DIRECTORATE GENERAL OF DRUG ADMINISTRATION

MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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FORM Title: Checklist for Post Marketing Authorization Variations of Vaccines

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
General Information									
1) Changes in the name of the antigen									
a) Changes in the name of the antigen (Note: This change generally applies only to influenza vaccines)									
1.	1 & 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Manufacture									
2. Changes to an antigen manufacturing facility									
a) Replacement or addition of a manufacturing facility for the antigen bulk, or any intermediate of the antigen									
1.	1, 2, 3, 4, 6, 7 & 8 from Annexure-1	☐	☐	☐	1, 2, 3 & 4 from Annexure-1	☐	☐	☐	
b) Deletion of a manufacturing facility or manufacturer of an antigen intermediate, or antigen bulk									
1.	5 & 6 from Annexure-1	☐	☒	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	Submitted? No	Submitted? NA	Conditions	Met? Yes	Met? No	Met? NA	DGDA Screening: Assessment Outcome
Manufacture									
3. Change to the antigen fermentation, viral propagation or cellular propagation process									
a) A critical change (a change with high potential to have an impact on the quality of the antigen or final product) (for example, incorporation of disposable bioreactor technology)									
1.	1, 2, 3, 4, 6, 7, 9 & 11 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) A change with moderate potential to have an impact on the quality of the antigen or final product (for example, extension of the in vitro cell age beyond validated parameters)									
1.	1, 2, 3, 4, 5, 6, 8 & 10 from Annexure-1	☐	☐	☐	2 & 4 from Annexure-1	☐	☐	☐	
c) A noncritical change with minimal potential to have an impact on the quality of the antigen or final product (for example, a change in harvesting and/or pooling procedures which does not affect the method of manufacture, recovery, intermediate storage conditions, sensitivity of detection of adventitious agents or production scale; or duplication of a fermentation train)									
1.	1, 2, 3 & 4 from Annexure-1	☐	☐	☐	1, 2, 3, 4, 5, 6, 9, 10 & 11 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening: Assessment Outcome
Manufacture									
4. Change to the antigen purification process involving									
a) A critical change (a change with high potential to have an impact on the quality of the antigen or final product) (for example, a change that could potentially have an impact on the viral clearance capacity of the process or the impurity profile of the antigen)									
1.	1, 2, 5–7, 9, 11, 12 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) A change with moderate potential to have an impact on the quality of the antigen or final product (for example, a change in the chemical separation method, such as from ion-exchange HPLC to reverse phase HPLC)									
1.	1, 2, 5–7, 10, 11 from Annexure-1	☐	☐	☐	2 & 4 from Annexure-1	☐	☐	☐	
c) A noncritical change with minimal potential to have an impact on the quality of the antigen or final product (for example, addition of an in-line filtration step equivalent to the approved filtration step)									
1.	1 & 2 from Annexure-1	☐	☐	☐	1 – 5 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted?			Conditions	Met?			DGDA Screening
		Yes	No	NA		Yes	No	NA	Assessment Outcome
Manufacture									
5. Change in scale of the manufacturing process									
a) at the fermentation, viral propagation or cellular propagation stage									
1.	2, 3, 5–7, 9, 11 from Annexure-1	☐	☐	☐	3 – 6, 11 – 13 from Annexure-1	☐	☐	☐	
b) at the purification stage									
1.	2, 5–7, 9, 11 from Annexure-1	☐	☐	☐	1, 3, 5, 7 from Annexure-1	☐	☐	☐	
6. Change in supplier of raw materials of biological origin (for example, fetal calf serum, human serum albumin, trypsin)									
1.	4, 8, 12, 13 from Annexure-1	☐	☐	☐	8 from Annexure-1	☐	☐	☐	
7. Change in source of raw materials of biological origin									
1.	4, 7, 12, 13 from Annexure-1	☐	☐	☐	8 from Annexure-1	☐	☐	☐	
8. Introduction of reprocessing steps									
1.	8, 10, 11, 14 from Annexure-1	☐	☐	☐	14 from Annexure-1	☐	☐	☐	
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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Manufacture									
9. Change to the cell banks									
a) generation of a new MCB									
1.	1, 2, 5 7 – 9 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
b) generation of a new working cell bank (WCB)									
1.	1 & 2 from Annexure-1	☐	☐	☐	2 – 4 from Annexure-1	☐	☐	☐	
c) change in cell bank storage site									
1.	10 from Annexure-1	☐	☐	☐	7 from Annexure-1	☐	☐	☐	
10. Change to the seed lots									
a) generation of a new MSL									
1.	1, 5 – 9, 11 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
b) generation of a new working seed lot (WSL)									
1.	5 – 9, 11 from Annexure-1	☐	☐	☐	2 – 4 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Manufacture									
c) generation of a new WSL by extending the passage level of an existing WSL beyond an approved level									
1.	5 – 7, 11 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
d) change in seed lot storage site									
1.	10 from Annexure-1	☐	☐	☐	7 from Annexure-1	☐	☐	☐	
