

# BOGA & ASSOCIATES

## NEWSLETTER

*To keep you up to date with the latest legal and economic developments, this newsletter prepared by our Team provides information that may affect the operation of your business in Albania.*

***“On Medicinal Products and Pharmaceutical Service”***



## Draft Law “On amending and supplementing the Law no. 105/2014 ‘On medicinal products and pharmaceutical service”

On 04.11.2022, the Ministry of Health and Social Protection submitted to the Parliament the draft law “On amending and supplementing the Law no. 105/2014 ‘On medicinal products and pharmaceutical service’, as amended (“**Draft Law**”).

The provisions of this Draft Law are partially harmonized with the Directive 2001/83/EC of the European Parliament and of the Council of 06 November 2001 on the Community code relating to medicinal products for human use.

The Draft Law provides for the increase of services in the pharmaceutical market aiming to provide a better environment for assuring patient safety as well as guaranteeing the supply of safe and efficient medicines.

Among others, the Draft Law introduces a new concept with regard to “**Managed Entry Agreements**” (MEAs). MEAs are a set of instruments to facilitate access to new medicines. They are defined as agreements between the ministry responsible for health and the pharmaceutical companies for originator drugs, within the period for which the molecule (INN) is protected by an international patent, in order to increase access to specific therapeutic treatments and guaranteeing cost/efficiency.

Types and procedures of special agreements (MEA) will be approved by Decision of the Council of Ministers.

The proposed provisions on this Draft Law affect citizens, businesses in the pharmaceutical field, National Agency for Medicinal Products and Medicinal Devices, Compulsory Health Care Insurance Fund and State Budget.

### Impact on citizens

New pharmacies shall be opened in geographical areas where there are not enough pharmacies. The lack of necessary drugs will be filled, and the quality of pharmaceutical service is expected to be increased. Cure opportunities with innovative/rare drugs for patients with special diseases will be covered 100% by the state budget.

### Impact on businesses operating in the pharmaceutical industry

The provisions of the Draft Law encourage pharmaceutical businesses to be licensed as Local Trade Authorization Holders, reducing their operating costs so that the pharmacovigilance system can be maintained by them. The process of preparing magistral and officinal formula will be under persistent control according to the certification criteria determined by the National Agency for Medicinal Products and Medicinal Devices. The authorization for the marketing of semi-finished products aims to stimulate the interest of pharmaceutical businesses to enter the market by offering one or several of the drug production processes. Through the proposed amendments, the number of new pharmaceutical businesses is expected to be increased by 5%.

This law enters into force 15 days after the publication in the Official Gazette. The rules for the holder of the local trade authorization enter into force 24 months after the publication.





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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](mailto: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](http://www.bogalaw.com)

[www.bogalawip.com](http://www.bogalawip.com)

**Pristina Office**

50/3 Sylejman Vokshi Str.  
10000 Pristina  
Kosovo

Tel +383 38 223 152

Fax +383 38 223 153

[www.bogalaw.com](http://www.bogalaw.com)

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AWARDS AND RECOGNITION 2022**

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**IFLR1000 2022:** Ranked **Tier 1** in Financial and Corporate

**Chambers Global 2022:** Ranked **Band 1** in Corporate/Commercial

**Chambers Europe 2022:** Ranked **Band 1** in 3 practice areas

**The Legal 500 2022:** Ranked **Tier 1** in Legal Market Overview

**Benchmark Litigation Europe 2022:** Top Ranked in Dispute Resolution

**WTR1000 2022:** Top Ranked in Trademarks

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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.