

## ANNEX B

### Frequently Asked Questions (FAQs) on the List of VAT-Exempt Health Products pursuant to Republic Act No. 11534, otherwise known as the “Corporate Recovery and Tax Incentives for Enterprises (CREATE) Act” Effectivity: 02 February 2022

#### 1. What are the products included in the List of VAT-Exempt Health Products?

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 health products that are exempted from Value-Added Tax (VAT) are medicines indicated for the prevention and management of diabetes, hypertension, cancer, high cholesterol, mental illnesses, tuberculosis, and kidney diseases, and medicines and medical devices specifically used for the prevention and treatment of COVID-19.

#### 2. Where can I get a copy of the List of VAT-Exempt Health Products?

A copy of the list of medicines for diabetes, hypertension, cancer, high cholesterol, mental illnesses, tuberculosis, and kidney diseases are attached as Annex A. The list of medicines and medical devices specifically used for the prevention and treatment of COVID-19, however, can be accessed at <https://doh.gov.ph/VAT-Exempted-Drugs-List>.

For convenience, a searchable database is uploaded at <https://verification.fda.gov.ph>, under the tab “VAT-Exempt Health Products”.

#### 3. How are medicines included in the List of VAT-Exempt Health Products?

The Department of Health (DOH) and the Food and Drug Administration (FDA) identify which specific medicines are included in the List of VAT-Exempt Health Products, and this List is transmitted to the Bureau of Internal Revenue (BIR).

The FDA is tasked to update and maintain the list of medicines for diabetes, hypertension, cancer, high cholesterol, mental illnesses, tuberculosis, kidney diseases, and COVID-19 medicines and medical devices. To do this, the FDA regularly updates the list based on the list of registered products with the FDA. Products are included in the respective list based on the indication approved by the FDA.

#### 4. When is the list updated?

Following Joint DOF-DOH-BIR-FDA Administrative Order No. 2-2018 dated 21 December 2018 and Joint DOH-DOF-FDA-BIR-BOC Administrative Order No. 2021-0001 dated 23 June 2021, the FDA must provide an updated list thirty (30) days prior the beginning of every quarter. Thus, the FDA endeavors to publish the list within the months of February, May, August, and November of every year.

#### 5. How can I request to add, remove, or correct an entry in the List?

Requests to add, remove, or correct any entries in the list of medicines for diabetes, hypertension, cancer, high cholesterol, mental illnesses, tuberculosis, or kidney diseases

are submitted through the 'Enquiry Form for the List of VAT-Exempt Medicines' at <https://bit.ly/vatexemptenquiry>. The same form is accessible at the FDA Verification Portal, <https://verification.fda.gov.ph>. Enquiring entities are requested to complete the following information, in order to appropriately process the query:

- a. Generic name
- b. Brand name (if applicable)
- c. Dosage strength
- d. Dosage form and route
- e. CPR Number (if available)
- f. Indication
- g. Type of request (inclusion, delisting, correction)
- h. Specific list pertained to in the request (medicines for diabetes, hypertension, cancer, high cholesterol, mental illnesses, tuberculosis, or kidney diseases)
- i. Other details of request (e.g. reason for request, type of correction requested)

Changes to the list are included in the regular quarterly update. Enquiries are consolidated at the end of January, April, July, and October of every year, to allow sufficient time for the publication of the list for the regular quarterly update.

For changes to the list of medicines and medical devices specifically used for the prevention and treatment of COVID-19, enquiring entities are advised to contact the FDA Policy and Planning Service at [pps@fda.gov.ph](mailto:pps@fda.gov.ph).

**6. If the medicine is included as an entry in the List, but is used for the treatment of a disease not identified among those under the CREATE Act, is the medicine still considered VAT-Exempt?**

The list issued by the FDA intends to identify drugs specifically used for the prevention and management of diseases (i.e. diabetes, hypertension, cancer, high cholesterol, mental illnesses, tuberculosis, and kidney diseases) which have been identified under the TRAIN Law and CREATE Act. The fields included in the list have, thus, been so designed to allow the identification of specific drugs which have been registered with the FDA for the purposes of preventing and treating the identified diseases included in the afore-cited laws.

However, it is also acknowledged 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. 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 aforecited laws, *ergo* if a product is not specifically prescribed for the treatment and/or prevention of the identified diseases, it should not be construed to be among the medicines which are considered VAT-Exempt pursuant to the TRAIN Law and the CREATE Act.

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 VAT-Exempt Products.

**7. If the medicine contains the same generic name but is in a different dosage form, is it considered the same as the entry in the List?**

No, the fields included in the tabulated list generated by the FDA were so designed in order to identify specific drugs which have been registered with the FDA for the purposes of preventing and treating the identified diseases included in the TRAIN Law and CREATE Act. Thus, if the product bears a dosage form not included in the List, it is **NOT** considered as the same as the entry.

Further note that active pharmaceutical ingredients of such drugs can be indicated for multiple diseases, and so in recognition of this, the FDA included the dosage forms of the drug products to accurately produce a list which fits the intention of the provisions of the afore-cited laws. However, as noted in FAQ No. 5, there remains to be circumstances which allow for further distinction.

**8. Can I request for a certification from the FDA that my product is exempted from VAT?**

The FDA does not certify if products are considered VAT Exempt. For the purposes of availing VAT Exemption, stakeholders are advised to take reference to the List published by the FDA along with their copy of the Certificate of Product Registration. Should there be any discrepancy, entities are advised to submit their queries following FAQ No. 4.