

## Regulatory environment & process in Turkey

**Cigdem Yilmaz**  
Sanofi, Turkey

Turkey is a developing and emerging country which ranks as the 16<sup>th</sup> largest pharmaceutical manufacturer worldwide and the 6<sup>th</sup> largest in Europe and expected to rise in the upcoming years. The government released its action plan in 2012 for the pharmaceutical industry key highlights were to increase R&D expenditures, export activities and investment possibilities. The healthcare system in Turkey has gone through a serious reform process with the 2003-2013 health transformation program. Many regulations changed, one of the most significant changes was implemented in Aug 2009; it was the obligation of GMP inspection of import products by Turkish inspectors. Due to unbalanced ratio of import products vs. local products and global budget the government implemented such a requirement before new submissions. The government supports local manufacturing and therefore since 2009 the number of import registrations decreased significantly (in 2012, 74% local registrations 26% import registrations.) Turkey's pharmaceutical regulations are generally in line with EU however there are some national deviations which may be a challenge for global companies. CTD format is applicable for the submission and the product is evaluated under several commissions once it is submitted such as advisory, technology, pharmacology, analysis of samples. Price can be submitted in parallel during registration phase or right after. In theory, registration process ends in 210 days however this is not the general case in practice. The recent examples show that it takes 15 months to three years. Despite many challenges such as regulation implementation without a reasonable transition period and price cuts, there are still opportunities as its one of the fastest growing markets with its 75 million populations.

### Biography

Cigdem Yilmaz graduated from Faculty of Pharmacy, Marmara University, Istanbul in 2003. During her 10 years in pharma sector, she gained experience in regulatory, pricing & reimbursement and pharmacovigilance areas. She has worked in regulatory affairs for pharmaceutical companies, including Eczacıbaşı, Zentiva and Sanofi. She has been involved in many projects including successful MAA and pricing & reimbursement submissions and approvals for NCEs, including Excegran® (Zonegran) and Mictonorm® and many first generic submissions and approvals in Turkey. She successfully lead "Re-branding Project" during acquisition of Eczacıbaşı company by Zentiva Group. In 2010 she joined Sanofi as Regulatory Manager responsible for Zentiva products. Recently by the end of July 2013, she has been Regulatory Manager of Volume Business within Sanofi Group responsible for both original and generic products and leading the reference country project.

Cigdem.Yilmaz@sanofi.com