**(Appendix 5 of WHO Guidance on Variation to a Prequalified Vaccine)**

**Submission of variations to a WHO prequalified vaccine**

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| **AUTHORIZED BY THE NATIONAL REGULATORY AUTHORITY (NRA)**  **AUTHORIZED BY THE NRA BUT NOT YET IMPLEMENTED BY THE MANUFACTURER**  **NOT YET AUTHORIZED BY THE NRA**  **REPORTING CATEGORY (tick all applicable options)**  **Type N  Single variation**  **Type A**  **Multiple variations**    **VARIATION(S) IMPACT ON:**  **Administrative Information (Appendix 1)**  **Manufacturing (Appendix 2)**  **Quality Control** **(Appendix 2)**  **Safety (Appendix 3)**  **Efficacy (Appendix 3)** |

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| **Name and address of the manufacturer:** | **Name and address of contact person:**  **Telephone number:**  **Fax number (optional):**  **E-mail:** |

**PRODUCTS CONCERNED BY THIS SUBMISSION**

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| --- | --- | --- | --- |
| (Proprietary / Invented name(s)) | Active component(s) | Presentation(s) | Strength(s) |
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If this list is very extensive (e.g. more than one page) it may be added as an annex to the form.

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| **Precise scope and background for the VARIATIONS, and justification IN CASE OF MORE THAN ONE VARIATION IN THE SAME SUBMISSION FORM (e.g. consecutive variations), if applicable.**  (*Include a description and background of all the proposed variations. If a variation concerns an unforeseen change (e.g. not included in the guidance document), provide a justification for its proposed reporting category).* |

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| **PRESENT CONDITION** | **PROPOSED CONDITION** |
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Specify the precise present and proposed wording or specification, including dossier (WHO PSF; WHO CTD format) section number(s).

For labelling and package leaflet variations, underline or highlight the changed words presented in the table above or provide as a separate Annex (including mock-up labels identifying the changes).

If this list is very extensive the table may be extended by adding pages as needed.

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| **Declaration by the manufacturer (**responsible or contact person**):**  I hereby submit a notification/application for the above variation(s) in accordance with the WHO Guidance document…….in the context of the Prequalification of Vaccines. I therefore declare that (*Please tick the appropriate declarations*):  There are no other changes than those identified in this submission  Where applicable, all conditions set for the variation(s) concerned are fulfilled;  All the documentation supporting each variation is available upon WHO request;  This notification/submission has been submitted / discussed with the NRA responsible for the regulatory oversight of the prequalified product*;* |

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| **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Status (Job title) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |