 65% to 85%.
- All tobacco products must be sold in unified packaging in terms of:
 - Font.
 - Font size.
 - Trademark position.
 - Packaging colour.
 - Any other text or shape.
- Signs such as logos are not permitted on the package.
- Tobacco products must be sold in closed cabinets, to prevent people reaching or seeing them.
- The Ministry of Agriculture and Forestry will prepare detailed regulations regarding the above issues, taking the opinion of the Ministry of Health.
- All tobacco products manufactured or imported prior to 5 December 2018 must be bought in line with the Law within seven months. The Ministry of Agriculture and Forestry can extend this period for a further six months.

It is expected that standardized packaging (which already exists in Australia, UK, Ireland, Norway and Hungary) will raise discussions about protection of industrial and intellectual property rights. Lawsuits filed by the large tobacco companies against the Australian government and related arbitration process have been on the international agenda for a long time.

Food advertising and supplements

The Pharmaceutical and Medical Device Authority's approval is now required for health declarations used on food and food supplement labels, or in promotions and advertisements.

Please see this [link](#) for the full text of the Omnibus Bill (only available in Turkish).

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