ASTRAZENECA STANDARD OPERATING PROCEDURE

AZIND: PROCEDURE FOR MANAGEMENT OF PRODUCT QUALITY COMPLAINTS

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KEY POINTS

- Any personnel from AZ India Marketing Company or AZ India Operations who becomes aware of a PQC from an external customer for AZPIL products by phone, email, fax, mail, social media, or other verbal/written communication shall report the event in one business day via CHAMPion form (https://contactazmedical.astrazeneca.com)

- This SOP should be read in conjunction with the following:
  - **SOP-0107501**: Product Quality Complaint Reporting (QCM-7-P30-cv-X)
  - **SOP-0107502**: Global Complaint Management (QCM-7-P29-cv-X)
  - **SOP-0107504** Management of Combined Complaints (QCM-7-P28-cv-X)
  - **SOP-0036263** GPF Global SOP - Reporting Product Security Incidents
  - **SOP-0033749** P-710 Management of Product Quality Issues Affecting Distributed Product that may require in-market action
  - **SOP-0046958** In market action
  - **SOP-0116138** Enterprise Quality Vault (EQV) Business Continuity Plan Procedure
  - **WI-0014922** How to Create and Manage a Complaint
  - **GUID-0021145** GUIDANCE Event/Defect Categorization - GPQS supporting 7-P29-cv-X

1 PURPOSE AND SCOPE

1.1 **PURPOSE:** This document stipulates the local procedures and responsibilities for management of Complaints with respect to all AstraZeneca Pharma India Limited (AZPIL) marketed and investigational products.

1.2 **SCOPE:** This Standard Operating Procedure (SOP) is applicable to all personnel (including contractors & consultants) within AZ India Marketing Company & AZ India Operations who encounter a Complaint arising from any AZPIL marketed and investigational products.

The scope of this local procedure covers:

- Reporting of product quality complaints
- Registering the complaint
- Management of return samples
- Management of complaint documentation
- Management of combined complaints
- Management of product security complaints
- Escalation/ Management of severe issues
- Business Continuity/ System Outages

2 DEFINITIONS

Terms	Definition
Product Quality Complaint	All manufacturing or packaging-related complaints involving AstraZeneca sample and trade Products received via either written, electronic, or oral communication. Customer may be a Patient, Pharmacist, Doctor or other Health Care Professional (HCP), wholesaler or regulatory authority. A Product Quality Complaint (PQC) may represent alleged deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance. PQCs do not include customer complaints regarding accounts, billing, transportation or shipping.
Product Security Complaint	Product Security Complaints arise from suspect samples within a market or from a proactive Internet surveillance operation managed by Global Security.
Combined Complaint	A case reported in which a specified Product Quality Complaint (PQC) or a Product Security Complaint is also associated with an Adverse Event (AE) (including Lack of Effect (LoE) or Medication Error (ME), or vice versa).
Adverse Event	The development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (eg. nausea, chest pain), signs (eg. tachycardia, enlarged liver) or the abnormal results of an investigation (eg. laboratory findings, electrocardiogram).

Please consult the *AstraZeneca Glossary* for clarity on definitions as needed.

3 WHAT YOU NEED TO DO (PROCEDURE)

3.1 Reporting of Product Quality Complaint:

Any personnel from AZ India Marketing Company or AZ India Operations who becomes aware of a Product Quality Complaint (PQC) from an external customer for AZPIL products by phone, email, fax, mail, social media, or other verbal/written communication shall report the event in one business day via CHAMPion form (https://contactazmedical.astrazeneca.com)

Alternatively, the PQC can be reported to the intake agent through the product quality complaints mailbox - productqualitycomplaints.india@astrazeneca.com with all the necessary details.

When receiving a PQC from an external customer, at minimum the following information must be collected with respect to complaint, if available:

a. Clear & concise complaint description
b. Product details including type (medication/ device), strength, pack type, etc.
c. Batch no. & expiration date
d. Defect start date & no. of defective units
e. Who administered the product, how many times have you previously administered the product, how were you trained to use this product?
f. Sample availability for return & return quantity (Where a complaint sample cannot or should not be returned, clear photographs of the defect sample with batch no. & expiry date must be obtained)
g. The Intake Agent contacts the complaint reporter and can make minimum of 3 attempts to obtain the required information & complaint sample. (If there is no response by the reporter, the same can be updated in ‘‘follow up information ‘’ section and the complaint could be closed within the timelines). Note: in case of receipt of return sample after the complaint is closed, the complaint shall be reopened.

h. Reporter follow-up is not conducted, if there is no consent to follow-up or the Reporter's contact information is unknown.

