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No educational material for patients shall be distributed

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The "Regulation on Promotional Activities for Medicinal Products for Human Use" prohibits promotional activities that address the general public (Article 5). The Turkish Medicines and Medical Devices Agency has extended this provision to cover certain educational materials provided by the pharmaceutical industry to patients, which have been deemed to be a form of advertisement.

Various associations active in the pharmaceutical industry, including for example, the Association of Research-Based Pharmaceutical Companies (AIFD), were sent a letter signed by the President of the Turkish Medicines and Medical Devices Agency, dated 17 January 2017, declaring that promotional material or any material that contained any type of advertisement could not be distributed to patients in any way. The letter included scenarios in which materials that contained promotional script or those that promoted a certain product or brand information could not be handed to patients, for example, even if the material would be necessary to enable the patient's use of the prescribed medicine, or if the material contained only information included in the instruction manual of the prescribed product.

The rationale of this provision appears to be that the prevention of the advertisement of medicinal products to the general public is expected to ultimately protect public health. Industry stakeholders who received the agency's letter have been anxious to point out the downsides of implementing this rule, stating that patients may no longer be provided with assistance in understanding how to use the medication prescribed by their doctors.

Source: *Turkish Medicines and Medical Devices Agency: The letter is sent to associations active in the pharmaceuticals industry, 17 January 2017* (no source link available).

Export and anonymisation of human samples obtained in clinical trials

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On 24 January 2017, the Turkish Medicines and Medical Devices Agency announced that the export of samples taken from human subjects for use in clinical trials are subject to regulations introduced in the amendments made on 10 April 2016 to the "Regulation on Medical Laboratories" dated 9 October 2013. According to the regulations, only licenced laboratories are able to send human samples abroad, and any party that wishes to send samples abroad must now do so through licensed laboratories.

The applicability of these regulations to clinical trials comes as a surprise to the pharmaceutical industry because the existing "Regulation on Clinical Trials" sets out a special procedure (along with subsidiary guidelines) for exporting human samples that is specific to clinical trials. Furthermore, the new procedure, which requires transparency in data relating to each sample, is entirely contrary to the system established for clinical trials, which requires that samples are anonymised.

At present, it is still unclear if the new procedure is intended to apply to samples used in clinical trials and how anonymity is to be safeguarded.

Source: *Turkish Medicines and Medical Devices Agency: Amendment of the Regulation on Medical Laboratories dated 10 April 2016, 24 January 2017* (Turkish language).

Consultation on draft Regulation on Registration of Medicinal Products

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On 31 January 2017, the Turkish Medicines and Medical Devices Agency (Agency) published the draft revision of the "Regulation on Registration of Medicinal Products". It was prepared in accordance with EU legislation. The most significant changes are that:

- The process for registration, correspondence and administration of the marketing authorisation is to be entirely electronic.
- Applications for established medical use of active substances are required to have been in use in the EU or US for at least ten years.
- The authorisation holder must give the Agency advance notice of at least one month for the planned market release date for the product.
- There is no need to apply for and obtain a marketing authorisation on the packaging information, specifications or instructions for use of the product.
- There is no need to obtain a new or amended sales authorisation for processes leading to the change of packaging information, specifications or instructions for use of the medicinal product as these are taken as basic to the registration. However, after the transfer of production place from abroad to Turkey or vice versa, or following a package size change or after the authorisation transfer procedures, a new sales authorisation must be obtained by making an application to the Agency together with the instructions for use and packaging sample or sample of sales.
- Conditional authorisation applications are introduced and can be filed for products intended for the treatment, prevention or medical diagnosis of life-threatening or severely

disabling diseases, products to be used in exceptional circumstances which seriously threaten public health that are accepted as communicable diseases, and orphan products. If certain conditions listed in the draft regulation are satisfied, the application can be filed even if comprehensive clinical data on efficacy and safety of the product have not been provided yet.

- The authorisation holder is no longer entitled to grant the authority to market its products to a third party on the basis of a commercial agreement.

The draft regulation is currently open to public consultation and may be amended before final publication. The consultation ends on 10 March 2017.

Source: *Turkish Medicines and Medical Devices Agency: Draft Regulation on Registration of Medicinal Products, 31 January 2017* (Turkish language).