Application Form

1	**Information about the applicant and the legal representative in the country**	
1.1	**Name of company**	
1.2	**Name and Address of manufacturer of drug substance(s)**	
	Name	
	Address	
1.3	**Name and Address of manufacturer of the finished product**	
	Name	
	Address	
1.4	**Name and Address of applicant/legal representative/marketing authorization holder**	
	Title	
	First Name	
	Surname	
	Company Name	
	Address	
1.5	**Name and Address of other manufacturer(s) involved in the manufacturing process**	
	1. Brief description of operation	
	Name	
	Address	
	2. Brief description of operation	
	Name	
	Address	
	3. Brief description of operation	
	Name	
	Address	

1.6	**Contact person for Quality and Pharmacovigilance**	
	Quality	
	Title	
	First Name	
	Surname	
	Company Name	
	Address	
	Pharmacovigilance	
	Title	
	First Name	
	Surname	
	Company Name	
	Address	
1.7	**Person/company authorized for communication between the MAH and NRA & Official(s) responsible for batch testing and batch release of finished product**	
	Person/company authorized for communication between the MAH and NRA	
	Title	
	First Name	
	Surname	
	Company Name	
	Address	
	Official responsible for batch testing of finished product	
	Title	
	First Name	
	Surname	
	Company Name	
	Address	
	Official responsible for batch release of finished product	
	Title	
	First Name	
	Surname	

	Company Name		
	Address		
2	**Information about the product**		
2.1	**Name of the medicinal product including non-proprietary name or common name of vaccine**		
2.2	**Pharmaceutical form**		
2.3	**Physical description of pharmaceutical form**		
2.4	**Commercial presentation(s)**		
2.5	**Indication(s)**		
2.6	**List of excipients, product shelf-life, storage condition, packaging configuration(s)**		
	List of excipients		
	Product shelf-life		
	Products storage condition		
	Packaging configuration(s)		
2.7	**Dosage and Administration**		
2.8	**Qualitative and Quantitative Composition** (Please fill details in attachment - I)		
2.9	**Name of drug substance(s)**		
3	**Regulatory status**		
3.1	**Date of first Authorization in country of origin**		
3.2	**List of countries in which finished product is registered**		
3.3	**List of countries where the product is marketed**		
3.4	**Did you apply for scientific advice before submission?**	**YES**	☐
		NO	☐
3.5	**Type of application**		

3.6	Annexed documents	
		☐
		☐
		☐
		☐
		☐
		☐
		☐
		☐

Attachment - I

Name of excipients	Quantity/Unit	Reference to Standard