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February 16, 2022

CUSTOMS MEMORANDUM CIRCULAR
NO. 24-2022

To: The Assistant Commissioner
All Deputy Commissioners
All Service Directors
All District/Port Collectors
All Others Concerned

SUBJECT: ENDORSEMENT OF THE UPDATES TO THE LIST OF VAT-EXEMPT PRODUCTS UNDER REPUBLIC ACT (RA) NOS. 10963 AND 11534

Attached is the letter addressed to Commissioner Caesar R. Dulay, Bureau of Internal Revenue (BIR) copy furnished the Commissioner of Customs dated November 8, 2021 from Rolando Enrique D. Domingo, MD, Director General, Food and Drug Administration (FDA), Department of Health (DOH) informing this Bureau that the aforementioned subject refers to the "List of VAT-Exempt Drugs for Hypertension, Cancer, Mental illnesses, Tuberculosis, Kidney Diseases, Diabetes and High Cholesterol".

Further, these updates include several changes, including the delisting of twenty four (24) and the addition of thirty four (34) entries. (Please see the attached Corrigendum for reference)

For information and guidance.

For record purposes, please confirm the dissemination of this Circular throughout your Offices within fifteen (15) days from receipt thereof.

REY LEONARDO B. GUERRERO

Commissioner



BOC-03-13144

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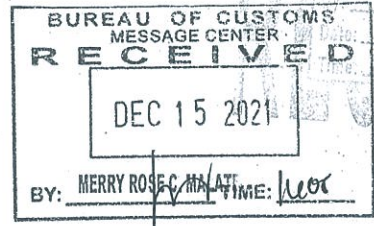


Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



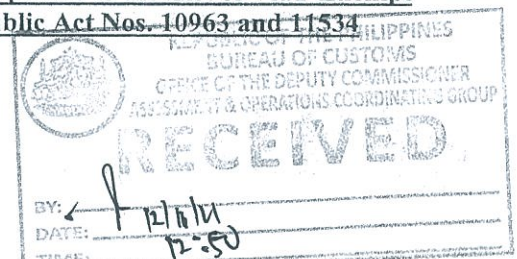
8 November 2021

CAESAR R. DULAY
Commissioner
Bureau of Internal Revenue
Quezon City



OFFICE OF THE DIRECTOR
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REVOKED

SUBJECT : Endorsement of the Updates to the List of VAT-Exempt Products under Republic Act Nos. 10963 and 11534



Dear Commissioner Dulay:

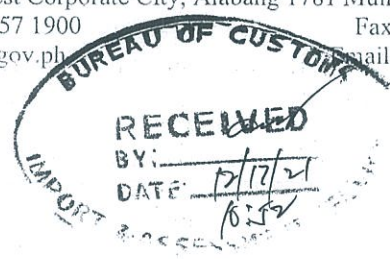
Greetings!

With reference to the Implementing Guidelines on the Value-Added tax (VAT) Exemption on several health products provided under Joint Administrative Order (JAO) No. 2-2018 dated 21 December 2018 and JAO No. 2021-0001 dated 23 June 2021, may we provide you with updates to the "List of VAT-Exempt Drugs for Hypertension, Cancer, Mental illnesses, Tuberculosis, Kidney Diseases, Diabetes, and High Cholesterol".

This update includes several changes, including the delisting of 24 entries and the addition of 34 entries. A summary of this update is indicated in the table below:

| Update(s) | Number of Entries Updated |
|--|---------------------------|
| Corrigendum to the List of Medicines for Hypertension, Cancer and Kidney Diseases | |
| A. Delisting from List of Medicines for Hypertension | 9 |
| B. Delisting from List of Medicines for Cancer | 10 |
| C. Delisting from List of Medicines for Kidney Diseases | 5 |
| Addendum to the List of Medicines for Diabetes, Hypertension, Cancer, Mental Illnesses, Tuberculosis, and Kidney Diseases | |
| A. Inclusion to the List of Medicines for Diabetes | 1 |
| B. Inclusion to the List of Medicines for High Cholesterol | 6 |
| C. Inclusion to the List of Medicines for Hypertension | 4 |
| D. Inclusion to the List of Medicines for Cancer | 3 |
| E. Inclusion to the List of Medicines for Mental Illnesses | 4 |
| F. Inclusion to the List of Medicines for Tuberculosis | 3 |
| G. Inclusion to the List of Medicines for Kidney Diseases | 13 |

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Should there be any questions or clarifications regarding the list, please coordinate with Ms. Gabrielle S. Gabriel at pps@fda.gov.ph.

Thank you very much.

