Unit: Variation Unit

APPLICATION FOR VARIATION TO A MARKETING AUTHORIZATION FOR BIOLOGICAL MEDICINAL PRODUCTS FOR HUMAN USE.

Name of the product/s:	**Applicant:**
Active substance(s):	**Manufacturer of finished product:**
	Name & address of contact:
Concentration:	**Telephone number:**
Dosage form & commercial presentation:	**Fax number:**
Registration number:	**E-mail:**

Classification of the Submitted Variation Type		
I-Administrative change		
II- Quality change	**Major**	
	Moderate	
	Minor	
	Notification	
	Non Reportable	**Kindly attach supporting guidelines**
III- Labeling update	**Insert Scientific update**	
	Insert Safety update	
	Pack update	

1-Administrative changes (Tick the appropriate change required)	**Main change**	**Consequential change**
Change in the name and/or address of the market authorization holder		
Change in the name of the medicinal product		
Change in name of the active substance		
Change in the name and/or address of a manufacturer of the active substance where no Ph. Eur certificate of suitability is available		
Change in the name and/or address of a manufacturer of the finished product		
Deletion of a supplier of packaging components or devices (when mentioned in the dossier)		
Replacement or addition of a supplier of packaging components or devices (when mentioned in the dossier)		
Change in pack size of the finished product:- Change in the number of units(e.g. ampoules) within the range of the currently approved pack sizes		
Change in the number of units outside the range of the currently approved pack sizes Change in the fill weight/fill volume of non-parenteral multi-dose products		
Change of the applicant		

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Editorial changes in CTD		
Editorial changes in SmPC and/or PIL		
Deletion of a supplier of packaging components or devices (when mentioned in the dossier)		
Replacement or addition of a supplier of packaging components or devices (when mentioned in the dossier)		
Other changes		
2- Quality changes (Tick the appropriate change required)	**Main change**	**Consequential change**
Change in the manufacturing process or sites of the active ingredients		
Change in the composition of the finished product.		
Change of immediate packaging of the product.		
Substantial changes to the formulation, specification or impurity profile of the active ingredient or finished medicinal product, which may have significant impact on the quality, safety or efficacy of the product.		
Variations related to changes outside the range of approved specifications, limits or acceptance criteria.		
Replacement or addition of Primary packaging site.		
Replacement or addition of a site or a manufacturer responsible for batch release where batch control/testing takes place.		
Change in the manufacturing process of the active substance or finished product.		
Change in batch size of active substance, intermediate or finished product.		
Addition of a new test parameter to the specification of an active substance, excipient or finished product.		
Change in test procedure for active substance or starting material, intermediate, or reagent used in the manufacturing process of the active substance.		
Change in the manufacturer (replacement or addition) of the active substance or starting. Material/reagent/intermediate in the manufacturing process of the active substance.		
Change in the re-test period of the active substance.		
Replacement of an excipient with a comparable excipient.		
Other changes to a test procedure, including replacement of an approved test procedure by a new test procedure.		
Change in synthesis or recovery of a non-pharmacopoeial excipient.		
Change in the qualitative and/or quantitative composition of the immediate packaging material.		
Change in the storage conditions of the finished product or the diluted/reconstituted product.		
Replacement or addition of a manufacturing site for part or all of the manufacturing process of the Secondary packaging of finished product		
Replacement or addition of a manufacturer responsible for batch release (Not including batch control /testing)		
Tightening of the specification limit of an active substance or a starting material/intermediate /reagent/ used in the manufacturing process of the active substance or excipient.		
Addition of new test parameter in specification of a starting material/intermediate /reagent/ used in the manufacturing process of the active substance		
Submission of a new or updated TSE certificate for an active substances or starting material/reagent/intermediate /excipient for a currently approved manufacturer & currently approved manufacturing process		
Change in the storage conditions for the active substance		
Minor change to an approved test procedure of the finished product for biological excipient or biological active substance		
Change in source of an excipient or reagent used in the manufacture of biological active substance from a TSE risk to a vegetable or synthetic material		

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Change to comply with an international pharmacopoeia		
Change to comply with an update of relevant monograph of an international pharmacopoeia)		
Tightening of the specification limit of the finished product/immediate packaging of finished product.		
Minor changes to an approved test procedure of the immediate packaging of the finished product		
Change in any part of the (primary) packaging material (such as color code rings on ampoules, change of needle shield (different plastic used).		
Tightening of in-process tests applied during the manufacture of the product		
Addition of new in-process tests & limits applied during the manufacture of the product		
Change in shape or dimensions of the container or closure		
Change in the shelf life of the finished product as packaged for sale		
Change in the shelf life of the finished product after dilution or reconstitution		
Other changes		
3- Labeling update (Tick the appropriate change required)		
A. Safety data update	**Main change**	**Consequential change**
Reduction of existing risk-management measures (for example, contraindications, adverse events and warnings)		
Addition of (contraindications, adverse events and warnings)		
Change in the summary of product characteristics due in particular to new pharmacovigilance findings.		
Other changes		
B. Scientific data update	**Main change**	**Consequential change**
Change in the strength or route of administration		
Change in the recommended dose and/or dosing schedule		
Co-administration with other biotherapeutic products or medicines		
Change in the summary of product characteristics due in particular to new quality, pre-clinical, clinical.		
Addition or modification in the therapeutic indication		
Other changes		
C. pack update	**Main change**	**Consequential change**
Editorial changes		
Consequential to a quality change		
Other changes		

SCOPE (Please specify scope of the change(s) in a concise way)

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BACKGROUND FOR CHANGE & JUSTIFICATION FOR CONSEQUENTIAL CHANGES (Please give brief background explanation for the proposed changes to your MA, as well as a justification in case of consequential changes)

Present	Proposed

DECLARATION OF THE APPLICANT FOR TYPE II:

I hereby submit an application for the above MA to be varied in accordance with the proposals given above, I declare that (please tick the appropriate declarations):

There are no other changes than those identified in this application.	
Where applicable, fees have been paid.	

***Change will be implemented from:**
Next production run/next printing Date:

Fees paid (if applicable) Amount:	
Main Signatory*: **Print name:** **Status (job title):** **Date:**	**Secondary signatory:** **Print Name:** **Status (job title):** **Date:**

**The main signatory is mandatory*

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