

PRESENTATION BY MR. TS.GANBOLD, HEAD OF INTERNAL POLICY DIVISION OF THE MINISTRY OF JUSTICE OF MONGOLIA ON THE “MONGOLIAN CURRENT SITUATION OF THE FRAUDULENT MEDICINES” AT THE TECHNICAL CONFERENCE ON THE TRAFFICKING IN FRAUDULENT MEDICINES ORGANIZED BY THE UNITED NATIONS OFFICE ON DRUGS AND CRIME

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Dear delegates, colleagues,

First of all, I would like to express my sincere gratitude to the United Nations Office on Drugs and Crime and its staffs for their kind efforts and support on organizing of this event and a kind invitation to the conference.

Today we are going to discuss about the current situation of the fraudulent medicines in Mongolia and determine the further actions that should be taken. Since the delegates shall discuss the joint strategy, programs and projects that could be implemented with mutual efforts, as well as actions that would be methodically implemented in order to seize utilization and consumption of the fraudulent medicines, I am fully confident that our discussions, experience sharing to be fruitful, and we shall learn to meet our common objective.

I am going to present about current fraudulent medicine situation in Mongolia and our further strategy to deal with this problem.

Our country has rather distinctive system, which requires tendering process for importing medicines and medical preparations. Medicine supplies are mainly imported from Russian Federation, German, Bulgaria and Hungary. Raw materials for the medicine production are usually bought from the People's Republic China. Fact that our neighbors, China and Russia, acknowledged the production of the fraudulent medicines causes risk to our imported medication products.

In October 1994, for the first time in Mongolia, fake penicillin was discovered; further in 2001 a large number fake vitamin B complex was seized and destroyed by our Buyant-Ukhaa airport custom authority.

In 2005-2007 with the support of World Health Organization our Ministry of Health and State Specialized Supervision and Inspection Authority conducted three nationwide surveys on “Counterfeit medicines assessment”. At that time, 147 medicines were chosen for laboratory analysis, from which 28 were determined as not meeting the required standards. This event clearly revealed that Mongolian medicine supply market has counterfeit medicines.

In Mongolia, process of registration of medicaments that fulfill the international standard requirements started in 1994. As for 2010, we have registered 1500 medication of 200 factories

from over 30 countries, 67 imported medicine materials from 41 factories of China, Russia and India, and domestically produced 51 medicines.

The medicine importing legal entities are required to submit the importing medicine chemical laboratory of the State Specialized Supervision and Inspection Authority for testing and approval. Moreover, the medicine to be imported must be used in the produced country for the period not lesser than 3 years and be exported for more than 3 years to other countries. However, we still encounter problems of importing and distribution of low quality medicine from abroad. Other problematic issues that we currently face are involving trade of low quality medicines in improper places illegal advertising and using medicine for tools to gain a profit.

Accordingly, there is a need to ensure the safety and quality of imported and domestically produced the medicine. In other words, due to increase of the private medicine factories and pharmacies, we need to standardize the medicine supply companies' structure and activities and to improve the quality of professional supervision inspection on medicine, and renew the legal regulations related to many new types of medicine that have been recently introduced.

Our medical experts and professionals have concluded that infants or toddlers who got the common cold or flu are not recovered due to usage of medicines that are not meet required standards or unidentified origins, and as an outcome, their condition worsen and turn into pneumonia, sometimes with fatal consequences. The above-mentioned problem also effect young women, especially pregnant women, contributing to newborn and maternity mortality.

According to survey, the number of investigation and enquiries related to the trafficking of fraudulent medicines and illicit drug, its production, import, trade, distribution and other seductive substances increases by each year. For instance, if in 2009 there were registered in total nine cases related to illicit drug's sale, transportation, storage, and preparation in 2012 it become 35 cases. Another nine cases related to illegal production, import, sale and storage of fraudulent medicine were registered 2008, but in 2012 the number reached to 20.

The number of tests performed by National Forensic Institute laboratory related to the cases on drugs and other seductive substances confiscated from the sites, suspects and accused also increased. For example in 2008, there were 53 done, but in 2012 it increased up to 160.