11. Change in cell bank/seed lot testing/storage site									
1.	10 from Annexure-1	☐	☐	☐	5 & 7 from Annexure-1	☐	☐	☐	
12. Change in cell bank/seed lot qualification protocol									
1.	3 & 4 from Annexure-1	☐	☐	☐	6 from Annexure-1	☐	☐	☐	
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Manufacture									
13. Change in equipment used in the antigen manufacturing process									
a) introduction of new equipment with different operating principles and different product contact material									
1.	1 – 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) introduction of new equipment with the same operating principles but different product contact material									
1.	1, 3 – 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
c) introduction of new equipment with different operating principles but the same product contact material									
1.	1 – 3, 5, 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
d) replacement of equipment with equivalent equipment (including filter)									
1.	1, 5 – 7 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
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		Yes	No	NA		Yes	No	NA	Assessment Outcome
Manufacture									
14. Change in specifications for the materials									
a) raw materials/intermediates: widening of the approved specification limits for starting materials/intermediates, which may have a significant effect on the overall quality of the antigen and/or final product and are not changes to the cell banks or seed lots									
1.	1,3 – 6, 8, 11 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) raw materials/intermediates: narrowing of the approved specification limits for starting materials/intermediates									
1.	1, 3 – 7 from Annexure-1	☐	☐	☐	1-4 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
15. Change to in-process tests and/or acceptance criteria applied during manufacture of the antigen									
a) narrowing of in-process limits									
1.	2 & 6 from Annexure-1	☐	☐	☐	3, 5, 8, 9 from Annexure-1	☐	☐	☐	
b) addition of new in-process test and limits									
1.	2 – 6, 8, 10 from Annexure-1	☐	☐	☐	4, 5, 10, 11 from Annexure-1	☐	☐	☐	
c) deletion of a non-significant in-process test									
1.	2, 6 & 9 from Annexure-1	☐	☐	☐	4-6 from Annexure-1	☐	☐	☐	
d) widening of the approved in-process limits									
1.	2 – 6, 8, 10, 11 from Annexure-1	☐	☐	☐	3-5 from Annexure-1	☐	☐	☐	
e) deletion of an in-process test which may have a significant effect on the overall quality of the antigen									
1.	2, 6, 8, 10 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
f) addition or replacement of an in-process test as a result of a safety or quality issue									
1.	2 – 6, 8, 10 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
16. Change in in-process controls testing site									
1.	12 from Annexure-1	☐	☐	☐	3 – 5, 7, 8 from Annexure-1	☐	☐	☐	
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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening: Assessment Outcome
Control of Antigen									
17. Change affecting the quality control (QC) (release and stability) testing of the antigen									
a) transfer of the QC testing activities for a non-pharmacopoeial assay to a new company not approved in the current MA or license									
1.	1 & 2 from Annexure-1	☐	☐	☐	1 – 3 Annexure-1	☐	☐	☐	
b) transfer of the QC testing activities for a pharmacopoeial assay to a new company not approved in the current MA or license									
1.	1 & 2 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
18. Change in the specification used to release the antigen									
45. deletion of a test									
1.	1, 5, 8 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
46. addition of a test									
1.	1 – 3, 5 from Annexure-1	☐	☐	☐	1 – 3 from Annexure-1	☐	☐	☐	
c) replacement of an analytical procedure									
1.	1 – 5 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Control of Antigen									
d) change in animal species/strains for a test (for example, new species/strains, animals of different age, new supplier where genotype of the animal cannot be confirmed)									
1.	6 & 7 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
e) minor changes to an approved analytical procedure									
1.	1, 4, 5 from Annexure-1	☐	☐	☐	4 – 7 from Annexure-1	☐	☐	☐	
f) change from an in-house analytical procedure to a recognized compendial/pharmacopoeial analytical procedure									
1.	1 – 3 from Annexure-1	☐	☐	☐	4, 7 from Annexure-1	☐	☐	☐	
g) widening of an acceptance criterion									
1.	1, 5, 8 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
h) narrowing of an acceptance criterion									
1.	1 from Annexure-1	☐	☐	☐	1, 8, 9 from Annexure-1	☐	☐	☐	
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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Reference Standards or Materials									
19. Qualification of a new reference standard against a new primary international standard									
1.	1 & 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
20. Change in the reference standard from in-house (no relationship with international standard) to pharmacopoeial or international standard									
1.	1 & 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
