

UAE counterfeit medical products: tightened measures to address an ever increasing problem

Rasha Al Ardah - Partner - Intellectual Property
r.alardah@tamimi.com - Dubai International Financial Centre

As the pandemic hit the world earlier this year, counterfeiters immediately took advantage of the situation, and markets in different parts of the world were full of counterfeit facemasks, hand sanitisers and unauthorised antiviral medication, in addition to many other products. In a worldwide operation for Interpol (Operation Pangea XIII) in March this year, US\$14 Million worth of pharmaceuticals were seized. The seized products included 4.4 million units of illicit pharmaceuticals worldwide and more than 37,000 unauthorised and counterfeit medical devices, such as surgical masks and self-testing kits (HIV and glucose). Of course the online market made it easy to distribute such products on a wider scale.

Counterfeit medical products is not a new problem. According to World Health Organization statistics, an estimated 1 in 10 medical products in low – and middle-income countries is falsified. Counterfeit medicine is defined by the World Health Organization as “a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source”. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient ingredients or with fake packaging

Effect of counterfeit medical products

Counterfeit or falsified medical products appear very similar to the original but the effectiveness and/or treatment failure thereof may trigger suspicion. Due to the ineffectiveness of counterfeit medications, a patient may not see any improvement and his or her condition may even deteriorate. In addition, such counterfeit medication may cause drug resistance and possibly even death. A counterfeit medical device may well have disastrous results; for example, a counterfeit glucometer testing strip may give a wrong reading to a diabetic patient, causing the patient to take the wrong level of insulin, which may possibly cause death.

On the other hand, a patient’s inability to receive the proper treatment may increase negative analytical feedback because they were not cured or healed and that, on its own, could potentially affect the original pharmaceutical business that will likely receive negative reviews thus causing harm to the business. The number of counterfeit medical and pharmaceutical products allegedly results in loss of revenue worth billions of dollars to pharmaceutical companies, and in ill health and sometimes death of patients. It is estimated that more than 700,000 deaths per year worldwide occur due to fake anti-malarial and anti-tuberculosis drugs.

The situation in the UAE

Like any other country in the world, the UAE is not immune from such activities. Currently, the most common types of counterfeit medicines entering the market include lifestyle drugs, such as those addressing erectile dysfunction or weight loss. Since the pandemic started this year, enforcement

authorities in the UAE have focused on all medical supplies. In a joint operation by the Dubai Police and the Dubai Department of Economic Development in April 2020, more than two million medical masks of unknown origin, tens of thousands of fake labels, packages, and covers for several brands, and thousands of thermometers were seized.

The UAE has increased its efforts to eliminate fake medicines and medical products from reaching consumers. Some of the initiatives made by the DOH include the use of a device that detects counterfeit medicines in about seven seconds. Earlier this year, the Department of Health announced that a new app that detects counterfeit medical products on sale in the UAE will be launched. The Dubai Health Authority, in its turn, announced the launch of a pharmaceutical track and trace system to closely monitor medicines manufactured in the UAE and elsewhere along the supply chain to in order to eliminate fake drugs.

Legislative perspective

In this section, we have addressed the key applicable laws.

Trademark Law

Intellectual property laws in the UAE have addressed counterfeit medical products. The Federal Trademarks Law No. 37 of 1992 and its amendments ('Trademarks Law') penalise anyone who deals with counterfeit products. Article 37 of the Trademarks Law provides for a penalty of imprisonment and a fine not less than AED 5,000 (approximately US\$1,400), or either of these two penalties for: "(1) Any person counterfeiting a duly registered trade mark or imitating it in such a way as to mislead the public in respect of goods and services distinguished by the original mark or the mark resembling it, as well as any person knowingly makes fraudulent use of a counterfeit or imitated trade mark;

- Any person who in bad faith uses a registered trademark belonging to another person on his products or uses such mark wrongfully;
- Any person who knowingly sells or offers for sale or distributes or possesses for the purpose of sale products bearing a trade mark which is counterfeit, imitated, or wrongfully affixed as well as any person who knowingly provides or offers services under a trade mark which is counterfeit, or imitated, or wrongfully used. "

Based on the Trademarks Law, enforcement authorities including Customs, Department of Economic Development, Ministry of Health and Prevention, and Police, have been conducting raids, seizing counterfeit medical products, and destroying the same,

Pharmacy Law

In December 2019, Federal Law No. 8 of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments was issued. It replaced Law No. 4 of 1983 on the Pharmacy Professional and Pharmaceutical Establishments and Law No. 20 of 1995 on the Drugs and Products. Pursuant to this law a 'Counterfeit Product' is defined as: "A product that is deliberately and fraudulently produced with intent of deception and fraud, including:

1. providing its cover, packing, identification label, or patient information leaflet with false or incorrect information in regards to its identity or origin and in a means not identical to the reality;
2. counterfeiting another drug using the same technical design, cover colours, packaging, and identification label of the original product;
3. addition or removal of an active or non-active ingredient(s) of the drug's formulation prescribed on its

- cover, packaging, identification label, or patient information leaflet without the permission of the competent department; and
4. change the volume or quantity of its active or non-active ingredient(s) without the permission of the competent department

The law has provided for increased penalties for dealing with counterfeit medical products. Pursuant to Article 110, a penalty of imprisonment and/or a fine of at least AED 200,000 (approximately US\$5,500))

to at most AED 1,000,000 (approximately US\$272,000)), would be imposed for whoever falsifies or imitates a medication, raw materials, chemicals, health foods or therapeutic cosmetics, or knowingly sells to third parties or illicitly imports or smuggles the same into the country. More severe penalties may be imposed, including the closure of the business for a period of three months or full closure with licence suspension, and the confiscation of all violating products.

The UAE has taken serious measures and steps in its fight against counterfeit medical products by, for example, introducing the latest technologies to prevent counterfeit products from entering the country and reaching customers as well as levying hefty penalties for dealing with counterfeit medical products, all of which aim to eliminate counterfeit medical products in the market.

For further information, please contact healthcare@tamimi.com.