PRODUCT COMPLAINT RECORD FORM

Email to product.complaints@pharmaxis.com.au or

Fax to :+61 2 9451 3622 **Telephone: +61 2 8412 7360**

To be completed by Pharmaxis Quality Assurance Complaints Officer			
Complaint Number		**Date Returned Product Received**	
Date Received		**Signature**	

PART 1 - REQUIRED FIELDS: *To be Completed by the Complaint/Falsified Product Reporter (Form Initiator)*

DETAILS OF FORM INITIATOR	
Name	
Healthcare Professional	**YES** ☐ **NO** ☐ *(tick relevant box)*
Occupation	
Telephone *Include country and area codes*	
Email	
DETAILS OF COMPLAINANT *(Person to whom Correspondence is to be sent. Do not forward Patient/Subject address details)*	**DETAILS OF FALSIFIED PRODUCT** *(Where the falsified product was obtained or suspected to be located)*
Name:	**Falsifier name or Company** *(If known):*
Correspondence Address *Note: complaint letter of acknowledgement/response will be sent to this address. A copy of the final response will be forwarded to the form initiator.*	**Falsifier Address** *(Physical address or website details)*
Letter of Response Requested? *(Required for Complaints Only)*	**YES** ☐ **NO** ☐ **(tick relevant box)** **If YES Specify Language: .....**
Telephone *Include country and area codes*	
Email	
PRODUCT DETAILS *(IMPORTANT: Please complete all fields)*	
Product Name	
Batch/Lot Number	
Expiry Date	

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Complaint No._____

PRODUCT TYPE *(tick relevant box)*	
• **Commercial Product**	☐
• **Clinical Trial Product**	☐
Give Details of Trial – including Site, Investigator and Subject/Patient Number	
• **Other Product**	☐
If other, please specify	

COMPLAINT DETAILS			
Complaint Involves *(tick relevant box)*			
Capsules	☐	**Device**	☐
Packaging	☐	**Other,** ***specify***	☐
Date of Initial Occurrence			
Frequency of Occurrence			
Product to be Returned to Pharmaxis		**YES** ☐ **NO** ☐ *(tick relevant boxes)* ***Address Returned Product to:*** *Pharmaxis Ltd, Complaints Department, Locked Bag 5015, Frenchs Forest NSW 2086, Australia.* **NCPR #** *(If required):*_____ ***Returned Product Retained*** ☐ ***Disposed*** ☐	

Full Details of Complaint

Describe the occurrence, problem or product use error. Give all details that may be used to assist the investigation (including product storage conditions, type of device used etc.). If English is not your native language, give a detailed explanation in your native language ***as well as*** *English.* **OR**

Full Details of Falsified Product

Provide a detailed description of the falsified product i.e. falsified characteristics. Note details of events that lead to the suspicion of a falsified product or, any adverse reactions associated with the suspected falsified Pharmaxis product.

Attach the original written complaint if available or additional sheets if necessary.

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PART 2 - COMPLAINT REVIEW: *To be Completed by the Pharmaxis Quality Assurance and Complaints Officer*

RISK ASSESSMENT *(tick relevant boxes)*	
Has a preliminary assessment of the risk to the patient been performed on the complaint? **Sign and Date: ..... *(QA Complaints Officer*** **Is a Formal Risk Assessment Required?** **If NO explain: .....** **.....**	**YES ☐ NO ☐** **YES ☐ NO ☐** **RAN: .....**
What is the Risk Level allocated to this complaint? **Sign: ..... *(QA Complaints Officer)*** **Sign: ..... *(Quality Assurance Manager)***	**NEGLIGIBLE ☐** **MINOR ☐** **MODERATE ☐** **MAJOR ☐** **SEVERE ☐**
Should the complaint be considered by a recall committee? **Sign: ..... *(QA Complaints Officer)***	**YES ☐ NO ☐**
Date Recall Committee Informed? *(if applicable)*	**.....**
Are there potential quality implications for other batches? **Sign: ..... *(QA Complaints Officer)***	**YES ☐ NO ☐**
If YES, describe actions taken to ensure potentially faulty batches are not produced, released or distributed.	

ADVERSE EVENT ASSESSMENT *(tick relevant boxes)*	
Is the complaint associated with product distributed within Australia or New Zealand? **If yes, email: quality@btchealth.com.au**	**YES ☐ NO ☐**
Has the complaint been assessed by the Pharmacovigilance Department?	**YES ☐ NO ☐**
Is there an Adverse Event associated with the complaint?	**YES ☐ NO ☐**
If yes, what is the AE reference number?	**AE Ref No.:.....**
Is the AE assessment email attached? **If NO explain :.....**	**YES ☐ NO ☐**

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COMPLAINT REVIEW TEAM *(tick relevant boxes)*			
QA Complaints Officer	☐	**Medical Director**	☐
Quality Assurance Manager	☐	**Head of Medical and Regulatory Affairs**	☐
Operations Manager	☐	**Other**	☐
Production Manager	☐	**Other**	☐

COMPLAINT INVESTIGATION	
Investigation Required? **Written by:** ..... *(QA Complaints Officer)* **Authorised by:** ..... *(Quality Assurance Manager)*	**YES** ☐ *If yes, attach complaint investigation report.* **NO** ☐ *If no, attach justification to not investigate.*
Required Corrective / Preventative Action *(CARs to be issued by QA)*	**CAR Numbers** .....
Documentation confirming correct batch number attached?	**YES** ☐ **NO** ☐ **NA** ☐
Complaint batch details entered correctly (i.e. ELB-027, letters, WB-044, report and FM-012)?	**1. Entered By/Date:** ..... **2. Verified By/Date:** .....
Correspondence Attached?	**YES** ☐ **NO** ☐

COMPLAINT CLOSURE *(Final signatures indicating satisfactory resolution of complaint - sign & date)*

TITLE	SIGNATURE	DATE
QA Complaints Officer		
Quality Assurance Manager		
Operations Manager		
Production Manager		
Head of Medical and Regulatory Affairs		
Medical Director		
Other		

Final Close Out by Head of Quality – sign & date:**.....**