



PAIA MANUAL

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1. INTRODUCTION TO LUNDBECK

Lundbeck (South Africa) (Pty) Ltd (“Lundbeck”), is registered as a private company in South Africa. Lundbeck is a subsidiary of H. Lundbeck A/S, an international, Danish, research-based pharmaceutical company focusing on the central nervous system. Lundbeck researches and markets products for Depression, Anxiety, Alzheimer’s disease, Parkinson’s disease and Schizophrenia.

2. CONTACT DETAILS

Executive Officer:	Wendy Cupido
Information Officer:	Wendy Cupido
Deputy Information Officer:	Mia Campbell
Physical Address:	Unit 9, Blueberry Office Park, Apple Street, Randpark Ridge
Postal Address:	PO Box 2171, Northriding, 2162
Telephone Number:	(+27) (0)11 699 1600
E-mail address:	south_africa@lundbeck.com
Website address:	www.lundbeck.co.za

3. GUIDE OF THE SA HUMAN RIGHTS COMMISSION / INFORMATION REGULATOR

The South African Human Rights Commission (“SAHRC”) / Information Regulator compiled a Guide, in terms of Section 10 of the Promotion of Access to Information Act (Act 2 of 2000) (“PAIA”), to assist persons wishing to exercise their rights in terms of this Act. This Guide is available in all the official languages and contains, amongst others, the following information:

- the purpose of PAIA;
- the manner, form and costs of a request for access to information held by a body;
- legal remedies when access to information is denied;
- when access to information may be denied; and
- the contact details of Information Officers in the national, provincial and local Government.

Any person wishing to obtain the Guide may either access it through the website of the SAHRC at <https://www.sahrc.org.za/home/21/files/Section%2010%20guide%202014.pdf> or should contact the Information Regulator at:

Physical address: JD House, 27 Stiemens Street, Braamfontein, Johannesburg, 2001

Postal address: PO Box 31533, Braamfontein, Johannesburg, 2017

Telephone: +27 (0) 10 023 5207 / +27 (0) 82 746 4173

E-mail address: infoereg@justice.gov.za

Website: <https://www.justice.gov.za/infoereg/>

The publication of the abovementioned Guide will be the responsibility of the Information Regulator with effect from 30 June 2021.

4. RECORDS

Lundbeck holds the following categories of records:

4.1 Company and operational records:

Documents related to the establishment and registration of Lundbeck such as documents required in terms of the Companies Act (Act 71 of 2008), the Medicines and Related Substances Act (Act 101 of 1965) and the Pharmacy Act (Act 53 of 1974), governance-related documents, position statements, policies and guidelines; documentation relevant to the Board of Directors and the management structure of Lundbeck; membership records related to the Innovative Pharmaceutical Association of South Africa (“IPASA”) and the Marketing Code Authority (“MCA”).

4.2 Employment and recruitment records:

Recruitment documents; employment contracts; conditions of employment and workplace policies; employment equity and skills development plans and reports; salary and payment records; leave records; performance management records; collective agreements; disciplinary records; training records; expense accounts; relevant tax information and related records; medical scheme and pension fund membership records; and certification records related to the South African Code of Marketing Practice for Health Products (“the Code”).

4.3 Medical professional records:

Agreements; prescription data; Continuing Professional Development (CPD) records; invoices, statements; and payments.

4.4 Patient records:

Adverse events-related records; regulatory records.

4.5 Health and safety records:

Evacuation plan; health and safety incident reports; COVID-19-related records.

4.6 Clinical trial records:

Records related to clinical trials.

4.7 Financial records:

Annual financial statements; auditors' reports; accounting records; bank statements; payment records; VAT records; tax returns and related records; stock sheets; delivery notes and orders; invoices and statements; asset register.

4.8 Regulatory records:

Records related to the the manufacturing, distribution and registration of medicines and other relevant regulatory matters as prescribed in legislation.

4.9 Agreements:

Agreements (and related documentation) with contractors, consultants, suppliers and vendors, including rental agreements, financing and lease agreements, sale and purchase agreements.

4.10 Records relating to legal processes:

Complaint records; legal and other documents pertaining to any actual, pending or potential legal matters.

4.11 Insurance records:

Insurance policies and related records; claims records.

