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Legal Department

LAW ON AMENDMENTS TO THE LAW ON REPUBLIC ADMINISTRATION

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LAW ON AMENDMENTS TO THE LAW ON REPUBLIC ADMINISTRATION

Article 1

In the Law on Republic Administration („Republika Srpska Official Gazette“, Nos. 115/18 & 111/21), in Article 39, under sub-paragraph 20), after the words „investments“, a comma shall be added and followed by a new sub-paragraph 21) to read as follows:

„21) the Agency for Medicinal Products and Medical Devices of Republika Srpska."

Article 2

After Article 58a, a new Article 58b shall be added to read:

„Article 58b

(1) The Agency for Medicinal Products and Medical Devices of Republika Srpska shall carry out the tasks relating to: issuing marketing authorizations for medicinal products, renewing cancelling, or amending such authorizations; conducting laboratory testing of medicinal product quality and providing expert evaluation of medicinal product quality; issuing good practice certificates (manufacturer, wholesale pharmacies, clinical, laboratory, transportation, etc.); registering or approving of clinical trials of medicinal products and monitoring adverse effects occurring during clinical trials; issuing of manufacturer of medicinal product authorisation based on certificates on complying with good manufacturer practices; issuing of wholesale marketing of medicinal products based on certificates on compliance with good distribution practices (good wholesale pharmacies practice); establishing and maintaining an updated record of imported medicinal products for which a marketing authorization has not been issued in the Republic; publishing an annual Register of medicinal products containing the list of medicinal products permitted for marketing in the Republic; collecting information, analysing, and responding to adverse effects of medicinal products (pharmacovigilance); carrying out the assurance control of medicinal products activities; organizing information systems on medicinal products, including establishing a database covering medicinal products authorized for marketing; collecting data about sales and usage of medicinal products networks, informing professionals and general public in the Republic about the medicinal products in view of the currently applicable legislation; participating in the international exchange of information regarding adverse effects of medicinal products; reviewing European Pharmacopoeia; assisting in the international exchange of information and keeping records of marketing narcotic drugs and psychotropic substances, subject to approval from the competent Republic authorities; making recommendations for harmonising the legislation from the area of medicinal products with legislation from the European Union and with the guidelines provided by international institutions; keeping a register of medical devices for the territory of the Republic; keeping a register of medical device manufacturers for the territory of the Republic; keeping a register of legal entities engaged in wholesale of medical devices for the territory of the Republic; issuing of

certificates of registering manufacturers of medical devices; issuing certificates of registering legal entities engaged in wholesale of medical devices; collecting information, analysing and responding to undesirable occurrences in application of medical devices (materiovigilance); assessing conformity and labelling of medical devices in the Republic with harmonized European standards and technical regulations in accordance with the Technical Requirements and Conformity Assessment of Products Act; carrying out professional inspection and supervision of manufacturing and wholesale marketing of medical devices, as well as of legal entities engaged in manufacturing of medical devices, or importing and wholesale marketing of medical devices within the scope of issued authorizations; establishing an information system of medical devices, including a database of registered medical devices, legal entities involved in their manufacturing, import and wholesale; collecting data about sale and usage of medical devices to facilitate the streamlining of medical device use; integrating into international information networks on medical devices; and performing other tasks as prescribed by law.

(2) The Agency for Medicinal Products and Medical Devices of Republika Srpska shall be an independent administrative organization with the capacity of a legal entity.“

Article 3

This law shall enter into force on the eighth day following the date of its publication in the „Republika Srpska Official Gazette.“

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SPEAKER
NATIONAL ASSEMBLY

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