JOURNAL OF FOOD AND DRUG ANALYSIS XXX (2017) 1–6

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Review Article

Regulatory analysis on the medical use of ephedrine-related products in Taiwan

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ARTICLE INFO

Article history:
Received 26 October 2017
Accepted 13 November 2017
Available online xxx

Keywords:
Ephedrine-related products
Taiwan Food and Drug Administration (TFDA)
Controlled Drugs Act
Pharmaceutical Affairs Act
Pharmacists Act

ABSTRACT

To prevent ephedrine-related products from being misused to produce amphetamine and/or its analogs, there's a need for more effective and achievable regulatory mechanisms for the health, police, investigational, prosecution and judiciary authorities in Taiwan. This review was conducted to evaluate the international and Taiwan's regulatory policies and management of medical ephedrine-related products through the corresponding information collected from international and Taiwan government agency authorities. The combat of illegal drugs should involve both supply and demand sides to be successful. Health authorities in Taiwan do not have the investigational power to manage the forbidden transformation, abusing and manufacture of the illegal drugs from ephedrine-related products. Take the judicial interventions in the United States and in Japan as the examples, the organizational cooperation in Taiwan can be one of the main key strategies to combat against illegal drugs from ephedrine-related products. It is necessary to integrate the judicial, police and health agencies to prevent the production of illegal drugs from the ephedrine-related products in Taiwan. The efforts and regulatory control measures should be integrated to speed up the collaboration between different government authorities. It might be achieved through reorganization involving Taiwan Food and Drug Administration.

1. Introduction

Medical ephedrine products, containing ephedrine, pseudoephedrine or methyl-ephedrine, could be used as the precursor chemicals in the illegal production of amphetamine and/or its analogs. Therefore, these products were listed as “Schedule 4 Controlled Drug Ingredients” in the Controlled Drugs Act in Taiwan [1]. However; those ephedrine-related materials are also produced as pharmaceutical products mainly for the treatment of cold, cough, asthma or allergy. In this case, these products are categorized as prescription or over-the-counter (OTC) drugs depending on their dosages and/or risk levels. These ephedrine-related medications are not listed as controlled medications but are managed and regulated as general medications by regulations of the Pharmaceutical Affairs Act. As a result of such regulation gap loophole leads to

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https://doi.org/10.1016/j.jfda.2017.11.002

the drug distributors buying large volume or quantities of ephedrine-related products to extract the necessary ingredients and further produce amphetamine and/or its analogs accordingly. In fact, some law enforcement agencies have uncovered several similar cases and this phenomenon began to attract social and political attention in Taiwan.

To prevent ephedrine-related products from being misused to produce amphetamine and/or its analogs, this article reviewed the international regulation systems regarding medical ephedrine-related products, and compared them with Taiwan's own pharmaceutical and controlled drugs regulations. As a result of this analysis, we have proposed seven effective and achievable regulatory management initiatives to the health, prosecution, police, investigation and judiciary authorities, based upon the premise of worry-free medical usage purposes and the corresponding circulation responsibility, for ephedrine-related products production and circulation.

2. Regulatory analysis

2.1. *Severity of the misuse problem*

It is not difficult to produce amphetamine and/or its analogs with ephedrine ingredients through halogen reduction and hydrogenation. Thus, producing methamphetamine with ephedrine-related ingredients has become a common concern of circulation loophole both domestically and internationally. It began as a means of profiteering just among few pharmaceutical manufacturers. However, some pharmacies and pharmaceutical distributors jumped on the bandwagon and got involved in inappropriate use or in events of transforming high dose ephedrine cold medications into amphetamines. According to the news report, the 60 mg ephedrine can be extracted from one commercially available tablet of cold medication and 1 g of ephedrine could be obtained from 20 tablets of cold medications costing about 200 NTD (approximately 6.50 USD) [2,3]. However, 1 g of amphetamine could easily be sold at 5000 NTD on the market. The profit of this kind of illegal transaction is tremendous.

Fraudulent persons purchased cold medications, containing high doses of ephedrine-related ingredients, from unwitting pharmaceutical manufacturers, and then sold the products to drug distributors [2–4]. They were familiar with the corresponding sales channels and utilized the following approaches to obtain these medications and avoid being investigated accordingly: borrowing pharmacy permits, forging approved medical organization certificates, and setting up paper companies for exporting declaration.

There are many possible ways to obtain these large volume medical ephedrine-related products between different parties in the supply chains. For instance, the ephedrine products could be ordered in large quantities from pharmaceutical manufacturers or the distributors by dishonest staffs at hospitals and/or clinics and then being intercepted the shipment on the halfway. Otherwise, these products could be obtained as prescription drugs at hospitals, clinics, pharmacies or pharmaceutical manufacturers, or be purchased as OTC drugs with big volume. The possible circulation scenarios are explained in Fig. 1.

2.2. *International regulations and strategies*

Ephedrine products are usually not categorized as controlled substances internationally. To prevent ephedrine products from being illegally transformed into the amphetamine and/or its analogs, these products are usually packaged and supplied in the limited quantities, and cannot be openly displayed in pharmacies. Furthermore, the buyers' information usually has to be recorded in pharmacies as well.

The United Nations (UN) requests all member countries to implement the monitoring mechanism of precursor chemicals, "PEN Online (Pre-Export Notification Online)" to control the production, circulation and sales of ephedrine products in order to prevent from illegally transformation [5].

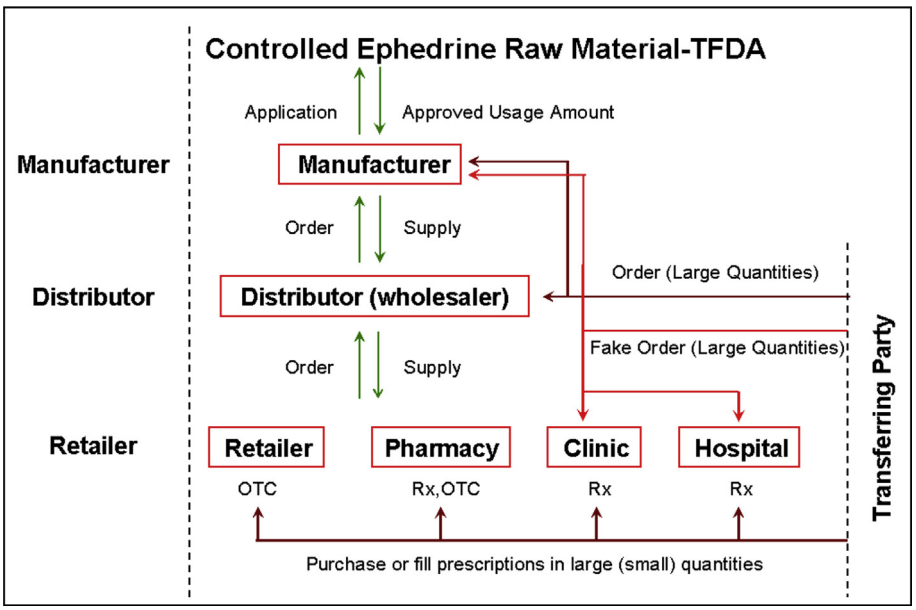

Fig. 1 – Possible ephedrine-related products circulation channel.

Please cite this article in press as: Yu W-N, et al., Regulatory analysis on the medical use of ephedrine-related products in Taiwan, Journal of Food and Drug Analysis (2017), https://doi.org/10.1016/j.jfda.2017.11.002