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PERFORMANCE AUDIT REPORT OF THE AUDITOR-GENERAL ON ENSURING SAFETY AND QUALITY OF MEDICINES IN GHANA

This report has been prepared in compliance With Article 187(2) of the 1992 Constitution of Ghana and Section 13(e) of the Audit Service Act, 2000(Act 584)

Richard Quartey
Auditor-General
Ghana Audit Service
22March 2016

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TRANSMITTAL LETTER

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22 March 2016

Dear Rt. Hon. Speaker

PERFORMANCE AUDIT REPORT OF THE AUDITOR-GENERAL ON ENSURING SAFETY AND QUALITY OF MEDICINES IN GHANA

I have the honour to submit to you a performance audit report on Ensuring Safety of Medicines in Ghana in accordance with my mandate under Section 187(2) of the 1992 Constitution of Ghana and Section 13(e) of the Audit Service Act which requires me to carry out performance audits.

2. The purpose of the audit was to find out whether Food and Drugs Authority's measures put in place to regulate the importation and manufacture of medicines on the Ghanaian market ensure that medicines are safe and meet the required quality standards for use by the public.

3. The audit team focused on FDA's activities to license, register, collaborate with border agencies (Customs Excise and Preventive Service and Ghana Immigration Service) and undertake quality assurance procedures to ensure that imported and locally manufactured medicines on the Ghanaian market are safe and meet the required quality standards. The audit team focused the study on four regions of Ghana, namely, Greater Accra, Volta, Ashanti and the Brong-Ahafo regions. The audit covered the period 2010 to 2013 and was carried out from June 2013 to March 2014.

4. FDA has developed and implemented control measures to ensure that medicines are safe and meet the required quality standards. The audit found that FDA is effectively carrying out its manufacturing licensing and monitoring activities to ensure that medicines are produced under approved procedures and to required standards.

5. However, the following challenges made us conclude that FDA has not been effective in ensuring that the medicines on the market are safe and of good quality. FDA has challenges in the system of control of importation, the management of the security of detained medicines, and the collaboration with other border agencies to control the entry of medicines into the country. The audit also found some medicines on the market which were not registered and were not found on FDA's data base.

6. In this report I have made recommendations to guide the Food and Drugs Authority in ensuring that the medicines in Ghana are safe and meet the required quality standards for use by the public. Unfortunately, FDA's responses which have been attached to the report as Appendix I largely failed to address the issues raised in the report or the recommendations made.

7. I trust that this report will meet the approval of Parliament.

Yours faithfully,

RICHARD Q. QUARTEY
AUDITOR-GENERAL

THE RIGHT HON. SPEAKER
OFFICE OF PARLIAMENT
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GLOSSARY OF TERMS

Approved Entry Routes: An officially designated point of entry for medicines into the country.

Dossier: A collection of documents containing detailed information about a particular medicine submitted to the regulatory body for the registration of that medicine.

Good Manufacturing Practice: is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use.

Quality of Medicine: The extent to which a medicine contains the required amount of active pharmaceutical ingredients and its genuineness in terms of identity and composition.

Safe Disposal: A regulated procedure for the destruction of unwholesome medicine which must be witnessed and supervised by the regulatory authority.

Safety of Medicines: The extent of assurance that a medicine will not cause harm or negative effect to the human body through the presence of toxic substances.

Seizure Notice: A document issued by the regulatory authority to pharmaceutical companies restricting their access to detained medicines.

Unapproved Routes: A route of entry though legal, is not officially designated for the entrance of medicines.

LIST OF ABBREVIATIONS

ADR	Adverse Drug Reaction
BNI	Bureau of National Investigation
CEPS	Customs Excise and Preventive Service
CEO	Chief Executive Officer
EPA	Environmental Protection Agency
FDA	Food and Drugs Authority
GCNet	Ghana Community Network
GIS	Ghana Immigration Service
GMP	Good Manufacturing Practices
GoG	Government of Ghana
IGF	Internally Generated Funds
IPN	International Policy Network
KIA	Kotoka International Airport
KNUST	Kwame Nkrumah University of Science and Technology
PMS	Post Market Surveillance
PNDC	Provisional National Defence Council
WHO	World Health Organisation

EXECUTIVE SUMMARY

Food and Drugs Authority (FDA) is mandated by the Public Health Act, Act 581 (2012) to regulate medicines on the Ghanaian market to ensure that they are safe and meet the required quality standards.

2. FDA has the responsibility to register, license, undertake post-market activities, control importation, undertake quality assurance procedures and sensitises the general public to ensure that medicines on the Ghanaian markets are safe and meet the required quality standards.

3. The audit was to find out whether FDA's measures put in place to regulate the importation and manufacture of medicines on the Ghanaian market ensure that medicines are safe and meet the required quality standards for use by the public. The audit covered the period 2010 to 2013 and was carried out from June 2013 to March 2014.

4. We found that:

i. FDA has licensed all the pharmaceutical companies visited by the audit team
ii. FDA monitored activities of pharmaceutical companies to ensure that they comply with approved manufacturing procedures
iii. FDA has not registered the medicines of some pharmaceutical companies
iv. FDA needs to strengthen its control systems on the importation of medicines
v. FDA needs to improve the management of detained medicines, and
vi. FDA needs to strengthen its collaboration with other border agencies to monitor and control the importation of medicines.

FDA has licensed all the pharmaceutical companies visited by the audit team

5. Section 131(1) of the Public Health Act (Act 851) 2012, requires that FDA shall issue manufacturing license for pharmaceutical companies. Section 115(1b)

states that, a person can only manufacture a drug under conditions specified in the guidelines of the Authority to ensure that the drug will be of good quality and safe for use.

6. We reviewed FDA's annual audit reports and found that, it had inspected and licensed all the 39 local pharmaceutical manufacturers to operate in the country. We also found that 18 out of 39 pharmaceutical companies had their licences renewed by FDA at the time of the audit.

FDA monitored activities of pharmaceutical companies to ensure that they comply with approved manufacturing procedures

7. FDA is expected to monitor activities of the pharmaceutical companies through GMP inspections to ensure that qualified personnel are used in production and medicines are stored under suitable conditions. FDA is also expected to carry out quality assurance audits to ensure that manufacturers conform to good distribution practices.

8. The audit team's review of monitoring reports showed that FDA conducted routine inspection on all manufacturers once every year while unannounced audits were done when FDA deemed it necessary. For instance, the audit team through document review noted that, on 12June 2012, a team from FDA conducted a routine inspection at the manufacturing facility of African Global Pharma Limited.

FDA has not registered the medicines of some pharmaceutical companies

9. Section 118(1) of the Public Health Act, (Act 851) 2012 expects FDA to ensure that no pharmaceutical company manufactures, prepares, imports, exports, distributes or exhibits for sale a drug, unless it has been registered by the FDA. Section 118(7a) of the Act states that, where the Authority approves the registration of a drug, it shall enter in the register the prescribed particulars of the drug; to ensure that only qualified and evaluated medicines are made available to the general public. In the situation where the samples do not meet the required safety and quality standards, FDA withdraws them.

10. We reviewed the drug list of 18 pharmaceutical companies out of the 39 operating in the country and compared it with the Drug Register of FDA and found that the following drugs; Griseofalun Suspension, Albendazole 500mg Tablet, Keltabs (Prednisolones) and Metronidazole + Furazolidone Suspension (100ml)) were not on FDA's register. FDA officials at the Drug Registration and Evaluation Department informed the audit team that, any medicine not found on its drug register is not registered and should therefore not be produced and distributed by pharmaceutical companies. However, the Drug Enforcement Unit did not identify and halt the production of the medicines listed.

Recommendations

11. We recommend that FDA should:

- Identify and stop all pharmaceutical companies producing unregistered medicines.
- Identify and withdraw all unauthorised medicines from the market immediatelyand apply the appropriate sanctions to the defaulting pharmaceutical companies.

FDA needs to strengthen its control systems on the importation of medicines

12. According to Section 131 of the Public Health Act (Act 851), 2012, FDA must issue importation licences to firms authorising them to operate as importers. FDA guidelines on importation also states that a licensed importer must obtain product import permit before importing any product into the country.

13. FDA's import control systems allow medicines to arrive at the ports before importers apply for import permit. The registration statuses of imported consignments are therefore verified only after the consignments have arrived at the ports. This has led to unregistered medicines easily entering the Ghanaian market through the designated ports of entry. Twenty-five of the 30 licensed importers interviewed by the audit team confirmed that, they apply for permit after arrival of consignments to clear them. FDA officials however told the audit team that the instituted procedure is to grant the permit as part of clearance procedures.

This however does not agree with their guidelines which state that product import permit should be obtained before importing the products.

Recommendation

14. We recommend that FDA should:

- verify the registration status of consignments importers want to import by ensuring that they obtain import permit before bringing in the consignments
- communicate the directives on importation of medicines to all pharmaceutical importers, and
- sanction importers that flout the laws on importation and order immediate re-exportation of consignments that arrive at the ports without permit to discourage the practice.

FDA needs to improve the management of detained medicines

15. World Health Organization (WHO) guidelines require that, a country's regulatory body ensures the security of medicines detained in the course of their regulatory work. It is expected that the FDA has measures in place that effectively secures detained medicines picked from Post Market Surveillance (PMS) and destination inspections at the ports. This is to ensure that the regulatory authority conducts further checks on suspected non-conforming products.

