COUNTERFEIT MEDICINES AND AVAILABILITY TO PATIENTS IN MACEDONIA, SERBIA AND BOSNIA AND HERZEGOVINA

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Introduction

The occurrence of counterfeit medicines represents a global problem, which affects patient's health, pharmaceutical industry and public health also. The aim of this study is to take an overview to: prevalence of counterfeit medicines, their basic characteristics and technologies for detection, recommendations of WHO, WTO, EU and other international organizations affected of falsified drugs.

Materials and methods

- comprehensive review of relevant literature sources
- recommendations of WHO, FDA, EU
- available data from the countries in this region.

Results and discussion

Definition (WHO): A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Results are presented in Table 1 and Table 2.

Table 1. Recommendations of WHO

	MEASURES	ACTIVITIES
WHO	Guidelines for the development of measures to combat counterfeit medicines, 1999	Advice on measures that should be taken by the various stakeholders in fight against counterfeit medicines
	Interventions to prevent drug counterfeiting	Legislation strengthening Development of communication strategy
	International Medical Products Anti – Counterfeting Taskforce (IMPACT), February 2006	Promotion and strengthening of international cooperation in the fight against counterfeit medicines
	Rapid Alert System, RAS 2005-2010	An electronic communication network- includes representatives of the states and territories in the region of WHO and partner organizations.

Table 2. Measures against pharmaceutical counterfeiting, taken by Macedonia, Serbia and BiH

	MEASURES	ACTIVITIES
Macedonia	Signed convention Medicrime, 2014	Implementation of provisions of the Convention in the legislation
	Law on medicines and medical devices	Regulation procedures Control input of the first importation of all medicines registered in the country
	Cooperation between the Ministry of Health and the Agency for drugs and medical devices with customs, police, health institutions	Established mechanisms to report suspicious drug control, removal and sanctions undertake.
Serbia	Signatory state of international documents for prevention of drug counterfeiting	Implementation in national legislation
	Law on medicines and medical devices	Regulated procedures to place medicines on the market Prohibition of internet pharmaceutical purchase
	Rulebook on the contents and method of labelling the outer and immediate packaging of a medicine, additional labelling, and contents of the package leaflet, 2008	The medicine manufacturer and/or marketing authorization holder shall paste a control stamp in the specially designed space on the outer package of a medicine (blue box) for human use in accordance with the Rulebook.
Federation BiH	Signatory state of Medicrime Convention, 04.12.2015	Protection of public health Compliance with EU regulations in combat against counterfeit medicines
	Operation PANGEA VIII, 2015	Combating the sale of illegal medicines online
	National Agency of medicines and medical devices	Promotional leaflet intended for citizens about appearance, features and recognition of suspicious medicines

Conclusion: According to the conducted research, Macedonia, Serbia and Bosnia and Herzegovina follow the recommendations and take appropriate measures to prevent / reduce the appearance of counterfeit drugs on the market.