COMPLAINTS HANDLING POLICY

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1.0 Introduction

We aim to ensure that all complaints are welcomed, recorded, investigated, and resolved in a way that is quick, fair, consistent, and transparent and that Fresenius Kabi/Calea learns from them to improve services and prevent recurrence.

Our objective is to;

- Provide a clear, accessible route for people to raise complaints
- Ensure complaints are handled promptly and proportionately, with agreed timescales and regular updates.
- Remain fair and person-centred: We listen carefully, consider individual circumstances, and aim to resolve issues promptly.
- Provide appropriate remedies (e.g., explanation, apology, corrective action) and clear escalation/review options.
- Meet legal/regulatory requirements.
- Capture themes and drive continuous improvement through governance, reporting, and corrective and/or preventive actions.
- Ensure people are at no disadvantage: Complaining will not adversely affect the care or support we provide

2.0 Definitions

Term	Definition
Concern	An issue raised that can often be resolved immediately or within a short timeframe without a formal investigation
Complaint	An expression of dissatisfaction requiring a response
Complainant	The person raising the concern/complaint (which may include a representative or advocate with appropriate consent/authority
Patient Safety Incident	An unintended or unexpected incident that could have or did lead to harm
Duty of Candour	The legal duty to be open and transparent with people when a notifiable safety incident occurs (Regulation 20).

3.0 Accessibility, Equality and Support

We will make reasonable adjustments so that people can raise concerns and complaints on an equal basis. This includes offering communication in alternative formats (for example, large print, easy read, translated materials) and using preferred communication methods where possible (for example, email rather than telephone).

We will signpost people to independent advocacy where appropriate and will support people who have difficulty communicating, lack capacity, or need help to express their views. Where

a complaint is raised by a representative, we will confirm consent/authority in line with confidentiality and mental capacity requirements.

4.0 How to Raise a Concern or Complaint

Concerns and complaints can be made verbally or in writing. People can raise issues in the following ways:

- Directly to any member of staff – For example, a Patient Care Co-ordinator, Advice Line Nurse, Manager or Clinical Nurse Advisor
- By telephone:
    - Calea 0800 121 8300
    - Enteral 0808 100 1990
    - Biosimilars 0800 090 2461
- By email: FK.Complaints-UK.Complaints@fresenius-kabi.com
- In writing to:

  Quality Assurance and Compliance
  Calea UK Ltd
  Cestrian Court
  Eastgate Way
  Runcorn
  Cheshire
  WA7 1NT
- Via a representative/advocate (with appropriate consent/authority)

If the concern relates to immediate safety (for example risk of harm, abuse, neglect, or urgent clinical deterioration), staff must take immediate action to keep the person safe and follow safeguarding and clinical escalation procedures in parallel with this policy.

5.0 Roles and Responsibilities

5.1 All Employees of Fresenius Kabi ltd and Calea UK ltd

Listen, take concerns seriously, act to reduce immediate risk, record and escalate in line with this policy.

5.2 Departmental Heads/Managers

Lead local resolution, support investigations, ensure timely updates and responses.

5.3 Quality Assurance Team

Oversee complaint handling, ensures acknowledgement, triage, investigation, response quality, and learning actions are dealt with within timescales.

5.4 Registered Manager, Care Quality Commission (CQC)/Scottish Care Inspectorate (SCI)

Ensures systems and resources are in place to comply with Regulation 16; reviews themes and ensures improvements are implemented.

5.5 Designated Safeguarding Lead and Deputy

Provides advice and oversight where safeguarding concerns are indicated and ensures external referrals/notifications are made where required.

6.0 Procedure for Handling Complaints

6.1 Receipt and acknowledgement

All complaints will be recorded on our Quality Management System within 24 hours of receipt. We will acknowledge receipt within three working days. The acknowledgement will confirm who within the Quality Assurance Team is dealing with the complaint, how to contact them, and the expected timescale for response.

6.2 Triage and initial risk assessment

Upon receipt of a complaint, we will assess the nature of the complaint to determine whether immediate action is required to reduce risk, whether the issue is a patient safety incident, whether safeguarding procedures apply, and the level of investigation required.

6.3 Investigation

Investigations will be proportionate to the issues raised and may include speaking with the complainant, reviewing care records and relevant documents, interviewing staff, reviewing policies/procedures, and identifying contributing factors. Where appropriate, we will carry out a structured review and identify corrective and preventative actions.

6.4 Keeping people informed

We will agree the complainant's preferred method of contact and provide updates at appropriate intervals. If we cannot meet an agreed timescale, we will explain why, provide an interim update, and agree a revised timeframe.

6.5 Response and outcome

We aim to provide a written response within 30 working days. Where this is not possible (for example, complex investigations may take longer), we will agree an

alternative timescale with the complainant and provide regular updates. The response will include:

- A summary of the issues raised
- Findings
- An apology where appropriate
- What we have done/will do to put things right (including any immediate corrective actions taken)
- How we will prevent recurrence (learning/actions)
- How to escalate if the complainant remains dissatisfied

6.6 Closure

A complaint will be closed when the response has been issued and any agreed actions have been completed or have clear owners and deadlines. Where appropriate, we will confirm with the complainant that the complaint is closed.

7.0 Duty of Candour and Patient Safety Incidents

If a complaint indicates that a notifiable patient safety incident may have occurred, we will follow our Duty of Candour procedure (Regulation 20). This includes being open and transparent, providing an apology, explaining what is known at the time, investigating appropriately, and providing a written account of the notification and any actions taken.

8.0 Safeguarding and External Reporting

Where a complaint raises safeguarding concerns about an adult or child, staff must follow safeguarding procedures without delay. Safeguarding actions and referrals are managed separately from, but alongside, the complaint process. Where required, we will share information with relevant agencies and/or notify the CQC/SCI in line with regulatory requirements and information governance regulations.