5. INFORMATION AVAILABLE IN TERMS OF OTHER LEGISLATION

Lundbeck holds records as may be required in terms of the following legislation subject to the specific protection offered by the various laws:

1. Basic Conditions of Employment Act (Act 75 of 1997);
2. Companies Act (Act 71 of 2008);
3. Compensation for Occupational Injuries and Diseases Act (Act 130 of 1993);
4. Competition Act (Act 89 of 1998);
5. Consumer Protection Act (Act 68 of 2008);

6. Disaster Management Act (Act 57 of 2002);
7. Electronic Communications and Transactions Act (Act 25 of 2002);
8. Employment Equity Act (Act 55 of 1998);
9. Income Tax Act (Act 58 of 1962);
10. Labour Relations Act (Act 66 of 1995);
11. Medicines and Related Substances Act (Act 101 of 1965);
12. Occupational Health and Safety Act (Act 85 of 1993);
13. Pharmacy Act (Act 53 of 1974);
14. Promotion of Access to Information Act (Act 2 of 2000);
15. Protection of Personal Information Act (Act 4 of 2013);
16. Skills Development Levies Act (Act 9 of 1999);
17. Skills Development Act (Act 97 of 1998);
18. Unemployment Contributions Act (Act 4 of 2002);
19. Unemployment Insurance Act (Act 63 of 2001); and
20. Value Added Tax Act (Act 89 of 1991).

6. RECORDS AUTOMATICALLY AVAILABLE

No notice has been submitted by Lundbeck to the Minister of Justice and Correctional Services regarding the categories of records, which are available without a person having to request access in terms of Section 52(2) of PAIA. However, the information on the website of Lundbeck is automatically available without having to request access in terms of PAIA. Access to and usage of the information on the website are subject to the Website Terms and Conditions of Lundbeck.

7. PURPOSE OF PROCESSING PERSONAL INFORMATION

Lundbeck processes personal information of data subjects for the following purposes:

- conduct of the business of Lundbeck;
- communication of relevant information, industry matters and events;
- maintenance of its records;
- employment, human resource and labour-related matters;
- appointment and related matters of directors;
- procurement of products and services;
- engagement with Regulators and relevant public and private bodies;

- marketing of Lundbeck's products and events;
- marketing and sales of products, events and services;
- determining market share;
- sales incentives;
- medical liaison;
- medical professional engagements;
- reporting to relevant regulators;
- CPD event attendance and records;
- pharmacovigilance;
- sharing of safety and other relevant medical information with its parent company;
- auditing purposes;
- historical, statistical and research purposes; and
- any other lawful purpose related to the business of Lundbeck.

8. DATA SUBJECTS, THEIR PERSONAL INFORMATION AND POTENTIAL RECIPIENTS OF THIS INFORMATION

Lundbeck holds the personal information in respect of the categories of data subjects specified below. The potential recipients of the personal information processed by Lundbeck are also specified. ***Information and records are only disclosed as may be necessary in the circumstances and authorised in terms of the law or otherwise with the consent of the relevant data subjects.***

8.1 Directors

Categories of personal information: CVs; names and surnames; contact details; identity numbers; race; gender; nationality; qualifications; bank details; remuneration; Financial Intelligence Centre Act (Act 38 of 2001) (FICA) documents where required; and correspondence.

Potential Recipients: Directors and employees; parent company of Lundbeck; South African Revenue Services ("SARS"); relevant services providers, suppliers and vendors; relevant public and private bodies; banks; vetting agencies; the public; professional and legal advisers; auditors; executors of estates; law enforcement structures, including courts and tribunals; future owners should a change in ownership occur; and other relevant persons or entities as required or permitted by law.

Personal information of nominators and nominees as provided on nomination forms is also held by Lundbeck and disclosed to the Lundbeck Board, Lundbeck's parent company, the auditors and professional and legal advisers, as may be relevant and required.

8.2 Employees and Job Applicants

Categories of personal information: Curriculum Vitae ("CVs"); names and surnames; contact details; identity numbers / dates of birth; race; gender; nationality; qualifications; registered professions; employment history and information; position held and job description; bank details; relevant health information; criminal behaviour; disciplinary-related information; correspondence; tax numbers and related tax information; leave records; remuneration; employment benefits; absenteeism information; Code certification; next-of-kin details.

Potential Recipients: Directors; other employees; parent company of Lundbeck; SARS; relevant service providers, suppliers and vendors of Lundbeck; relevant public and private bodies (e.g., the South African Health Products Regulatory Authority ["SAHPRA"], Chemical Industries Education and Training Authority ["CHIETA"], IPASA and the MCA); banks; vetting agencies; professional and legal advisers; auditors; executors of estates; law enforcement structures, including courts and tribunals; future owners should a change in ownership occur; and other relevant persons or entities as required or permitted by law.

8.3 Medical Professionals

Categories of personal information: Names and surnames; practice-related information; relevant staff details; contact details; addresses; identity numbers; gender; nationality; qualifications; statutory council registration numbers; registered professions; website addresses; opinions; correspondence; banking details; Broad-Based Black Economic Empowerment ("BBBEE") related information; VAT (Value Added Tax) numbers; prescribing habits; engagement-related information; and other information included in agreements.

Potential Recipients: Directors; employees; Banks; auditors; professional and legal advisers; Board of Directors; relevant public and private bodies, including relevant regulators; relevant service providers, suppliers and vendors; accreditation providers; accreditation providers; parent company in Denmark; insurers; law enforcement

structures, including courts and tribunals; future owners should a change in ownership occur; and other relevant persons or entities as required or permitted by law.

