FOOD AND DRUGS AUTHORITY COUNTE And tha date of this ve office Letter should be quoted

My Ref. No.: MOH/PD-10/17

Your Ref. No.:



MINISTRY OF HEAL? P O BOX MB-44 ACCRA.

REPUBLIC OF GHANA

May 10, 2017.

THE EXECUTIVE OFFICER FOOD AND DRUGS AUTHORITY ACCRA.

Dear Madam,



EXECUTIVE INSTRUMENT FOR LIST OF MEDICINES TO BE RESTRICTED FROM IMPORTATION AND RESERVED FOR THE LOCAL MANUFACTURE ONLY

Please find attached the gazette Executive Instrument 181 as gazette notification from the Assembly Press.

You are by this authorised to take the necessary steps to implement the Executive Instrument accordingly.

Thank you.

Yours faithfully,

Hon. Kwaku Agyeman-Manu

(Minister of Health)

Deputy Ministers, MOH cc:

Chief Director, MOH

Chief Director, Trade & Industry

Ag. Chief Executive, NHIA

Director, Pharmaceutical Services, MOH

President, PMAG

President, Chamber of Pharmacy

Chairman, Parliamentary Select Committee on Health

EXECUTIVE INSTRUMENT

E.I. 181

INSTRUCTIONS FOR THE RESTRICTION OF A SELECT LIST OF MEDICINES FROM IMPORTATION AND THE RESERVATION OF THE SELECT LIST OF MEDICINES FOR LOCAL PRODUCTION ONLY

WHEREAS the Republic of Ghana subscribes to the African Union's Pharmaceutical Manufacturing Plan for Africa and has, as a result, prioritised local pharmaceutical manufacturing;

WHEREAS the Republic of Ghana has in place a select list of medicines restricted from importation and reserved for local manufacture only, which has been in place for the past twenty-seven years:

WHEREAS the local pharmaceutical manufacturing industry is developing and has gained enormous capacity, both in production quality and quantity, to produce a certain category of medicines;

WHEREAS the Republic of Ghana intends to use the local pharmaceutical industry to secure its medicine-related needs and to improve access to essential medicines and in the process create jobs for its people;

WHEREAS the Minister for Health constituted a Committee made up of the Ministry of Health, the Ministry of Trade and Industry, the National Health Insurance Authority, the Food and Drugs Authority and the Pharmaceutical Manufacturers Association of Ghana to review the restricted list and to recommend a new list of medicines to be restricted from importation and reserved for local production only;

WHEREAS the recommendations of the Committee were subjected to broad stakeholder consultations with stakeholders including parliamentarians and importers of the medicines recommended for import restriction, before the final recommended list was submitted to the Minister for Health;

WHEREAS the Minister for Health is satisfied with the work of the Committee and its recommendations and is also further satisfied that a restriction of the selected medicines will not affect the supply and availability of those medicines in the Republic of Ghana;

NOW THEREFORE, in exercise of the power conferred on the Minister for Health by section 116 of the Public Health Act, 2012 (Act 851), this Instrument is made this 6th day of December, 2016.

Restriction

1. (1) Within three months after notification in the Gazette, the list of medicines outlined in this Instrument referred to as "the Restricted List" shall be restricted from importation and reserved for local production only.

(2) On the implementation of subsection (1), the Food and Drugs Authority shall not accept a new application for the registration of a medicine on the Restricted List unless the application is in respect of a locally-produced medicine on the Restricted List.

(3) A medicine registered before the implementation of the restriction shall continue to be imported until the regis-

tration period of the medicine expires.

- (4) An application for the registration of a medicine on the Restricted List which is lodged with the Food and Drugs Authority before the implementation of the restriction shall be accepted by the Food and Drugs Authority and taken through the requisite registration process for a marketing authorisation to be either granted or denied.
- (5) Where the Food and Drugs Authority grants marketing authorisation, the medicine shall be allowed to be imported into Ghana until the registration period of the medicine expires.
- (6) The restriction shall not apply to an innovator brand of the medicines indicated on the Restricted List.

Restricted List

2. The following is the list of medicines to be restricted from importation and reserved for local production only.

(a) Aluminium Hydroxide Tablet;

- (b) Aluminium Hydroxide or Magnesium Trisilicate Suspension;
- (c) Aluminium Hydroxide or Magnesium Trisilicate
- (d) Amoxicillin Capsules (250 mg, 500 mg);
- (e) Amoxicillin Suspension (125 mg/5ml, 250 mg/ 5ml);

- (f) Aspirin or Caffeine Tablet;
- (g) Aspirin Tablet (300 mg);
- (h) Bendrofluazide Tablet:
- (i) Cetirizine Syrup (5 mg/5 ml);
- (i) Cetirizine Tablet (10 mg);
- (k) Chlordiazepoxide Capsule (5 mg, 10 mg);
- Co-trimoxazole Suspension (40/200mg per 5m1);
- (m) Co-trimoxazole Tablet (80.400 mg, 160/800 mg);
- (n) Cough Mixture that is cough mixture containing Carbocisteine, Diphenhydramine, Gualfenesin or Ammonium chloride as a single ingredient or in combination with each other;
- (o) Dexamethasone Tablet (0.5 mg, 1 mg);
- (p) Diazepam Tablets (5 mg, 10mg);
- (q) Diclofenac Tablet (50 mg);
- (r) Doxycycline Capsules (100 mg);
- (s) Ferrous Ammonium Citrate;
- (t) Ferrous Fumarate;
- (u) Ferrous Sulphate;
- (v) Ferrous Sulphate, Ferrous Fumarate or Ferrous Ammonium Citrate in combination with Folic Acid;
- (w) Folic Acid Tablet (5 mg);
- (x) Glibenclamide Tablets (5 mg);
- (y) Griseofulvin Tablet (125 mg, 500 mg)
- (z) Hydrochlorothiazide Tablet:
- (aa) Ibuprofen Tablet (200 mg, 400 mg);
- (bb) Iron III Polymaltose tablet or syrup;
- (cc) Lisinopril Tablet (5 mg/10 mg/20 mg);
- (dd) Magnesium Trisilicate Suspension;
- (ee) Magnesium Trisilicate Tablet:
- (ff) Metronidazole Suspension (100 mg/5ml, 200 mg/5ml);
- (gg) Metronidazole Tablet (200 mg, 400 mg);

- (hh) Multivitamin Syrup (Vitamins A Acetate, BI, B2, B12, D3, Nicotinamide, Calcium Pantothenate);
- (ii) Multivitamin Tablet (Vitamins A Acetate, Bi, B2, B12, D3, Nicotinamide, Calcium Pantothenate);
- (ii) Oral Rehydration Salts;
- (kk) Oxytetracycline Capsule (250 mg);
- (11) Paracetamol Caffeine Tablet;
- (mm) Paracetamol Syrup (120 mg/5 ml);
- (nn) Paracetamol Tablet (500 mg);
- (00) Paracetamol or Codeine Tablet;
- (pp) Paracetamol or Asprin or Caffeine Tablet;
- (qq) Phenobarbitone Tablet (30 mg, 60 mg);
- (rr) Prednisolone Tablet (5 mg);
- (ss) Simethicone containing antacids;
- (tt) Simple Linctus Syrup;
- (uu Tetracycline Capsules (250 mg); and
- (vv) Vitamin B Complex Tablet.

MR. ALEX SEGBEFIA Minister for Health

Date of Gazette notification: 23rd December, 2016.