21. Qualification of a new lot of reference standard against the approved reference standard (including qualification of a new lot of a secondary reference standard against the approved primary standard)									
1.	1, 2 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
22. Change to reference standard qualification protocol									
1.	3, 4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
23. Extension of reference standard shelf-life									
1.	5 from Annexure-1	☐	☐	☐	2 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Container Closure System									
24. Change in the primary container closure system(s) for the storage and shipment of the antigen									
1.	1 - 5 from Annexure-1	☐	☐	☐	1	☐	☐	☐	
25. Change in the specification of the primary container closure system for the antigen									
a) deletion of a test									
1.	1, 2 from Annexure-1	☐	☐	☐	1, 2 from Annexure-1	☐	☐	☐	
b) addition of a test									
1.	1 – 3 from Annexure-1	☐	☐	☐	3	☐	☐	☐	
c) replacement of an analytical procedure									
1.	1 – 3 from Annexure-1	☐	☐	☐	6, 7 from Annexure-1	☐	☐	☐	
d) minor changes to an analytical procedure									
1.	1, 3 from Annexure-1	☐	☐	☐	4 – 7 from Annexure-1	☐	☐	☐	
e) widening of an acceptance criterion									
1.	1 – 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
f) narrowing of an acceptance criterion									
1.	1 from Annexure-1	☐	☐	☐	8 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Stability									
26. Change in the shelf-life/hold-time for the antigen or for a stored intermediate of the antigen									
a) Extension									
1.	1 – 5 from Annexure-1	☐	☐	☐	1 – 5 from Annexure-1	☐	☐	☐	
b) reduction									
1.	1 – 5 from Annexure-1	☐	☐	☐	6 from Annexure-1	☐	☐	☐	
27. Change in the post-approval stability protocol of the antigen									
a) significant change to the post-approval stability protocol or stability commitment, such as deletion of a test, replacement of an analytical procedure or change in storage temperature									
1.	1 – 6 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
b) addition of time point(s) into the post-approval stability protocol									
1.	4, 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
c) addition of test(s) into the post-approval stability protocol									
1.	1, 2, 4, 6 from Annexure-1	☐	☐	☐	2 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Stability									
d) deletion of time point(s) from the post-approval stability protocol beyond the approved shelf-life									
1.	4, 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
e) deletion of time point(s) from the post-approval stability protocol within the approved shelf-life									
1.	4, 6 from Annexure-1	☐	☐	☐	3 from Annexure-1	☐	☐	☐	
28. Change in the storage conditions for the antigen, involving									
a) addition or change of storage condition for the antigen (for example, widening or narrowing of a temperature criterion)									
1.	1 – 4 from Annexure-1	☐	☐	☐	1, 2 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Changes to Final Product									
29. Change in the description or composition of the final product									
a) addition of a dosage form or change in the formulation (for example, lyophilized powder to liquid, change in the amount of excipient or new diluent for lyophilized product) Note: Change in formulation does not include changes in antigen(s) or adjuvants. A change in antigen(s) or adjuvant(s) requires the filing of a new application for MA or licensure. MA holders are encouraged to contact the NRA for further guidance.									
1.	1 – 10 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) change in fill volume (that is, same concentration, different volume)									
1.	1, 5, 7, 10 from Annexure-1	☐	☐	☐	1 – 3 from Annexure-1	☐	☐	☐	
c) addition of a new presentation (for example, addition of a new prefilled syringe where the approved presentation is a vial for a vaccine in a liquid dosage form)									
1.	1, 5, 7 – 10 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening / Assessment Outcome
Description and composition of the final product change to an adjuvant									
30. Change involving an approved chemical/synthetic adjuvant									
a) change in supplier of a chemical/ synthetic adjuvant									
1.	4, 5, 10, 11 from Annexure-1	☐	☐	☐	1-3 from Annexure-1	☐	☐	☐	
b) change in manufacture of a chemical/synthetic adjuvant									
1.	3 – 5, 10, 11 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
c) change in specification of a chemical/synthetic adjuvant (including tests and/or the analytical procedures)									
1.	7 – 11 from Annexure-1	☐	☐	☐	1 & 3 from Annexure-1	☐	☐	☐	
31. Change involving a biological adjuvant									
a) change in supplier of a biological adjuvant									
1.	1 – 7, 10 – 13 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) change in manufacture of a biological adjuvant									
1.	1 – 7, 10 – 12 from Annexure-1	☐	☐	☐	4 from Annexure-1	☐	☐	☐	
c) change in specification of a biological adjuvant (including tests and/or the analytical procedures)									
1.	6 – 10 from Annexure-1	☐	☐	☐	1 & 3 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Description and composition of the final product: change to a diluent									
32. Change to the diluent									
a) change in manufacturing process									
