



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 631

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 adequate revenue records;
- less collected revenues amounting to 12.861.000 in the procedure for registration of medical devices;
- 3.767.000 denars paid to persons engaged with a work contract without precise definition of professional qualifications and work tasks and without proof of the work performed;
- 13 irregular commissions were formed where members were MALMED employees performing activities that are part of their regular work tasks, for which 4.652.000 denars were paid.

Audit Opinion*

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



Key Recommendations

- to establish analytical accounting records for all types of revenue;
- to collect fee for registration in the register of medical devices for each product separately;
- to define clearly professional qualifications and work tasks of persons engaged with a work contract
- activities of irregular commissions not to be part of regular work tasks.

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