16. Review of Post-Market Surveillance (PMS) documents by the audit team revealed that on 27 November 2013, the Drug Enforcement Department of FDA found through inspections that medicines previously detained under seizure notice at a client's warehouse had reduced in stock. FDA officials told the audit team that the pharmaceutical companies whose detained medicines were found to have reduced in stock were fined by the authority. However, FDA was unable to provide the audit team with the total amount realised from fines within the period under review.

Recommendations

17. We recommend that FDA should:

- issue a directive to pharmaceutical companies requiring them to demarcate separate areas within their warehouses, accessible to only the FDA, where detained medicines should be kept
- dedicate rooms within their office premises across the country to keep and secure detained medicines, and
- negotiate with owners of private warehouses to hold detained medicines at a cost to the defaulting company or individual under regulated temperatures.

FDA needs to strengthen its collaboration with port agencies to monitor and control the importation of medicines

18. According to FDA's Strategic Plan (2007-2011), FDA has planned to enhance collaboration with border agencies at the entry ports of the country to monitor and control medicines imported into the country. To ensure effective collaboration, we expect the FDA to have a Memorandum of Understanding that defines how FDA works with the border agencies to monitor and control importation of medicines at the entry points.

19. The team's review of FDA's strategic plan showed that, it has not outlined specific activities that it intends to carry out to strengthen collaboration with all agencies at the entry points. There was some form of collaboration between the FDA and border agencies at some ports and border posts, however, at border post where FDA had no presence the audit team did not find evidence of collaboration between FDA and other border agencies.

Recommendations

20. We recommend that FDA should:

- have a Memorandum of Understanding (MOU) which formally guides their collaboration with the other border agencies

- instruct its regional officials to hold regular meetings with officers of other border agencies at border posts in the region where FDA officials are not at post to address emerging challenges, and

- develop a strategy involving all relevant border agencies to combat the importation of counterfeit and substandard medicines.

CHAPTER ONE
INTRODUCTION

1.1 Reasons for the audit

The Advance Learner's Dictionary defines medicine as a substance that is used in treating diseases or relieving pain and that is usually in the form of a pill or a liquid. Access to safe and quality medicine makes economic sense for a developing country like Ghana that needs a healthy workforce to build its economy. However, according to the World Health Organization (WHO), counterfeit drugs could make up as much as half of the global pharmaceutical markets, with the largest share circulating in the developing world where regulation and enforcement capacity is comparatively weak.[1] This has the potential of negatively affecting the economic development of these countries.

2. In Ghana Food and Drugs Authority (FDA) is the body mandated by the Public Health Act, Act 581 (2012) to regulate medicines on the Ghanaian market. In recent times, there have been reports by both the print and electronic media on an increasing number of medicines on the Ghanaian market being substandard and counterfeit.

3. A report by the International Policy Network (IPN) titled, "Combating the spread of fake drugs in poor countries" revealed that fake tuberculosis and malaria drugs alone are estimated to kill 700,000 people yearly in developing countries, including Ghana. Myjoyonline.com on 10 March 2013 reported that, Food and Drugs Authority (FDA) had uncovered widespread fraud by three giant Ghanaian pharmaceutical companies that has put the lives of millions at risk of real fatality[2].The three companies imported three brands of medicines: Oxytocin, Ecogormetrine and Quinine injections, which according to the Authority when given to women would fail to control bleeding after child delivery and could result in death.

[1]World Health Organization, "Combating counterfeit drugs: A concept paper for effective international cooperation," 27 January 2006, p.3.
[2]www. myjoyonline.com

4. Also, a study carried out by Professor Ofori-Kwakye and Mariam El-Duah[3]found that 14 of 17 (82.4%) sampled Artesunate tablets sold in pharmacies in Kumasi failed to meet European Pharmacopeia[4]content requirements. The Minister of Health at a workshop on 26th March 2013 indicated that, the illegal trade in counterfeit medicines in Ghana is assuming a threatening dimension.[5]This could in the long term lead to the loss of public confidence in the health system.

5. The Auditor-General, in line with section 13e of the Audit Service Act, Act 584, 2000, carried out a performance audit to find out whether FDA's measures to control importation and manufacture of medicines has ensured that medicines on the Ghanaian market are safe and meet the required quality standards.

1.2 Purpose, Scope, Audit Questions and Assessment Criteria

1.2.1 Purpose and Scope

6. The purpose of the audit was to find out whether FDA's measures put in place to regulate the importation and manufacture of medicines on the Ghanaian market ensure that medicines are safe and meet the required quality standards for use by the public.

7. We focused on FDA's activities to license, register, collaborate with border agencies (Customs Excise and Preventive Service and Ghana Immigration Service) and undertake quality assurance procedures to ensure that imported and locally manufactured medicines on the Ghanaian market are safe and meet the required quality standards.

8. The audit team focused the study on four regions of Ghana, namely: Greater Accra, Volta, Ashanti and the Brong-Ahafo regions.

[3]Senior lecturers of the Department of Pharmaceutics (Kwame Nkrumah University of Science and Technology), published in the*49 edition of the Vector Borne Dis Journal (pp.131–139) on September 2012*

[4]A set of published standards for the composition and quality of medicinal substances.

[5] Ghana News Agency (27th March 2013)

9. The audit covered the period 2010 to 2013 and was carried out from June 2013 to March 2014.

1.2.2 Audit Questions and Assessment Criteria

10. The questions that the audit sought to answer and the criteria upon which the performance of FDA was assessed are detailed in Appendix A.

1.3 Methods and Implementation

11. The team selected Greater Accra, Volta, Brong-Ahafo and Ashanti regions for the study. Volta and the Brong-Ahafo regions were selected because of the high risk of entry of counterfeit and substandard medicines into these regions through the country's borders from neighbouring countries. Greater Accra and Ashanti regions were selected because together they have 32 of the 39 manufacturing pharmaceutical companies that exist in the country.

12. The methods used in the collection of data were document review, physical inspection and interviews.

1.3.1 Document reviewed

13. The team reviewed documents to gather evidence on the measures FDA has put in place to achieve its objectives and the extent of achievement of those objectives. Appendix B shows the documents reviewed and the reasons for reviewing them.

1.3.2 Interviews

14. We interviewed 14 key personnel at FDA's head office and regional offices. This was to enable us gather information and evidence on the activities of these personnel in ensuring that medicines on the Ghanaian market are safe for consumers and meet the required quality standards. We also interviewed officials of 18pharmaceutical companies to gather information on how they register their products and carry out quality assurance procedures. The audit team further interviewed officials of 30 pharmaceutical importers whose products constitute more than 80% of

all medicines imported into the country. We also interviewed officials of Customs Excise and Preventive Service (CEPS) and Ghana Immigration Service (GIS) to gather information on the kind of collaboration they have with FDA in controlling importation at the ports of entry into the country and if the efforts have yielded positive results. See Appendix C for the list of officials interviewed and the reasons for interviewing them.

1.3.3 Physical Inspection

15. The audit team inspected manufacturing premises to assess conditions under which medicines are manufactured. We also inspected warehouses of pharmaceutical importers and manufacturers to ascertain conditions under which medicines are kept. The audit team inspected FDA's offices to gain insight into how medicines seized through its PMS activities are stored.

CHAPTER TWO

DESCRIPTION OF THE AUDIT AREA

2.1 Background

16. Medicines are used to prevent, cure or manage diseases. Access to safe and quality medicines is very vital because of its direct effect on the health of the user. World Health Organisation (WHO) has estimated that 25% of all the medicines in developing countries are counterfeit.[6] WHO defines a counterfeit medicine as one that is "deliberately and fraudulently mislabelled with respect to identity and/or source," and substandard drugs as, "genuine drug products which do not meet quality specifications set for them[7]".

17. FDA is the body responsible for regulating medicines on the Ghanaian market. Before 1990, the regulation of drugs and the practice of pharmacy profession were under the Pharmacy and Drugs Act (Act 64) 1961. In 1992, the Food and Drugs Law 1992 (PNDCL 305B) was enacted to control the manufacture, importation, exportation, distribution, use and advertisement of food, drugs, cosmetics, chemical substances and medical devices. The Food and Drugs Law 1992 (PNDCL 305B) has since been replaced by the Public Health Act 2012 (Act 851) which upgraded the Food and Drugs Board (FDB) into an Authority.

18. FDA registers, licenses, undertakes post-market activities, control importation, undertakes quality assurance procedures and sensitises the general public to ensure that medicines on the Ghanaian markets are safe and meet the required quality standards.

2.1 Statutory Mandate

19. The Public Health Act (Act 851) 2012, puts the control of, the manufacture, importation, exportation, distribution, use and advertisements of food, drugs,

[6] http://www.who.int/mediacentre/factsheets/2003/fs275/en/

[7] Counterfeit Drugs and National Security, Brian D. Finlay (2011),

cosmetics, medical devices and household chemicals under the purview of the FDA with respect to ensuring their safety, quality and efficacy.

2.2 Vision

20. The vision of the Food and Drugs Authority is to become a centre of excellence in food and drug regulatory affairs on the African continent.

2.3 Mission

21. The Food and Drugs Authority aims to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy, and quality for all food, drugs, cosmetics, household chemical substances and medical devices that are locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the law regulating food and drugs in force in Ghana.

