REGARDING TRADITIONAL HERBAL MEDICINAL PRODUCTS MANUFACTIRING IN TURKEY

- LAW BULLETIN -

BULLETIN DATE: 28/06/18

I. INTRODUCTION

In the consequence of increasing interest in herbal products, several regulations have been published on manufacturing, licensing, sale and supervision of these products. This memorandum is in reference to the traditional herbal medicinal product manufacturing set forth by Regulation dated October 6, 2010.

Within the scope of this bulletin, the Regulation is studied so as to understand **(i)** the terms and conditions set forth in relation to the license application for manufacturing traditional herbal medicinal products in Turkey, **(ii)** the procedure about effectiveness, reliability and quality that shall be followed.

II. DOCUMENTS TO BE SUBMITTED

Information and documents that should be submitted in the application file and labelling rules are detailed in the Regulation. We will prepare a file for license application to submit to the Ministry of Health, in this regard we can provide legal services that you can find a short summary below:

- Preparing application file;
- Drafting and reviewing relevant contracts,
- Following notary transactions,
- Notarizing subcontracts if required,
- Collecting and compiling documents concerning the product specified in the Regulation;
- Getting expert reports concerning the effectiveness and reliability of the medicinal plants done,
- Obtaining required documents/certificates from abroad,
- Getting required translations done,
- Getting Good Manufacturing Practices document from the Ministry or authorized institutions,
- Getting Good Agriculture Practises Certificate,
- Preparing and collecting the information concerning the administration;
- Compiling legal entity documents from Trade Registry if required,

Varyap Meridian A Blok No: 40 D: 230 Ataşehir/İSTANBUL
Tel : 0216 510 14 45 | Fax: 0216 510 14 46
info@forensislaw.com - www.forensislaw.com

- Drafting documents for position of exclusive agent,
- Making relevant applications to recognize the position of exclusive agent,
- Preparing the documents describing the position of product safety manager,
- Preparing the documents describing science department,
- Collecting the information concerning control of starting materials, manufacturing method and control of finalized products;
- Preparing the file of summary of product characteristics**;**
- Checking compliance of package insert, inner and outer packages with legislations;
- Submitting the application file to the Ministry in line with the rules,
- Managing the application process and providing legal consultancy regarding project strategy,
- Making phone calls and meetings with governmental institutions and Ministry to follow up the conclusion,
- In addition to the license application, setting up the legal infrastructure for manufacturing the product.

III. HOW TO APPLY

License applications shall be made by real persons or legal entities settled in Turkey by meeting the conditions set forth in the Regulation and preparing an application file in Common Technical Document format. The application shall be made by a real person who is graduated from pharmacy, medical or chemistry faculties and who has the authority to practice his/her profession in Turkey or by a legal entity that hires a real person with these requirements in the position of "authorized person".

The information and documents set forth in the Regulation shall be submitted precisely to the Ministry of Health. Analysis of the products shall be get made by the Ministry in its referenced laboratories. After evaluating the information and documents attached to the application file, if there are not any obstacles in the analysis, license shall be regulated. The Ministry shall conclude the evaluation process within 210 days after the acceptance of the application.

Sincerely,

Forensis Law Firm

Note: The information in our bulletin is discussed in general terms. We kindly suggest you to contact Forensis Law Firm for detailed information prepared special for you.

Varyap Meridian A Blok No: 40 D: 230 Ataşehir/İSTANBUL
Tel : 0216 510 14 45 | Fax: 0216 510 14 46
info@forensislaw.com - www.forensislaw.com