1.	1 – 5 from Annexure-1	☐	☐	☐	1 & 3 from Annexure-1	☐	☐	☐	
b) replacement of or addition to the source of a diluent									
1.	1 – 5 from Annexure-1	☐	☐	☐	1 & 3 from Annexure-1	☐	☐	☐	
c) change in facility used to manufacture a diluent (same company)									
1.	1, 3, 5 from Annexure-1	☐	☐	☐	1 & 2 from Annexure-1	☐	☐	☐	
d) addition of a diluent filling line									
1.	1, 3, 5 from Annexure-1	☐	☐	☐	1, 2, 4 from Annexure-1	☐	☐	☐	
e) addition of a diluent into an approved filling line									
1.	1, 3, 5 from Annexure-1	☐	☐	☐	1, 2 from Annexure-1	☐	☐	☐	
f) deletion of a diluent									
1.	None	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Manufacture (Final Product)									
33. Change involving a final product manufacturer/ manufacturing facility									
a) replacement or addition of a manufacturing facility for the final product (including formulation/ filling and primary packaging)									
1.	1 – 8 from Annexure-1	☐	☐	☐	1-5 from Annexure-1	☐	☐	☐	
b) replacement or addition of a secondary packaging facility, a labelling/storage facility or a distribution facility									
1.	1– 3 from Annexure-1	☐	☐	☐	2, 3 from Annexure-1	☐	☐	☐	
c) deletion of a final product manufacturing facility									
1.	None	☐	☐	☐	None	☐	☐	☐	
34. Change in the final product manufacturing process									
a) scale-up of the manufacturing process at the formulation/filling stage									
1.	1 – 6 from Annexure-1	☐	☐	☐	1 – 4 from Annexure-1	☐	☐	☐	
b) addition or replacement of equipment (for example, formulation tank, filter housing, filling line and head, and lyophilizer); see change 13 above									
1.	1 – 9 from Annexure-1	☐	☐	☐	5 from Annexure-1	☐	☐	☐	
c) addition of a new scale bracketed by the approved scales or scale down of the manufacturing process									
1.	1 & 4 from Annexure-1	☐	☐	☐	1 – 4 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Manufacture (Final Product)									
d) addition of a new step (for example, filtration)									
1.	1 – 6 from Annexure-1	☐	☐	☐	3 from Annexure-1	☐	☐	☐	
35. Change in the controls (in-process tests and/or acceptance criteria) applied during the manufacturing process or on intermediates									
a) narrowing of in-process limits									
1.	1, 5 from Annexure-1	☐	☐	☐	2, 3, 7 from Annexure-1	☐	☐	☐	
b) addition of new in-process test and limits									
1.	1 – 6, 8 from Annexure-1	☐	☐	☐	2, 3, 8, 9 from Annexure-1	☐	☐	☐	
c) deletion of a non-significant in-process test									
1.	1, 5, 7 from Annexure-1	☐	☐	☐	2 – 4 from Annexure-1	☐	☐	☐	
d) widening of the approved in-process limits									
1.	1 – 6, 8, 9 from Annexure-1	☐	☐	☐	1 – 3 from Annexure-1	☐	☐	☐	
e) deletion of an in-process test which may have a significant effect on the overall quality of the final product									
1.	1, 5, 6, 8 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
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Manufacture (Final Product)									
f) addition or replacement of an in-process test as a result of a safety or quality issue									
1.	1 – 6, 8 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
g) addition or replacement of an in-process test as a result of a safety or quality issue									
1.	1 – 6, 8 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
36. Change in in-process controls testing site									
1.	10 from Annexure-1	☐	☐	☐	**1 – 3, 5, 6** from Annexure-1	☐	☐	☐	
37. Change in the specification used to release the excipient									
a) deletion of a test									
1.	1, 3 from Annexure-1	☐	☐	☐	5,8 from Annexure-1	☐	☐	☐	
b) addition of a test									
1.	1 – 3 from Annexure-1	☐	☐	☐	4 from Annexure-1	☐	☐	☐	
c) replacement of an analytical procedure									
1.	1, 2 from Annexure-1	☐	☐	☐	1 – 3 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
d) minor changes to an approved analytical procedure									
1.	1, 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
e) change from an in-house analytical procedure to a recognized compendial analytical procedure									
1.	1, 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
f) widening of an acceptance criterion									
1.	1, 3 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
g) narrowing of an acceptance criterion									
1.	1 from Annexure-1	☐	☐	☐	3, 4, 6, 7 from Annexure-1	☐	☐	☐	
38. Change in the source of an excipient from a vegetable or synthetic source to a human or animal source that may pose a TSE or viral risk									
1.	2 – 7 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
39. Change in the source of an excipient from a TSE risk (for example, animal) source to a vegetable or synthetic source									
1.	1, 3, 5, 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
40. Replacement in the source of an excipient from a TSE risk source to a different TSE risk source									
1.	2 – 7 from Annexure-1	☐	☐	☐	5, 6 from Annexure-1	☐	☐	☐	
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Manufacture (Final Product)									
41. Change in manufacture of a biological excipient									
1.	2 – 7 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
42. Change in supplier for a plasma derived excipient (for example, human serum albumin									
1.	1 from Annexure-1	☐	☐	☐	3, 4, 6, 7 from Annexure-1	☐	☐	☐	
