VIAGRA®, CIALIS® and LEVITRA®– the analysis of original and counterfeit tablets used to treat erectile dysfunction

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Erectile dysfunction (ED) affects millions of men all over the world. It is estimated that more than half of all men over forty has difficulties getting or maintaining an erection. In 1998, the Federal Drug Administration (FDA) approved Viagra®, the first oral medication to treat ED. Since that time, Levitra® and Cialis® have also been approved. The commonness of erectile dysfunction causes that millions of mentioned tablets are sold every year. Organized crime has become increasingly involved in counterfeiting as it becomes more profitable. The counterfeiting results from the progress of technology causing that production of everything, from labels to active pharmaceutical ingredients, is now widely available. Globalization has made distribution channels easy targets for introducing counterfeit products. The Internet provides counterfeiters with ready access to consumers and markets. Therefore, it is very difficult to estimate how many tablets to treat ED are sold illegally.

The aim of the study was to compare the original products provided by manufacturers and tablets seized by police.

In order to quantitate the active substances, sildenafil citrate (Viagra®), tadalafil (Cialis®) and vardenafil (Levitra®), high-performance liquid chromatography (HPLC) was applied. The analyses were carried out on LaChrom D-7000 System (Merck-Hitachi) equipped with Chromolith Performance RP-18e (100 – 4.6) monolithic column. 0.01 % aqueous solution of phosphoric acid and acetonitryle were eluents and diode array detector (DAD) was used for identification. The composition of tablet masses was assessed by Fourier-transformed infrared spectroscopy (FT-IR). The spectrometer Avatar 370 FT-IR, manufactured by Thermo Nicolet, equipped with attenuated total reflectance (ATR) accessory was used. The spectra in the range 500 to 4000 cm-1 were collected. The chemometric methods, such as cluster analysis and principal component analysis, were applied to distinguish the spectra.

The results of study indicated that each examined tablet contained the appropriate active substance. In most of the cases, their content was comparable with the declared value and the differences did not exceed an analytical error. Only in some tablets the determined concentration was significantly lower. It concerned mainly Cialis® tablets. In none of the cases, the higher concentration than the declared one was not determined. On the other hand, the differences in FT-IR spectra of original products and tablets seized by police were significant. The chemometric methods allowed combining the tablets coming probably from the same illegal producer.

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The similarity of counterfeit tablets to the original products is very high. It causes that consumers may not know that the medicines they have purchased are counterfeits. In some cases they may not be getting the therapeutic benefit they expect. A fake drug also could interact with other medications they are taking and create potential health issues. Counterfeit products may be manufactured in substandard environments without appropriate controls that ensure their safety and efficacy and they could contain dangerous contaminants. The study indicated differences in the content of inactive components. Their detailed analysis was out of the scope of the study and therefore it is difficult to assess the toxicity of seized products.

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