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Global Investigation Procedure

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1 Introduction and Purpose

Investigations conducted at H. Lundbeck A/S and affiliates (“Lundbeck”) into potential misconduct may arise from issues reported via the Compliance Hotline or be triggered by other sources such as complaints sent directly to management, audits or internal monitoring.

This investigation manual (“Manual”) has been developed in order to govern the investigation process and instruct Lundbeck personnel involved in such investigations. The main objectives are to:

- Define the scope of issues that must be reported via the Compliance Hotline
- Specify the roles and responsibilities of the key stakeholders in the process
- Provide detailed instructions regarding how to conduct investigations
- Ensure compliance with data protection requirements

2 Scope

The process described in this Manual applies to the handling and investigation of issues in scope (see below) that are reported from Lundbeck and external stakeholders worldwide. The investigation process will ensure compliance with the legislation of specific countries that only allow a narrower scope of reporting or prohibit the anonymity of the Complainant.

Only issues that involve either alleged legal, serious financial or reputational risks to Lundbeck are to be reported via the Compliance Hotline and investigated according to this Manual. These issues include but are not limited to the below. Issues that fall outside this scope will be reported to local management or the responsible corporate function as specified in Lundbeck’s Code of Conduct.

Category Misconduct	Examples of allegations
Financial	<ul style="list-style-type: none">• Misappropriation of assets including theft and misuse• Unlawful behaviour in connection with accounting principles, internal accounting controls or auditing matters• Deliberate errors in the preparation or maintenance of financial statements or records
Business Ethics	<ul style="list-style-type: none">• Serious conflicts of interest• Payment of bribes or facilitation payments• Unethical gifts and donations to business partners, healthcare professionals (“HCPs”) or government officials• Alleged breaches of competition law
Unlawful Promotion and Marketing	<ul style="list-style-type: none">• Non-compliant events• Allegations of off-label promotion• Misuse of product samples

Category Misconduct	Examples of allegations
Quality	<ul style="list-style-type: none"> • Serious misconduct related to Good Manufacturing Practice (“GMP”), Good Clinical Practice (“GCP”), Good Laboratory Practice (“GLP”) and Good Pharmacovigilance Practice (“GVP”)
Animal Ethics	<ul style="list-style-type: none"> • Serious misconduct relating to animal ethics legislation or Lundbeck policies and procedures
Health, Safety and Environment	<ul style="list-style-type: none"> • Serious misconduct relating to health, safety and environment legislation or Lundbeck policies and procedures
Supplier Evaluation	<ul style="list-style-type: none"> • Serious misconduct or major breaches by Third Parties or Suppliers (as defined in Appendix 18679) relating to Lundbeck’s Code of Conduct and/or supplier obligations
Employee Relations	<ul style="list-style-type: none"> • Workplace harassment, threats and discrimination
Lundbeck’s Ombudsman	<ul style="list-style-type: none"> • Issues involving personal or organisational conflict which cannot be solved through dialogue with management or HR. e.g. dismissals or warnings; issues related to mental health and working environment or conflicts in relation to personal development

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3 Roles and Responsibilities

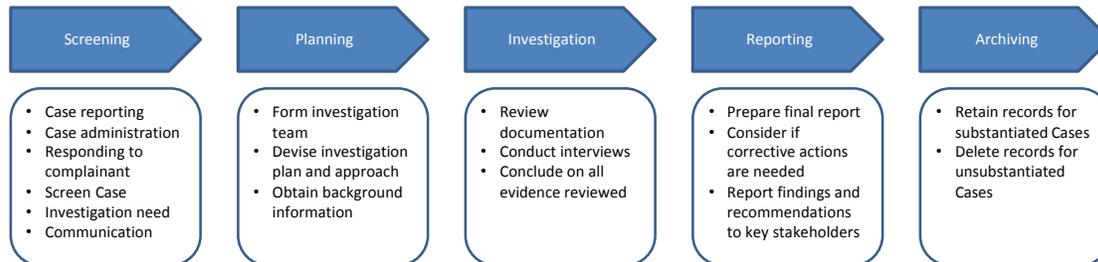
Role	Responsibilities
Chief Compliance Officer	<ul style="list-style-type: none"> • Process owner • Providing the Case Expert with support during the investigation • Reporting to the CMG Legal, Quality Review Committee • Reporting to the Audit Committee
Internal System Administrators, Corporate Compliance & CSR	<ul style="list-style-type: none"> • Performing initial screening to determine the case category • Providing the Case Expert with support during the investigation • Oversight and monitoring of all issues reported