2.4 Objectives

22. The objectives of FDA are to:

- ensure that importers obtain import permit before they import medicinal products into the country
- ensure that all medicines locally manufactured, imported and exported are registered to ensure their safety, efficacy and quality
- ensure that all local manufacturers of medicines are licensed and their operations conform to current codes of Good Manufacturing Practices (GMP)
- liaise with Port Officers and offices to monitor drugs and other products donated, imported or exported, and
- enforce quality assurance systems in the industry.

2.5 Activities

23. To ensure that medicines on the Ghanaian market are safe and meet the required quality standards, FDA undertakes the following activities through its various units and departments:

a. Register all medicines

FDA registers all medicines prior to their manufacture, or importation into the Ghanaian market. Registration certificates are issued for each product, after passing a set of prequalification procedure and may be renewed by FDA after three years.

b. License all pharmaceutical companies

FDA licenses all manufacturers of pharmaceuticals in the country. This is done after Good Manufacturing Practice (GMP) audit. This audit is re-conducted each year as a pre-condition for the mandatory annual renewal of the manufacturing license.

c. Control importation of medicines

FDA liaises with port officers to monitor medicines imported into the country. It is also responsible for the issuance of import permits which authorises importers of pharmaceutical products to import registered products.

d. Post Market Surveillance

Drug Enforcement Department of FDA carries out post-market surveillance of medicines that have been given market authorisation or are in distribution on the Ghanaian market. The purpose is to check and take action on non–compliant medicinal products on the Ghanaian market.

e. Quality Assurance

FDA through its departments and unitsundertakes activities to ensure that all medicines manufactured and distributed in the country meet their approved standards. FDA also monitors the activities of pharmaceutical companies to ensure that they comply with approved manufacturing procedures.

2.6 Organisational Structure

24. FDA is governed by a 14 member board with membership drawn from various stakeholder bodies. The Chief Executive takes executive responsibility for operational management, service delivery and strategic issues of the FDA Ghana.

25. Under the Chief Executive are five Specialised Divisions headed by Deputy Chief Executives, namely; Food Safety Division, Food Inspectorate Division, Cosmetics, Medical Devices and Household Chemicals Division, Drug Registration and Inspectorate Division and Safety Monitoring and Clinical Trials Division.

26. The five specialised divisions have units that reports to their respective Deputy Chief Executives. The following departments and units however report directly to the Chief Executive: Import and Export control Department, Laboratory Service Department, Regional Offices Internal Audit Unit, Public Education and Communications Unit, Human Resource Unit, Project, Research and Management Information System Department, Finance Department and Administration Department. The organisational structure of FDA is attached as Appendix D.

2.7 Funding

27. Activities of FDA are funded by Government of Ghana (GoG) and Internally Generated Fund (IGF). Financial information received by the audit team is shown in Table 1.

Table 1: Financial Information of FDA from 2010 to 2013

YEARS	2010	2011	2012	2013	TOTAL
GOG Subvention	593,981.00	3,891,482.00	10,716,420.00	11,504,071.00	**26,705,954.00**
IGF Retained (50%)	4,504,851.00	6,283,819.50	7,036,147.00	10,554,494.00	**28,379,311.50**
TOTAL	5,098,832.00	10,175,301.50	17,752,567.00	22,058,565.00	**55,085,265.50**
Service Expenditure	2,379,926.00	2,919,324.00	6,344,205.00	5,249,847.00	**16,893,302.00**

IGF	9,009,702.00	12,567,639.00	14,072,294.00	21,108,988.00	**56,758,623.00**

Source: FDA Finance & Administration Department (Compiled in 2015)

28. From Table 1, the FDA received a total of GH¢26,705,954.00 from Government and also retained a total of GH¢28,379,311.50 of its Internally Generated Funds (IGF) over the period 2009 to 2013. An amount of GH¢16,893,302.00 of total receipts was spent on service activities which include regulatory activities on medicines.

2.8 Key Players and their activities

29. The key players and their activities with respect to ensuring safety and quality of medicines on the Ghanaian market are shown in Appendix E.

2.9 Process Description

28 The process description regarding licensing of pharmaceutical companies, registration of medicines, controls on importation of medicines, post-market activities and quality assurance are provided as Appendix F to the report.

CHAPTER THREE

FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

3.1 Introduction

30. To ensure medicines on the Ghanaian market are safe and meet the required quality standards, FDA licenses local manufacturers, registers all products, controls the importation of medicines and undertakes quality assurance procedures. It also carries out Post Market Surveillance (PMS) activities to ensure that products already on the market have met the quality standards.

31. The audit was carried out to determine whether FDA is able to regulate importation and local manufacture of medicines to ensure that medicines on the Ghanaian market are safe and meet the required quality standards.

32. The audit team concluded on the following findings:

- FDA has licensed all the pharmaceutical companies visited by the audit team
- FDA monitored activities of pharmaceutical companies to ensure that they comply with approved manufacturing procedures
- FDA has not registered the medicines of some pharmaceutical companies
- FDA needs to strengthen its control systems on the importation of medicines
- FDA needs to improve the management of detained medicines, and
- FDA needs to strengthen its collaboration with other border agencies to monitor and control the importation of medicines.

3.2 FDA has licensed all the pharmaceutical companies visited by the audit team

33. Section 131(1) of the Public Health Act (Act 851), 2012states that, FDA shall issue manufacturing license for pharmaceutical companies. Section 115(1b) states that, a person can only manufacture a drug under conditions specified in the guidelines of the Authority to ensure that the drug will be of good quality and safe for use. Section 132 also empowers FDA to order the closure of any premises where drugs are manufactured, stored or prepared, if the Authority has reason to believe that

the drugs are exposed to the risk of contamination or deterioration and to take further action appropriate in the circumstances.

34. We found that FDA annually assessed and renewed the licenses of pharmaceutical companies that applied for licenses. The team reviewed FDA's annual audit reports and found that, it had inspected and licensed all the 39 local pharmaceutical manufacturers to operate in the country. We also reviewed GMP reports for the pharmaceutical companies from 2010 to 2013. The reports showed FDA annual assessment of the premises, production processes, and equipment, sanitation and quality control procedures of the pharmaceutical companies were carried out prior to the issuance of the licenses. We also inspected the manufacturing licenses of 18 out of the 39 pharmaceutical companies and confirmed that FDA renewed their manufacturing licenses annually. Table 2 shows examples of pharmaceutical companies and licences issued by FDA.

Table 2: Examples of Pharmaceutical Companies and their licences

Company Name	**Licences Number**
African Global Pharmaceutical Ghana Ltd	PPM 13/1034
Trade Winds Chemists	PPM 13/1031
PokuPharma Ltd.	PPM 13/1033
Salom Pharmacy Ltd	FDB/RPI/0029/11
Amponsah-Effah Pharmaceutical Ltd	FDB/RPI/0010/11

Source: Audit Team's Compilation, 2013

3.3 FDA monitors activities of pharmaceutical companies

35. To ensure that pharmaceutical companies comply with the approved manufacturing procedures, FDA is expected to monitor activities of the pharmaceutical companies through Good Manufacturing Practices[8](GMP) inspections

[8] GMP: It is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate for their intended use.

which include ensuring that qualified personnel are used in production and medicines are stored under suitable conditions. GMP inspections are to be carried out once annually on each pharmaceutical company.

36. The team interviewed FDA officials and reviewed monitoring reports, and found that FDA monitors the activities of pharmaceutical companies through GMP inspections and quality assurance audits. Review of monitoring reports by the team showed that FDA conducts routine and unannounced audits (inspection) on all manufacturers. The GMP audits were done once every year, whiles the unannounced audits were done when FDA deemed it necessary.

37. Our review of GMP Inspection Reports showed that FDA reviewed documents on production done by the pharmaceutical companies, documents on the qualification of personnel used in production of medicines, inspected manufacturing sites, warehouses of the pharmaceutical companies and made recommendations to the manufacturers. FDA does follow-ups to ensure the recommendations are implemented before licenses are renewed. This was confirmed through review of audit reports at pharmaceutical companies visited by the audit team.

38. For instance, the audit team through document review noted that on 12 June 2012, a team from FDA conducted a routine inspection at the manufacturing facility of African Global Pharma Limited.

3.4 FDA has not registered medicines of some licensed pharmaceutical companies

39. Section 118 (1) of the Public Health Act, (Act 851) 2012expects FDA to ensure that no pharmaceutical company manufactures, prepares, imports, exports, distributes or exhibits for sale a drug, unless it has been registered by the FDA. Further, Section 118 (7a) of the Act states that, where the Authority approves the registration of a drug, it shall enter in the register the prescribed particulars of the drug and the relevant conditions. This is to ensure that only qualified and evaluated

medicines are made available to the general public. FDA's Post Surveillance Unit is also expected to carry out routine post market activities that should identify unregistered medicines on the market.

40. We reviewed the drug lists of 18out of the 39 pharmaceutical companies operating in the country and compared it with the Drug Register of FDA as at 30 May 2014 and found that drugs shown in Table 3 were not in FDA's drug register. FDA officials at the Drug Registration and Evaluation Department informed the audit team that, any medicine not found on its drug register is not registered and should therefore not be produced and distributed by pharmaceutical companies. Table 3 shows 12 medicines from five pharmaceutical companies which were not found in the FDA's Drug Register as at 30 May 2014.

