ANNEX 1 - Recall Information (INITIAL REPORT to SAHPRA)

Recall information	Information by the HCR/Parallel importer
1. Name of person/organisation reporting the problem	
2. Company	
3. Physical address	
4. Telephone number	
5. Facsimile number	
6. E-mail address	
7. Date of report	
8. Name of recipient at the MRA/SAHPRA	
Product (medicine) details	
1. Name of product affected	
2. Name of Active Pharmaceutical Ingredient (API)	
3. Source (Manufacturer) of the API	
4. SAHPRA allocated registration number	
5. Dosage form	
6. Strength of the product	
7. Pack size/type	
8. Batch number and expiry date	
9. Manufacturer/holder of the certificate of registration, address and contact details	
10. Date manufactured	
11. Date released	
12. Total quantity prior to distribution	
13. Quantity released for distribution prior to the recall	
14. Date of distribution	
15. Local distribution (include distribution list)	
16. international distribution (give full details and	

Nature of defect 1. Source of complaint (e.g. patient/ hospital/pharmacy/manufacturer, etc)	
2. Details of complaint	
3. Number of complaints received	
4. Initial date complaint was received	