

Sanofi Manual to Accessing Information (“Manual”)

This Manual has been prepared in terms of section 51 of the Promotion of Access to Information Act 2 of 2000 (“PAIA”) and updated in the light of the Protection of Personal Information Act 4 of 2013 (“POPIA”).

1. Introduction

This Manual is for Sanofi Aventis South Africa Proprietary Limited, Registration Number: 1996/010381/07 (“Sanofi Aventis SA”), and Sanofi Industries South Africa Proprietary Limited Registration Number: 1931/002901/07 (“Sanofi Industries SA”) Collectively referred to as “the Company”. This manual has been prepared in accordance with Section 51 of the Promotion of Access to Information Act, No. 2 of 2000 (Private Body). On 9 March 2001, the Promotion of Access to Information Act, No. 2 of 2000 became operative, giving effect to the section 32(2) of the Constitution providing for a constitutional right of access to information. On 1st July 2020, the Protection of Personal Information Act 4 of 2013 also came into effect, which started the one-year grace period for private and public bodies to comply with POPIA.

2. Purpose of PAIA

PAIA is an act that was passed to give effect to the constitutional right, held by everyone in South Africa, of access to information which is held by the State or by another person and which is required for the exercise or protection of any right. Where a request is made in terms of PAIA, the body to which the request is made is obliged to give access to the requested information, except where the Act expressly provides that the information may or must not be released.

It is important to note that PAIA recognises certain limitations to the right of access to information, including, but not exclusively, limitations aimed at the reasonable protection of privacy, commercial confidentiality, and effective, efficient and good governance, and in a manner which balances that right with any other rights, including such rights contained in the Bill of Rights in the Constitution.

POPIA was enacted in November 2013, to promote the protection of personal information processed by public and private bodies. POPIA amended certain provisions of PAIA, balancing the need for access to information against the need to ensure the protection of personal information.

3. Information manual

One of the main requirements specified in PAIA is the compilation of an information manual that provides information on both the types and categories of records held by a private body. This document serves as the Company's information manual. This Manual is compiled in accordance with section 51 of PAIA and the Schedule to POPIA. It is intended to give a description of the records held by and on behalf of the Company; to outline the procedure to be followed and the fees payable when requesting access to any of these records in the exercise of the right of access to information, with a view of enabling requesters to obtain records which they are entitled to in a quick, easy and accessible manner.

This Manual is available for public inspection:

- at the physical address of the Company, recorded in paragraph 4 below, free of charge; and
- on this website, free of charge; and
- on request by any person (along with payment of a prescribed fee).

The Manual is available from the designated Information Officer, whose details appear below.

4. Contact details of the Information Officer of the Company

The responsibility for administration of, and compliance with, PAIA and POPIA have been delegated to the Information Officer.

Requests pursuant to the provisions of PAIA and/or POPIA should be directed to the Information Officer as follows:

Information Officer:	Mr. Kgositsile Mogamme
Postal Address:	Sanofi Aventis South Africa
	Hertford Office Park, Building I
	5 th Floor, 90 Bekker Road
	Midrand 2196

E-mail Address: zadatarequests@sanofi.com

5. Information Regulator's Information.

An official Guide has been compiled which contains information to assist a person wishing to exercise a right of access to information in terms of PAIA and POPIA. This Guide is made available by the South African Human Rights Commission (mandated in terms of POPIA). Copies of the updated Guide are available from South African Human Rights Commission on its website: www.sahrc.org.za

For further information, the requester may contact the Information Regulator whose details are as below:

Postal Address: **The Information Regulator (South Africa)**

33 Hoofd Street
Forum III, 3rd Floor Braampark
P.O Box 31533
Braamfontein, Johannesburg, 2017
Mr Mosalanyane Mosala
Chief Executive Officer

Telephone Number: +27 (0) 10 023 5207

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

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

6. Automatic disclosure

A private body may, on a voluntary basis, make available a description of categories of records that are automatically available without a person having to request access in terms of PAIA.

The only fee for access to these records may be a prescribed fee for reproduction; •

Patient Information Leaflet

7. Types and categories of records

RECORDS HELD IN ACCORDANCE WITH OTHER LEGISLATION

A requester may request information that is available in terms of other legislation, such as:

- Medicines and related substances Act of 1965 ;
- Competition Act 89 of 1998;
- The Companies Act 71 of 2008;
- The Labour Relations Act 66 of 1995;
- Employment Equity Act 55 of 1998;
- Basic Conditions of Employment Act 75 of 1997;
- Compensation for Occupational Injuries and Diseases Act 130 of 1993;

- Employment Equity Act 55 of 1998;
- Income Tax Act 58 of 1962;
- Occupational Health and Safety Act 85 of 1993;
- Unemployment Insurance Act 63 of 2001;
- Value-added Tax Act 89 of 1991;

The above is not an exhaustive list of statutes that may require the Company to keep records.