Table 3: Medicines in the Drug List of some Pharmaceutical Companies which were not found in FDA's Drug Register as at 30 May 2014

No.	Pharmaceutical Company	Name of Medicine
1.	Midland	Griseofalun Suspension Hydrogen Peroxide
2.	Geo Medicore	Albendazole 500mg Tablet
3.	AmponsahEffah	Keltabs (Predmisolone)
4.	GR Industries	Clomox G Cream (Triple Action Cream) Metronidazole + Furazolidone Suspension (100ml)
5.	Letap	Tetracyllin 250mg Blister OxytetracyclineHCl 250mg Capsule Letamox Suspension 60ml Cough & Cold Syrup 100ml Chloramphenicol 250mg Capsules Amoxycillin Suspension 100ml

Source: Product List of Pharmaceutical Companies, 2014

41. FDA officials confirmed that all the medicines shown in Table 3were not on their drug register as at 30 May 2014. Officials of the pharmaceutical companies selected, informed the audit team that the products which were not listed on FDA's drug register were either pending full registration or have been submitted for

registration. The team sought the views of the FDA officials to find out if pharmaceutical companies can begin production of products pending full registration. In response, the team was told that only medicines approved and registered are allowed to be produced and sold in the market. This could mean that, these medicines are being manufactured without FDA's certification and our checks showed similar medicines on the market. However, we were unable to ascertain whether they were from the same pharmaceutical companies. Medicines pending registration or submitted for renewal of registration may not meet FDA's quality standards and therefore such medicines can be harmful to consumers.

42. Through interviews, the team also found that FDA's Drug Enforcement Unit (DEU) has been carrying out monitoring activities within the facilities of the pharmaceutical companies as well as on the market. These activities were carried out on daily basis throughout the year. However, the DEU did not identify and halt the production of the medicines listed in Table 3as at the time of the audit.

43. We are of the view that the differences between the medicines on FDA's drug register and the drug list of pharmaceutical companies is due to FDA's inability to regularly update its drug register. Since FDA's drug register serves as a monitoring tool for PMS, a register which is not regularly updated implies that FDA is unable to effectively regulate medicines on the market.

Conclusion

44. Although FDA had licensed all the pharmaceutical companies sampled by the audit team, some of the medicines of these companies were not registered. FDA might not have tested these medicines to ensure their safety and quality for public consumption.

Recommendations

45. To ensure that all medicines are registered, we recommend that FDA should:

- identify and stop all pharmaceutical companies producing unregistered medicines, and
- identify and withdraw all unauthorised medicines from the market immediatelyand apply the appropriate sanctions to the defaulting pharmaceutical companies.

FDA's Response

46. Local manufacturers are to submit samples of the products they intend to manufacture with all the necessary documentation to the FDA for evaluation before they are given marketing authorisation to manufacture and sell those products. The FDA will like to state that when unregistered products are found through its Post Market Surveillance activities manufacturers of these products are sanctioned according to the Public Health Act, Act 851. However products which have expired registration may be found on the market since they might have been put on the market before the expiration of the validity of the registration. The FDA in reviewing the list of medicines from local manufacturers cited in Table 3 of the report as not found in FDA's Drug Register as at 30 May 2014 noted a number of inaccuracies and these are stated in the remarks below. We hope you would amend your records accordingly to reflect the true situation in this matter.

Table 3a: Sample of Medicines in the market and which are found in FDA's Drug Register as at 30 May 2014

No.	Pharmaceutical Company	Name of Medicine	FDA's Remarks
1.	AmponsahEffah	Keltabs (Predmisolone)	Registered: FDB/GD. 03-8114
2.	DelmaPharma	Carbodel Adult Syrup (Carbocisteine Syrup 250mg/5ml) Carbodel Infant Syrup (Carbocisteine Syrup 100mg/5ml)	Registered: FDB/SD. 143-5564 Registered: FDB/SD. 113-85
3.	GR Industries	Clomox G Cream (Triple Action Cream) Metronidazole+Furazolidone Suspension	Registered: FDB/SD. 143-5564 Registered: FDB/SD. 113-8530
4.	Letap	Oxytetracycline HCI 250mg Capsule Letamox Suspension 60ml Cough & Cold Syrup 100ml Chloramphenicol 250mg Capsules Amoxycillin Suspension 100ml	Registered: FDB/GD. 083-10157 Registered: FDB/SD. 03-2045 No product with this name Registered: FDB/GD. 03-1018 Registered: FDB/GD. 083-10152

Source: Field Survey, 2014

Auditor's Comment

47. We requested and obtained FDA's drug register as of 30 May 2014, which was attached to a letter with reference number FDA/DER/SMER/01/06-14/M6, which captured the registration status of the medicines as registered, pending or expired. The list of medicines in Table 3 was not found in the register provided. However, FDA in its response to the draft audit report, dated 17 February 2015 with reference number FDA/DRID/DED/PMS/15/0217, stated the drugs were registered. This statement is not consistent with the list of medicines in the FDA's drug register provided the audit team on 30 May 2014.

3.5 FDA needs to strengthen its control systems on importation of medicines

48. According to Section 131 of the Public Health Act (Act 851), 2012, FDA must issue importation licences to firms authorizing them to operate as importers. FDA

guidelines on importation also states that a licensed importer must obtain product import permit before importing any product into the country.

49. We found from review of the documents trail of the importation control system and interviews of officials at the Import, Export Controls Department of FDA that a prospective importer obtains a license to operate as an importer, which is renewable annually. An importer wishing to import a particular medicine must obtain samples from its agents abroad and submit them together with the required documentation (dossiers) to FDA for registration. The product is entered into a register of authorised drugs kept by FDA. The importer then brings in consignments of the product and applies for import permit before the products are inspected and cleared. Appendix G shows some medicines that arrived at the ports before permit were applied for.

50. When an importer brings in unregistered products, FDA issues a detention notice, restraining the importer from use of the product while being kept at the importers warehouse pending further regulatory action. The importer is fined an administrative charge and allowed to go through the product registration process. When the products are found not to be of the required quality, FDA supervises their destruction following safe disposal procedures.

51. The prevailing system of importers applying for permit when consignments arrive at the ports, presents a high risk of unauthorised medicines entering the country. This is because the permit acquisition process, which is a control measure to confirm product registration, is done after products have already reached Ghana's ports. The audit team found through review of import documents that various unregistered medicines were imported into the country between 2012 and 2013 as shown in Appendix H. These medicines which were brought in by licensed importers could have been prevented from entering the country if it was mandatory for importers to obtain import permit before importing consignments

52. Twenty-five of the 30 licensed importers interviewed by the audit team confirmed that, they apply for permit after arrival of consignments to clear them. These importers informed the audit team that, import permit could be obtained at any time before clearance at the ports and that it has been the custom to apply for permits after consignments have arrived at the ports. However, the remaining five importers sampled informed the audit team that they obtain import permit before importing their products into the country.

53. FDA officials however told the audit team that the instituted procedure is to grant the permit as part of clearance procedures. This however does not agree with their guidelines which state that product import permit should be obtained before importing the products.

Conclusion

54. FDA's import control systems allow medicines to arrive at the ports before importers apply for import permit. The registration statuses of imported consignments are therefore verified only after the consignments have arrived at the ports. This has led to unregistered medicines easily entering the Ghanaian market through the designated ports of entry. Appendix G shows a list of unregistered medicines that entered the Ghanaian market.

Recommendations

55. To strengthen controls on the importation of medicines, we recommend that FDA should:

- verify the registration status of consignments importers want to import by ensuring that they obtain import permit before bringing in the consignments
- communicate the directives on importation of medicines to all pharmaceutical importers, and
- sanction importers that flout the directives and order immediate re-exportation of consignments that arrive at the ports without permit to discourage the practice.

FDA's Response

56. In its response, FDA quoted Section 122. (1) of the Public Health Act, Act 851 which states that "A person who has not been issued with a licence or permit under this Part, shall not import a drug, herbal medicinal product, medical device, cosmetic or household chemical substance."

Auditor's Comment

57. FDA's response neither addresses the issues raised nor the recommendations made in the report. The audit found a flaw in the system as it exists currently which increases the risk of unregistered medicines finding their way into the Ghanaian market. The only time the registration status of in-bound consignment is checked is when the importer applies for permit to clear medicines. At which point they have already arrived at the port. This weakness in the importation control system led to various unregistered medicines entering the country.

3.6 FDA needs to improve the management of detained medicines

58. World Health Organization (WHO) guidelines[9]require that, a country's regulatory body ensures the security of medicines detained in the course of their regulatory work. It is expected that the FDA has measures in place that effectively secures detained medicines picked from Post Market Surveillance (PMS) and destination inspections at the ports. This is to ensure that the regulatory authority conducts further checks on suspected non-conforming products.

59. The audit team's review of PMS documents and interaction with FDA officials showed that FDA keeps detained medicines at clients' own warehouses under seizure notices. For instance, review of documents obtained from the Drug Enforcement Department (DED) of the FDA covering products seized by the Authority in September 2013 showed that 43,895 cartons of medicinal products which were detained by FDA were all kept at the clients' warehouses.

[9]WHO Technical Report Series No. 863, 1996; Annex 12 – Guidelines on Import Procedures for Pharmaceutical Products.

60. Inspections carried out at ten warehouses of the pharmaceutical companies confirmed that FDA keeps detained medicines at the clients' warehouses. According to FDA officials, when medicines are detained they record details of each medicine including its name, quantity and batch numbers. Officials of the Drug Enforcement Department regularly use these details to check if any of the products have reduced in quantity or have been tampered with.