Role	Responsibilities
Issue Owner, Lundbeck Senior Manager responsible for issue category	<ul style="list-style-type: none"> • Providing Lundbeck’s Chief Compliance Officer with a designated Case Expert from the relevant area of responsibility • Ensuring the Case Expert is provided with adequate time and resources to conduct the investigation
Case Expert	<ul style="list-style-type: none"> • Conducting the investigation of the reported issues relating to areas of expertise and will also be designated as the Investigation Leader if solely responsible for the case • Primary point of contact during the investigation for all communication regarding the case
Investigation Leader	<ul style="list-style-type: none"> • Case Expert responsible for leading the investigation and forming an investigation team if required by multi issue or complex cases
Vendor Hotline Expert	<ul style="list-style-type: none"> • External vendor receiving and recording all reported issues reported by the telephone hotline • Provision of the secure and confidential Case Management System, (“The System”), which is the repository for all documentation relating to the reported issue
Complainant	<ul style="list-style-type: none"> • The person reporting issues that involve either legal, serious financial or reputational risks to Lundbeck
Regional HR Management	<ul style="list-style-type: none"> • Determining the applicable sanctions if the reported issue is substantiated in conjunction with Local HR and Local Management
CMG Legal, Quality Review Committee (“LQRC”)	<ul style="list-style-type: none"> • Overseeing and monitoring all cases reported and investigated
Audit Committee	<ul style="list-style-type: none"> • Overseeing all investigations of issues that fall within the Audit Committee’s Terms of Reference (6.8)

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4 Procedures

The Lundbeck investigation process comprises of the following five key steps:



4.1 Screening

4.1.1 Case Reporting

The Complainant can report an issue via the Compliance Hotline's designated telephone numbers, Intranet or Internet. If the telephone option is chosen, the Vendor's Hotline Expert will take the call, ask any pertinent questions, select the issue category and log the report in the Case Management System. For issues, reported via the Internet or Intranet, the report will be sent directly to the System Administrators. The Complainant is provided with an option to upload any supporting documentation. All reported issues are registered as a case in the system. Once registered, the Complainant will receive a reference number enabling them to track the progress of the case.

If a potential issue is reported outside of the system, the System Administrators are responsible for entering the details into the system.

4.1.2 Case Administration

The System Administrators will be automatically alerted of a new case entering the system. An initial screening is performed to determine the category of the case. The relevant case is then sent to the designated Case Expert appointed by the Issue Owner. Corporate Compliance & CSR grants the Case Expert access to the specific case as required.

4.1.3 Special Cases

For special cases involving allegations against Corporate Compliance & CSR, the Chief Financial Officer ("CFO") is responsible for coordinating the investigation. Allegations against Executive Management or the General Counsel are investigated by the Audit Committee. Allegations against Board Members are investigated by External Auditors.

4.1.4 Responding to the Complainant

Upon receipt of the case from the System Administrators, the Case Expert must send a confirmation response the Complainant stating that the case will be evaluated. This correspondence must emphasize Lundbeck's non-retaliation policy for all issues reported in good faith.

4.1.5 Screening the Case

The first step of the investigation is to review the authenticity of the allegations. When performing this initial review, the Case Expert must consider the following factors:

- **Scope:** Does the case fall within scope of the process as defined in section 2?
- **Intent:** Do the allegations indicate intent or negligence by the employee accused of misconduct (referred to hereafter as the Accused)?
- **Reliability:** Is the Complainant a reliable source of information?
- **Evidence:** Has the Complainant sent any initial documentation or other information to substantiate the reported allegations?
- **Impact:** What is the potential legal, financial and reputational impact of the allegations for Lundbeck?

4.1.6 Investigation Need

A decision is then made by the Case Expert on whether a further investigation of the case is needed. If it is evident that the case falls outside the scope of the system or is inadmissible due to lack of evidence, the procedures specified in section 5 must be followed.

For cases in which employees have not been able to solve personal or organizational conflicts through dialogue with their manager and HR, the Complainant should be directed to Lundbeck's Ombudsman for further resolution.

4.1.7 Communication

The Case Expert must not inform any party including his or her manager about the details of any investigation unless specific authorisation to do so is granted by Lundbeck's Chief Compliance Officer.

The Accused is always presumed innocent until proven otherwise. To determine whether to inform the Accused of the allegations, the Case Expert must consider whether this is permissible in conjunction with local labour, data privacy and employment laws.

In general, the Accused should not be informed of the ongoing investigation if this may hinder or obstruct the investigation. If informed, the Case Expert is responsible for this communication.

For issues that potentially involve significant financial or reputational damage to Lundbeck, the Case Expert must contact Lundbeck's Chief Compliance Officer who will be responsible for informing the General Counsel, the CFO and Chief Executive Officer ("CEO") as needed (see section 4.4).

4.2 Planning the Investigation

4.2.1 Forming the Investigation Team

The Case Expert responsible for the case will be the designated Investigation Leader. It is the responsibility of the Investigation Leader to form an investigation team comprising of other internal case experts. For complex cases or those involving potential breach of legislation, it may be necessary to recruit external experts such as forensic auditors or external legal counsel in conjunction with the System Administrator if appropriate. Local interpreters may also be required for countries in which English is not widely spoken.

4.2.2 Investigation Plan

During the planning phase, the Investigation Leader should obtain all available background information to understand the allegations and enable the drafting of the investigation plan ("Investigation Plan"). Such information will include but is not limited to documents, agreements, records, statements, accounts etc.

