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The Turkish Medicines and Medical Devices Agency published *Guidelines on Protection of Personal Data in Pharmacovigilance Activities* (Turkish language) on 1 August 2019. The guidelines entered into force upon publication.

The guidelines state that no explicit consent is required for the processing of patient data reported by "adverse effect notification", regardless of whether the person making the "adverse effect notification" is a healthcare professional, patient or relative of the patient. Additionally, pursuant to the guidelines, the persons under the confidentiality obligation stated in Article 6 of Data Protection Law No 6698 shall process adverse effect data without explicit consent for the purposes of protecting public health and preventive medicine. According to Article 6, personal data related to health or sexual data can only be processed by persons under an obligation of confidentiality, or by authorised institutions and establishments, for the purposes of protecting public health, protective medicine, medical diagnosis, and treatment and care services.

The Turkish Institution of Protection of Personal Data has not yet confirmed the interpretation of Article 6 as set out in the guidelines. The pharmaceutical industry is therefore awaiting guidance from the Institution on whether pharmaceutical companies can be defined as persons under an obligation of confidentiality. If so, the obligation must be explicitly stated in law and cannot be introduced by guidelines.