
A PROCLAMATION TO PROVIDE FOR THE ESTABLISHMENT OF THE DRUG FUND AND THE PHARMACEUTICAL SUPPLY AGENCY

WHEREAS, as health is a pillar of securing proper life and productivity of the people and pharmaceuticals share a vital role in the health service;

WHEREAS, pharmaceuticals expenditure is much significant as compared to other health service budget;

WHEREAS, it is necessary to supply quality assured essential pharmaceuticals at affordable prices in a sustainable manner to the public;

WHEREAS, it is considered appropriate to design a system of mobilizing funds from different sources to ensure uninterrupted and sustainable supply of pharmaceuticals to all public health facilities and thereby serve the public in an equitable manner;

NOW, THEREFORE, in accordance with Article 55 Sub-Articles (1) and (12) of the Constitution, it is hereby proclaimed as follows:

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1. Short Title

This Proclamation may be cited as the “Drug Fund and Pharmaceuticals Supply Agency Establishment Proclamation No. 553/2007.”

2. Definitions

In this proclamation, unless the context otherwise requires:

1/ “Pharmaceuticals” means any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease, and includes medical instruments and medical supplies;

2/ “medical supplies” means any Article that may be used on the inner or outer part of the human body for diagnosis or treatment of disease, and includes suturing materials, syringes, needles, bandages, gauze, cotton and similar products, chemicals and x-ray films;

3/ “medical instrument” means any instrument that may be used on the inner or other part of the human body for diagnosis or treatment of a disease, and includes various diagnostic, laboratory, surgery and dental instruments;

4/ “public health institution” means a health service rendering institution owned by the Federal or a Regional State;

5/ “regional state” means any state referred to in Article 47(1) of the Constitution of the Federal Democratic Republic of Ethiopia, and includes the Addis Ababa and Dire Dawa city administrations.

6/ “appropriate body” means a body responsible body to regulate the competency of health service institutions and pharmaceuticals safety, efficacy and quality;
2/ "මිනිස්තු" සහ "මිනිස්ත්රිය" යනුවූ සම්බන්ධ ලියෝවා සිටීමට මෙම බොහෝ සංඛ්‍යාවක් විය. මෙම බොහෝ සංඛ්‍යාවක් මෙම බොහෝ සංඛ්‍යාවක් නොමැත හැකිවා උපාජීය විය.

3. Establishment

The Drug Fund (hereinafter referred as the "Fund") is hereby established.

4. Sources of the Fund

The Fund shall have the following sources.

1/ net income generated from the supply of pharmaceuticals pursuant to this Proclamation; 

2/ resources allocated by the Government in kind or in cash; and 

3/ grants in kind or in cash from donor agencies.

5. Utilization of the Fund

The Fund shall, after covering all overhead costs, in turn expend for the procurement of pharmaceuticals and the expansion and strengthening of pharmaceutical services.

PART THREE
THE PHARMACEUTICAL SUPPLY AGENCY

6. Establishment

1/ The Pharmaceutical Supply Agency (hereinafter referred as "the Agency") is hereby established as an autonomous federal organ having its own legal personality; 

2/ The Agency shall be accountable to the Ministry.

7/ Head Office

The Agency shall have its head office in Addis Ababa and may have branch offices elsewhere as may be necessary.

8/ Objectives of the Agency

The Agency shall have the following objectives:-
1/ to enable public health institutions to supply quality assured essential pharmaceuticals at affordable prices in a sustainable manner to the public;

2/ to play a complementary role in developmental efforts for health service expansion and strengthening by ensuring enhanced and sustainable supply of pharmaceuticals:

3/ to create enabling conditions for enhancing the accumulation of the Fund in its revolving and cost recovery process and thereby ensure the realization of the objectives referred to in Sub-Articles (1) and (2) of this Article.

9. Powers and Duties of the Agency

The Agency shall have the powers and duties to:

1/ establish and implement efficient and effective procurement and distribution systems to deliver, by using the Drug Fund and focusing on the country’s major health problems, quality assured pharmaceuticals at affordable prices sustainably to public health institutions.

2/ provide adequate and proper pharmaceutical storage facilities to ensure uninterrupted supply through establishing a modern storage management system;

3/ expand and strengthen storage and distribution outlets based on equity and effectiveness;

4/ supply essential pharmaceuticals of quality, safety and efficacy approved by the appropriate body to all public health institutions; where appropriate and in accordance with directives of the Board, supply to private and non governmental health institutions selected pharmaceuticals which are not adequately available;

5/ deliver pharmaceutical directly to districts, hospitals and selected health centers through establishing an effective transport network system;
6/ establish a logistics management information system compatible with the overall pharmaceuticals logistics system;
7/ prepare and implement short, medium and long-term plan for procurement, storage and distribution, and monitor its implementation;
8/ provide consultancy and training services in its field of operation;
9/ where necessary, establish committees, guide and coordinate their activities;
10/ collect service charges pursuant to the directives of the board;
11/ own property, enter into contracts and sue and be sued in its own name;
12/ perform other activities to pursue its objectives.

