Transparency provisions to prevent corruption in pharmaceutical sector

GÜN + PARTNERS
AVUKATLIK BÜROSU

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Introduction

The fight against corruption is a serious challenge in the pharmaceutical sector in Turkey and worldwide. This is because the state is generally the main buyer of goods and services provided by pharmaceutical companies and healthcare professionals such as doctors play a significant role as decision makers in the purchasing process.

Interactions between pharmaceutical companies, healthcare professionals and healthcare organisations are highly regulated by general legislation concerning public officials and specific regulations that focus on the pharmaceutical sector. Companies may have interactions with healthcare professionals and organisations that involve 'transfers of value' between the parties (eg, subsidised meals and travel expenses). However, these interactions are closely scrutinised.

A pharmaceutical company can sponsor a healthcare professional to attend a scientific congress as part of his or her ongoing education by paying for registration, travel and accommodation. A company may also make a donation in cash or in kind to a healthcare organisation (eg, a public hospital) to improve its facilities or research opportunities. In some cases, companies may even make direct payments to healthcare professionals in return for services received. For example, a doctor may help a company to develop a new treatment or medicine as a consultant in return for a service fee.

Crimes such as bribery and official misconduct are punishable under the Criminal Code (5237), regardless of the sector in which they are committed. Therefore, interactions between the pharmaceutical industry and healthcare professionals and organisations, including transfers of value, must be carried out in line with the Criminal Code. To ensure that these interactions do not lead to unfair practice or corruption:

- they must be fully transparent and documented in writing;
- transfers of value must be modest or reflect a fair market value; and
- companies should not carry out repeated transfers of value with the same healthcare professionals and organisations.

To help minimise risk, self-regulatory initiatives have been established in the pharmaceutical sector that set monetary limits on the appropriate amount that should be spent on hospitality activities or a fair market value for service agreements. Although it is easier to provide guidance on hospitality expenses, such as setting maximum rates for dinners to which healthcare professionals can be invited during educational activities, it is more difficult to set limits for fees for services, as their scope and characteristics may differ on a case-by-case basis.

Transparency and disclosure provisions

Transparency and disclosure provisions ensure that transfers of value do not exceed the limits set or that transfers are fair and not repeated to an extent that would raise corruption claims where no such limits exist.

The United States took the initiative in this regard in with its 2010 Sunshine Provisions, which require pharmaceutical companies to disclose transfers of value made to healthcare professionals and organisations that exceed $10. In July 2013 the European Federation of Pharmaceutical Industries and Associations (EFPIA) introduced its Code of Disclosure. As a result, association members and member companies of the EFPIA – including the Turkish Association of Research-Based Pharmaceutical Companies (AIFD) – have been required to document transfers of value as of January 1 2015 to be disclosed in 2016.

Turkey has taken positive steps regarding transparency and disclosure in the pharmaceutical sector through the AIFD, which represents most companies that have implemented the EFPIA disclosure scheme.

On July 3 2015 the Ministry of Health published the Regulation on the Promotional Activities for Medicinal Products for Human Use in the *Official Gazette*, which introduced a requirement to disclose transfers of value.

With this new disclosure rule, transfers of value (in cash or in kind) made by marketing authorisation holders to healthcare professionals and organisations (ie, universities, unions, associations and foundations active in the field of healthcare or non-governmental organisations established for the purpose of the protection and advancement of health) which exceed 10% of the applicable gross monthly minimum wage (approximately €40 as of November 24 2015) must be disclosed to the Pharmaceutical and Medical Device Agency.

The regulation sets out a transitional period for implementing the disclosure rule, which will come into force on January 1 2016. Companies will start documenting transfers of value made from that date and disclosure submissions for the calendar year will be made to the Ministry of Health within the first six months of the subsequent year. This data will be reviewed and retained by the Ministry of Health, but will not be published or made publicly available.

The regulation requires healthcare professionals and organisations to consent to disclosure before entering into a relationship with a company, as no interaction can be undertaken without such consent.

Consent becomes an issue when the disclosure requirement stems from industry practice rather than official legislation. As public disclosure is voluntarily imposed by companies, healthcare professionals and organisations are not required to provide their consent to public disclosure if they do not wish to participate in this scheme, which aims at increasing transparency and ethical behaviour in the sector.

Under the new regulation, as of January 1 2016 healthcare professionals and organisations will be entitled to enter into a transaction with companies (including a transfer of value) only if they have provided consent for its disclosure to the Ministry of Health. However, this consent does not cover the disclosure of transfers of value to the general public; thus, companies will be required to seek additional consent in that regard.

Comment

The law does not yet require the level of transparency which the pharmaceutical industry imposes on itself through the EFPIA scheme. However, it is promising that Turkey is following the worldwide disclosure trend and emerging as a jurisdiction in which transparency and the disclosure of transfers of value between the pharmaceutical industry and healthcare professionals and organisations is regulated by law.

For further information on this topic please contact Filiz Toprak,Ceren Aral or Bensu Aydın at Gün & Partners by telephone (+90 212 354 00 00) or email (filiz.toprak@gun.av.tr, ceren.aral@gun.av.tr or bensu.aydin@gun.av.tr). The Gün & Partners website can be accessed at www.gun.av.tr.


Filiz Toprak Esin


Ceren Aral


Bensu Aydın