8.4 Patients

Categories of personal information: Names and surnames; contact details; identity numbers; dates of birth; gender; relevant health information.

Potential Recipients: Directors; employees; professional and legal advisers; relevant public and private bodies, including relevant regulators; parent company in Denmark; insurers; future owners should a change in ownership occur; law enforcement structures, including courts and tribunals; and other relevant persons or entities as required or permitted by law.

8.5 Suppliers, Vendors, Service Providers, Public and Private Bodies, Other Persons and Entities

- **Categories of personal information:** Names and surnames; organisation names and details; addresses; registration numbers; contact details; website addresses; Names, surnames, titles and contact details of relevant contact persons and officials; Profession and qualifications; CVs and information included therein; information included in agreements; market information; price structures; official documentation, including newsletters and policies; benefit / fee structures; financial and payment information, including bank details and bank letters; CIPC [Companies' and Intellectual Property Commission]; registration certificates; shareholder information; VAT numbers; Tax Clearance Certificates / Status; Broad-Based Black Economic Empowerment (BBBEE) status of suppliers; Covid-19 screening information of visitors; engagement-related information and correspondence.
- **Potential Recipients:** Directors; employees; banks; auditors; professional and legal advisers; accreditation providers; Board of Directors; employees; future owners should a change in ownership occur; law enforcement structures, including courts and tribunals; and other relevant persons or entities as required or permitted by law.

8.6 Insurers

Categories of personal information: Names and contact details; premiums;

correspondence.

Potential Recipients: Directors; employees; auditors; professional and legal advisers; relevant public and private bodies; Board of Directors; future owners should a change in ownership occur.

9. PLANNED TRANSBORDER FLOWS OF PERSONAL INFORMATION

Lundbeck stores electronic information, including personal information of data subjects, on servers, which may be located outside of the borders of the Republic of South Africa. Information is currently stored in countries such as Denmark, India, Germany, the United Kingdom, the United States of America, Singapore, Poland, Mauritius, Namibia and Botswana, subject to adequate protection mechanisms being in place.

10. SECURITY MEASURES TO PROTECT PERSONAL INFORMATION

Lundbeck is committed to ensuring the security of the personal information in its possession or under its control in order to protect it from unauthorised processing and access as well as loss, damage or unauthorised destruction. It continually reviews and updates its information protection measures to ensure the security, integrity and confidentiality of this information in accordance with industry best practices. Lundbeck has implemented extensive controls to protect personal information and to detect and respond to cyber-attacks and data breaches. The measures it adopts to ensure the security of personal information includes technical and organisational measures and internal policies to prevent unauthorised access, loss or use of personal information, for example, the physical securing of hard copy records; access control to electronic records; and off-site data back-ups. In addition, only those employees, directors, service providers, suppliers and vendors that require access to the information to discharge their functions relating to Lundbeck's business will be permitted access to the relevant information and only if they have concluded agreements with or provided undertakings to Lundbeck requiring them to implement appropriate security measures and to maintain the confidentiality of the information. All security breaches are taken seriously and are addressed in accordance with the law.

11. PROCEDURE TO OBTAIN ACCESS TO RECORDS OR INFORMATION

The fact that information and records are held by Lundbeck as listed in this Manual should not be construed as conferring upon any requester any right to that information or record. PAIA

grants a requester access to records of a private body, if the record is required for the exercise or protection of any right. If a public body lodges a request, the public body must be acting in the public interest. Access to records and information (other than that listed on Lundbeck's website) is not automatic. Any person, who would like to request access to any of the above records or information, is required to complete a request form, which is available from the Information Officer of Lundbeck or the Information Regulator at the contact details stipulated above.

The requester must provide sufficient detail on the request form to enable the Information Officer to identify the record and the requester. The requester must identify the right he/she is seeking to exercise or protect and explain why the record requested is required for the exercise or protection of that right. If a request is made on behalf of another person, the requester must submit proof of the capacity in which the request is made to the satisfaction of the Information Officer. Access to the requested records or information or parts of the records or information may be refused in terms of the law. Requesters will be advised of the outcome of their requests.

12. FEES PAYABLE TO OBTAIN THE REQUESTED RECORDS OR INFORMATION

Fees may be charged for requesting and accessing information and records held by Lundbeck. These fees are prescribed in terms of PAIA. Details of the fees payable may be obtained from the Information Officer. The fees are also available from the Information Regulator.

13. AVAILABILITY OF THIS MANUAL

A copy of this Manual is available for inspection, free of charge, at Lundbeck's offices and on its website. A copy of the Manual may also be requested from the Information Officer against payment of the appropriate fee, which may be obtained from the Information Officer.