Yours truly,


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20211103210830

CC:

Department of Health – Office of the Secretary

Department of Finance – Bureau of Customs

Department of Trade and Industry – Office of the Secretary

**CORRIGENDUM TO THE
LIST OF MEDICINES FOR HYPERTENSION, CANCER, AND KIDNEY DISEASES**

A. Delisting from List of Medicines for Hypertension

| No | Generic name | Dosage strength | Dosage form |
|----|--------------------------|-----------------|----------------------------|
| 1 | Tamsulosin hydrochloride | 400 mcg | Extended-release capsule |
| 2 | Tamsulosin hydrochloride | 400 mcg | Film-coated tablet |
| 3 | Tamsulosin hydrochloride | 400 mcg | Prolonged-release capsule |
| 4 | Sildenafil (as citrate) | 100 mg | Chewable tablet |
| 5 | Sildenafil (as citrate) | 100 mg | Film-coated tablet |
| 6 | Sildenafil (as citrate) | 50 mg | Film-coated tablet |
| 7 | Sildenafil (as citrate) | 50 mg | Oral jelly (Orange flavor) |
| 8 | Macitentan | 10mg | Film-coated tablet |
| 9 | Doxazosin (as mesylate) | 4mg | Controlled release tablet |

B. Delisting from List of Medicines for Cancer

| No | Generic name | Dosage strength | Dosage form |
|----|--|------------------------|---|
| 1 | Highly Purified Menotrophin | 600 IU | Powder for Solution for Injection (SC) |
| 2 | Menotrophin | 150 IU | Powder For Solution For Injection (IM/SC) |
| 3 | Menotrophin | 75 IU | Powder For Solution For Injection (IM/SC) |
| 4 | Everolimus | 250 mcg | Tablet |
| 5 | Everolimus | 500 mcg | Tablet |
| 6 | Cyproterone acetate | 50 mg | Film-Coated Tablet |
| 7 | Cyproterone acetate + Ethinylestradiol | 2.0mg/35 mcg | Sugar-Coated Tablet |
| 8 | Ciclosporin | 1mg/mL | Ophthalmic emulsion |
| 9 | Pirenoxine | 50 mcg/mL (0.005% w/v) | Ophthalmic suspension |
| 10 | Inosiplex | 250 mg/5mL | Syrup, Oral |

C. Delisting from List of Medicines for Kidney Diseases

| No | Generic name | Dosage strength | Dosage form |
|----|---|--|---|
| 1 | Phyllanthus niruri L. (meniran whole plant) | 250 mg (equivalent to 25mg extract) | Phyllanthus niruri L. (meniran whole plant) |
| 2 | Phyllanthus niruri L. | 25mg/5mL | Phyllanthus niruri L. |
| 3 | Each 100g (approx. 82.64 mL) syrup contains: 34.5g Herbal ethanolic mixture (see reverse) | Each 100g (approx. 82.64 mL) syrup contains: 34.5g Herbal ethanolic mixture from: Sambucus nigra L. (Elder flower) 207 mg Primula veris L. and Primula elatior (L.) Hill (Primula flower with calyx) 207 mg Rumex crispus L. (Common sorrel herb) 207 mg Verbena officinalis L. (Verbena herb) 207 mg Gentiana lutea L. (Gentian root) 69 mg | Each 100g (approx. 82.64 mL) syrup contains: 34.5g Herbal ethanolic mixture (see reverse) |
| 4 | Each dragée contains: Sambucus nigra L. (Elder flower) 36mg; Primula veris L. and Primula elatior (L.) Hill (Primula flower with calyx) 36mg; Rumex crispus L. (Common sorrel herb) 36mg; Gentiana lutea L. (Gentian root) 12mg | Each dragée contains: Sambucus nigra L. (Elder flower) 36mg; Primula veris L. and Primula elatior (L.) Hill (Primula flower with calyx) 36mg; Rumex crispus L. (Common sorrel herb) 36mg; Gentiana lutea L. (Gentian root) 12mg | Each dragée contains: Sambucus nigra L. (Elder flower) 36mg; Primula veris L. and Primula elatior (L.) Hill (Primula flower with calyx) 36mg; Rumex crispus L. (Common sorrel herb) 36mg; Gentiana lutea L. (Gentian root) 12mg |

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| No | Generic name | Dosage strength | Dosage form |
|----|---|-------------------------|---|
| 5 | Gentianae Radix (Gentian Root), Primulae Flos (Primrose Flowers With Calyx), Rumicus Herba (Common Sorrel Herb), Sambuci Flos (Elder Flowers), Verbenae Herba (Shop Vervain Wort) | 6mg/18mg/18mg/18mg/18mg | Gentianae Radix (Gentian Root), Primulae Flos (Primrose Flowers With Calyx), Rumicus Herba (Common Sorrel Herb), Sambuci Flos (Elder Flowers), Verbenae Herba (Shop Vervain Wort) |

