ANNEX A - SUPPORTING DOCUMENTS REQUIRED FOR IMPORTATION OF ARBs, METFORMIN, AMITRIPTYLINE, RANITIDINE AND VARENICLINE CONTAINING PRODUCTS INTO BRUNEI DARUSSALAM

i) The batch numbers and quantity of the finished products that are planned to be imported into Brunei Darussalam including where it is supplied to

ii) Certificate of Analysis of Finished Product corresponding to the batch imported into Brunei Darussalam

iii) Certificate of Analysis of the Active Pharmaceutical Ingredient used to manufacture the finished product corresponding to the batch imported into Brunei Darussalam

iv) Information on the level of nitrosamine impurities, including but not limited to the list below for the specific batch imported into Brunei Darussalam:

- N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA) and N-nitroso-N-methyl-4-aminobutyric acid (NMBA) – For ARBs, Metformin, Amitriptyline and Ranitidine containing products
- Azido Impurity – For ARB containing products
- N-nitroso-varenicline (NNV) – For Varenicline containing products

v) Declaration letter from the manufacturer of the finished product indicating impurity is not detected / below acceptable levels in cases where the impurity result is unavailable for the specific batch imported into Brunei Darussalam.