

LEGAL NOTICE NO. 224

REPUBLIC OF TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister on the recommendation of the Drug Advisory Committee in accordance with paragraph 7, Division 3 of the Second Schedule of the Food and Drugs Regulations.

The Minister signifies his approval in respect of the following new drugs:

| TRADE NAME AND FORM   | MANUFACTURER  | COUNTRY OF ORIGIN        | CONDITION OF SALE   |
|---|---|--------------------------|---|
| Pfizer-BioNTech COVID-19 Vaccine<br>Tozinameran COVID-19 mRNA Vaccine<br>(nucleoside modified)<br>Concentrate for Dispersion for Injection<br>2mL/Multi-dose Vial<br>(Change of Condition of Use) | Pharmacia & Upjohn Company LLC<br>7000 Portage Road<br>Kalamazoo, MI 49001,<br>United States of America | United States of America | Pandemic Use/<br>Emergency Use<br>Authorisation/<br><br>Individual 12 years and above<br><br>New Indication<br>Pregnant Women<br>(second and third trimester) |
| TOZINAMERAN<br>COVID-19mRNA Vaccine<br>(nucleoside modified)<br><br>COMIRNATY®<br><br>Concentration for injection<br>2ml/Multidose Vial<br>(Change of Condition of Use)                           | Baxter Oncology GmbH<br>Kantstraße 2, 33790<br>Halle/Westfalen,<br>Germany                              | Germany                  | do.   |
| TOZINAMERAN<br>COVID-19mRNA Vaccine<br>(nucleoside modified)<br><br>COMIRNATY®<br><br>Concentration for injection<br>2ml/Multidose Vial<br>(Change of Condition of Use)                           | Pfizer Manufacturing<br>Belgium NV<br>Rijksweg 12, 2870 Puurs<br>Belgium                                | Belgium                  | do.   |

| TRADE NAME AND FORM   | MANUFACTURER   | COUNTRY OF ORIGIN           | CONDITION OF SALE  |
|---|--|-----------------------------|--|
| <p>TOZINAMERAN<br/>COVID-19mRNA Vaccine<br/>(nucleoside modified)</p> <p>COMIRNATY®</p> <p>Concentration for injection<br/>2ml/Multidose Vial<br/>(Change of Condition of Use)</p>                                    | <p>Novartis Pharma Stein AG<br/>Schaffhauserstrasse,<br/>4332 Stein,<br/>Switzerland</p>   | Switzerland                 | <p>Pandemic Use/<br/>Emergency Use<br/>Authorisation/<br/><br/>Individual 12 years<br/>and above</p> <p>New Indication<br/>Pregnant Women<br/>(second and third<br/>trimester)</p> |
| <p>TOZINAMERAN<br/>COVID-19mRNA Vaccine<br/>(nucleoside modified)</p> <p>COMIRNATY®</p> <p>Concentration for injection<br/>2ml/Multidose Vial<br/>(Change of Condition of Use)</p>                                    | <p>Mibe GmbH Arzneimittel<br/>Münchener Straße 15,<br/>06796 Brehna,<br/>Germany</p>   | Germany                     | do.  |
| <p>Pfizer-BioNTech COVID-19 Vaccine<br/>Tozinameran COVID-19 mRNA<br/>Vaccine<br/>(nucleoside modified)<br/>Concentrate for Dispersion<br/>for Injection<br/>2mL/Multi-dose Vial<br/>(Change of Condition of Use)</p> | <p>Hospira Inc.,<br/>a Pfizer Company<br/>1776 Centennial Drive,<br/>McPherson, Kansas 67460,<br/>United States of America</p>                   | United States<br>of America | do.  |
| <p>TOZINAMERAN<br/>COVID-19mRNA Vaccine<br/>(nucleoside modified)</p> <p>COMIRNATY®</p> <p>Concentration for injection<br/>2ml/Multidose Vial<br/>(Change of Condition of Use)</p>                                    | <p>BioNTech Manufacturing<br/>GmbH<br/>An der Goldgrube 12,<br/>55131 Mainz,<br/>Germany</p>   | Germany                     | do.  |
| <p>TOZINAMERAN<br/>COVID-19mRNA Vaccine<br/>(nucleoside modified)</p> <p>COMIRNATY®</p> <p>Concentration for injection<br/>2ml/Multidose Vial</p>   | <p>BioNTech Manufacturing<br/>GmbH<br/>Kupferbergterrasse 17-19,<br/>55116 Mainz,<br/>Germany</p>  | do.                         | <p>Pandemic Use/<br/>Emergency Use<br/>Authorisation/<br/><br/>Individual 18 years<br/>and above</p>   |
| <p>COVID-19 Vaccine<br/>(ChAdOx1-S [recombinant])<br/>Suspension for Injection<br/>Multi-dose Vial</p>  | <p>KM Biologics Co. Ltd.,<br/>Koshi Production Center.<br/>3766-1, Sakae, Koshi-shi,<br/>Kumamoto,<br/>Japan</p> <p>MAH: AstraZeneca AB</p>      | Japan                       | <p>Pandemic Use/<br/>Emergency Use<br/>Authorisation/<br/><br/>Individual 18 years<br/>and above</p>   |
| <p>COVID-19 Vaccine<br/>(ChAdOx1-S [recombinant])<br/>Suspension for Injection<br/>Multi-dose Vial</p>  | <p>Daiichi Sankyo Biotech<br/>Co., LTD.,<br/>Kitamoto Site,<br/>6111, Arai, Kitamoto City,<br/>Saitama,<br/>Japan</p> <p>MAH: AstraZeneca AB</p> | do.                         | do.  |

| TRADE NAME AND FORM   | MANUFACTURER  | COUNTRY OF ORIGIN | CONDITION OF SALE |
|---|---|-------------------|-------------------|
| COVID-19 Vaccine<br>(ChAdOx1-S [recombinant])<br>Vaxzevria<br>Suspension for Injection<br>Multi-dose Vial | IDT Biologika GmbH<br>Am Pharmapark<br>Dessau-Rosslau 06861<br>Germany                                  | Germany           | do.               |
| COVID-19 Vaccine<br>(ChAdOx1-S [recombinant])<br>Vaxzevria<br>Suspension for Injection<br>Multi-dose Vial | CP Pharmaceuticals<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | United<br>Kingdom | do.               |

Dated this 24th day of August, 2021.

T. DEYALSINGH  
*Minister of Health*