61. The system of keeping detained medicines within the warehouses of pharmaceutical companies limits FDA's control over the medicines and makes them less secure. There has been instances where detained medicines in clients' warehouses have reduced in quantity and have found their way onto the market. For instance, review of PMS documents by the audit team revealed that on 27 November 2013, the Drug Enforcement Department of FDA found through inspections that medicines previously detained under seizure notice at a client's warehouse had reduced in stock. Table 4 shows instances of this claim.

Table 4: Detained Medicines by FDA and the variation in Stock as at27 Nov. 2013

Product Name	Stock on detention Note 6 September 2013 (Cartons)	Stock re-taken on 27 November 2013 Quantity (Cartons)	Difference (Cartons)
Santriax 500	90	27	63
Agycin Suspension	44	2	42
Amovulin	169	29	140
Foligrow	343	77	266
Gudapet Syrup	4260	1813	2447
Kofof Baby	1659	268	1391
Lonart 20/120	2175	458	1717
Today Contraceptive	218	4	214
Lonart Suspension	1740	0	1740
Gvither Forte Injection	870	0	870

Source: PMS Report, November 2013

62. Interview with FDA officials revealed that the pharmaceutical companies whose medicines were found to have reduced in stock were fined by the authority. However, FDA was unable to provide the audit team with the total amount realised from fines within the period under review.

63. Also at FDA's Head Office, the audit team found that FDA uses part of its canteen to store medicines seized through its PMS activities. Keeping seized medicines at the canteen, makes them accessible to unauthorised persons. Interviews with FDA officials showed that, medicines stored under such circumstances in the past have been pilfered. Picture 1 which was taken as at the time of the audit, shows FDA's canteen being used as a holding place for medicines seized during its PMS activities. Further, detained medicines are not stored under controlled temperatures as required, so when finally certified by FDA and released unto the market would have lost their efficacy.

Picture 1: Detained Medicines being stored at FDA's canteen

Source: Audit Service and FDA, 13th February 2014

Conclusion

64. FDA is unable to ensure the security of detained medicines picked from PMS and imported consignments. The FDA's use of client's warehouses and the issuance of detention notices have not been sufficient in securing detained medicines. There is still a high risk of such medicines finding their way onto the market.

Recommendations

65. For FDA to improve the security of detained medicines, we recommend that it:

- issues a directive to pharmaceutical companies requiring them to demarcate separate areas within their warehouses, accessible to only the FDA, where detained medicines should be kept
- dedicates rooms within their office premises across the country to keep and secure detained medicines, and

- negotiates with owners of private warehouses to hold detained medicines at a cost to the defaulting company or individual under regulated temperatures.

FDA's Response

66. FDA monitors non-compliant products detained in the premises of importers and distributers. Detention notes issued to that effect are signed by officers of the FDA and the owners of the consignment. Any violation of such detention orders attracts regulatory sanctions. In paragraph (56) and (57) of the drafted report, the list of products are from one particular importer. The importer of the medicines was given an administrative fine for importation and distribution of unregistered medicines and violation of the detention order.

Auditor's Comment

67. FDA's response reiterated its current measures without addressing the issues raised in the audit report nor the recommendations made in relation to those measures. The audit found the measures ineffective in ensuring the security of the detained medicines as large quantities were found missing whiles under FDA's seizure notices.

3.7 FDA needs to strengthen its collaboration with port agencies to monitor and control the importation of medicines

68. According to FDA's Strategic Plan (2007-2011), FDA has planned to enhance collaboration with border agencies at the entry ports of the country to monitor and control medicines imported into the country. To ensure effective collaboration, we expect the FDA to have a Memorandum of Understanding that defines how FDA works with the border agencies to monitor and control importation of medicines at the entry points. FDA is also expected to plan and hold regular stakeholder meetings and training sessions to coordinate efforts and device strategies to deal with emerging trends on smuggling in of substandard and counterfeit medicines.

69. The team's review of FDA's strategic plan showed that, it has not outlined specific activities that it intends to carry out to strengthen collaboration with all agencies at the entry points. The audit team found some form of collaboration

between the FDA and border agencies at some ports and border posts. However, at border post where FDA had no presence the audit team did not find evidence of collaboration between FDA and other border agencies. An example is the Sampa Border Post where FDA had no presence. Document reviewed also showed no evidence of a memorandum of understanding between FDA and any of the border agencies that binds them to effectively work together at the ports of entry. FDA could not provide the audit team with documentation proving it has been actively collaborating with other agencies through mediums such as forums, meetings and seminars. For instance, at the Sampa Border Post, the GIS and CEPS officials informed the audit team that there has not been any formal meeting with FDA officials and they do not have the contact details of FDA.

70. FDA officials informed the audit team that, they do not have a memorandum of understanding with any of the border agencies. This is because they expect that as part of their statutory mandate, FDA should collaborate with the border agencies in monitoring and controlling the importation of medicines.

71. Lack of collaboration has resulted in FDA not being able to coordinate with other border agencies to develop strategies to monitor and control importation of medicines at the entry points. Consequently, there is a risk that the FDA will not be informed by border agencies on occurrences and emerging trends at the ports of entry in order to devise effective strategies to combat the entry of substandard and counterfeit medicines into the country.

Conclusion

72. The audit team found no memorandum of understanding, activity plans as well as evidence of meetings and seminars which will enable the FDA and other port agencies to effectively work together. This, in the audit team's opinion reduces the FDA's ability to collaborate effectively with border agencies to monitor and control the importation of medicines at the entry points.

Recommendations

73. To strengthen collaboration with border agencies FDA should:

- have a Memorandum of Understanding(MOU) which formally guides their collaboration with the other border agencies
- instruct its regional officials to hold regular meetings with officers of other border agencies at border posts in the region where FDA officials are not at post to address emerging challenges, and
- develop a strategy involving all relevant border agencies to combat the importation of counterfeit and substandard medicines.

FDA's Response

74. The FDA will like to state that there is a strong collaboration between it and CEPS at all designated entry points (Tema Port and KIA) through which medicines are imported. FDA still looks for further ways of strengthening this collaboration with all relevant stakeholders. An inter-agency committee on medicines of compromised quality is being formed in furtherance of the collaboration.

Auditor's Comment

75. FDA's response does not address the issues raised in the report. The audit team found no evidence of collaboration within the period under review at the border posts where FDA was not present. Thus our recommendations were targeted at increasing collaboration at these border posts. The audit acknowledged the fact that FDA has collaboration with CEPS and other border agencies at the entry ports where they are stationed.

3.8 Overall Conclusion

76. FDA has developed and implemented control measures to ensure that medicines are safe and meet the required quality standards. The audit found that FDA is effectively carrying out its manufacturing licensing and monitoring activities to ensure that medicines are produced under approved procedures and to required standards.

77. However, the following challenges make us conclude that FDA has not been effective in ensuring that the medicines on the market are safe and of good quality. FDA has challenges in the system of control of importation, the management of the security of detained medicines, and the collaboration with other border agencies to control the entry of medicines into the country. The audit also found some medicines on the market which were not registered and were not found on FDA's data base.

APPENDICES

Appendix A

Appendix A- Audit Questions and Assessment Criteria

a. Has FDA licensed all pharmaceutical companies?

Criteria: Section 131 (1) of the Public Health Act (Act 851), 2012states that, FDA shall issue manufacturing license for pharmaceutical companies. Further, Section 115 (1b) states that, a person can only manufacture a drug under conditions specified in the guidelines of the Authority to ensure that the drug will be of good quality and safe for use.

b. Does FDA monitor activities of pharmaceutical companies to ensure that they comply with approved manufacturing procedures?

Criteria: FDA is expected to regularly inspect conditions under which medicines are produced to ensure that they conform to GMP; check if personnel engaged in drug production are appropriately qualified, review production documentations, conduct laboratory testing of batch samples, ensure manufactured medicines are stored under suitable conditions and ensure that manufacturers adhere to good distribution practices.

c. Did all registered medicines of pharmaceutical companies meet FDA's safety and quality standards?

Criteria: According to Section 118 (1) of the Public Health Act, (Act 851) 2012, a person shall not manufacture, prepare, import, export, distribute or exhibit for sale a drug, unless it has been registered by the Authority. Further, Section 118 (7a) of the Act states that, where the Authority approves the registration of a drug, the Chief Executive Officer shall enter in the register the prescribed particulars of the drug, and the relevant conditions or particulars.

d. Does FDA's import control systems provide assurance that all medicines are registered before they arrive at the ports?

Criteria: Section 131 of the Public Health Act (Act 851), 2012, FDA must issue importation licences to firms authorizing them to operate as importers. FDA guidelines on importation also states that a licensed importer must obtain product import permit before importing any product into the country.

e. Is FDA able to manage the security of detained medicines?

Criteria: World Health Organisation (WHO) guidelines[10]require that, a country's regulatory body has temporary storage facilities to hold detained medicines picked from Post Market Surveillance (PMS) activities and detained imported medicines. It is expected that FDA ensures the security of the detained medicines. This is to enable the regulatory authority to conduct further checks, including laboratory analysis, verification of product labels, and analysis of product details after physical inspections have been carried out.

f. Has FDA collaborated with other border agencies to monitor and control the importation of medicines?

Criteria: According to FDA's Strategic Plan (2007-2011), FDA has planned to enhance collaboration with border agencies at the entry points to monitor and control medicines imported into the country.

[10]WHO Technical Report Series No. 863, 1996; Annex 12 – Guidelines on Import Procedures for Pharmaceutical Products.