**ADDENDUM TO THE
LIST OF MEDICINES FOR DIABETES, HIGH CHOLESTEROL, HYPERTENSION,
CANCER, MENTAL ILLNESSES, TUBERCULOSIS, AND KIDNEY DISEASES**

A. Inclusion to the List of Medicines for Diabetes

| No | Generic name | Dosage strength | Dosage form |
|----|---------------------------|-----------------|-------------------|
| 1 | Desmopressin (as acetate) | 100mcg | Oral Lyophilisate |

B. Inclusion to the List of Medicines for High Cholesterol

| No | Generic name | Dosage strength | Dosage form |
|----|---------------------------------------|-----------------|--------------------------|
| 1 | Ezetimibe + Atorvastatin (as calcium) | 10mg/20mg | Film-Coated Tablet/ Oral |
| 2 | Ezetimibe + Atorvastatin (as calcium) | 10mg/40mg | Film-Coated Tablet/ Oral |
| 3 | Ezetimibe + Atorvastatin (as calcium) | 10mg/80mg | Film-Coated Tablet/ Oral |
| 4 | Ezetimibe + Simvastatin | 10mg/ 10mg | Tablet / Oral |
| 5 | Ezetimibe + Simvastatin | 10mg/ 20mg | Tablet / Oral |
| 6 | Ezetimibe + Atorvastatin (as calcium) | 10mg/20mg | Film-Coated Tablet/ Oral |

C. Inclusion to the List of Medicines for Hypertension

| No | Generic name | Dosage strength | Dosage form |
|----|---|-----------------|--------------------------------|
| 1 | Isosorbide dinitrate | 5 mg | Sublingual tablet |
| 2 | Isosorbide-5-mononitrate | 60 mg | Prolonged-Release Tablet; Oral |
| 3 | Losartan potassium + Amlodipine camsylate | 50mg/ 5mg | Tablet / Oral |
| 4 | Losartan potassium + Amlodipine camsylate | 100mg/ 5mg | Tablet / Oral |

D. Inclusion to the List of Medicines for Cancer

| No | Generic name | Dosage strength | Dosage form |
|----|--------------------------|-----------------|----------------------------------|
| 1 | Everolimus | 10 mg | Tablet |
| 2 | Everolimus | 5 mg | Tablet |
| 3 | Epirubicin hydrochloride | 50mg | Lyophilized Powder for Injection |

E. Inclusion to the List of Medicines for Mental Illnesses

| No | Generic name | Dosage strength | Dosage form |
|----|-------------------|-----------------|--------------------|
| 1 | Pregabalin | 75mg | Capsule |
| 2 | Pregabalin | 150mg | Capsule |
| 3 | Zolpidem Tartrate | 10 mg | Film-coated Tablet |
| 4 | Carbamazepine | 100 mg/5 mL | Suspension |

F. Inclusion to the List of Medicines for Tuberculosis

| No | Generic name | Dosage strength | Dosage form |
|----|----------------------|-----------------|-------------|
| 1 | Rifampicin | 300mg | Capsule |
| 2 | Rifampicin | 600mg | Tablet |
| 3 | Bedaquiline Fumarate | 100 mg | Tablet |

G. Inclusion to the List of Medicines for Kidney Diseases

| No | Generic name | Dosage strength | Dosage form |
|----|---------------------------------------|-----------------|--------------------------------|
| 1 | Everolimus | 250 mcg | Tablet |
| 2 | Everolimus | 500 mcg | Tablet |
| 3 | Recombinant Human Erythropoietin Alfa | 4000 IU/0.4 mL | Solution for Injection (IV/SC) |

