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.

A post-approval change management protocol (PACMP) is planned to be included in subsequent CMC rolls in support of anticipated additional manufacturing facilities to support additional supply.

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.

Please refer to 3.2.R.5 N-Nitrosamines Risk Assessment for further details.

2.3.R.6. POST-APPROVAL CHANGE MANAGEMENT PROTOCOLS (PACMP) ADDING ADDITIONAL DP SITE(S)

The applicant intends to submit the change – adding an additional DP manufacturing site to the commercial supply chain – by referring to the EU Commission Regulation (EC) No 1234/2008, as amended, with the submission of a type II variation category B.II.g.2.

2.3.R.7. POST-APPROVAL CHANGE MANAGEMENT PROTOCOLS (PACMP) ADDING ADDITIONAL DS SITE

The applicant intends to submit the change – adding an additional DS manufacturing site to the commercial supply chain – by referring to the EU Commission Regulation (EC) No 1234/2008, as amended, with the submission of a type II variation category B.I.e.2.

For the PACMP please refer to 3.2.R.7 Post-Approval Change Management Protocols (PACMP) adding additional DS site.

2.3.R.8. POST-APPROVAL CHANGE MANAGEMENT PROTOCOLS (PACMP) ADDING ADDITIONAL DP SITE(S) NOVARTIS & DELPHARM

The applicant intends to submit the change – adding two additional DP Fill and Finish manufacturing sites Novartis and Delpharm to the commercial supply chain – by referring to the EU Commission Regulation (EC) No 1234/2008, as amended, with the submission of a type II variation category B.II.g.2.

For the PACMP please refer to 3.2.R.8 Post-Approval Change Management Protocols (PACMP) adding additional DP site(s) Novartis

2.3.R.9. POST-APPROVAL CHANGE MANAGEMENT PROTOCOLS (PACMP) ADDING ADDITIONAL DP SITE(S) NOVARTIS & DELPHARM

The applicant intends to submit the change – adding two additional DP Fill and Finish manufacturing sites Novartis and Delpharm to the commercial supply chain – by referring to the EU Commission Regulation (EC) No 1234/2008, as amended, with the submission of a type II variation category B.II.g.2.

For the PACMP please refer to 3.2.R.9 Post-Approval Change Management Protocols (PACMP) adding additional DP site(s) Delpharm.

2.3.R.10. POST-APPROVAL CHANGE MANAGEMENT PROTOCOLS (PACMP) ADDING ADDITIONAL BULK DP SITE ALLERGOPHARM

The applicant intends to submit the change – adding the additional BNT162b2 Bulk DP manufacturing site Allergopharma GmbH & Co. KG to the commercial supply chain – by referring to the EU Commission Regulation (EC) No 1234/2008, as amended, with the submission of a type II variation category B.II.g.2.

2.3.R.11. POST-APPROVAL CHANGE MANAGEMENT PROTOCOLS (PACMP) ADDING ADDITIONAL FILL AND FINISH SITE CATALENT ANAGNI

The applicant intends to submit this change – adding an additional BNT162b2 fill and finish site to Catalent Anagni, Località Fontana del Ceraso, S.P. Casilina 12 n. 41, 03012 Anagni FR, Italy to the commercial supply chain – by referring to the EU Commission Regulation (EC) No 1234/2008, as amended, with the submission of a type II variation category B.II.g.2.