The outbreak of Coronavirus COVID-19 has wide-ranging implications for businesses, governments and institutions across markets and industries. This newsletter prepared by our Legal Team contains information on the potential impact this pandemic may have on your businesses.

BOGA & ASSOCIATES has established a dedicated *directline* service, available to our clients and business partners. You can contact our dedicated COVID-19 Legal Team at our *directline* by clicking here.

Law No. 21/2020 dated 05.03.2020 "On some amendments to Law No. 89/2014 "On Medical Devices"

The Albanian Parliament has adopted the Law No. 21/2020 dated 05.03.2020 "**On some amendments to Law no. 89/2014 "On Medical Devices" ("The Law").**

The Law is published in the Official Gazette no. 54 dated 31.03.2020. It is partially aligned with Regulation (EU) 2017/745 of the European Parliament and of the European Council of 5 April 2017, "*On medical devices, amending Directive 2001/83/ EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009* and repeals *Council Directives 90/385 / EEC and 93/42 /EEC*".

The Law aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users. At the same time, this Law sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products.

The Registration Process

All medical devices defined by the Law which are classified in different categories (i.e. Classes) for purposes of placement into the Albanian market shall be registered at the National Register of Medical Devices kept by the National Agency of Medicines and Medical Devices.

The registration is carried out by the manufacturer or the manufacturer's representative in the Republic of Albania or the wholesaler, upon the authorization of the manufacturer.

The registration certificate is issued by the National Agency for Medicines and Medical Devices in a timely manner depending to the category of the medical devices (i.e., from 5 to 30 working days from the application date).

The registration certificate is valid for a period of 5 years from the date of its issuance.

Labeling and Instructions for Use

Every medical device that is placed into the market and put into service must contain the label in the Albanian language, which must be presented in a visible and readable form.

The rules on labeling and instructions for the use of medical devices shall be adopted upon decision of the Council of Ministers.

Manufacture of Medical Devices

It is the Minister in charge for health that approves the manufacturing of medical devices by licensed entities. The proposal for the granting of the approval for manufacturing is submitted to the minister by the Commission for Verification of Conditions of Production.

The Commission for Verification of Conditions of Production of Medical Devices is established upon the order of the Minister responsible for health.

The licensing requirements shall be determined upon decision of the Council of Ministers. The latter shall also determine the storage and transportation requirements.

Advertisement of the medical devices

The advertisement of medical devices shall be subject to a decision of Council of Ministers depending to the characteristics of the medical devices.

Advertisement of medical devices shall exclude any information that:

a) describes functions and features of the devices which the devices do not actually have;
b) creates a false impression about treatment, diagnosis, functions or features that the devices do not have;
c) fails to inform the user or the patient of a potential risk associated with the use of the devices, as indicated by it;
d) suggests use of the devices, other than those for which conformity assessment has been obtained and which serves the purpose of the devices.

E-Commerce

The wholesalers and retailers of medical devices may purchase and sell them through the Internet in accordance with the rules set forth in this Law and other applicable legislation.

Wholesalers and retailers of medical devices shall communicate, in advance, to the National Medical Devices Agency the necessary information on the devices they will trade online.

The order setting the criteria for the wholesale or retail sale of medical devices in the internet shall be approved by the Minister responsible for health.

Devices Presenting a Health and Safety Risk

The competent authority, where it finds that a medical devices placed into the market poses a risk to the health or safety of patients, users or other persons, shall require the manufacturer of the relevant devices or its representative to take action and bring the devices in accordance with the requirements of this law, restrict the placing on the market of the devices, return it or remove the devices from the market within a reasonable period, clearly specified and communicated to the manufacturer / devices representative. Medical devices, during their life cycle, are subject to periodic checks by specific authorities to ensure the quality and operation, as specified in the order of the Minister responsible for health.

If you wish to know more on issues highlighted in this edition, you may approach your usual contact at our firm or the following:

info@bogalaw.com

Tirana Office
40/3 Ibrahim Rugova Str.
1019 Tirana
Albania
Tel +355 4 225 1050
Fax +355 4 225 1055
www.bogalaw.com

Pristina Office
50/3 Sylejman Vokshi Str.
10000 Pristina
Kosovo
Tel +383 38 223 152
Fax +383 38 223 153
www.bogalaw.com

BOGA & ASSOCIATES
TOP TIER ACHIEVEMENTS 2020

IFLR1000 2020: Ranked in Tier 1 in Financial and Corporate and Project Development

Chambers Global 2020: Ranked in Band 1 in General Business Law

Chambers Europe 2020: Top Ranked in 3 practice areas

The Legal 500 2019: Top Ranked in Legal Market Overview

Benchmark Litigation Europe 2020: Top Ranked in Dispute Resolution

WTR1000 2020: Top Ranked in Trademarks

Boga & Associates

Boga & Associates, established in 1994, has emerged as one of the premier law firms in **Albania** and **Kosovo**, earning a reputation for providing the highest quality of legal, tax and accounting services to its clients. Until May 2007, the firm was a member firm of KPMG International and the Senior Partner/Managing Partner, Mr. Genc Boga, was also the Senior Partner/Managing Partner of KPMG Albania.

The firm's particularity is linked to the multidisciplinary services it provides to its clients, through an uncompromising commitment to excellence. Apart from the widely consolidated legal practice, the firm offers the highest standards of expertise in tax and accounting services, with keen sensitivity to the rapid changes in the Albanian and Kosovo business environment. The firm delivers services to leading clients in major industries, banks and financial institutions, as well as to companies engaged in insurance, construction, energy and utilities, entertainment and media, mining, oil and gas, professional services, real estate, technology, telecommunications, tourism, transport, infrastructure and consumer goods.