Please refer to SOP-0107501: Product Quality Complaint Reporting (QCM-7-P30-cv-X) for further details.

3.2 Registering of Product Quality Complaint:

Within one Business Day of receipt of the complaint by the PQC intake agent, the intake agent shall process the complaint record to initiated state in Global Pharmaceutical Quality System (GPQS) otherwise known as Enterprise Quality Vault (EQV) & assign it to the Owning Business Area (supplying site/ relevant function) for investigation.

Note: If a reported complaint is a duplicate record, cancel the newest complaint record.

Please refer to the below table for assignment of complaint based on its nature:

Sr. No.	Nature of complaints	Investigating Site
1.	Complaints pertaining to products manufactured in India/ Complaints pertaining to repacking or rework on AZPIL products	Bangalore Operations site
2.	Complaints pertaining to bulk/ finished AZPIL products imported into India	Overseas supplying site
3.	Complaints pertaining to Temperature Excursions, damages, changes, or discrepancies to the product (Supply logistics) for AZPIL products provided through Patient Assistance Programs	Market Access function

The PQC intake agent must acknowledge the receipt of the complaint to the complainant.

Please refer to SOP-0107502: Global Complaint Management (QCM-7-P29-cv-X) for further details.

3.3 Management of Return Samples:

For all the complaints, the PQC intake agent must request the complainant to send the return sample on below address unless the complaint owner of the supplying site/ relevant function considers that the sample is not necessary for investigation.

Kind Attention: Quality department

Address: AstraZeneca Pharma India Ltd. Survey No. 5-2/E, 12th Mile, Bellary Road, Yelahanka, Bangalore – 560063, India, Tel: +91-80-6774 8000

The intake agent will arrange for the return of the concerned product sample from the complainant to supplying site for investigation in case required.

Note: When requesting samples, ensure that the product is in an acceptable condition to be returned.

Once the samples are received from the complainant by the intake agent, the intake agent shall send the samples to the Central Warehouse where they must be stored in an identified location in a secured manner as per the necessary storage conditions till the samples are sent to the supplying site/ relevant function for investigation. Maintain the sample reconciliation in Annexure 1.

3.4 Management of PQC Documentation:

All the documentation related to complaints (Email Received, Scan copy of written materials, Initial response shared with Complainant, Photographs of defect samples, Bill of purchase, Complainant Response Email, etc.) must be maintained in a common box folder (EQV Complaint Records) under individual complaint folders for ready reference. Each individual Complaint folder is named by EQV record no. and product name

for identification. A local tracker PQC master tracker is also maintained in the common box folder for complaint details.

3.5 Management of Combined Complaints:

Any personnel from AZ India Marketing Company or AZ India Operations who becomes aware of a Combined Complaint from an external customer for AZPIL products by phone, email, fax, mail, social media, or other verbal/written communication must report the Adverse Event in addition to PQC in one business day via CHAMPion form (https://contactazmedical.astrazeneca.com) by accordingly ticking the report type.

Please refer to SOP-0107504 7-P28-cv-X: Management of Combined Complaints for further details.

3.6 Management of product security complaints

Any personnel from AZ India Marketing Company or AZ India Operations who becomes aware of any product related suspicious activity must report to Global Security within one working day via GS Secure Global Security's Reporting Platform

Please refer to SOP-0036263 GPF Global SOP - Reporting Product Security Incidents for reporting product security cases.

If the reported PQC or combined complaint requires investigation as a possible counterfeit then the global AZ process for the handling of suspect samples and the authentication outcomes must be followed in accordance with the SOP-0107504 7-P29-cv-X Global Complaint Management.

On availability of an investigation report from the supplying site on the product security related issue, the Regulatory Affairs Manager (RAM) shall notify the investigation report to the concerned State/Union Territory Drugs Controller with a copy to the concerned zonal Central Drugs Standard Control Organization (CDSCO) office if required.

3.7 Escalation/ Management of serious events

Should the PQC concern a possible product defect which may require escalation or further action to be taken (e.g. product recall), the PQC intake agent/ complaint owner must inform the Local Recall Administrator/ Central Recall Administrator (Quality Operations) to convene a discussion with the Local and Central Issue Management Team.

Please refer to SOP-0033749 P-710 Management of Product Quality Issues Affecting Distributed Product that may require in-market action & SOP-0046958 In market action for further details.

3.8 Customer Response

a. For commercial PQCs, the Owning Business Area or Supplying Site must notify the Intake Agent to send the customer response (as applicable) and to close the complaint record in the complaint database.

b. If the complainant requires a response, the Intake Agent must provide a response to the customer based on the final investigation report. (Email the customer response PDF downloaded from complaint record)

c. Responses to complainant must be sent by the intake agent within a target of five (5) calendar days from notification from the Owning Business Area or Supplying Site

d. The customer response email to be stored in the Box folder (EQV Complaint Records) and also upload in respective EQV complaint record.

3.9 Record Extension

a. If a complaint record cannot be closed by the target due date, the complaint record must be extended to reflect the expected closure date.

b. The extended target due date reflects the investigation required and must be done timely.

3.10 Amend Complaint

When a closed complaint needs to be amended, the supply site/Owning Business Area must initiate the amendment process for the complaint and process further investigation to conclude within the complaint record.

3.11 Tracking & Closure

The intake agent holds responsible for tracking and closing the complaint records within the timelines. Following are to be monitored on monthly basis and same needs to be recorded in the monthly checklist.

- Complaints are timely initiated (pending state to initiation state within 1 business day)
- Proper OBA is identified.
- Complaint owner is assigned.
- Assessment and investigation is completed within the set timelines (3, 14, 42, 60 calendar days)
- complaints are timely closed.

3.12 Business Continuity/ System Outages

Please refer to SOP-0116138 Enterprise Quality Vault (EQV) Business Continuity Plan Procedure for contingency plans during EQV system outage.

During system outages, any local process steps, e.g., investigations, not involving the system can be progressed and entered into the system when it becomes available.

High priority activities involving system transactions are continued outside the system, but a log of all “missed’ transactions is to be kept so it can be duplicated in the system retrospectively.

These priority changes are progressed outside the systems through agreement by the impacted functions.

4 ROLES & RESPONSIBILITIES

Role Designation	Responsibilities
Employees of AZ India Marketing Company or AZ India Operations	• Reporting a product quality complaint/ combined complaint/ product security complaint via appropriate channels stipulated in this SOP within one (1) business day. • Collecting complaint information from the originator
PQC Intake Agent	• Process PQCs to initiated state in the GPQS system & assign it to appropriate Owning business area 3 (supplying site/ relevant function). • Collecting complaint information from the complainant & following-up on sample availability, sample return. • Manage the return samples until sent for investigation. • Manage relevant PQC documentation in common box folder. • Respond to customer. • Inform the Local/ Central Recall Administrator in case of serious event. • Monitor & close within timelines.
Regulatory Affairs Manager	• Reporting to central/state health authorities in case of product security event, if applicable

5 REFERENCES & ASSOCIATED DOCUMENTS

Document Number (if applicable)	**Reference/Document Title**
SOP-0107501	Product Quality Complaint Reporting (QCM-7-P30-cv-X)
SOP-0107502	Global Complaint Management (QCM-7-P29-cv-X)
SOP-0107504	Management of Combined Complaints (QCM-7-P28-cv-X)
SOP-0036263	Reporting Product Security Incidents
SOP-0033749	Management of Product Quality Issues Affecting Distributed Product that may require In-market action
SOP-0046958	In market action
SOP-0116138	Enterprise Quality Vault (EQV) Business Continuity Plan Procedure
FORM-0122301	AZIND: monthly checklist for complaint
FORM-0122300	AZIND: tracking Return Sample reconciliation
GUID-0021145	GUIDANCE Event/Defect Categorization - GPQS supporting 7-P29-cv-X
WI-0014922	How to Create and Manage a Complaint
NA	CHAMPion form (https://contactazmedical.astrazeneca.com)
NA	GS Secure Global Security's Reporting Platform

6 DOCUMENT HISTORY

Version	**Description of Change**
1.0	Conversion of Guidance document to SOP; Guidance document made obsolete GCM is replaced by GPQS as the global pharmaceutical quality system Deletion of all duplicate information & reference to global SOPs wherever applicable Update in procedure for management of complaints, return samples, documentation & system outages Addition of procedure for escalation/ management of serious events Addition of appendix: Process Flow chart of complaints management
2.0	Update in the hyperlink of CHAMPion form
3.0	• Reference SOPs included. • Clarity on how to follow up is updated in Reporting of complaint (section 3.1) • Modifications done in 3.2 section (registering PQC) • Clarity provided under section 3.3 - return sample management. • Introduced Annexures1 & 2 (FORM-0122301 & FORM-0122300) • Added new sections 3.8 (customer response), 3.9 (record extension), 3.10 (amendment), 3.11 (track & closure). • Updated responsibilities for intake agent. • Box folder links provided

7 ANNEXURE

Annexure 1: Return Sample reconciliation (FORM-0122301)

Sl No.	QE record No.	Product & its strength	Sample received date	Sample stored date	Sample taken out date	Remarks

Reviewed by:

Annexure 2: monthly checklist for complaint tracking (FORM-0122300)

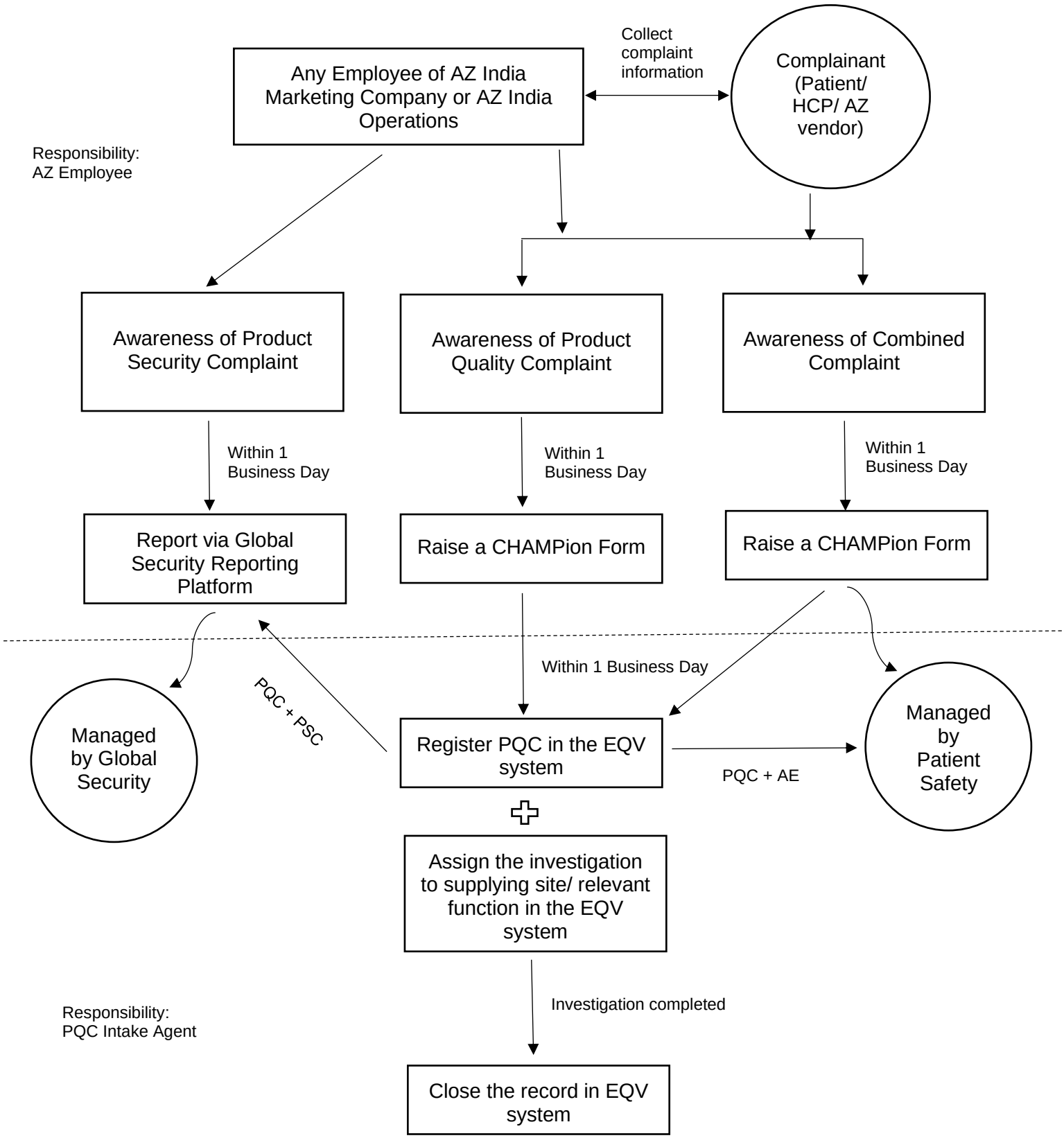
Month: Year:					
QE record No.	Initiated timely? (yes/no)	Is proper OBA identified? (yes/no)	Is Complaint owner assigned? (Yes/No)	Assessment and Investigation completed within timelines.? (Yes/No/due date)	Is the complaint closed timely? (Yes/No)

Reviewed by:

8 APPENDIX

Appendix: Process Flow chart of complaints management

PROCESS FLOW CHART OF COMPLAINTS MANAGEMENT



Document Approvals

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