**Document Approval**

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**Document History**

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| **Version** | **Date** | **Summary of the changes** |
| 1.0 | 13-02-2021 |  |
| 1.1 | 06-12-2022 | Review of the procedure and addition of clauses 4.1.1, 4.1.2 and 4.1.5 |
| 1.2 | 01-06-2023 | Reviewed and no changes made, except for updating the SafeCare logo |
| 1.3 | 14-03-2024 | Reviewed to capture licensee partners |

# Purpose

The purpose of this procedure is to describe handling of incidents, enquires, complaints and compliments received from the client, in house and from other parties in relation to SafeCare Certification activities. The management of appeals is addressed in the document QA-CER-001 SafeCare Certification Process.

# Scope

This procedure covers all incidents, enquires, complaints and compliments received at PharmAccess and/or SafeCare Certification country offices by any means such as, written, verbal, electronic etc. The procedure also includes incidents, enquiries, complaints and compliments received during a certification assessment by a licensee partner.

# Responsibility

Line Managersshall be responsible for receiving the incident, enquiry, or complaint from the clients / other parties. The Line Manager, in consultation with the office staff and assessors, are responsible for handling, validating and analysis of the incident, enquiry or complaint to the satisfaction of the clients / other parties.

# Procedure

## Incidents and Enquiries

4.1.1 All incidents, enquiries, complaints, and compliments can be filed with the SafeCare team by emailing [info@Safe-Care.org](mailto:info@Safe-Care.org), placing a call to the specific country office telephone numbers or in person to any SafeCare staff onsite.

4.1.2 These avenues shall be communicated to partners, healthcare facilities and patients through the SafeCare website, shared feedback forms and brochures where necessary.

4.1.3 Any notice of an incident or enquiries shall be received by any staff of PharmAccess’ central office or country office and dealt with immediately.

4.1.4 Where the incident or enquiry needs further information that is not immediately available or requires investigation, it shall be documented and forwarded to the relevant officer/licensee partner for onward completion.

4.1.5 When the incident, complaint or enquiry is applicable to non-SafeCare staff or services, it shall be forwarded to the grievance email address of the specific non-SafeCare partner.

## Complaints on activities and services of the SafeCare Certification Program

4.2.1 Complaints received by phone shall be documented by the staff receiving the complaint and forwarded to relevant line manager.

4.2.2 For written complaints, they shall be forwarded to the line manager concerned.

4.2.3 The complaint shall be filed in a complaint register at the PharmAccess office.

4.2.4 The line manager shall ensure that all complaints are acknowledged, in writing, within 7 days.

4.2.5 The line manager shall investigate each complaint received and indicate in the register the details of investigation and way forward including corrective actions.

4.2.6 Turnaround time for resolution of complaints shall not be more than 30 working days.

## Complaints concerning the services provided by a certified client

4.3.1 Complaints related to a certified client shall be dealt with as indicated in clause 4.2 above except that, after acknowledgement of the complaint, the line manager shall inform the certified client in writing concerning the received complaint.

4.3.2 The certified client is accountable for the investigation of the complaint and communication with the patient or family filing the complaint.

4.3.3 When the complaint is filed anonymously, the certified client makes every effort to investigate the complaint and resolve any issues identified.

4.3.4 The certified client informs the SafeCare line manager of the investigation and any resolution of the complaint.

4.3.5 The certified client may seek SafeCare assistance when they cannot resolve the complaint.

4.3.6 Once correction, and/or corrective actions have been completed and verified, the line manager documents the resolution of the complaint.

## Tracking of incidents, enquiries and complaints is the probability that an adverse event, which could cause materialization of the risk, may occur.

4.4.1 All incidents, enquiries and complaints shall be tracked, and records kept in the appropriate sections and filed in PharmAccess Complaints file at line manager’s office.

4.4.2 Complaints in both hard and soft copy registers shall be tracked by indicating dates of actions taken.

4.4.3 The line manager shall update the complaints records on the PharmAccess complaint record.

4.4.4 When indicated, the incident, enquiry or complaint is referred into the PharmAccess quality improvement processes.

## Impartiality

Any individual or team involved in the resolution of incidents, enquiries and complaints shall:

(a) not be persons named in the subject of the said incident, enquiry, or complaint

(b) be independent of the assessment and/or certification process that is the subject of the incident, enquiry, or complaint.

## Treatment of an individual or organization filing an incident report, an enquiry, or a complaint

Submission, investigation and decision on any incident, enquiry or complaint shall not result in any discriminatory actions against the individual or organization filing the incident report, enquiry, or complaint.