Annex IV

CHECKLIST OF INFORMATION AND DOCUMENTS TO BE SUBMITTED BY THE MANUFACTURERS ALONG WITH THE ONLINE APPLICATION FORM

Please use the following template for identifying, cross-referencing any accompanying summary test results and supporting documents. Please list the title of each attachment in the expandable text box under the relevant heading.
PLEASE UPLOAD THIS DOCUMENT UNDER PART B IN THE ONLINE APPLICATION FORM

Sr No	Type of the document	Checklist (Tick the boxes below)	Title of each document shared as an attachment
1.	Manufacturing protocol for the purified protein derivative (PPD) of avian tuberculin.	☐	
2.	Documents indicating Quality Control procedures.	☐	
3.	Documents indicating information on the production strain used and sequencing data of the strain, origin and passage history of the strain should be provided.	☐	
4.	Documents indicating long-term consistent production history with use of products in bovine tuberculosis (bTB) control programmes. The information must include the number of tests which have been administered to animals in the last ten years.	☐	
5.	Document outlining standard operating procedure used to establish potency for avian PPD and batch release criteria.	☐	
6.	Documentation of history of regulatory oversight of the products and external agency providing oversight.	☐	
7.	Documentation such as 'Certificate of Analysis' including features such as toxicity, sterility, sensitizing effect, specificity and potency data passing the European Pharmacopoeia requirement for tuberculin purified protein of derivative,	☐	
9	Any relevant datasets or raw data in excel or CSV format	☐	