Appendix B - Documents reviewed

Documents reviewed	Reasons for review
1. Public Health Act, 2012 (Act 851)	To know what the mandate and functions of FDA entails
2. Annual Reports of FDA (2008-2012)	To gather information on the activities and performance of FDA over the five year period
3. Quarterly Reports of the Import & Export Control Department of FDA	To gather information on the activities of the department with respect to medicine importation over the audit period.
4. Quarterly Reports of the Drug Enforcement Department of FDA	To gather information on drug enforcement activities of the d**e**partment over the audit period.
5. PMS Reports	To study, analyse and conclude on specific events that took place on PMS visits.
6. Food and Drugs Authority Five Year Strategic Plan (2007-2011)	To know the strategic objectives and plan of FDA.
7. Internal Guidelines and Operational Manuals	To know how FDA carries out its regulatory activities
8. FDA Drug Register	To obtain information on registered medicines and the Pharmaceutical companies that produces or imports them.
9. Product list of pharmaceutical companies	To gather information on the medicines pharmaceutical companies are producing and to compare it with FDA's drug register.
10. Internal Controls Reports (2008-2012)	To know if FDA has prepared a risk profile and has put in place appropriate controls to manage the identified risks.
11. WHO Guideline on Importation Procedures for Pharmaceutical Products	To obtain knowledge on international standards and best practices on importation of pharmaceutical products.
12. Import permits and other documentation on imports	To examine whether set procedures and controls on importation of medicines were adhered to.

Source: Audit Service Compilation (2013)

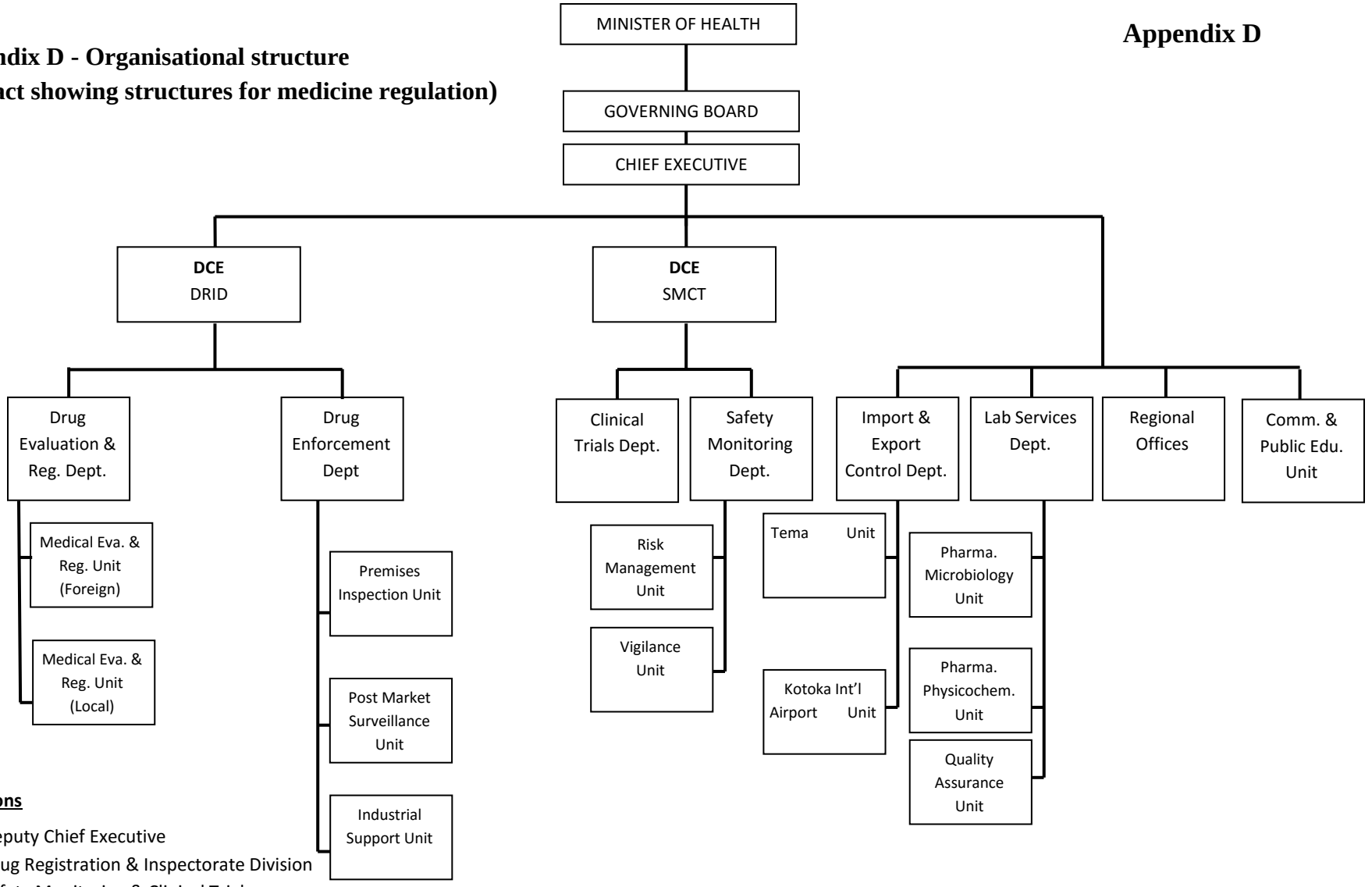
Appendix C

Appendix C- List of Interviewees

Personnel interviewed	Reason
FDA OFFICIALS	
1. **Head of Import and Export Control Department**	To gather information on the regulation of importation of medicines into the country.
2. **Head of Drug Enforcement Department**	To gather information about the post-market surveillance activities to ensure safety of medicines.
3. **Head of GCNet Unit**	To gather information on the issuing of import license to importers of medicines to Ghana.
4. **Head of Drugs Evaluation and Registration Department**	To gather information about the registration of medicines in Ghana.
5. **Head of PMS**	To gather information on FDA's PMS activities.
6. **Head of Premises Inspection Unit**	To gather information about how premises inspection is done.
7. **Head of Internal Audit Unit**	To know how FDA monitor and evaluates the activities of its various departments.
8. **Regional Heads (Greater Accra, Ashanti, Brong-Ahafo and Volta regions)**	To know how FDA regulates activities of pharmaceutical companies at the regions and ports of entry.
9. **Border Post Officers (Aflao, Akanu, Kpoglo)**	To know FDA's activities in relation to regulating importation of medicines at the points of entry.
CEPS Officials 10. **Deputy Commissioner, Operations** 11. **Assistant Commissioners (Tema Harbour, Aflao Border)** 12. **CEPS Chemists (Tema Harbour, KIA)** 13. **Sector Heads (Akanu, Kpoglo, Sampa)**	To know and assess the collaboration between FDA and CEPS in regulating importation of medicines at the points of entry.
GIS Officials 15. **Head of border patrols** 16. **Sector Heads (Aflao, Akanu, Kpoglo, Sampa)**	To know and assess the collaboration between FDA and GIS in regulating importation of medicines at the ports of entry.
Officials of Pharmaceutical companies 17. **Chief Executive Officers** 18. **Heads of Quality Control** 19. **FDA Liaison Officers**	To know how FDA regulates their activities and how they comply with FDA rules.

Source: Audit Service Compilation (2013)

Appendix D - Organisational structure
(Extract showing structures for medicine regulation)



Abbreviations

DCE Deputy Chief Executive
DRID Drug Registration & Inspectorate Division
SMCT Safety Monitoring & Clinical Trials

Appendix E - Key Players and their activities

Key Players	Activities
1. **Drug Evaluation and Registration Department of FDA**	Registration of medicinal products, evaluation of dossier information and issuance of registration certificates.
2. **Drug Enforcement Department of FDA**	Carry out pre and post-licensing inspection of products and drug manufacturing facilities. These functions are performed under three operational units: the Premises Inspection Unit, the Post Market Surveillance Unit and the Industrial Support Unit.
3. **Import and Export Control Department of FDA**	Regulate the importation and exportation of medicines through the various entry routes.
4. **Technical Advisory Committee for Safety Monitoring**	They look at all reports on adverse drug reaction and determine whether a particular drug is the cause of drug reaction.
5. **Ghana Standards Authority**	Cooperates with FDA to ensure adequate and effective standards for the drugs
6. **Pharmaceutical Society of Ghana**	Continuously educate their members on the requirements and regulations of the FDA
7. **Customs Excise and Preventive Services**	Controls the verification and clearance processfor imported drugs and other relate products. .
8. **Pharmaceutical Companies**	Manufacture and import medicines.

Source: Audit Service Compilation (2013)

Appendix F - Process Description

Licensing of pharmaceutical companies

1. FDA issues license to local pharmaceutical companies which enables them to manufacture medicines. Prospective manufacturers apply in writing to the Authority by following guidelines obtained from the FDA. Attached to the application are copies of a site master file (this includes general information on premises, sanitation, equipment, production and quality control), EPA permit, building permit and basic floor plan showing plant installation, submitted with the appropriate fee to the FDA. Upon receipt of the application, a date is scheduled for premises inspection. The application and results of the premises inspection are assessed and this forms the basis of recommendations for approval or disapproval. Upon approval, a manufacturing license is issued to the applicant, which should be renewed annually. Where the application is rejected, FDA writes to the client making recommendations for the shortfalls that must be remedied before re-application.