The Investigation Plan should contain the following:

- The methodology to be used when performing the investigation. This may include desktop review of documentation, interview of relevant personnel, onsite visits etc. dependent upon the nature of the allegations
- A timeline for the investigation including timelines for the individual allegations being investigated. As a general rule, the investigation should not take longer than 90 days to complete
- An interview schedule that will enable the uncovering of the facts of the investigation. If feasible, the Complainant should be interviewed already at the planning stage to enable a more detailed understanding of the allegations
- Required additional documentation and information needed to be reviewed in order to reach a conclusion including how these documents will be obtained

If a site visit is required, the purpose of such visit should also be included in the Investigation Plan including how this will be communicated to local management.

If access to an Accused's email system, company mobile telephone etc. is needed for forensic investigations, this can only be granted by Lundbeck's CEO and subject to relevant legislation, including local data protection requirements and Lundbeck's IT procedures.

4.3 Performing the investigation

4.3.1 Documentation Review

Once the Investigation Leader has obtained all necessary documentation, a detailed analysis of the evidence must be performed. The review should:

- Assess the quality of the evidence. Is it for example objective data or subjective witness statements?
- Consider the reliability of the persons providing the information. Are they independent or are there are potential conflicts of interest due to close connections with the Complainant or Accused?
- Determine the importance of the evidence in relation to each of the allegations
- If no conclusions can be drawn from the documentation, determine what additional evidence should be reviewed or follow up interviews are needed to continue the investigation

4.3.2 Conducting Interviews

The Investigation Leader will need to determine the persons to be interviewed during the investigation. Typically, these will include the Complainant, the Accused and other individuals identified that may be able to provide additional evidence for the facts of the case. Generally, the Accused should be interviewed last to enable the presentation of facts and the evidence obtained relating to the allegations.

An interview checklist should be prepared in advance to ensure all relevant questions are covered. The interview should be conducted in a discreet location away from the person's place of work if feasible.

When conducting interviews, the Investigation Leader and the Case Expert must:

- State that all matters discussed under interview are confidential for the interviewee and must not be disclosed by the interviewee to any other party
- Only reveal sources of information if this is relevant to performing the interview
- Remind the interviewee of Lundbeck's commitment to protecting the Complainant against any form of retaliation
- Conduct the interview in an open manner
- Observe the manner and conduct of the interviewee under the interview
- Respect the rights of the interviewee during the interview. This includes allowing them to invite a representative to the interview such as HR or Legal

Detailed notes must be taken during the interview then recorded as formal minutes. These records must be stored in the Case Management System.

4.3.3 Conclusion

Following an evaluation of all the facts, documentation reviewed, all persons interviewed and other information sources, the Investigation Leader must decide and conclude whether the factual evidence substantiates or refutes the allegations contained in the reported case.

4.4 Reporting

All investigations will be concluded in a report that contains:

- A high-level summary of the findings and conclusions
- Statement of the reported allegations and scope of investigation
- Factual summary and conclusion for each of the allegations raised in the case, including the methodology employed
- Corrective action recommendations if the investigation reveals control weaknesses
- Recommendations for possible sanctions for the Accused, if the allegations are substantiated

The Investigation Leader will be the primary point of contact for communications after the investigation has been concluded. The Investigation Leader must not inform any party including his or her manager about the results of any investigation unless specific authorisation to do so is granted by Lundbeck's Chief Compliance Officer.

The final report is submitted by the Investigation Leader to the General Counsel and other applicable recipients on a strictly need to know basis. Decisions regarding sanctions shall be made by the relevant CMG members based on the report recommendations in consultation with Lundbeck's General Counsel, Regional HR Manager and potentially local management.

Subsequently, the Accused and Complainant must be informed regarding the outcome of the investigation by the Investigation Leader. Local Management is responsible for the communication of the potential sanctions to the Accused.

For major cases that could impact on Lundbeck's reputation, the Investigation Leader must also inform Corporate Communication of the outcome to determine whether an issue management plan is needed.

The Audit Committee will receive a summary report of all investigations containing no personal data references, on a quarterly basis as reported to the LQRC.

5 Confidentiality and Data Privacy

All documentation received during the course of the investigation must be treated as highly confidential and stored in the secure, Case Management System. Only the Case Experts directly involved in the investigation are given access to the information contained in the case.

The status and outcome of all cases are contained in a summary report as reported to LQRC on a quarterly basis and in a case monitoring report available from the system.

Substantiated Cases

Cases that are found admissible and substantiated must be retained for a minimum of five years or longer, if required by the legislation of the country in which the investigation is conducted.

Unsubstantiated Cases

Any personal data relating to cases that were found inadmissible during the initial screening process or investigated, but not substantiated, must be deleted forthwith from the Case Management System. Exceptions to this rule are cases that will need to be retained for subsequent external inspections by government authorities.

6 Changes since last edition

New version

7 Appendices

None

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