INTRODUCTION

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.

EXPERIMENTAL

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.

RESULTS

Number of samples analyzed in period 2007 - 2013

- Compliance with the specification: 33.7%
- Do not comply with the specification: 66.3%

Identification results

- Positive: 39.8%
- Negative: 44.2%

Quantification results

- Sildenafil citrate assay in counterfeit medicine samples

CONCLUSION

The most of the seized medicines were in pharmaceutical form of tablet.

- The 14.2% of samples were false labeled for the active compound.
- The most frequently identified active substances were those for treatment of erectile dysfunction.
- The most of the analyzed products contained the active substance 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.

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