43. Change in supplier for an excipient of non-biological origin or of biological origin (excluding plasma-derived excipient)									
1.	2, 3, 5 – 7 from Annexure-1	☐	☐	☐	1, 5, 6 from Annexure-1	☐	☐	☐	
44. Change in excipient testing site									
1.	10 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Control of Final Product									
45. Change affecting the QC testing of the final product (release and stability)									
a) transfer of the QC testing activities for a non-pharmacopoeial assay (in-house) to a new company or to a different site within the same company									
1.	1, 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) transfer of the QC testing activities for a pharmacopoeial assay to a new company									
1.	1, 2 from Annexure-1	☐	☐	☐	1 Annexure-1	☐	☐	☐	
46. Change in the specification used to release the final product									
a) for products or components subject to terminal sterilization by heat (for example, diluent for reconstitution of lyophilized vaccines), replacing the sterility test with process parametric release									
1.	1, 2, 6, 8, 10 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) deletion of a test									
1.	2, 9, 10 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
c) addition of a test									
1.	2 – 4, 8 from Annexure-1	☐	☐	☐	1, 2, 9 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Control of Final Product									
d) change in animal species/strains for a test (for example, new species/strains, animals of different ages, and/or new supplier where genotype of the animal cannot be confirmed)									
1.	5, 11 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
e) replacement of an analytical procedure									
1.	2 – 4, 7, 8 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
f) minor changes to an approved analytical procedure									
1.	3, 8 from Annexure-1	☐	☐	☐	3 – 6 from Annexure-1	☐	☐	☐	
g) change from an in-house analytical procedure to a recognized compendial analytical procedure									
1.	2 – 4, from Annexure-1	☐	☐	☐	3, 6 from Annexure-1	☐	☐	☐	
h) widening of an acceptance criterion									
1.	2, 8, 10 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
i) narrowing of an acceptance criterion									
1.	2 from Annexure-1	☐	☐	☐	7 – 10 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Reference Standards or Materials									
47. Qualification of a reference standard against a new primary international standard									
1.	1, 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
48. Change of the reference standard from in-house (no relationship with international standard) to pharmacopoeial or international standard									
1.	1, 2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
49. Qualification of a new lot of reference standard against the approved reference standard (including qualification of a new lot of a secondary reference standard against the approved primary standard)									
1.	2 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
50. Change to the reference standard qualification protocol									
1.	3, 4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
51. Extension of the shelf-life of the reference standard									
1.	5 from Annexure-1	☐	☐	☐	2 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Container Closure System									
52. Modification of a primary container closure system (for example, new coating, adhesive, stopper or type of glass) **Note: The addition of a new container closure system (for example, addition of a pre-filled syringe where the currently approved presentation is only a vial) is considered a change in presentation**									
1.	1-7 from Annexure-1	☐	☐	☐	1-3 from Annexure-1	☐	☐	☐	
53. Change from a reusable container to a disposable container with no changes in product contact material (for example, change from reusable pen to disposable pen)									
1.	1, 3, 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
54. Deletion of a container closure system									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
55. Change in the supplier for a primary container closure component									
a) replacement or addition of a supplier									
1.	4, 5 from Annexure-1	☐	☐	☐	1, 2 from Annexure-1	☐	☐	☐	
b) deletion of a supplier									
1.	None	☐	☐	☐	None	☐	☐	☐	
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Section	Supporting Documents	Submitted? Yes	Submitted? No	Submitted? NA	Conditions	Met? Yes	Met? No	Met? NA	DGDA Screening – Assessment Outcome
Container Closure System									
56. Change in the specification used to release a primary container closure component or functional secondary container closure component									
a) deletion of a test									
1.	1, 2 from Annexure-1	☐	☐	☐	1, 2 from Annexure-1	☐	☐	☐	
b) addition of a test									
1.	1, 2 from Annexure-1	☐	☐	☐	3 from Annexure-1	☐	☐	☐	
c) replacement of an analytical procedure									
1.	1-3 from Annexure-1	☐	☐	☐	6,7 from Annexure-1	☐	☐	☐	
d) minor changes to an analytical procedure									
1.	1-3 from Annexure-1	☐	☐	☐	4-7 from Annexure-1	☐	☐	☐	
e) widening of an acceptance criterion									
1.	1-2 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
f) narrowing of an acceptance criterion									
1.	1 from Annexure-1	☐	☐	☐	8 from Annexure-1	☐	☐	☐	
Submitted By (Sign & Seal)									

