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Taiwan includes medicinal nitrous oxide in Trace & Track system

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The medicinal product license holders and wholesalers are required to submit the tracking and tracing information electronically before 10th of every month



Medicinal nitrous oxide is commonly used for anesthesia and pain relief. In order to manage the distribution of medicinal nitrous oxide and prevent it from being used for recreational purposes, the medicinal nitrous oxide has been included in the trace and track system of medicinal products according to Pharmaceutical Affairs Act since October 1st, 2020.

The medicinal product license holders and wholesalers are required to submit the tracking and tracing information electronically before 10th of every month.

With a view to strengthening the management of medicinal products distribution, Taiwan Food and Drug Administration (TFDA) stipulated the “Regulations governing the trace and track system for medicinal products” based on Pharmaceutical Affairs Act on September 6, 2016.

TFDA has given priority to include specific medicinal products in the trace and track system of medicinal products since July 1st, 2017.

Currently TFDA has included blood preparations, vaccines, botox, high concern type 50 items, preparations of ephedrine/pseudoephedrine and medicinal nitrous oxide in the system.

There are diverse ways for the pharmaceutical company to declare the trace and track data, such as data import, automatic upload, or online data entry etc., and the operating interface of the declaration system was improved to simplify the declaration process for pharmaceutical company.

In addition, the system has established the cross-reference and statistical analysis function, which is able to provide statistics, inquiries, and output of reports.

Furthermore, the authority is given to the medicinal products license holders for conducting query and cross reference of declaration information in the national health insurance database, assisting in the flow control of prescription medicinal

products, and enhancing the management of medicinal products flow for the pharmaceutical firms.