



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, Self-financing activities account 787

### 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;
- not established controls and improper recording, calculation and collection of revenues
- not established analytical records and absence of data on the amount of collected revenues for each type of certificate or approval issued.

### Audit Opinion\*

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

### Key Recommendations

- to fill out vacancies in the Financial Affairs Unit and foreseen managerial positions in the departments;
- to prescribe and adopt procedure for calculation and collection of revenues and full implementation of the same;
- to establish analytical accounting records for all types of revenue.

### 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

### Comments on Draft Audit Report

We have not received comments on the Draft Audit Report

### Response on Draft Audit Report Comments

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\* unqualified qualified adverse disclaimer of opinion