

FDA ADVISORY  
No. **2024-0006**

02 JAN 2024

**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.2023-0256<sup>1</sup> which provided the new implementation date of updates on the List of VAT-Exempt Health products, pursuant to BIR Revenue Memorandum Circular No. 99-2021<sup>2</sup>.

In this regard, provided below are the latest updates on the List of VAT-Exempt Health Products pursuant to RA 11534, effective 04 December 2023:

## I. Inclusion

### A. Medicines for Cancer

Generic Name	Dosage Strength	Dosage Form
Panitumumab	100 mg/5 mL (20 mg/mL)	Concentrate for Solution for Infusion (IV)
Fulvestrant	50 mg/mL (250 mg/5 mL)	Solution for Injection (IM)

### B. Medicines for Diabetes

Generic Name	Dosage Strength	Dosage Form
Teneligliptin ( as hydrobromide hydrate)	20 mg	Film-Coated Tablet
Sitagliptin (as phosphate monohydrate) + Metformin Hydrochloride	50 mg/500 mg	Film-Coated Tablet
Sitagliptin	50 mg	Film-Coated Tablet
Sitagliptin	100 mg	Film-Coated Tablet
Metformin Hydrochloride	500 mg	Prolonged-Release Tablet

### C. Medicines for High Cholesterol



Generic Name	Dosage Strength	Dosage Form
Atorvastatin Calcium	20 mg	Film-Coated Tablet
Atorvastatin + Fenofibrate	40 mg/160 mg	Film-Coated Tablet

#### D. Medicines for Hypertension

Generic Name	Dosage Strength	Dosage Form
Clonidine hydrochloride	150 mcg/mL	Solution For Injection (IM/IV)
Clonidine hydrochloride	150 mcg	Tablet
Lisinopril (as dihydrate)	5 mg	Tablet
Lisinopril (as dihydrate)	10 mg	Tablet
Lisinopril (as dihydrate)	20 mg	Tablet

#### E. Medicines for Kidney Disease

Generic Name	Dosage Strength	Dosage Form
Mannitol	20 g/100 mL (20%)	Solution for Injection (IV)
Tolvaptan	15 mg	Tablet
Tolvaptan	30 mg	Tablet
Alpha Ketoanalogues + Essential Amino Acids	Each film-coated tablet contains: Calcium-4-methyl-2-oxovalerate ( $\alpha$ -ketoanalogue of leucine, calcium salt) 202 mg, Calcium-3-methyl-2-oxobutyrate ( $\alpha$ -ketoanalogue of valine, calcium salt) 172 mg, Calcium-2-oxo-3-phenylpropionate ( $\alpha$ -ketoanalogue of phenylalanine, calcium salt) 136 mg, Calcium-3-methyl-2-oxovalerate ( $\alpha$ -ketoanalogue of isoleucine, calcium salt) 134 mg, Calcium-DL-2-hydroxy-4-(methylthio)-butyrate ( $\alpha$ -	Film-Coated Tablet

	hydroxyanalogue of methionine, calcium salt) 118 mg, L-Lysine acetate 210 mg, L-Threonine 106 mg, L-Histidine 76 mg, L-Tyrosine 60 mg, L-Tryptophan 46 mg, Total Nitrogen Content 72 mg	
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#### F. Medicines for Mental Illness

Generic Name	Dosage Strength	Dosage Form
Desvenlafaxine (as succinate monohydrate)	50 mg	Controlled-Release Tablet

#### G. Medicines for Tuberculosis

Generic Name	Dosage Strength	Dosage Form
Bedaquiline (as Fumarate)	100 mg	Tablet
Isoniazid + Pyridoxine Hydrochloride	200 mg/10 mg per 5 mL	Syrup

## II. Deletion

#### A. Medicines for Hypertension

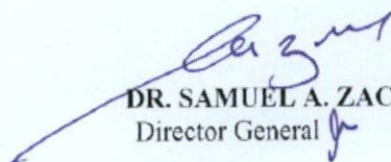
Generic Name	Dosage Strength	Dosage Form
Macitentan	10 mg	Film-Coated Tablet

*Justification: The pharmacologic category of Macitentan is an endothelin receptor antagonist (ERA) with an approved indication for targeted pulmonary arterial hypertension (PAH) therapy which is not synonymous to systemic hypertension.*

Further, provided in the Annex is the signed letter dated 29 November 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](mailto:pps@fda.gov.ph).

Dissemination of this Advisory to all concerned is kindly requested.

  
DR. SAMUEL A. ZACATE  
Director General

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