APPENDIX 9A ANNEX 1 – CHECKLIST FOR THE REGISTRATION OF HUMAN THERAPEUTIC PRODUCTS CONTAINING MATERIALS OF ANIMAL ORIGIN

Appendix section	Document	Yes/No (Encl. #)
1.1	**Products Containing TSE-Relevant Animal-Derived Materials WITH a Valid TSE Risk Evaluation Certificate of Suitability (CEP)**	
1.1 (a)	TSE Risk Evaluation Certificate of suitability (CEP) *(Please put the number and date of certificate and attach a copy of the CEP to this checklist).*	
1.1 (b)	Certificate of analysis for each animal-derived material used.	
1.1 (c)	Purpose of each animal-derived material used:	
	▪ As a drug substance	
	▪ As an excipient or adjuvant	
	▪ As a starting material used in the manufacture of a drug substance	
	▪ As a starting material used in the manufacture of excipient	
	▪ As a reagent or culture media component used in manufacture	
	▪ As a reagent or culture media component used in establishing master cell bank(s)	
	▪ As a reagent or culture media component used in establishing working cell bank(s)	
	▪ Others; please give details	

Appendix section	**Document**	**Yes/No (Encl. #)**
1.2	**Products Containing TSE-Relevant Animal-Derived Materials WITHOUT a Valid TSE Risk Evaluation Certificate of Suitability (CEP)**	
1.2 (a) (i)	Rationale for using animal-derived materials	
1.2 (a) (ii)	Information on all countries which the animal was sourced from	
1.2 (a) (iii)	Nature of animal material used and measures taken to minimise BSE risk	
1.2 (a) (iii) a.	A declaration of the nature (tissue/ fluid type) of the animal tissue used should be submitted.	
1.2 (a) (iii) b.	Procedures used in collecting the intended animal tissues/organs and the measures in place to avoid cross-contamination with a higher risk material; if applicable	
1.2 (b)	Detailed Assessment Report on the risk of TSE	
1.2 (b) (i)	Details of the risk factors associated with the route of administration, quantity of animal material used, maximum therapeutic dosage (daily dosage and duration of treatment) and intended use of the drug product and its clinical benefits. The presence of a species barrier should also be considered.	
1.2 (b) (ii)	Production process steps for inactivation of TSE agents	
1.2. (c)	Certificate of analysis for each animal-derived material used.	
1.2 (d)	Purpose of each animal-derived material used:	
	▪ As a drug substance	
	▪ As an excipient or adjuvant	

	▪ As a starting material used in the manufacture of a drug substance	
	▪ As a starting material used in the manufacture of excipient	
	▪ As a reagent or culture media component used in manufacture	
	▪ As a reagent or culture media component used in establishing master cell bank(s)	
	▪ As a reagent or culture media component used in establishing working cell bank(s)	
	▪ Others; please give details	

Appendix section	**Document**	**Yes/No (Encl. #)**
1.3	**Products Containing Non TSE-Relevant Animal-Derived Materials**	
1.3 (a)	Information on all countries which the animal was sourced from*	
1.3 (b)	Relevant information to demonstrate that the manufacturing process is capable of inactivating adventitious agents, where applicable	
1.3 (c)	Certificate of analysis for each animal-derived material used	
1.3 (d)	Purpose of each animal-derived material used:	
	▪ As a drug substance	
	▪ As an excipient or adjuvant	
	▪ As a starting material used in the manufacture of a drug substance	
	▪ As a starting material used in the manufacture of excipient	
	▪ As a reagent or culture media component used in manufacture	
	▪ As a reagent or culture media component used in establishing master cell bank(s)	
	▪ As a reagent or culture media component used in establishing working cell bank(s)	
	▪ Others; please give details	

**To provide information on source country only if the animal-derived material is of a mammalian or avian origin, and used as the drug substance, excipient and/ or adjuvant.*

REVISION HISTORY

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