SUBJECT CATEGORIES OF RECORDS

The information is classified and grouped according to records relating to the following subjects and categories:

PERSONNEL RECORDS

"Personnel" refers to any person who works for or provides services to or on behalf of the Company and receives, or is entitled to receive, remuneration and any other person who assists in carrying out or conducting the business of the Company. It includes, without limitation, directors (executive and non-executive), all permanent, temporary and part-time staff, as well as contract workers.

Personal records provided by personnel include:

- Records provided by a third party relating to the Company personnel;
- Conditions of employment and other personnel-related contractual and quasi-legal records, including job applications;
- Internal evaluation records and other internal records;
- Correspondence relating to, or emanating from, personnel (internal and external to the organization); and • Training schedules and material;
- Payment records (and beneficiary payments), including banking details.

CLIENT RELATED RECORDS

"Client" refers to any juristic entity that receives goods or services from the Company. This includes prospective clients who submit applications to the Company, but which or who ultimately do not become the Company clients.

Client related records include:

- Transactional records;
- Correspondence with a Client that is implicitly or explicitly of a private or confidential nature

PATIENT RELATED RECORDS

“**Patient**” refers to any natural person that have used, use, or may use a medicine, pharmaceutical product and/or substance, as provided for in the Medicines and Related Substances Act of 1965, which is manufactured or marketed by the Company, or in the context of a clinical study.

Patient related records may include:

- Pharmacovigilance records.

HCP RELATED RECORDS

“**Health Care Professional**” or “**HCP**” refers to persons registered with any statutory council regulating healthcare practitioners, including the Health Professions Council of South Africa (HPCSA), the South African Veterinary Council (SAVC), the Allied Health Professions Council of South Africa (AHPCSA), the South African Nursing Council (SANC) and the South African Pharmacy Council (SAPC), and includes clinical and non-clinical persons registered with these councils such as medical practitioners, nurses, technicians, research coordinators, pharmacists and pharmacists’ assistants, as well as clinical engineers registered with the Engineering Council of South Africa.

HCP related records may include:

- Contact information;
- Reports of adverse events in the context of pharmacovigilance;
- Attendance records.

PRIVATE BODY RECORDS

These records include, but are not limited to, the records which pertain to the Company's own affairs. These include:

- Financial records;
- Operational records;
- Information technology;
- Communication;
- Administrative records, such as contracts and service level agreements;
- Product records;
- Statutory records;
- Internal Policies and procedures; and
- Human resources records.

OTHER PARTY RECORDS

These records include:

- Records held by the Company pertaining to other parties, including without limitation, financial records, correspondence, contractual records, records provided by the other party (for example third party beneficiaries or employees of a client), and records third parties have provided about the Company's contractors / suppliers.
- the Company may possess records pertaining to other parties including, but not limited to, contractors, suppliers, and service providers and such other parties may possess records that can be said to belong to the Company.

8. Processing details

In terms of POPIA, data must be processed for a specified purpose. The purpose for which data is processed by the Company will depend on the nature of the data and the particular data subject. This purpose is ordinarily disclosed, explicitly or implicitly, at the time the data is collected.

PURPOSE OF THE PROCESSING

Personnel data

the Company processes personnel data for business administration purposes. For example, personnel data is processed for payroll purposes. Personnel data is also processed to the extent required by legislation and regulation. For example, the Company discloses employees' financial information to the Commissioner for the South African Revenue Service, in terms of the Income Tax Act 58 of 1962 and employee's sensitive personal information in terms of the Employment Equity Act 55 of 1998.

Client related data the Company processes client related records for the purpose of conducting its business.

Patient related data

The Company may process patient related records for, without limitation, the purpose of pharmacovigilance, to propose educational support or other support services to patients, or in the context of clinical studies.

HCP related data

The Company may process HCP related data for, without limitation, the purpose of answering requests from HCPs on Company products, to propose educational materials or events to HCPs, for market research, for compliance and BBEE audits purposes, and for pharmacovigilance purposes.

Third party data the Company processes third party records for business

administration purposes. **Other party data**

the Company processes "other party" records for business administration purposes. For example, personnel data may be processed in order to effect payment to contractors and / or suppliers.

