



FDA ADVISORY

No. **2023-0476**

22 MAR 2023

TO : ALL CONCERNED STAKEHOLDERS

SUBJECT : Endorsement of Updates on the List of VAT-Exempt Health Products

Section 12 of Republic Act (RA) No. 11534 known as the “*Corporate Recovery and Tax Incentives for Enterprises (CREATE) Act*” provided Value-Added Tax (VAT) Exemption to certain health products including, Drugs for Hypertension, Cancer, Mental Illnesses, Tuberculosis, Kidney Diseases, Diabetes, High Cholesterol, and COVID-19 medicines and medical devices. Pursuant to the said law, the Food and Drug Administration (FDA) is directed to identify and transmit the VAT-Exempt Health products to other implementing agencies such as the Bureau of Internal Revenue (BIR), Bureau of Customs and Department of Trade and Industry.

Relative thereto, the FDA has issued FDA Advisory (FA) No. No.2023-0256¹ which provided the new implementation date of updates on the List of VAT-Exempt Health products, pursuant to BIR Revenue Memorandum Circular No. 99-2021².

In this regard, provided below are the latest updates on the List of VAT-Exempt Health Products pursuant to RA 11534, effective upon the issuance of this Advisory:

I. Inclusion

A. Medicines Cancer

Generic Name	Dosage Strength	Dosage Form
Apalutamide	60 mg	Film-Coated Tablet
Brigatinib	30 mg	Film-Coated Tablet
Brigatinib	90 mg	Film-Coated Tablet
Brigatinib	180 mg	Film-Coated Tablet
Dabrafenib (As Mesilate)	50 mg	Capsule
Dabrafenib (As Mesilate)	75 mg	Capsule
Daratumumab	1,800 mg/15 mL (120 mg/mL)	Solution for Injection (SC)
Doxorubicin hydrochloride	2 mg/mL (50 mg/25 mL)	Pegylated Liposomal Concentrate Solution for Injection for I.V. Infusion
Fluorouracil	50 mg/mL (250 mg/5 mL)	Solution For Injection (IV)
Gemcitabine (as hydrochloride)	10 mg/mL	Solution for Injection for I.V. Infusion (Ready-to-Infuse)
Goserelin (as Acetate)	3.6 mg	Depot In Pre-Filled Syringe (SC Injection)



Goserelin (as Acetate)	3.6 mg	Implant in Pre-filled Syringe for Subcutaneous (SC) Injection
Goserelin (as Acetate)	10.8 mg	Implant in Pre-filled Syringe for Subcutaneous (SC) Injection
Goserelin Acetate (equivalent to Goserelin Base)	10.8 mg	Depot Solution for Subcutaneous Injection
Irinotecan (as hydrochloride)	20 mg/ mL (500 mg/ 25 mL)	Concentrate Solution for Intravenous (I.V.) Infusion
Irinotecan Hydrochloride	20 mg/mL (500 mg/25 mL)	Powder For Prolonged-Release Suspension for Injection (IM/SC)
Irinotecan Hydrochloride	20 mg/mL (300 mg/15 mL)	Powder for Prolonged-Release Suspension for Injection (IM/SC)
Leuprorelin Acetate	1.88mg/mL	Powder For Prolonged-Release Suspension for Injection (IM/SC)
Leuprorelin Acetate	3.75mg/mL	Powder For Prolonged-Release Suspension for Injection (IM/SC)
Leuprorelin Acetate	11.25mg/mL	Powder for Prolonged-Release Suspension for Injection (IM/SC)
Nilotinib (as hydrochloride dihydrate)	200 mg	Capsules
Nilotinib (as hydrochloride dihydrate)	150 mg	Capsules
Ondansetron (as hydrochloride dihydrate)	4 mg/5 mL	Syrup
Ondansetron (as hydrochloride)	2 mg/mL	Solution For Injection (IM/IV)
Pralsetinib	100 mg	Capsule
Trifluridine + Tiparicil (as Hydrochloride)	15mg/6.14mg	Film-Coated Tablet
Trifluridine + Tiparicil (as Hydrochloride)	20mg/8.19mg	Film-Coated Tablet

B. Medicines for Diabetes

Generic Name	Dosage Strength	Dosage Form
Gemigliptin (as tartrate sesquihydrate) + Metformin hydrochloride	50 mg/1g	Film-Coated tablet

Insulin Lispro	100 Units/mL (3.5 mg/mL) (50% Insulin Lispro and 50% Insulin Lispro Protamine)	Suspension for Injection (SC)
Insulin Lispro (rDNA)	100 Units/mL (3.5 mg/mL) (25% Insulin Lispro Solution + 75% Insulin Lispro Protamine)	Suspension for Injection (SC)
Metformin Hydrochloride	1 g	Prolonged-Release Tablet
Pioglitazone (as Hydrochloride + Metformin Hydrochloride)	15 mg/500mg	Sustained-Release Tablet
Pioglitazone (as Hydrochloride + Metformin Hydrochloride)	30 mg/500mg	Sustained-Release Tablet

