

		<b>SOP 027.1 Complaints - Pharmacovigilance and Medical Devices Reporting Form</b>		
<b>Responsible Person Approval</b>		<b>Approval Date</b>	26 Nov 2025	<b>Version</b> 1.1
<b>Name</b>	Brian Hood	<b>Effective Date</b>	27 Nov 2025	
<b>Signature</b>		<b>Review Date</b>	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 <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