| No | Generic name | Dosage strength | Dosage form |
|----|--|--|---|
| 4 | Hemofiltration Solution | Sodium Chloride 6.136 g Sodium Hydrogen Carbonate 2.940 g Calcium Chloride Dihydrate 220.5 mg Magnesium Chloride Hexahydrate 101.7 mg Glucose Monohydrate (equivalent to anhydrous glucose 1.000 g) 1.100 g | Solution for Intraperitoneal Administration |
| 5 | Peritoneal Dialysis Solution with 1.5% Dextrose | Calcium Chloride Dihydrate 257.3 mg Sodium Chloride 5.786 g Sodium (S) Lactate Solution (Containing sodium (S) lactate 3.925 g) 7.85 g Magnesium Chloride Hexahydrate 101.7 mg Dextrose (as anhydrous glucose 15 g) 16.5 g | Solution for Intraperitoneal Administration |
| 6 | Peritoneal Dialysis Solution with 1.5% Dextrose | Dextrose (as anhydrous glucose 15 g) 16.5 g Sodium (S) Lactate Solution [(Containing sodium (S) lactate 3.925 g) 7.85 g, Sodium Chloride 5.786 g, Calcium Chloride Dihydrate 183.8 mg, Magnesium Chloride Hexahydrate 101.7 mg] | Solution for Intraperitoneal Administration |
| 7 | Peritoneal Dialysis Solution with 4.25% Dextrose | Calcium Chloride Dihydrate 257.3 mg Sodium Chloride 5.786 g Sodium (S) Lactate Solution (Containing sodium (S) lactate 3.925 g) 7.85 g Magnesium Chloride Hexahydrate 101.7 mg Dextrose (as anhydrous glucose 42.5 g) 46.75 g | Solution for Intraperitoneal Administration |
| 8 | Peritoneal Dialysis Solution with 4.25% Dextrose | Glucose monohydrate (as anhydrous glucose 42.5 g) 46.75 g Sodium (S) Lactate Solution (Containing sodium (S) lactate 3.925 g) 7.85 g Sodium Chloride 5.786 g Calcium Chloride Dihydrate 183.8 mg Magnesium Chloride Hexahydrate 101.7 mg | Solution for Intraperitoneal Administration |
| 9 | Peritoneal Dialysis Solution with 2.3% Dextrose | Calcium Chloride Dihydrate 257.3 mg Sodium Chloride 5.786 g Sodium (S) Lactate Solution (Containing sodium (S) lactate 3.925 g) 7.85 g Magnesium Chloride Hexahydrate 101.7 mg Dextrose (as anhydrous glucose 22.73 g) 25 g | Solution for Intraperitoneal Administration |

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| No | Generic name | Dosage strength | Dosage form |
|----|---|---|---|
| 10 | Peritoneal Dialysis Solution with 2.3% Dextrose | Dextrose (as anhydrous glucose 22.73 g) 25 g Sodium (S) Lactate Solution (Containing sodium (S) lactate 3.925 g) 7.85 g Sodium Chloride 5.786 g Calcium Chloride Dihydrate 183.8 mg Magnesium Chloride Hexahydrate 101.7 mg | Solution for Intraperitoneal Administration |
| 11 | Dextrose Hydrus + Electrolytes | Each 100 ml contains: Dextrose Hydrus 2.5 g; Sodium Chloride 538 mg; Sodium Lactate 448 mg; Calcium Chloride 18.3 mg; Magnesium Chloride 5.08 mg | Solution for Injection (Intraperitoneal) |
| 12 | Peritoneal Dialysis Solution with 7.5% Icodextrin | Each 100 mL contains: Icodextrin 7.5 g; Sodium Chloride 538 mg; Sodium Lactate 448 mg; Calcium Chloride 25.7 mg; Magnesium Chloride 5.08 mg | Solution for Intraperitoneal Administration |
| 13 | Spherical Carbon Absorbent | 2 g | Fine granules |



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



15 November 2021

HONOREE E. IBARRA
Regulatory Affairs Manager
Novo Nordisk

SUBJECT : Response to Query on the List of VAT-Exempt Products

Dear Mr. Ibarra:

Greetings!

This is in reference to your letter dated 30 September 2021 requesting for a clarificatory statement or an addendum regarding the entry on 'Liraglutide 6mg/mL Solution for Injection (SC)' in the List of Medicines for Diabetes.

We wish to clarify that the list issued by the Food and Drug Administration (FDA) intends to identify the drugs indicated for the prevention and management of diseases (i.e. diabetes, hypertension, cancer, high cholesterol, mental illnesses, tuberculosis, and kidney diseases) specified under Republic Act (RA) 10963, otherwise known as the "Tax Reform for Acceleration and Inclusion or TRAIN Law", and RA 11534, otherwise known as the "Corporate Recovery and Tax Incentives for Enterprises Act or CREATE Act". The list is designed to reflect the drugs which are registered with the FDA for the purposes of preventing and treating the identified diseases in the afore-cited laws.

We also acknowledge that drug products containing the same active pharmaceutical ingredients and bearing the same dosage strength and form may remain to be indicated for multiple diseases, just as in the case of the products cited in your query. However, in such cases, a distinction can be made when such drugs are used for the management of a disease other than those identified in the afore-cited laws. Please be also informed that the FDA is currently undertaking a review of the drug registry database to address this in the long-term, with the aim of improving the accuracy of reflected products in the published list of Value Added Tax (VAT)-Exempt Products.

In view of the above, please be advised that it is construed that 'Liraglutide 6mg/mL Solution for Injection (SC)' is only considered to be VAT-exempt if its use falls under the management of diabetes. Corollary to this, your cited indication for 'Liraglutide 6mg/mL Solution for Injection (SC)' under the brand name 'Saxenda', i.e. management of overweight and obesity, does not fall under the identified afore-cited diseases included in both the TRAIN Law and the CREATE Act.

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Should you have any further questions or clarifications, you may send an e-mail to pps@fda.gov.ph.

For your guidance.

Yours truly,


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20211026143303

CC:
Bureau of Internal Revenue
Bureau of Customs