C. Medicines for Kidney Disease

Generic Name	Dosage Strength	Dosage Form
Ketoanalogues + Essential Amino Acids	630 mg	Film-Coated Tablet
Peritoneal Dialysis Solution with 1.5% Dextrose	Each L of solution contains: Glucose anhydrous (equivalent to 16.5 g glucose monohydrate)..15 g Calcium Chloride Dihydrate... 257.3 mg Magnesium Chloride Hexahydrate... 101.7 mg Sodium Lactate... 3.925 g Sodium Chloride... 5.786 g	Dialysis Solution (Intraperitoneal)
Peritoneal Dialysis Solution with 1.5% Dextrose	Each L of solution contains: Glucose (equivalent to 15 g glucose anhydrous)..... 16.5 g Calcium Chloride Dihydrate.....183.8 mg Magnesium Chloride Hexahydrate.....101.7 mg Sodium Lactate.....3.925 g Sodium Chloride.....5.786 g	Solution for Peritoneal Dialysis (Intraperitoneal)
Peritoneal Dialysis Solution with 4.25% Dextrose	Each 1000 mL contains: Sodium Lactate.....3.925 g Sodium Chloride.....5.786 g Magnesium Chloride Hexahydrate....0.1017 g Calcium Chloride Dihydrate.....0.2573 g	Peritoneal Dialysis Solution

	Glucose Monohydrate (Glucose anhydrous).....42.5g	
Peritoneal Dialysis Solution with 4.25% Dextrose	Each L of solution contains: Glucose (Dextrose) (equivalent to 46.75 g glucose monohydrate).....42.5 g Sodium Chloride.....5.786 g Sodium Lactate.....3.925 g Calcium Chloride equivalent to 0.1838 g calcium chloride dihydrate.....0.1387 g Magnesium Chloride equivalent to 0.1017 g magnesium chloride hexahydrate.....0.0577 g	Solution for Peritoneal Dialysis (Intraperitoneal)

D. Medicines for Mental Illness

Generic Name	Dosage Strength	Dosage Form
Lurasidone Hydrochloride	40 mg	Film - Coated Tablet
Lurasidone Hydrochloride	80 mg	Film - Coated Tablet
Lurasidone (as Hydrochloride)	80 mg	Film - Coated Tablet
Risperidone	1 mg	Orodispersible Tablet
Risperidone	2 mg	Orodispersible Tablet

E. Medicines for Tuberculosis

Generic Name	Dosage Strength	Dosage Form
Rifampicin + Isoniazid + Ethambutol Hydrochlorid	150 mg/75 mg/ 300 mg	Film-Coated Tablet

II. Correction

A. Medicines for High Cholesterol

Generic Name	Dosage Strength	Dosage Form	
		Previously uploaded	Correct
Ezetimibe + Simvastatin	10mg/ 10mg	Tablet/Oral	Tablet
Ezetimibe + Simvastatin	10mg/ 20mg	Tablet/Oral	Tablet
Ezetimibe + Simvastatin	10mg/ 40mg	Tablet/Oral	Tablet

B. Medicines for Hypertension

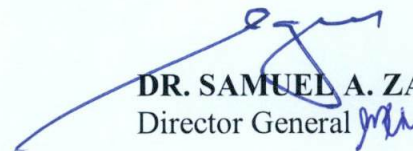
Generic Name		Dosage Strength	Dosage Form	
Previously uploaded	Correct		Previously uploaded	Correct
Losartan potassium +	Losartan potassium + Amlodipine	50mg/ 5mg	Tablet/Oral	Film-Coated Tablet

Amlodipine camsylate	camsylate (as camsilate)			
Losartan potassium + Amlodipine camsylate	Losartan potassium + Amlodipine camsylate (as camsilate)	100 mg/ 5mg	Tablet/Oral	Film-Coated Tablet

Further, provided in the Annex is the signed letter dated 21 February 2023, endorsing the said updates to the BIR.

Should you have any question/clarifications, you may contact the FDA Policy and Planning Service via email at pps@fda.gov.ph.

Dissemination of this Advisory to all concerned is kindly requested.


DR. SAMUEL A. ZACATE
 Director General

¹ Effectivity of Updates on the List of Vat-Exempt Health Products

² Clarifies issues relative to the Value-Added Tax (VAT) Exemption of certain medicines and other medicinal devices for COVID-19 under Sections 109(1)(AA) and 109(1)(BB)(ii) of the National Internal Revenue Code of 1997 (Tax Code), as amended by Republic Act (RA) Nos. 10963 (TRAIN Law), 11467 and 11534 (CREATE Act)