In performing these various tasks, the Company may, amongst others, collect, collate, process, store and disclose personal information.

The lists of processing purposes are non-exhaustive.

CATEGORIES OF DATA SUBJECTS

The Company may hold information and records on the following category of data subject:

- Employees / personnel of the Company;
- Patients;
- Health Care Professionals;
- Clients of the Company;
- Any third party with whom the Company conducts its business services;
- Contractors of the Company;
- Suppliers of the Company;
- Service providers of the Company.

This list of categories of data subjects is non-exhaustive.

RECIPIENTS TO WHOM PERSONAL INFORMATION MAY BE SUPPLIED

Depending on the nature of the data, the Company may supply information or records to the following categories of recipients:

- Statutory oversight bodies, regulators or judicial commissions of enquiry making a request for data (i.e. South African Health Products Regulations Authorities);
- Any court, administrative or judicial forum, arbitration, statutory commission, or ombudsman making a request for data or the Company in terms of the applicable rules (i.e. the Competition Commission in terms of the Competition Act 89 of 1998);

- South African Revenue Services, or another similar authority;
- Third parties with whom the Company has a contractual relationship for the retention of data (for example, a third party archiving services);
- Research/ academic institutions;
- Auditing and accounting bodies (internal and external);
- Anyone making a successful application for access in terms of PAIA.

This list of categories of recipients is non-exhaustive.

PLANNED TRANSBORDER FLOWS OF PERSONAL INFORMATION

The Company may transfer personal information to a third party who is in a foreign country in order to administer certain services, but may only do so subject to the provisions of POPIA. For example, academic / market research may be conducted by a company within the Company group and / or by a contracted research and survey provider, which may be inside or outside South Africa. Thus internal cross-border transfers, as well as external cross-border transfers of information are envisaged, subject to the provisions of POPIA.

SECURITY MEASURES

The Company takes extensive information security measures to ensure the confidentiality, integrity and availability of personal information in the Company's possession. the Company takes appropriate technical and organizational measures designed to ensure that personal data remain confidential and secure against unauthorized or unlawful processing and against accidental loss, destruction or damage.

9. Grounds for refusal of access to records

The Company may refuse a request for information on the following basis:

- Mandatory protection of the privacy of a third party who is a natural person, which would involve the unreasonable disclosure of personal information of that natural person;

- Mandatory protection of the commercial information of a third party, if the record contains:
 - Trade secrets of that third party;
 - Financial, commercial, scientific or technical information which disclosure could likely cause harm to the financial or commercial interests of that third party; and
 - Information disclosed in confidence by a third party to the Company, if the disclosure could put that third party at a disadvantage in negotiations or commercial competition.
- Mandatory protection of confidential information of third parties if it is protected in terms of any agreement or legislation;
- Mandatory protection of the safety of individuals and the protection of property;
- Mandatory protection of records which would be regarded as privileged in legal proceedings; • The commercial activities of the Company, which may include:
 - Trade secrets of the Company; ○ Financial, which, if disclosed, could put the Company at a disadvantage in negotiations or commercial competition; ○ A computer program which is owned by the Company and which is protected by copyright.
- The research information of the Company or a third party, if its disclosure would disclose the identity of the institution, the researcher or the subject matter of the research and would place the research at a serious disadvantage;
- Requests for information that are clearly frivolous or vexatious, or which involve an unreasonable diversion of resources shall be refused.

10. Access procedure

A requester is any person making a request for access to a record of, or held by, the Company. The requester is entitled to request access to information, including information pertaining to third parties but the Company is not obliged to grant such access. Apart from the fact that access to a record can be refused based on the grounds set out in paragraph 9 above, in order to successfully access information the requester must fulfil the prerequisite requirements for access in terms of PAIA, including the payment of a request and access fee.

ACCESS REQUEST PROCEDURE

A requester requiring access to information held by the Company must complete the prescribed form, enclosed herewith as **Annexure 2 (“Access Request Form”)**, submit it to the Information Officer at the postal or physical address, fax number or electronic mail address recorded in paragraph 4 and pay a request fee (and a deposit, if applicable).

In order to facilitate a timely response to requests for access, all requesters should take note of the following when completing the Access Request Form:

- The Access Request Form must be comprehensively completed.
- Proof of identity is required to authenticate the identity of the requester. Therefore, in addition to the access request form, requesters will be required to supply a copy of their identification document.
- Every applicable question must be answered. If a question does not apply "N/A" should be stated in response to that question. If there is nothing to disclose in reply to a particular question "Nil" should be stated in response to that question.