9.0 Confidentiality, Consent and Data Protection

We will handle all complaint information confidentially and in line with data protection legislation. Information will be shared only with those who need it to investigate and respond. Where a representative raises a complaint, we will confirm the person's consent or lawful authority to act. Where the person lacks capacity, decisions will be made in their best interests and documented.

10.0 Learning, Improvement and Governance

We will analyse complaints to identify themes, trends and learning. Actions will be recorded, allocated to named owners, and tracked to completion. Learning from complaints will be shared with relevant staff through appropriate routes (for example, clinical governance committees, clinical supervision and team meetings).

11.0 Escalation and Review

If a complainant is unhappy with the complaint response, they can request a further review. A senior person from our Executive Leadership Team who has not been directly involved in the investigation will review the handling and outcome and respond within an agreed timeframe.

If after this further review they remain unhappy with the complaint response, they can contact the Parliamentary and Health Service Ombudsman on 0345 015 4033.

12.0 Records Management

We will keep a complete, accurate and auditable record of each complaint in our Quality Management System, including dates, communications, findings, outcomes, and actions. Records will be retained in accordance with our records management and retention schedule.

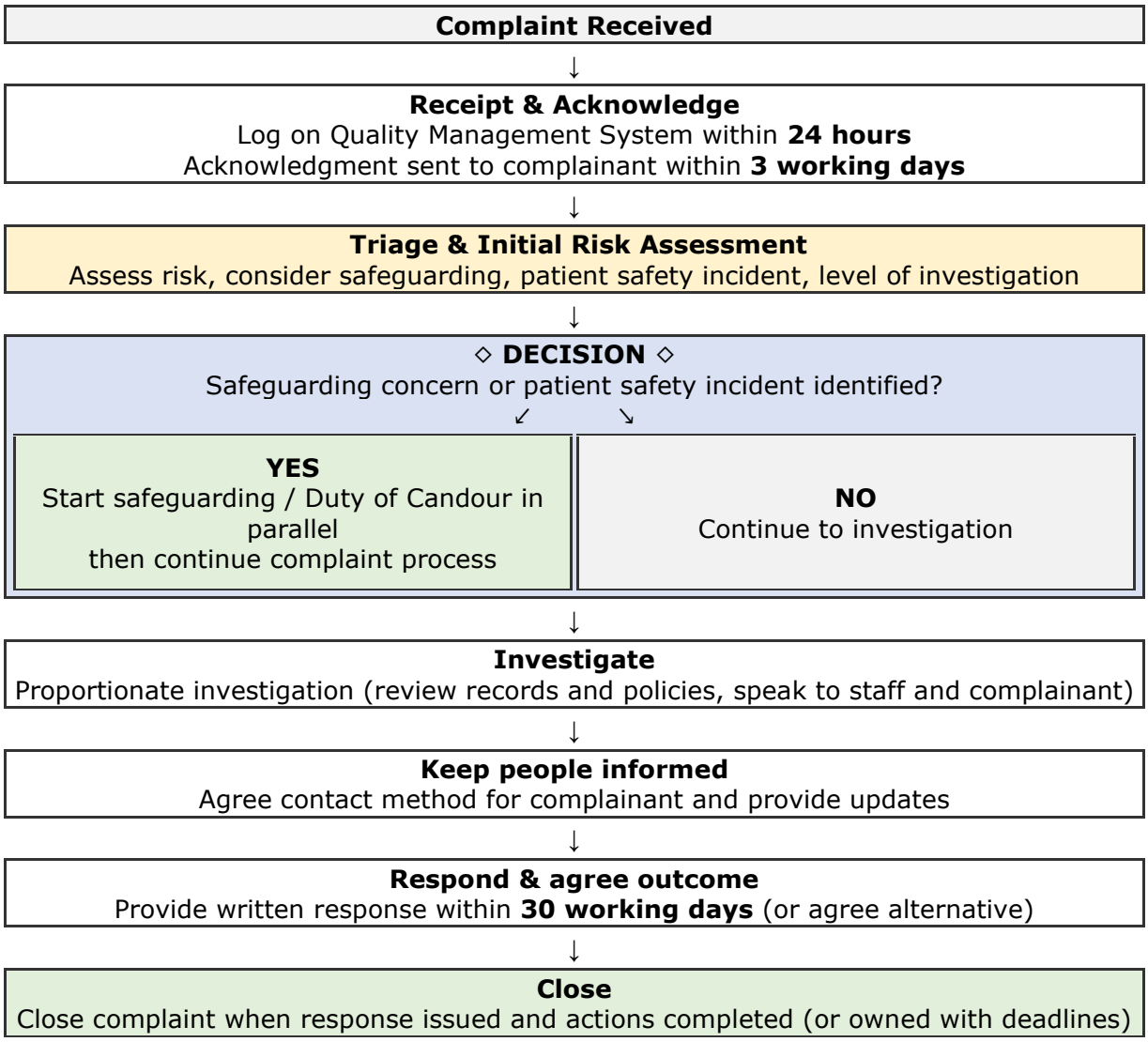
13.0 Monitoring, Reporting and Review of the Policy

Handling of complaints will be monitored against Key Performance Indicators and reported at our clinical governance committees. This policy will be reviewed at least every 12 months, or sooner if there are relevant regulatory changes, learning from incidents/complaints, or service changes.

14.0 Document Change History

Version	Reason for change and change description
1.0	Document newly established

15.0 Annex 1. Complaint Handling Process Flow



Note: Safeguarding actions and Duty of Candour requirements may run in parallel with this complaint process where indicated during triage (section 6.2). All communications, decisions, findings and actions should be recorded on the Quality Management System.