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Stability									
57. Change in the shelf-life of the final product									
a) extension (includes extension of shelf-life of the final product as packaged for sale, and hold-time after opening and after dilution or reconstitution)									
1.	1 – 5 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) reduction (includes reduction as packaged for sale, after opening, and after dilution or reconstitution)									
1.	1 – 5 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
58. Change in the post-approval stability protocol of the final product									
a) major change to the post-approval stability protocol or stability commitment, such as deletion of a test, replacement of an analytical procedure or change in storage temperature									
1.	1 – 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) addition of time point(s) into the post-approval stability protocol									
1.	4, 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
c) addition of test(s) into the post-approval stability protocol									
1.	4, 6 from Annexure-1	☐	☐	☐	1 from Annexure-1	☐	☐	☐	
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Stability									
d) deletion of time point(s) from the post-approval stability protocol beyond the approved shelf-life									
1.	4, 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
e) deletion of time point(s) from the post-approval stability protocol within the approved shelf-life									
1.	4, 6 from Annexure-1	☐	☐	☐	2 from Annexure-1	☐	☐	☐	
f) replacement of the sterility testing by the container/closure system integrity testing									
1.	1, 2, 4, 6 from Annexure-1	☐	☐	☐	3 from Annexure-1	☐	☐	☐	
59. Change in the labelled storage conditions for the final product or the diluted or reconstituted vaccine									
a) addition or change of storage condition(s) for the final product, or for diluted or reconstituted vaccine (for example, widening or narrowing of a temperature criterion, or addition of or change to controlled temperature chain conditions)									
1.	1 – 4, 6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) addition of a cautionary statement (for example, "Do not freeze")									
1.	1, 2, 4, 5 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
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Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening: Assessment Outcome
Product Labelling Information Changes									
a) Addition of an adverse event identified as consistent with a causal association with immunization with the vaccine concerned									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) Change in the frequency of occurrence of a given adverse reaction									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
c) Addition of a contraindication or warning (such as identification of a specific subpopulation as being at greater risk, such as individuals with a concomitant condition or taking concomitant medicines, or a specific age group). These changes may include the provision of recommended risk-management actions (for example, required testing prior to vaccination, specific monitoring following vaccination and ensuring patient awareness of certain risks)									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
d) Strengthening or clarification of product labelling information text relating to contraindications, warnings, precautions and adverse reactions									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
e) Revisions to the instructions for use, including dosage, administration and preparation for administration to optimize the safe use of the vaccine									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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Urgent Product Labelling Information Changes									
a) Addition of an adverse event identified as consistent with a causal association with immunization with the vaccine concerned									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) Change in the frequency of occurrence of a given adverse reaction									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
c) Addition of a contraindication or warning (such as identification of a specific subpopulation as being at greater risk, such as individuals with a concomitant condition or taking concomitant medicines, or a specific age group). These changes may include the provision of recommended risk-management actions (for example, required testing prior to vaccination, specific monitoring following vaccination and ensuring patient awareness of certain risks)									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
d) Strengthening or clarification of product labelling information text relating to contraindications, warnings, precautions and adverse reactions									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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Annexure – 2

