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The Rights and Obligations of the new Medicine and Medical Devices Regulatory Authority

Until December 2020, the Ministry of Health, the Centre for Health Development and the relevant departments of the General Agency of Specialized Inspection were responsible for the regulation with regards to import, export and distribution of medicines and medical devices under their respective functions. According to a study in the pharmaceutical sector in 2018, Mongolia imported medicines amount of 362.5 billion tugriks (127.2 million USD) and sold the amount of 299 billion tugriks (105 million USD) (wholesale price), which is respectively increased by the amount of 128.4 billion tugriks (45 million USD) in import of medicines and grow in the amount of 77,8 billion tugriks (27.2 million USD) in medicine sales compared to 2017.[1]

According to an independent study conducted by BioMed Central Public Health in 2020, when samples of 1770 medicine products were taken from Ulaanbaatar and 4 provinces, the 179 samples equal to 10.1% did not meet the requirements of the standard and 76 samples equal to 4.3% of the total amount of the samples were not registered in Mongolia[2]

The Government of Mongolia established a new agency, which named as Medicine and Medical Devices Regulatory Authority in accordance with the Decree No 222 of the Government of Mongolia[3] dated 16 December 2020 in order to overcome the existing inconsistent and inefficient structure to make the state regulation and supervision in the pharmaceutical market. The newly established Medicine and Medical Devices Regulatory Authority shall exercise and fulfill the following rights and obligations for the importing and distribution of medicines and medical devices.

Read more

For more information or any queries, please feel free to contact Bolormaa.V, Partner of GRATA International Law Firm by bvolodya@gratanet.com or 976 70155031.

[1] http://hdc.gov.mn/media/files/2018_Kedu7Vn.pdf

[2] https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-08897-x

[3] https://www.legalinfo.mn/law/details/15843?lawid=15843

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