



ДРЖАВЕН ЗАВОД ЗА РЕВИЗИЈА  
ENTI SHËTETËROR I REVIZIONIT  
STATE AUDIT OFFICE

## Final Audit Report Abstract

**Key Entities Covered by the Audit Report**  
Agency for Medicines and Medical Devices

### Audit Subject

Audit of financial statements together with compliance audit for 2020, Core budget account 603

### Audit Objective

To obtain reasonable assurance about whether financial statements are free from material misstatement, and whether activities and financial transactions contained in the financial statements are in accordance with the legislation, guidelines and policies in place.

### Key Conditions Identified

- not established proper financial management and control and division of duties and responsibilities in the area of financial operations;
- not established complete and efficient control environment due to unfilled managerial positions;
- Rulebook on job systematization in Financial Affairs Unit does not provide for position of accountant in charge, and the tasks are performed by an external person engaged with employment contract.

### Key Recommendations

- to fill out vacancies in the Financial Affairs Unit and foreseen managerial positions in the departments;
- to systematize the position of responsible accountant

### Comments on Draft Audit Report

We have not received comments on the Draft Audit Report

### Audit Opinion\*

We expressed unqualified opinion on the reality and objectivity of financial statements and unqualified opinion on the compliance with legal regulations, guidelines and policies in place for 2020.

### Key Systemic Weaknesses

- It is necessary to further regulate laws and bylaws
- to define deadlines for action on some procedures for issuing certificates and approvals;
- to ensure transparency in clinical examinations and to define the share of funds that should be revenue of PHI;
- to amend the Law on Medicines and Medical Devices to facilitate placing of medicines for treatment of diseases that could cause epidemic or pandemic on the drug market

### Response on Draft Audit Report Comments

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\*  unqualified  qualified  adverse  disclaimer of opinion