# Agency for Pharmaceuticals and Medical Devices of Bosnia and Herzegovina

**Agency for Pharmaceuticals and Medical Devices of Bosnia and Herzegovina**

The Agency for Pharmaceuticals and Medical Devices of Bosnia and Herzegovina (hereinafter the "BiH Agency") was established by the BiH Law on Pharmaceuticals and Medical Devices as the only body authorized and responsible for registration, control and granting marketing permits of pharmaceuticals and medical devices produced and used in human medicine in BiH. It started operating on 1 May 2009.

The BiH Agency performs certain activities under BiH law in order to protect and promote public health by providing quality, safe and effective pharmaceuticals and medical devices for use in human medicine by establishing a functional, coordinated and unified regulatory system of pharmaceuticals and medical devices and by establishing and monitoring a single market of pharmaceuticals and medical devices in order to ensure their availability and safety across Bosnia and Herzegovina. [1]

**The RS Law on Pharmaceuticals and Medical Devices**

The Law on Pharmaceuticals and Medical Devices of the Republika Srpska was published in the RS Official Gazette on 28 December and will enter into force on June 28th, 2022. This law violates the BiH Constitution, and BiH Law, in particular the competences and unimpeded functioning of the BiH Agency for Pharmaceuticals and Medical Devices, and is in contravention of Bosnia and Herzegovina's obligations under the Stabilization and Association Agreement. It establishes a parallel legal and institutional set-up to the one existing

under the State Law, which will include among others the RS Agency for pharmaceuticals and medical devices and its control laboratory with the same competencies as the State level agency but with exclusive jurisdiction over the RS. This would seriously undermine the role of the BiH Agency and therefore affect its role in protecting and promoting public health by providing quality, safe and effective pharmaceuticals and medical devices across the country. In particular it will certainly undermine the single market in BiH (including the freedom of movement of goods throughout BiH) as well as BiH's international obligations arising from international conventions relating to the trafficking of narcotic drugs and psychotropic substances. If the RS Law on Pharmaceuticals and Medical Devices is implemented, Bosnia and Herzegovina would backslide in its alignment with the EU acquis under chapter 28, in the area of consumer and health protection, further delaying country's path to EU membership.

The application of the RS law would in particular result in:

The establishment of different regulations for the treatment of the same goods and their commercial activity which would compromise the legal certainty;

- Compromise the adequate controls currently being carried out by the state Agency, which could cause not only the circulation of untested and potentially dangerous pharmaceuticals or a shortages of pharmaceuticals that have passed the prescribed controls at State level but not at RS level;.
- Division of the pharmaceuticals and medical devices market along the entity line which would result in subjecting importers and wholesale companies to two different marketing authorizations, to register two offices (at BiH level and RS level) and to undergo different laboratory controls at BiH level and RS level and ultimately undermine patients' equal protection and equal access to healthcare and medicines throughout

Bosnia and Herzegovina.

- Additionally, there is a high risk of unequal consumer protection of patients in terms of efficiency, quality and safety of medicines and medical devices in the Republika Srpska Entity and in the whole Bosnia and Herzegovina.
- The expiration of licenses issued by the State Level Agency (State level licenses are issued for a 5 years period) could lead to shortages in RS pending the issuance of RS licenses. This situation may be even worse for patients relying on innovative or biological or biosimilar medicines, due to the absence of alternatives
- Jeopardizing the role of the BiH Agency for pharmaceuticals and medical in particular regarding control of import of pharmaceuticals and medical devices insofar as the RS might establish its own parallel controls;
- Hindering the operations of pharmaceuticals and medical devices importers, wholesale companies, pharmaceuticals and medical devices transporters etc. by requiring additional procedures for obtaining different authorizations (production, wholesale, import, transport storage permits). Specifically, both the company (each of its business activities) and each individual product will have to go through additional, very often time-consuming and expensive procedure in order to be allowed on the RS market;
- Undermine Bosnia and Herzegovina’s obligations arising from international conventions relating to the trafficking of narcotic drugs and psychotropic substances insofar as the State level Agency is in charge of implementing such obligations.
- Backsliding in implementation of the European Commission’s Opinion on Bosnia and Herzegovina’s application for EU membership findings, which established that the country needs to simplify and

harmonize business registration, licensing procedures between entities to improve businesses, to create single economic space.

- Contravening the EU recommendations from the meetings of the Joint Bodies under EU-BiH Stabilization and Association Agreement focused on ensuring well managed, good quality and accessible public health care for all citizens.

---

[1] In particular the BiH Agency performs among others the following tasks: Issuance, renewal, transfer as well as termination of licenses for pharmaceuticals (including traditional herbal and homeopathic pharmaceuticals); establishes the BiH pharmacovigilance (supervise and inform about the adverse pharmaceuticals reactions) and ensures its compliance with the EU pharmacovigilance; issues certificates for the export of pharmaceuticals in accordance with the recommendations of the WHO (World Health Organization); categorizes pharmaceuticals; Approves the advertising of pharmaceuticals; collects and processes data on the turnover and consumption of pharmaceuticals; provides information and suggestions for the rational use of pharmaceuticals to the public, Communicates and represents BiH with the international pharmaceutical information networks and agencies etc.