**ANNEX 3 – Post Recall Information (FINAL REPORT to SAHPRA)**

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| **Post recall information** | **Information by the HCR / Parallel importer** |
| 1. Name of product |  |
| 2. Name of Active Pharmaceutical Ingredient(s) (APIs) |  |
| 3. Source (Manufacturer) of the APIs |  |
| 4. SAHPRA allocated registration number |  |
| 5. Dosage form |  |
| 6. Strength of product |  |
| 7. Pack size/type |  |
| 8. Batch number and expiry date |  |
| 9. Nature of defect |  |
| 10. Action taken (taking into account the area of distribution of recalled medicine), if exported confirmation from the Regulatory Authority and the holder of the distribution authorization in the foreign country |  |
| 11. Urgency of the action taken |  |
| 12. Reason for the action |  |
| 13. Indication of the health risk and the reported clinical problems |  |
| 14. Steps taken to prevent re- occurrence of the problem (CAPA) |  |
| 15. Fate of the recalled product (including the decision taken –ie destruction)  NB: A destruction certificate must be supplied to SAHPRA in order to close the recall) |  |
| 16. The result of the recall-quantity of stock returned, corrected, outstanding, etc |  |
| 17. Confirmation that customers have received the recall letter (include mailing list) |  |
| 18. Copies of all recall correspondence including previous correspondences to SAHPRA regarding this recall. |  |