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

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.	