Registration of medicines

2. Drug Registration and Evaluation Department of FDA is responsible for the registration of medicines of pharmaceutical companies that want to manufacture medicines locally and wholesalers or retailers who intend to import medicines from other countries. Prospective applicants obtain guidelines and registration forms from FDA and are required to prepare and submit a dossier with samples of medicines they intend to manufacture or import. The dossier is submitted to the Client Service Unit of FDA with the client paying the required amount of registration fees.

3. Upon receipt of the registration form, FDA carries out premises inspections to ensure that Good Manufacturing Practices (GMP) are being adhered to. GMP are internationally recognised industry standards of best practice and entails standards for the manufacturing environment, the equipment and infrastructural holdings; the qualification of personnel, etc. A technical team of assessors evaluates the dossier as well as reports of sample tests and GMP audits to ascertain whether an applicant meets the requirements. The assessors present their reports at a meeting to approve,

reject or give a conditional approval to the application. Where an approval is granted, a registration number is given to the applicant and entered into the product register of FDA. The applicant is issued with a certificate of registration which gives authorisation for manufacturing or importation of the registered medicine.

4. Where the application is rejected, the applicant is notified. Registration of medicines takes between 3 to 6 months.

Controls on importation of medicines

5. FDA controls importation of medicines by restricting them to the Kotoka International Airport and Tema Harbour. This is to regulate access points in order to manage the importation of medicines into Ghana.

6. The process of importation starts by the prospective importer applying for import permit through the Ghana Community Network (GCNet) software after registration of the product. This application is vetted by the Premises Inspection Unit, Drug Evaluation and Registration Department and the Import and Export Control Department. The Registration Department verifies the existence of the product on FDA's register. If the application passes the vetting process, a provisional permit is issued through the GCNet. On arrival of medicine consignments, the importer presents the provisional permit to the Import and Export Control Department which conducts a physical inspection of the products and grants a final permit for consignments to be cleared.

7. Where products are found to be non-conforming to the required standards, they are allowed to be cleared under seizure notice, which is a restraining order preventing the owner from selling the products until the FDA has completed any further regulatory action on the consignment. In the event of detection of counterfeit medicines, the public is alerted through a press release by the FDA. The product may be detained for further regulatory actions, destroyed or re-exported.

8. At the entry points where FDA does not have personnel stationed, it relies on other security agencies such as Customs Excise and Preventive Service (CEPS), Ghana Immigration Service and National Security to intercept medicines and alert them.

Post-Market Activities

9. The Public Health Act 851 (2012) prohibits the sale and advertisement of drugs which are unregistered, unwholesome and sub-standard to consumers. In enforcing this law the FDA performs Post Market Surveillance and Safety Monitoring activities.Drug Enforcement Department of FDA carries out post-market activities on medicines that have been given market authorisation or in distribution on Ghanaian market. The purpose is to check and take action on non–compliant medicinal products on the Ghanaian market. The Post Market Surveillance Unit takes samples of medicinal products on the open market and performs laboratory checks to ascertain whether they meet quality and safety standards approved during registration and also checks the validity of the packaging information. Any medicine found not to meet the required safety and quality standards is withdrawn from the market.

10. The FDA monitors the safety of medicines that have received market authorization using two methods; i.e. active and passive surveillance. Active surveillance is based on monitoring and gathering data on a selected number of patients who have used or are using a particular medicine. Passive surveillance on the other hand is where FDA issues reporting forms to health professionals and institutions throughout the country to report on adverse drug reactions (ADR), therapeutic failure and suspected pharmaceutical defects.

11. A Technical Advisory Committee for Safety looks at all reports on adverse drug reaction and determines whether a reported case was caused by the particular drug. A decision is then taken on whether to withdraw the drug, change the package information, limit the use of the drug or write to health professionals to further monitor the effects of those drugs.

Quality Assurance

12. FDA performs quality assurance procedures to ensure that all medicines manufactured and distributed on the Ghanaian market are safe and of the required quality. Quality assurance is not a one-off process but is embedded into all of FDA's regulatory activities. FDA undertakes quality assurance through the under listed processes:

- Registration of Medicines
- Assurance audits
- GMP inspections of manufacturing sites, and
- PMS activities.

Registration of Medicines

13. Samples of medicines submitted by applicants for registration are tested in FDA's laboratory to assess their potency and quality. The Drug Evaluation and Registration Department examines the dossiers submitted by applicants to ensure that information given on samples presented for testing are accurate and meet the required quality standards.

Assurance Audits

14. FDA conducts two types of quality assurance audits on all pharmaceutical companies: the annual audits (where FDA notifies companies) and the unannounced audits. This is to examine documentations on each batch produced during the past year. All pharmaceutical companies are required by the FDA to keep documentations and samples of all batches of medicines manufactured, which are assessed during the audit. FDA after each audit makes recommendations to the pharmaceutical companies in the form of reports which they are expected to implement.

GMP Inspections

15. FDA conducts routine (annual) and special inspections to ensure the adherence by manufacturers to all licensing provisions and specifically to GMP. The objectives are to control and enforce general standards of production and to provide

authorization for the manufacture of specific pharmaceutical products. FDA verifies that production and quality control procedures employed in the manufacture of specific products are performed correctly and that they agree with data supplied in the licensing applications. Routine inspections involve inspecting all applicable components of GMP and licensing provisions. Special inspections are undertaken following complaints from consumers or recalls related to suspected quality defects in products.

PMS Activities

16. The Drug Enforcement Department of FDA ensures quality of all registered products by picking samples from the market and submitting them for testing at the authority's laboratory. The department also follows up on adverse drug reports to detect drugs that do not meet the quality standards.

Appendix G

Appendix G - List of unregistered medicines imported into the country for the period 2012 – 2013

1. Tres-orix	2. Ronfenac
3. Ergomentrine Tablets	4. Oxytocyn injection
5. Elfa-Ergot injection	6. Konvite Plus
7. Lofnac Eye Drops	8. Coartem
9. Bliss Cold	10. Atenolol
11. Promethazin Injection	12. Vitamin K1 Injection
13. Amodiaquine Suspension	14. Procold
15. Quine Syrup	16. Ceta-Ibu
17. Commit Hundred	18. Zentel
19. Ciferol D3 Drops	20. Geditone Syrup
21. Congeno 10ml	22. Clindancyin Tablet
23. Methyldopa Tablet	24. Secindazol Tablet
25. Upron-20 Capsules	26. Lofnac-50 Tablet
27. Gsunate 12Kit	28. Gsunate 200
29. Santriax 500	30. Cal-G Tone Plus
31. Imazole 200-V	32. X'Tone Forte Syrup
33. Ferrous Sulphate Tablets	34. Vital –X Carbonyl Iron Capsules
35. Funbact 30	36. Vomi 10 Suppository
37. Seenagyl Tablets	38. Hyoscine Butyl Bromine
39. Hydro Cortisone Injection	40. Benzyl Penicillin Injection
41. Mucotin	42. Amitone Syrup
43. Demona Eye Drops	44. Pip off Gel
45. Agycin 250 Tablets	46. Amurox-500
47. Ketopron	48. BG-Fenamex Oral Suspension
49. EntrimaClotrimazole Cream	50. BG-Mol
51. Adrenaline	52. Sanfox
53. Frusemide Injection	54. Today (Vaginal Contraceptive)
55. Xonase – Nasal Drops USP	56. Abitos
57. GacetSupp 250mg	58. ATS Injection
59. Plemether (Artemether Injection 80mg/ml)	60. XIPEOD
61. EcozolePess	62. Allsoft Petroleum Jelly
63. Uprone 40mg Injection	64. Uprone 20 Capsules
65. Blopen (Para Diclofe)	66. GVzole Cream
67. Ergomentrine Injection	68. Sanfurus
69. Funbact ZP	70. X'Tone Forte Syrup
71. X'FluxFlucloxacillin Oral Solution BP	72. Ometaz

Source: FDA PMS Document, 2012/2013

Appendix H - Some medicines that were imported through the Tema Port and KIA in 2012 and 2013 before importers applied for permit

No.	Name Of Product	Quantity	Date of Arrival of Consignment	Date Of Application For Import Permit
1.	Ibuprofen	102		
	Mefart Suspension 100ml	106	16/10/2013	31/10/2013
	Cirotamin Caplets	139		
2.	Lexzen Suspension 10ml	15,000	30/11/2012	03/12/2012
3.	Abytab Forte Tablets	23,520		
	Abyworm Tablets	19,250	11/11/2013	25/11/2013
4.	Sodium Chloride 9GM/LT	49,680		
	Compound Sodium Lactate	49,680	21/11/2013	02/12/2013
	Glucose Intravenous Infusion	24,840		
5.	DNS Sodium Chloride	24,840		
	NS Sodium Chloride	24840		
	Intravenous – Infusion 500ml		18/10/2013	30/10/2013
	Compound Sodium Lactale –	49,680		
	Intravenous Infusion			
6.	Neutrosec Liquid 200ml	3887		
	Astyfer Liquid 200ml	352		
	AstyminLiquiid 200ml	4,003	05/11/2012	04/11/2013
	Ferup Syrup 100ml	12,049		
7.	Ronaxicam	468		
	Roncold	634	11/12/2013	11/12/2013

Source: FDA Import & Export Control Department, 2012/2013

Appendix I - Auditee's comments

FOOD AND DRUGS AUTHORITY
FDA
GHANA

Food & Drugs Authority

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CHIEF EXECUTIVE: **HUDU MOGTARI**

FDA/DRID/DED/PMS/15/0217

17th February, 2015

Office of the Auditor General
RECEIVED
18 FEB 2015
HEADQUARTERS

THE AUDITOR-GENERAL
AUDIT SERVICE
P.O.BOX M96
ACCRA

Dear Sir,

RE:DRAFT PERFORMANCE AUDIT REPORT OF THE AUDITOR-GENERAL ON ENSURING SAFETY AND QUALITY OF MEDICINES IN GHANA

We write to acknowledge receipt of your letter dated 22nd January, 2015 with reference no: PSAD/ADM/17/VOL 3/100 and titled "*DRAFT PERFORMANCE AUDIT REPORT OF THE AUDITOR-GENERAL ON ENSURING SAFETY AND QUALITY OF MEDICINES IN GHANA*".

