

Application Form for amendment in the EUA of Medicinal Products

I/We..... hereby apply for the grant of amendment in the Emergency Use Authorization for the following medicinal product:

1. Name of Vaccine:
2. Brand Name (if any):
3. Manufacturer:
4. Emergency Use Authorization no.:

Proposed amendment:

Please attach following evidences:

1. Approval of the amendment by WHO or referenced National Regulatory Authority (NRA)
2. Artworks of package, label and insert (if changes apply)
3. Product Information Sheet highlighting the changes

Declaration:

☐ I, hereby declare that all information provided on this application is complete, true and correct to the best of my knowledge and will be liable for any consequences if any information provided is proven to be false or misleading.'

☐ I, hereby declare that any updates related to safety and efficacy of the product will be communicated as part of post authorization changes.

☐ I, hereby declare that the vaccine to be supplied is the same as the one listed on WHO-EUL list or reference NRA.

Signature of applicant

Name:

Address:

Date: