

		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)	

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	
<input type="checkbox"/> Tick here if N/A <input type="checkbox"/>	

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

<i>Version History</i>		
<i>Version</i>	<i>Description of Change</i>	<i>Date Changed</i>
1.0	Form Creation	18-Jun-2024
1.1	Minor updates to form	25-Nov-2025