2.3.R. REGIONAL INFORMATION

2.3.R.1. PROCESS VALIDATION SCHEME FOR DRUG PRODUCT

Process Validation Data at commercial scale are provided for the Drug Substance and for the Drug Product with the Application. Consequently, submission of a Process Validation Scheme is not required.

The Puurs PPQ protocol, revised from the protocol included in Roll 1, is provided in 3.2.R.1 Process Validation Scheme for the Drug Product - Covid 19 RTU MDV - Puurs PV Protocol 21019-10000-PVP0-A3.

2.3.R.2. MEDICAL DEVICE

Not applicable.

2.3.R.3. CERTIFICATES OF SUITABILITY

Not applicable.

2.3.R.4. MEDICINAL PRODUCTS CONTAINING OR USING IN THE MANUFACTURING PROCESS MATERIALS OF ANIMAL ORIGIN AND/OR HUMAN ORIGIN

The materials covered by the Note for Guidance used in the manufacture of BNT162b2 are provided in 3.2.R.4.4 Medicinal Products Containing or Using in the Manufacturing Process Materials of Animal and/or Human Origin.

2.3.R.5. N-NITROSAMINES RISK ASSESSMENT

In accordance with EMA expectations ("Questions and answers for marketing authorisation holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products" EMA/409815/2020), Pfizer has assessed their COVID-19 (BNT162b2) Vaccine drug product and manufacturing process for nitrosamine risks. Pfizer has conducted a comprehensive assessment of the potential nitrosamine risk factors associated with the active substance, drug product and primary packaging components.

This assessment was initially performed for the BNT162b2 PBS/Sucrose formulation and has been updated for the Tris/Sucrose formulation.

Please refer to 3.2.R.1 N-Nitrosamines Risk Assessment BNT162b2 Tris-Sucrose for further details.