The Access Request Form must be completed with enough particularity to enable the Information Officer to identify:

- The record(s) requested;
- The identity number of the requester;
- The form of access required if the request is granted;
- The postal address or fax number of the requester.
- The requester must also state that he or she requires the information in order to exercise or protect a right, and clearly state the nature of the right to be exercised or protected. In addition, the requester must clearly specify why the record is necessary to exercise or protect such a right.

If a request is made on behalf of another person, then the requester must submit proof of the capacity in which the requester is making the request to the reasonable satisfaction of the Information Officer.

If an individual is unable to complete the prescribed form because of illiteracy or disability, such a person may make the request orally.

The requester will be informed in writing whether access has been granted or denied. If, in addition, the requester requires the reasons for the decision in any other manner, he must state the manner and the particulars so required.

PAYMENT OF FEES

Payment details can be obtained from the Information Officer and can be made either via a direct deposit, by bank guaranteed cheque or by postal order. Proof of payment must be supplied when the Access Request Form is submitted.

The following fees may be payable:

- Request fee
- Access fee
- Reproduction fee

Request fee

An initial “request fee” is payable on submission of the Access Request Form. The prescribed fee is set out below in Annexure 1.

Note that the requester may lodge a complaint to the Information Regulator or an application with a court against the tender or payment of the request fee.

Access fee

If the request for access is successful, an access fee must be paid. This fee is for the search, reproduction and/or preparation of the record(s). The access fee will be calculated based on the prescribed fees set out below in Annexure 1.

Note that the requester may lodge a complaint to the Information Regulator or an application with a court against the tender or payment of the access fee.

Reproduction fee

This fee is applicable in respect of documents/records which are voluntarily disclosed (see ‘Automatic Disclosure’ above). This is for reproduction, copying and transcribing the relevant documents / records. The reproduction fee will be calculated based on the prescribed fees set out below in Annexure 1.

Deposit

If the search for, and the preparation of, the record for disclosure would, in the opinion of the Information Officer, require more than 6 hours, the requester may be required to pay as a deposit one third of the access fee (the fee which will be payable if the request is granted).

Note that the requester may lodge a complaint to the Information Regulator or an application with a court against the tender or payment of the deposit.

If a deposit has been paid in respect of a request for access which is subsequently refused, then the Information Officer must refund the deposit to the requester.

The requester must pay the prescribed fee before any processing, or any further processing, can take place. **THIRD**

PARTY NOTIFICATION

the Company must take all reasonable steps to inform a third party to whom or which a requested record relates if the disclosure of that records would -

- involve the disclosure of personal information about that third party;
- involve the disclosure of trade secrets of that third party; financial, commercial, scientific or technical information (other than trade secrets) of that third party, the disclosure of which would be likely to cause harm to the commercial or financial interests of that third party; or information supplied in confidence by a third party, the disclosure of which could reasonably be expected to put that third party at a disadvantage in contractual or other negotiations; or to prejudice that third party in commercial competition;
- constitute an action for breach of a duty of confidence owed to a third party in terms of an agreement; or
- involve the disclosure of information about research being, or to be, carried out by or on behalf of a third party, the disclosure of which would be likely to expose the third party, a person that is or will be carrying out the research on behalf of the third party, or the subject matter of the research, to serious disadvantage.

the Company will inform the third party as soon as reasonably possible, but in any event, within 21 days after that request is received.

Within 21 days of being informed of the request, the third party may-

- make written or oral representations to the Information Officer why the request for access should be refused; or
- give written consent for the disclosure of the record to the requester.

the Company will notify the third party of the outcome of the request. If the request is granted, adequate reasons for granting the request will be given.

The third party may lodge a complaint to the Information Regulator or an application with a court against the decision within 30 days after notice is given, after which the requester will be given access to the record after the expiry of the 30 day period.

11. Notification of decision

The Information Officer will, within 30 days of receipt of the request, decide whether to grant or decline the request and give notice with reasons (if required) to that effect.

The 30 day period, within which the Company has to decide whether to grant or refuse the request, may be extended for a further period of not more than 30 days if the information cannot reasonably be obtained within the original 30 day period. For example, the time period may be extended if the request is for a large amount of information, or the request requires the Company to search for information held at another office of the Company.

The Information Officer will notify the requester in writing should an extension be required. The requester may lodge a complaint to the Information Regulator or an application with a court against the extension.

12. Remedies available when the Company refuses a request for information

INTERNAL REMEDIES

The Company does not have internal appeal procedures. Therefore, the decision made by the Information Officer is final. Requesters who are dissatisfied with a decision of the Information Officer will have to exercise external remedies at their disposal.

