healthxchange group	SOP 027.1 Complaints - Pharmacovigilance and Medical Devices Reporting Form			
Responsible Person Approval		**Approval Date**	26 Nov 2025	**Version** 1.1
Name	Brian Hood	**Effective Date**	27 Nov 2025	
Signature		**Review Date**	27 Nov 2026	

SECTION 1 to 4 MUST BE COMPLETED IN FULL BY RELEVANT PRACTITIONER PRIOR TO SUBMISSION

SECTION 1 - Pharmacovigilance (Adverse Event/ Reaction) Reporting

Report Completed By (enter name)	Date	Time

SECTION 2 - Contact Details

Name of Person Submitting Report	Customer Name
Account Number/ Reference	**Email and Telephone Details**
Order Number & Order Platform	**Date of Order/ Date Prescribed**
Please specify if ordered from Healthxchange/ SkinStation/ Clever Patients etc	

SECTION 3 - Product & Complaint Details

Name of Product or Device	Strength
Dosage Form	**Pack Size**
Batch Number/ Device Serial No.	**Expiry Date**

Date and Timeline of Event

Treatment Plan/ Intervention given

Please provide details of regimen/protocol/frequency as well as patch test

Description of Reaction

Please provide details of symptoms (i.e. Itching, swelling, burning etc)
Treatment Given

Outcome of Reaction

SECTION 4 - Patient Details	
Sex (M/F)	Age (years)
Fitzpatrick Skin Type	Initials (of patient)

Medical History and Drugs/Supplements Taken in Previous 3 Months	
Tick here if N/A	☐

Patient Consents to Share Information with Healthxchange

Other Information

SECTION 5 - MHRA Reporting	
Has the customer reported the ADR to the MHRA?	Date Reported
Has HXC reported the ADR to the MHRA?	Date Reported

Reported to the MHRA by:	

SECTION 6 - Supplier Reporting	
Has this ADR been reported to the Supplier?	Supplier Name
Date Reported	Reported to

SECTION 7 - Traceability		
Date Products Invoiced	Invoice #	Quantity

Stock Quarantined?	
Date Quarantined	
Recall Initiated?	
Recall Date	

SECTION 8 - Final Regulatory Review	
Print Name	
Job Title	
Signature	
Date	

**Please attach all supporting information to the form*

Version History		
Version	*Description of Change*	*Date Changed*

1.0	Form Creation	18-Jun-2024
1.1	Minor updates to form	25-Nov-2025