

REGULATION AND PREQUALIFICATION DEPARTMENT

VACCINES ASSESSMENT TEAM

TEMPLATE MODEL FORMAT FOR PRODUCT RE-EVALUATION REPORT Doc No: IMD/TP/10c Version No: 2 Revise before: 15 Nov 2027 Effective date: 15 Nov 2024 Replaces: Annex 3 Page 1 of 1 Approved by: TL-VAX, date: 31 Oct 2024 UH-PQT, date: 31 Oct 2024 Once printed or copied from the Master, this document is no longer controlled and only valid on the day of printing or copying

| PQS product re-evaluation report | | Date: <dd.mm.yy></dd.mm.yy> |
|--|---|--|
| PQS reference: <ref></ref> | | Prequalification date: <dd.mm.yy></dd.mm.yy> |
| <pre><pre><pre><pre><pre><pre><pre><pre></pre></pre></pre></pre></pre></pre></pre></pre> | | |
| 1. | UNICEF Supply Division Quality Assurance Centre (QAC) reports: <br< th=""></br<> | |
| 2. | Results of structured field performance monitoring: <b< td=""></b<> | |
| 3. | Performance feedback from governments and donor agencies: <b< td=""></b<> | |
| 4. | Manufacturers' Change Notifications: | |
| 5. | Manufacturers' Product Defect Reports: <br< th=""></br<> | |
| 6. | Questionnaires: <b< td=""></b<> | |
| 7. | Anecdotal reports from the field: <b< td=""></b<> | |
| 8. | Relevant policy decisions: <br< th=""></br<> | |
| 9. | Recommendation: <b< td=""></b<> | |
| | Re-validate product: Suspend pr | oduct: Remove product: |
| | Date of suspension notification: <dd.mm.yy></dd.mm.yy> | |