

# New R&D incentives encourage growth of domestic pharmaceutical companies

GÜN + PARTNERS  
AVUKATLIK BÜROSU

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## Introduction

On February 19 2014 an omnibus law (Law 6518) was published in the *Official Gazette* that amends certain laws and decree-laws – including the Decree-Law on the Organisation and Duties of the Ministry of Family and Social Politics – and introduces new incentives. At first glance, these new incentives appear to be aimed at increasing local production of mid-tech and high-tech products by encouraging local research and development (R&D). As the pharmaceutical industry dominates the world's R&D expenditure through the development of new drugs, this sector is likely to be one of those most affected by the new law.

This update outlines the recent incentives introduced for R&D activities and their impact on the Turkish pharmaceutical sector, and discusses whether such incentives place local producers at an advantage over foreigners.

## VAT exemption

Through an amendment to Article 17 of the Value Added Tax (VAT) Law (3065), VAT shown in purchase documents related to the delivery of goods or performance of services for the lease, transfer or sale of IP rights – whether arising from patent or utility models exempted from tax or VAT, or included in the costs of such goods or services – may be deducted from the VAT calculated on the taxable transactions of the taxpayer.

Among other things, the legislature aims to encourage the commercialisation of pharmaceutical patents and utility models, and the utilisation of activities subject to patent and utility models, by companies operating in Turkey. While a company's origin is not an issue in this regard, it must operate within Turkey to enjoy the exemption. Hence, pharmaceutical companies with a local office in Turkey will be able to benefit from the VAT exemption in their licence agreements.

## Public tender exemption

Article 3 of the Public Procurement Law (4734) has been amended so that the purchase of goods and services involving industry participation or set-off applications aimed at innovation, domestication and technology transfer are no longer covered by the law. Under the amendment, the procurement of goods and services made by state institutions in

connection with set-off applications may now be made through direct procurement without tender procedures. For example, in tenders for public hospitals initiated for the supply of pharmaceuticals, hospitals need not follow tender procedures; instead, they can conduct direct procurement.

The basic principles of public tender law are:

- transparency;
- competition;
- equal treatment;
- reliability;
- confidentiality;
- public control;
- satisfaction of needs at appropriate conditions and in a timely manner; and
- efficient use of resources under Article 5 of the Public Procurement Law.

However, with the recent incentive introduced by the omnibus law with regard to set-off applications, it could be argued that an exception has been introduced to the principles of equal treatment and provision of competition.

According to the General Agreement on Tariffs and Trade (GATT) and World Trade Organisation (WTO) rules, to which Turkey is a party, the principles of equal treatment and non-discrimination between domestic and imported products with respect to public procurement are not applied and freedom is given to member states for public procurement. Since Turkey is a party to the public procurement treaty annexed to the WTO rules, the introduction of this provision does not conflict with the WTO Treaty and its annexes. However, the regulation fails to comply with EU legislation and is in breach of EU directives.

### **Price advantage for local producers**

In another amendment to the Public Procurement Law, Article 63 now states that it is mandatory to provide a price advantage of up to 15% in favour of bidders proposing domestic products in tenders for medical devices, pharmaceutical products and other goods identified by the Ministry of Science, Industry and Technology as mid-tech and high-tech industrial products. The opinions of related institutions and establishments must be obtained, and will be published by the institution in January each year. For an industrial product to qualify as a 'domestic product':

- it must be produced by companies holding industry registration documents issued by the Ministry of the Science, Industry and Technology; and
- an important part of the production, processes and economically essential workmanship must be conducted in Turkey.

For the time being, there is a question mark over whether this definition is still valid or whether producers must also check the ministry's list in order to be sure what qualifies as an industrial domestic product. In any case, this revision will place medical device and pharmaceutical companies importing products into Turkey at a significant disadvantage.

The Public Procurement Law proposes that tenders should be conducted in a transparent and competitive environment, with no discrimination among bidders. Before the amendment, the administration could provide advantages in favour of domestic bidders. Following the amendment, such advantages have been made mandatory with respect to certain goods. Since Turkey is not an EU member state, the related provision arguably does not constitute a problem; however, the imposition of such mandatory advantage by Turkey, which is targeting EU membership, could be interpreted as inappropriate. Moreover, even if the proposals of foreign bidders are more advantageous with respect to cost, quality and suitability for purpose, according to the provision, domestic products that do not satisfy these qualities may be excluded only on the grounds of this necessity. This will also cause problems with respect to the efficient and effective use of public resources.

### **Corporate tax exemption for revenues arising out of IP rights**

A new section entitled "Exception in Industrial Property Rights" has been added to Article 5 of the Corporate Tax Law (5520), which regulates the revenues that are exempt from corporate tax. A basic condition is proposed before such exemption can apply – the invention must have arisen as a result of R&D or software activities realised in Turkey. Under a literal interpretation, where even one part of the innovative activity (especially the final part) is conducted in Turkey, it may fall within the scope of the law, as the law does not require that all of the R&D and innovation and software activities be conducted in Turkey.

Furthermore, for such exemption to apply, the invention must also be subject to either a patent document with an examination patent certificate or a utility model certificate as a result of an investigation report. In this regard, if a clinical trial for a new drug is being conducted in Turkey and a patent application has been made accordingly, the revenues to be gained with regard to the use of such patent will be exempt from the Corporate Tax Law.

### **Comment**

The aim of the omnibus law is to increase R&D activities and the manufacture of innovative products in Turkey, in the pharmaceutical sector in particular. A supportive law in this respect would clearly create a serious disadvantage for importers. It remains to be seen whether the plan will work and Turkey will become a centre for the R&D and manufacture of goods that used to be imported, or whether the new legislation will cause many foreign market players to leave the market.

*For further information on this topic please contact Selin Sinem Yalincaklı Erciyas or Tuğçe Avcisert Geçgil by telephone (+90 212 354 00 00), fax (+90 212 274 20 95) or email (selin.yalincakli@gun.av.tr or tugce.avcisert@gun.av.tr). The Mehmet Gün & Partners website can be accessed at [www.gun.av.tr](http://www.gun.av.tr).*

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Selin Sinem Erciyas Tuğçe Avcisert Geçgil