
ÇELEN LAW FIRM

Pharmaceutical License Registration Dossiers in Turkey: Confidential in Entirety?

The Turkish Ministry of Health (“MoH”) is obliged to keep the content of the license registration dossiers confidential under Article 28 of the Turkish License Regulation¹ and article 39 of TRIPS². Despite wide spread rumors regarding biased practice, the MoH and the courts also recognize the MoH’s confidentiality obligation for both original and generic pharmaceutical products.

Undoubtedly, the information contained in the license registration dossiers is invaluable to both the applicant and its competitors. Even the knowledge of whether a generic product application exists can be very important. Reportedly, a generic product can take as little as 3 months to obtain a license from the MoH whereas it can easily take 3 years for an original product. Furthermore, as soon as the first generic of an original product is licensed in Turkey, the original product’s sales price to wholesalers is decreased to 66% of its reference price in the MoH database.³

The Turkish State Council has examined the confidential nature of the license application and the content of the license registration dossier in a case initiated by an original pharmaceutical product license holder.

The said company’s lawyers had requested from the MoH copies of a generic product application dossier which referenced the original product of the claimant. The claimant asserted that the MoH should provide copies of the license dossier to the lawyers as per the Turkish Lawyer’s Code article 2 which stipulates that governmental authorities should assist lawyers in doing their work. The MoH denied

¹ License Regulation published in the Official Gazette dated 19.01.2005 and numbered 25705 “Beşeri ve Tıbbi Ürünler Ruhsatlandırma Yönetmeliği”

² TRIPS became part of Turkish law as of its publication in the Official Gazette dated 25.2.1995 and numbered 22213

³ The Pharmaceutical Pricing Decree published in the Official Gazette on 22.9.2007 and numbered 26651 (last updated on 11.06.2010)

this request citing their confidentiality obligation. The nature of the information contained in the dossier, aim and scope of TRIPS article 39 and the relevant provision of the Regulation were discussed at length throughout the proceedings.

Finally, the Turkish State Council ruled that in light of the principle of the transparency of the state, the scope of the MoH's confidentiality obligation is limited to the "confidential information" contained in the license application dossier.⁴ It is confirmed that all scientific, technical, financial and marketing data contained in the license application is considered completely confidential and that the generic dossier cannot be disclosed for the review of third parties. However, the State Council clarified that the existence of the registration application, and identity of the applicant is not confidential and this information can be shared with the license holder of the original product.

Since timely access to whether there has been a generic license application is still crucial in many cases, the clarification of the confidentiality obligation of the MoH by the State Council is worth remembering.

The information contained herein constitutes only the general framework regarding the referenced subject. Please contact legal counsel for advice regarding specific matters.

⁴ State Council 10th circuit decision no. 2007/891, dated 6.3.2007