FORM Title: Checklist for Post Marketing Authorization Variations of Vaccines

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-003/F02-01	01	JUN' 22	JUN' 27		29.05.22	33 of 38

Section	Supporting Documents	Submitted? Yes	Submitted? No	Submitted? NA	Conditions	Met? Yes	Met? No	Met? NA	DGDA Screening: Assessment Outcome
Administrative Product Labelling Information Changes									
a) Change in the name of the MA holder and/or manufacturer (such as change of name due to a merger)									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) Change in the trade name of the vaccine									
1.	1 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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NRA-MA-003/F02-01	01	JUN' 22	JUN' 27		29.05.22	34 of 38

Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Changes of Strains of Influenza Vaccine									
a) Annual changes in the vaccine strain composition									
1.	1-6 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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NRA-MA-003/F02-01	01	JUN' 22	JUN' 27		29.05.22	35 of 38

Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening: Assessment Outcome
Safety and Efficacy Changes									
a) addition of a new indication (such as prevention of a previously unspecified disease)									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
b) modification of an approved indication (such as expansion of the age of use or restriction of an indication based on clinical studies demonstrating lack of efficacy)									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
c) addition of a new vaccination regimen (such as addition of accelerated vaccination regimens),									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
d) addition or modification of the existing vaccination regimen (such as addition of a booster dose or modification of the recommended time interval for booster vaccinations)									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
e) Change to add information on shedding and transmission									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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NRA-MA-003/F02-01	01	JUN' 22	JUN' 27		29.05.22	36 of 38

Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Safety and Efficacy Changes									
f) Change to the use in specific at-risk groups (such as addition of information on use in pregnant women or immunocompromised patients)									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
g) Change to add information on co-administration with other vaccines or medicines									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
h) Change to add a new route of administration									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
i) Change to add a new dosage form1 (such as replacement of a suspension for injection with a lyophilized cake)									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
j) Change to add a new strength									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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Annexure – 2

	FORM Title: Checklist for Post Marketing Authorization Variations of Vaccines					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-003/F02-01	01	JUN' 22	JUN' 27		29.05.22	37 of 38

Section	Supporting Documents	Submitted? Yes	No	NA	Conditions	Met? Yes	No	NA	DGDA Screening Assessment Outcome
Safety and Efficacy Changes									
k) Change to add a new delivery device (such as adding a needle-free jet injector)									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
l) deletion of an existing route of administration, dosage form and/or strength due to safety reasons									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
m) deletion of a contraindication (such as use in pregnant women).									
1.	1-4 from Annexure-1	☐	☐	☐	None	☐	☐	☐	
Submitted By (Sign & Seal)									

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Annexure – 2

	FORM Title: Checklist for Post Marketing Authorization Variations of Vaccines					
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Assessment Started on		**Assessment Completed on**		Total Duration	
Assessment Summary			**Assessment Done By/Date**		
Recommendation of Head of Vaccine and Biologics			**Head of Vaccine & Biologics Sign/Date**		

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Annexure-3

	FORM Title: Format for the Application form of Variation MA					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-003/F03-04	04	JUN' 22	JUN' 27		29.05.22	01 of 01

Date

Dairy No

To
Director General
Directorate General of Drug Administration
Aushad Bhavan, Mohakhali, Dhaka-1212, Bangladesh.

Subject: Submission of Application for variation of Marketing Authorization of Product Name(s)

Dear Sir,

We are pleased to submit the application for variation of Marketing Authorization of following product(s)

Proprietary name (trade name) .....

Approved generic name(s) .....

Strength(s) per dosage unit .....

Dosage form.....

Name of License holder.....

Marketing authorization number .....

Date of Marketing Authorization .....

Expiry date of this marketing authorization .....

Nature of variation (s) applied for

1.

2.

3.

Yours sincerely,

<Signature>
<Name>
<Title>
<Phone number>
<Email address>

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Annexure-4

	FORM Title: Log Book of Registration/MA Variation					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-003/F04-04	04	JUN' 22	JUN' 27		29.05.22	of

Sl No.	Company Name & Address	License Number	Generic Name	Brand Name	Strength	Name of Variation/s	Application Received Date & Dairy Number	Decision (Approved/ Rejected)	Letter issued with dispatch Number (Dispatched By and Sign)

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Issued by:
Issue date: 30 MAY 2022

Annexure – 5

FORM Title: Reporting Categories and Review Timelines for Variations of Vaccines

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-003/F05-00	00	JUN' 22	JUN' 27		29.05.22	1 of 1

The review time would start when the supplement has been accepted for review and found to be complete and would end at the time when the initial assessment is shared with the MA holder, either by the issuance of an approval notification or a noncompliance notification with a list of comments and deficiencies. In the case of the latter, the MA holder may seek approval for the change by submitting an amendment to the supplement with responses to all the comments in the notification of noncompliance.

Table: **Review timelines for a prior approval supplement (PAS)**

Category	Supplement	Maximum review period
Quality Changes		
Major quality changes	PAS	6 months
Moderate quality changes	PAS	3 months
Minor quality changes	Do not require notification to DGDA	N/A
Safety, efficacy and product labelling information changes		
Safety and efficacy changes	PAS	10 months
Product labelling information changes	PAS	5 months
Urgent product labelling information changes	PAS for urgent safety restrictions	Immediate implementation on receipt of supplement by DGDA
Administrative product labelling information changes	PAS	30 days
	Do not require approval prior to implementation	N/A
Strain of Influenza Vaccine changes	PAS	30 days