

COMMENT: Closing the gap - counterfeit drugs in Turkey

By bne IntelliNews August 6, 2013

The World Health Organisation (WHO) define counterfeit pharmaceutical products as follows: "a counterfeit medicine is one 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 active ingredient or with fake packaging."

The counterfeit pharmaceutical industry is one of the global economy's most profitable black markets, with annual profits believed to range from \$75bn to \$200bn annually. The WHO estimate that, as of 2010, over 14% of the world's drug supply is potentially counterfeit. As well as the obvious adverse implications for public health and safety that are naturally synonymous with the widespread dissemination of counterfeit medicines, the black market pharmaceutical trade is also one of the world's most dangerous, and damaging.

Despite high-profile efforts by the WHO and the EU to quell the production and distribution of counterfeit pharmaceuticals in recent years, official figures point to an ever-increasing number of counterfeit drugs in circulation worldwide, and a significant rise in the fraudulent manufacture of pharmaceuticals in emerging markets and developing countries. Turkey's unique geographical location and previously loose counterfeiting laws have cemented the country's status as a pivotal platform, not only for the manufacture and distribution of counterfeit goods, but also a bridging point of entry for bootleg produce manufactured in the East.

For more than a decade, harmonising internal legislation with EU standards and regulations in every area has been a primary concern of Turkish governments, and in recent years there have been strenuous efforts to tackle this.

With growing awareness as to the prevalence of counterfeit medicines and associated products, one of the major targets for the Turkish government is the eradication of counterfeiting activities. This article will attempt to provide a basic overview of what steps have been taken to counteract

counterfeiting, and what further steps the Turkish government could take to intensify their battle on counterfeit pharmaceuticals.

Current remedies

Apart from general provisions such as the "Smuggling Act", Turkish Law boasts a range of focused measures specifically designed to combat the counterfeit pharmaceutical trade.

In this respect, the Article 186 of the Turkish Criminal Code (TCC) reads that, "Any person who sells, procures, stores decayed, transformed foodstuffs, beverages or drugs causing risk for other's life and health, shall be punished with imprisonment of one year to five years, and also a punitive fine. The punishment to be imposed is to be increased by one third in case of commission of this offense within the scope of a proficiency or craftsmanship activity." Further, Article 187 of the TCC reads that, "Any person who produces or sells drugs in such a way to risk others' life and health is punished with imprisonment from one year to five years, and also imposed punitive fine. The punishment to be imposed is increased by one third in case of commission of this offense by a physician or pharmacist or within the scope of a proficiency or craftship activity."

Likewise, the right to a "healthy life" is already protected by the Turkish Constitution, as well as international treaties to which Turkey is a signatory.

In connection with the WHO's definition, the sale of counterfeit or expired pharmaceutical products can indeed be subject to Articles 186 and 187 of the TCC. If counterfeit drugs are sold with original packaging, or the expired drugs are repackaged, Articles 186 and 187 should apply. However, these Articles are primarily concerned with whether such drugs endanger human life or not, and the law enforcement officers are authorized to take ex officio action upon determination of such criminal activities.

Another problem with Articles 186 and 187 is their wording. As per Turkish Criminal Law, it is not possible to extend the scope of a criminal Article by interpretation, which effectively means that law practitioners are bound to the specific wording of criminal provisions. The difficulty with these wordings is that they employ an "and" while setting forth the main definition of causing risk against "other's life and health" instead of an "or". This wording leads to the conclusion that the sales of a counterfeit drug that does not directly endanger the life of another would not be considered to be in breach of these Articles.

When this condition is sought for penalization of counterfeiters, it becomes nearly impossible to penalize most of the acts in practice, other than the ones related to drugs containing poisonous ingredients. This wording also creates a problem of definition as to what endangers life, and it is indeed questioned whether or not "not receiving the necessary treatment against a life threatening disease from a medicine" should be considered endangering the life - however this "interpretation" can be considered as extending the scope of criminal provision as well.

Furthermore, if the packaging of a drug is in some way forged, another applicable law will be the "Trademark Decree Law no.556", and its Article 61/A specifically, which reads that "anyone who manufactures, offers for sale and sells the goods or services bearing identical or confusingly similar trademarks shall be punished with an imprisonment term between one and three years and to pay criminal fines."

However, a drawback of this Article is that the police are not authorized to take ex officio action based on Decree Law no.556 against counterfeits. In other words, the counterfeiting acts are not prosecuted if the complaint of the relevant IR right's owner lacks. This regulation limits the authority of the law-enforcement officers and the strategic involvement of the right owners remains inalienable.

It is clear that criminal penalties - in particular, prison terms - are far from satisfactory for such crimes, and it is obvious that as it is inevitable for both governments and right owners to struggle against counterfeits, changes in the applicable law are necessary.

What can be done?

In order to gain substantial protection, IP right owners are always advised to register their rights before the Turkish Patent Institute (TPI) as a first step.

Although, the Turkish Criminal Code indirectly makes provisions for counterfeiting through anti-trust legislation, with severe criminal penalties for those found to be in breach of competition laws, an action based on unfair competition will never be as effective as one based on registered rights.

It is also advisable to protect IP rights at Turkish Customs, bearing in mind that customs applications do not only cover exported and imported goods, but also cover goods in transit (and even goods within free trade zones). It is possible to file customs application forms online, and within any determined time frame, with an upper limit of one year - applications are processed efficiently, and

generally take no longer than a fortnight. These applications should be deemed most important for IP right owners, as for Turkish law considers imported undeclared goods as "smuggled", whereas exported goods are not.

Presently, the pharmaceutical industry use technological developments to protect their products more than any other sector. Measures such as distinctive hologrammatic labels and colour-changing inks are popular, and are also useful for local law practitioners as well, as they allow for easy differentiation between original products and counterfeits - which brings us to the importance of training relevant enforcement parties. Apart from details that should obviously kept secret, it is crucial to train groups such as the police and customs officers, and establish clear points of communication between manufacturers and administrative elements. So far, the Turkish government has been fully supportive of information sharing and education efforts, and has organized online training seminars for the police forces of 81 provinces of Turkey in 2013 alone.

Furthermore, under Turkish Law, drugs can only be sold through licensed pharmacies. However, there are an enormous number of online drug stockists in operation in the country. While the focus of these websites is mostly on fraudulent weight loss and sexual enhancement drugs, they're also an unregulated point of entry for bogus pharmaceutical products. Despite joint raid operations organized by the Turkish Ministry of Health and led Turkish police, under the sponsorship and guidance of IP right owners, such platforms persist operation. Put simply, it is not easy to control the online sales - but it is absolutely vital that stakeholders at every level try.

In conclusion, it is perhaps tautological to assert that the war against counterfeit drugs is a complex one, which requires the support and dedication of both right owners and local governments. Pharmaceutical companies are a formidable lobbying force, and the onus is very much on them to push local law makers for improved protection; chief amongst their objectives should be eliminating defects within local laws, such as the inadequate wording of Articles 186 and 187 of the TCC, increasing the negligible criminal penalties associated with counterfeiting, and the impossibility of taking ex officio action based on certain provisions.

Baris Kalayci, is Partner, Zeynep Seda Alhas is Senior Associate, and Ahu Savaskan Associate at Mehmet Gun & Partners.