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A LABORATORY EXPERIENCE IN ANALYSIS OF SEIZED MEDICINES IN THE REPUBLIC OF MACEDONIA

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A counterfeit medicine is defined as a medicinal product which is manufactured by an illegal manufacturer or deliberately mislabeled with respect to identity of registered product. Once they enter the market, those medicines could pose a serious public health risk in a way that they do not deliver the desired effect and/or their use could lead to unexpected adverse effects, such as: anaphylaxis or developing resistance to the medicinal product. Therefore, fighting the entrance of counterfeit medicines in the country presents a significant national issue and requires a well-organized health system as well as market surveillance regulation. The Department for Medicines Quality Control at the Institute for Public Health of the Republic of Macedonia was actively involved in combating counterfeit drugs. In the period from 2007 – 2013, fourteen samples seized from the Customs of Macedonia were submitted to the Bureau of Medicines (Ministry of Health) to be analyzed in the Department for Medicines Quality Control. The identification and determination of the content of active substances was successfully achieved using laboratory methods from the registration documentation provided by the manufacturers of the licensed finished medicinal products or the internal HPLC methods validated previously and intended for control of the potentially counterfeit products. The most of the seized medicines were in pharmaceutical form of tablet (85.8 %), labeled as "Viagra", "Cialis" or "Levitra", and only 7.1 % were undeclared. The 14.2 % of samples were false labeled for the active compound. Regarding to the composition of the seized samples, the results showed that the most frequently identified active substances were those for treatment of erectile dysfunction: sildenafil citrate (50.5 %), tadalafil (21.4 %) and vardenafil HCl H2O (7.2 %). The most of the analyzed products contained the active substance (64.3 %) outside the acceptable 95 % to 105 % margin of deviation from the declared value. The assay results for sildenafil citrate in the seized tablets were in range 52.1 % - 70.6 % from the declared content. These deviations verified the suspicion of counterfeit. However, for definite confirmation, more discriminating analytical techniques are needed, such as the near infrared spectroscopy (NIR) and/or mass spectrometry (MS). Additionally, the limited resource of reference standards in national quality control laboratories requires more extensive collaboration with international organizations.

Key words: counterfeit medicines; erectile dysfunction medicines; quality control