The Management of the FDA will like to throw light on some inaccuracies it noted in the draft report as follows:

- ***FDA has not registered the medicines of some licensed pharmaceutical companies (3.4 (39))***

Local manufactures are to submit samples of the products they intend to manufacture with all the necessary documentation to the FDA for evaluation before they are given marketing authorization to manufacture and sell those products. The FDA will like to state that when unregistered products are found through its Post Market Surveillance activities manufacturers of these products are sanctioned according to the Public Health Act, Act 851.However products which have expired registration may be found on the market since they might have been put on the market before the expiration of the validity of the registration. The FDA in reviewing the list of medicines from local manufacturers cited in Table 3 of the report as **not found in FDA's Drug Register as at 30 May, 2014** noted a number of inaccuracies and these are stated in the remarks below. We hope you would amend your records accordingly to reflect the true situation in this matter.

Table 3: Sample of Medicines in the market and which are not found in FDA's Drug Register as at 30th May 2014.

No.	Pharmaceutical Company	Name of Medicine	FDA's Remarks
1	Salom	Maleate + Sodium Citrate	No such product exist
2.	Amponsah Effah	Keltabs (Predmisolone)	Registered FDB/GD.03-8114

Page 1 of 3

② DAG/PSAD
Fyg pls
AG 18/3/15

③ AAG (Lawrence)
Pls handle this with team and let's discuss.
05/03/2015

3.	Delma Pharma	Carbodel Adult Syrup (Carbocisteine Syrup 250mg/5ml) Carbodel Infant Syrup (Carbocisteine Syrup 100mg/5ml)	Registered FDB/SD.135-8594 Registered FDB/SD.135-8595
4.	GR Industries	Clomox G Cream (Triple Action Cream) Metronidazole+Furazolidone Suspension	Registered FDB/SD.143-5564 Registered FDB/SD.113-8530
5.	Letap	Oxytetracycline HCl 250mg Capsule Letamox Suspension 60ml Cough & Cold Syrup 100ml Chloramphenicol 250mg Capsules Amoxycillin Suspension 100ml	Registered FDB/GD.083-10157 Registered FDB/SD.03-2045 No product with this name Registered FDB/GD.03-1018 Registered FDB/GD.083-10152

- "Through interviews, the team also found that FDA has been carrying out post market activities throughout the country. "***This activity is carried out twice every year". (41)***

This statement is not entirely accurate. Post market surveillance activities are carried out routinely throughout the year in other words they are day to day activities such as:

- ✓ Receiving and acting on products complaints
- ✓ Raids and swoops
- ✓ Product quality monitoring (PQM) which involves sampling of a particular product line for laboratory analysis - this is done at least twice in a year when specific therapeutic lines are considered based on potential risk and pharmacovigilance reports Products that fail lab analysis during PQM are identified and recall from the market and appropriate regulatory sanctions taken against the perpetrators
- ✓ Destination inspections
- ✓ Outreach programmes at churches, mosque, market centers, district assemblies
- ✓ Radio and TV talk shows
- ✓ Advert vetting and monitoring
- ✓ Supervision of safe disposal
- ✓ Investigations and unannounced inspections etc.

- ***FDA is unable to manage the security of detained medicines (3.6 (53))***

FDA monitors non-compliant products detained in the premises of importers and distributors. Detention notes issued to that effect are signed by officers of the FDA and the owners of the consignment.

Any violation of such detention orders attracts regulatory sanction. In paragraph (56) and (57) of the drafted report, the list of products are from one particular importer. The importer of the medicines was given an administrative fine for importation and distribution of unregistered medicines and violation of the detention order.

- ***FDA does not ensure that all importers obtain permit before initiating importation of medicines (3.5)***

  122. *(1) A person who has not been issued with a licence or permit under this Part, shall not import a drug, herbal medicinal product, medical device, cosmetic or household chemical substance.*

Section 122 of the Public Health Act, 2012, Act 851 as quoted above talks about licence to import or permit to import. The FDA under section 131 of the Public Health Act, 2012, Act 851 issue licence to all importers of medicines and this licence is valid for a year.

1. The FDA license all medicine importers
2. Medicines are to be registered before importation
3. Permits had to be obtained before products are cleared at the designated port of entry.
4. Permits are not issued for unregistered products except in cases of programme-drugs usually imported by the Ministry of Health.
5. The FDA however does not have control over when importers purchase or place order for their consignments and when they apply for permit to clear.

- ***Poor collaboration between FDA and border agencies to monitor and control the importation of medicines (3.7)***

The FDA will like to state that there is a strong collaboration between it and CEPS at all designated entry points (Tema Port and KIA) through which medicines are imported.
FDA still looks for further ways of strengthening this collaboration with all relevant stakeholders. An inter-agency committee on medicines of compromised quality is being formed in furtherance of the collaboration..

Yours faithfully

HUDU MOGTARI
CHIEF EXECUTIVE OFFICER

FOOD AND DRUGS AUTHORITY
FDA
GHANA

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CHIEF EXECUTIVE:
HUDU MOGTARI

FDA/DER/SMER/01/06-14/M6

June 2, 2014

Office of the Auditor General
RECEIVED
03 JUN 2014
HEADQUARTERS

THE AUDITOR-GENERAL
AUDIT SERVICE
P .O. BOX M 96
ACCRA

Dear Sir/Madam,

RE: PERFORMANCE AUDIT ON ENSURING SAFETY AND QUALITY OF MEDICINES IN GHANA.

This is with reference to your letter requesting for the registered product list for the attached pharmaceutical company.

Please find attached the list of the companies and their products as at May 30, 2014.

Yours faithfully,

HUDU MOGTARI
Ag. CHIEF EXECUTIVE

Page 1 of 1

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FOOD AND DRUGS AUTHORITY
FDA
GHANA

Food & Drugs Authority

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FDA/DER/SMER/02/06-14/M6

June 2, 2014

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THE AUDITOR-GENERAL
AUDIT SERVICE
P .O. BOX M 96
ACCRA

Dear Sir/Madam,

RE: PERFORMANCE AUDIT ON ENSURING SAFETY AND QUALITY OF MEDICINES IN GHANA.

This is with reference to your letter requesting for registration status of the attached list of products from the attached pharmaceutical companies.

Please find attached the list of the products and their registration status as at May 30, 2014.

Yours faithfully,

HUDU MOGTARI
Ag. CHIEF EXECUTIVE

(2) DAG (PSAD)
FNA
AG 4/6/14

(3) AAGs / PAU
FNA pl.
4/6/14

922

REGISTRATION STATUS OF THE UNDERLISTED DRUGS

PANACEA PHARMACEUTICALS	
1. EASYLIFE VITAMIN C +ZINC	REGISTERED AND VALID
2. EASYLIFE MULTIVITAMIN	REGISTERED AND VALID
3. EASYLIFE FERROVITE	REGISTERED AND VALID
SALOM PHARMACY	
1. AMCOF SENIOR SYRUP (COUGH SYRUP 125ML)	PENDING REGISTRATION
2. EXPECT-SED-COUGH SYRUP	PENDING
3. FENIC BLOOD TONIC (IRON TONIC 200ML)	REGISTERED AND VALID
4. MIST MAG TRISILICATE (M.M.T)	PENDING REGISTRATION
5. MULTIVITE SYRUP 125ML	PENDING REGISTRATION
6. SALO APETI 200ML (CYPROHEPTADINE +VITAMINS)	PENDING REGISTRATION
7. SALOMOL SYRUP 125ML (JACKET)	REGISTERED AND VALID
8. MALEATE + SODIUM CITRATE	NOT IN RECORDS
9. GRAND PAA TABLET (PARACETAMOL, ASPIRIN AND CAFFEINE)	REGISTERED AND VALID
LAGRAY PHARMACEUTICALS	
1. CLENZAID	REGISTERED BUT EXPIRED
2. LEMEPRIM-480	PENDING REGISTRATION

GEO MEDICORE	
1. METAZOLE TABLET	REGISTERED VALID
2. ALBENDAZOLE 500MG TABLET	NOT REGISTERED
3. HB TONE TONIC	REGISTERED AND VALID
AMPONSAH EFFAH PHARMACEUTICALS	
1. KELTABS (PREDNISOLONE)	NOT REGISTERED
2. PERZATIL TABLETS	PENDING REGISTRATION

Mission Statement

The Ghana Audit Service exists

To promote

- good governance in the areas of transparency, accountability and probity in the public financial management system of Ghana

By auditing

- to recognized international auditing standards, the management of public resources

And

- reporting to Parliament