10. Organization

The Agency shall have:

1/ a Board;
2/ a Director General and two Deputy Director Generals to be appointed by the Government;
3/ the necessary staff.

11. Members of the Board

1/ The Board shall have members, including the chairperson, to be designated by the Federal Government upon the recommendation of the Minister and others drawn from representatives of Regional States.
2/ The number of members of the Board shall be determined by the Government as may be necessary.

12. Powers and Duties of the Board

The Board shall have the powers and duties to:
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1/ oversee and supervise the activities of the Agency;

2/ examine and approve the Agency’s strategies and implementation guidelines and monitor and supervise their implementation;

3/ approve and ensure the implementation of the annual work plan and budget of the Agency;

4/ approve and monitor the implementation of collection and disbursement procedures of the Drug Fund;

5/ approve and monitor the implementation of pharmaceutical procurement, storage and distribution manuals;

6/ decide on the amount and payment schedule of bank loans to be taken by the Agency;

7/ approve the recruitment, placement and termination of services of officials accountable to the Directors of the Agency;

8/ approve the annual financial reports of the Agency; appoint external auditors; ensure that adequate measures are taken in accordance with audit reports, and ensure that the audit reports are made public;

9/ decide on disposal of fixed assets and accounts to be written off;

10/ Where it finds it necessary, establish advisory committees, guide and coordinate their activities;

11/ decide on the rate of service charges to be collected by the Agency.

13. Meeting of the Board

1/ The Board shall meet once every three months; provided, however, that extraordinary meetings of the Board may be held at any time at the call of the chairperson;

2/ There shall be a quorum where more than two third of the members of the Board are present at a meeting;
3/ Any decision of the Board shall be made by a simple majority vote of the members present; in case of a tie, the chairperson shall have a casting vote.

4/ Without prejudice to the provision of this Article, the Board may adopt its own rules of procedures.

14. Powers and Duties of the Director General

1/ The Director General shall be the chief executive officer of the Agency and shall, subject to the overall guidance of the Board, direct and administer the activities of the Agency.

2/ Without limiting the generality of Sub-Article (1) of this Article the Director General shall:

a) exercise the powers and duties of the Agency provided for in Article 9 of this Proclamation;

b) employ and administer the employees of the Agency in accordance with directives to be approved by the Board following the basic principles of the federal civil service laws;

c) prepare and submit to the Board the annual work plan and budget of the Agency and implement same upon approval;

d) keep the Agency’s books of accounts, open and operate bank accounts;

e) represent the Agency in all its dealings with third parties;

f) submit reports to the Board on the Activities of the Agency;

g) perform other duties assigned to him by the Board.
3/ The Director General may delegate part of his powers and duties to the Deputy Directors and Employees of the Agency to the Extent necessary for the efficient performance of its activities.

15. Modalities of Procurement of Pharmaceuticals and Payment of Service Fees

1/ The Agency shall, without prejudice to the general government procurement principles, have its own procurement manual,

2/ Public health institutions shall place orders only to the Agency for the supply of essential pharmaceuticals; the Agency shall, in case of failure to supply the pharmaceuticals, advice the institutions of the best alternatives thereof. Detailed particulars shall be determined by directives.

3/ Government health institutions and other bodies delivered with essential pharmaceuticals shall be responsible to effect payment in cash to the Agency pursuant to this Proclamation and directives issued hereunder.

16. Budget and Extent of Liability

1/ The budget of the Agency shall be covered by the revenue to be collected pursuant to Article 15 (3) of this Proclamation and shall be approved by the Board.

2/ The Agency may not be held liable beyond its total assets.

17. Bank Accounts

The financial contributions referred to in Article 4 of this Proclamation shall be deposited in a bank accounts opened in the name of the Agency.

18. Disbursement

Disbursement of the Drug Fund shall only be made in accordance with the approved work plan of the Agency and directives of the Board.


The Agency shall keep complete and accurate books of accounts of the Drug Fund.
20. Audit

The books of accounts and other financial documents of the Agency shall be audited annually by external auditors. Audited financial reports shall be submitted to the Board within four months following the end of the budget year.

PART FOUR
MISCELLANEOUS PROVISIONS

21. Transfer of Rights and Obligations

The rights and obligations of the Pharmaceuticals and Medical Supplies Import and Wholesale Share Company are hereby transferred to the Agency.

22. Powers to Issue Regulations and Directives

1/ The Council of Ministers may issue regulations necessary for the proper implementation of this Proclamation.

2/ The Board may issue directives necessary for the proper implementation of this Proclamation.

23. Repealed and Inapplicable Laws

No law, regulations, directives or practices shall, in so far as they are inconsistent with this Proclamation, be applicable with respect to matters provided for in this Proclamation.

24. Effective Date

This Proclamation shall come into force on Publication in the Federal Negarit Gazeta.

Done at Addis Ababa, this 4th day of September, 2007

GIRMA WOLDEGIORGS

PRESIDENT OF THE FEDERAL
DEMOCRATIC REPUBLIC OF ETHIOPIA