Mongolia joined in the United Nation's convention on drugs /1961/, the Convention about mental effective substances /1971/, the Convention about inspection on the drugs and mental effective medicine circulations /1981/ in 1990, 1999, and in 2001 respectively.

According to the responsibilities under the international conventions, Mongolia adopted separate law on inspection on the drugs and mental effective medicine circulation in 2002,

which significantly contributed control and monitoring procedure. However, the law does not contain provisions concerning regulations on granting licenses and permission to the companies running business activities related to drugs and mental effective substances.

Thus, under these circumstances, an amendment was made on the 26th May 2011 in order to narrow down the regulations to produce, store, sell, and distribute drugs and mental effective substances. By the amendment, the type of administrative responsibilities have been increased for the law breakers, the measurements have become stricter based on the damage and effect.

In past 5 years, 79 medicine related cases with 44 suspects of illegal sales, imports, and misuse of medicine that unrecognized by the Mongolian medicine registration had been revealed. During the investigation, 410 types of 45.000 medicines worth 538.5 million tugrigs were confiscated.

The inspection 775 legal entities revealed that 42 organizations /5.4 percent/ from them had breached norms and standards of serving the unrecognized products by the Mongolian medicine registration. The breaches included violations related to packaging, labeling custom requirements and laboratory testing.

We conclude that poor legal regulation, insufficient implementation of existing legislation, the weak legal punishments, big corruption and conflict interests, dishonesty of distributors including false increase of the price followed by supply demand, poor cooperation of the authorities and companies cause and maintain of the trafficking of fraudulent medicines production.

Within the framework of the “Healthy Mongolian” objective of the Mongolian Reform Government Action plan 2012-2016, some actions are to be taken. These actions include renewal of the policies, and developing programs and projects to improve the monitoring and combat the crimes related to fake medicine, providing the safe environment in the medicine import and ensure the food safety of the citizens’.

By the order of the Minister for Health of Mongolia, the National strategy to combat the trafficking of fraudulent medicine has been approved and being implemented. Within the framework of this strategy, the following measures are to be taken:

Revise the legal documents and policies on medicine, to expand the multilateral operations for the implementation; improve the system and arrangement of supply, information about proper use of medicine; as well as requirements and processing of license and permission granting, approval and monitoring of medicine, medicine registration. By doing so, we can prevent from import, utilization, advertisement, usage of fraudulent medicines in production and supply.

Improve the personnel qualification on medicine registration, expand the software; the develop reliable system for monitoring fraudulent medicines at the urban and rural level; have a advanced network for information exchange between monitoring and other organizations; to improve capacity and skills of professionals and staff; to prepare professional custom inspectors; to have one data base of medicine quality validation, to introduce an express testing method in rural area and take appropriate measures to improve the packaging and labeling of the domestic medicine factories' products in order to prevent from fake medicine production.

Establish a system that exchanges information connected to the express warnings about fake medicine from the World Health Organization, in order to increase the participation and to improve the cooperation of the border, customs, police, inspectors, and health organization in fighting fake medicine.

Provide the citizens with accurate and truthful information on the side effects and damages of counterfeit medicines via mass media; set up rewarding policy for the individuals who report about the sales and distribution of fake medicine; organize community based training to improve the awareness of the people and teach them to recognize counterfeit medicines, also, implement a policy to improve the connection of medicine advertisement monitoring organizations.

Systematic measures and combined inspections should be taken by the authorized organization to stop the illegal actions of poor quality or fraudulent medicines producing, supplying and serving.

In 2011, the State inspection and investigating authorities such as specialized supervision and inspection, police, customs, intelligence conducted a joint inspection on 13 medicine factories, over 77 medicine supply companies and possible unsafe and venerable places /such as market, kiosks in hospitals etc./ for sells, importing, transporting, storing, and distributing counterfeit medicines, bio preparations and medical supplies. As a result, 14 felonious and violations were revealed. As a result, fines were imposed according to the relevant legislations and 2 entities' operations were suspended.

In the future, we would definitely need the support and assistance of the United Nations Office on Drugs and Crime member countries in order to stop the fraudulent medicines use and combat this type of crime. With your participation, I believe that we will reach a certain result by developing joint strategies and programs.

Thank You for the attention