EXTERNAL REMEDIES

All complaints, by a requester or a third party, can be made to the Information Regulator or a court, in the manner prescribed below.

Complaints to the Information Regulator

The requester or third party, as the case may be, may submit a complaint in writing to the Information Regulator, within 180 days of the decision by the Information Officer, alleging that the decision was not in compliance with the provisions of PAIA.

The Information Regulator will investigate the complaint and reach a decision – which may include a decision to investigate, to take no further action or to refer the complaint to the Enforcement Committee established in terms of POPIA. The Information Regulator may serve an enforcement notice confirming, amending or setting aside the impugned decision, which must be accompanied by reasons.

Application to court

An application to court may be brought in the ordinary course. For purposes of PAIA, any reference to an application to court includes an application to a Magistrates' Court.

ANNEXURE 1: PRESCRIBED FEES Reproduction fees**REPRODUCTION FEES**

Where the Company has voluntarily provided the Minister with a list of categories of records that will automatically be made available to any person requesting access thereto, the only charge that may be levied for obtaining such records, will be a fee for reproduction of the record in question.

The applicable fees for reproduction as referred to above are: (VAT inclusive)	R
For every photocopy of an A4-size page or part thereof	1,25
For every printed copy of an A4-size page or part thereof held on a computer or in electronic or machine readable form	
For a copy in a computer-readable form on:	
• Stiffy disc	8,55
• Compact disc	79,80
A transcription of visual images for an A4-size page or part thereof	45,60
For a copy of visual images	68,40
A transcription of an audio record, for an A4-size page or part thereof	22,80
For a copy of an audio record	34,20

Request Fees

Where a requester submits a request for access to information held by the Company on a 50,00 person other than the requester himself/herself, the request fee is payable up-front before the institution will further process the request received.

Access Fees

An access fee is payable in all instances where a request for access to information is granted, except in those instances where payment of an access fee is specially excluded in terms of the Act or an exclusion is determined by the Minister in terms of section 54(8). The applicable access fees which will be payable are:

The applicable fees which will be payable are: (VAT inclusive)	1,25
For every photocopy of an A4-size page or part thereof	
For every printed copy of an A4-size page or part thereof held on a computer or in electronic 0,85 or machine readable form	
For a copy in a computer-readable form on:	
• Stiffy disc	8,55
• Compact disc	79,80
A transcription of visual images for an A4-size page or part thereof	45,60
For a copy of visual images	68,40
A transcription of an audio record, for an A4-size page or part thereof	22,80

For a copy of an audio record 34,20
To search for a record that must be disclosed (per hour or part of an hour reasonably required 34,20 for such search)

Where a copy of a record needs to be posted the actual postal fee is payable.

Deposits

Where the Company receives a request for access to information held on a person other than the requester himself/herself and the Information Officer upon receipt of the request is of the opinion that the preparation of the required record of disclosure will take more than 6 hours, a deposit is payable by the requester.

The amount of the deposit is equal to 1/3 of the amount of the applicable access fee.

Please note: In terms of Regulation 8, Value Added Tax (VAT) must be added to all fees prescribed in terms of the Regulations. Therefore, the fees reflected above are VAT inclusive.

ANNEXURE 2: Request Forms

FORM C

REQUEST FOR ACCESS TO RECORD OF PRIVATE BODY

(Section 53(1) of the Promotion of Access to Information Act, 2000

(Act No. 2 of 2000)

[Regulation 10]

A. Particulars of private body

The Head:

B. Particulars of person requesting access to the record

- (a) The particulars of the person who requests access to the record must be given below.
- (b) The address and/or fax number in the Republic to which the information is to be sent must be given.
- (c) Proof of the capacity in which the request is made, if applicable, must be attached.

Full names and surname:

Identity number:

Postal address:

Fax number:

Telephone number:

E-mail address:

Capacity in which request is made, when made on behalf of another person:

C. Particulars of person on whose behalf request is made

This section must be completed *ONLY if a request for information is made on behalf of another person.*

Full names and surname:

Identity number:

Particulars of record

- (a) Provide full particulars of the record to which access is requested, including the reference number if that is known to you, to enable the record to be located.
- (b) If the provided space is inadequate, please continue on a separate folio and attach it to this form.
- (c) The requester must sign all the additional folios.

1. Description of record or relevant part of the record:

2. Reference number, if available:

3. Any further particulars of record:

E. Fees

- (a) A request for access to a record, other *than* a record containing personal information about yourself, will be processed only after a request fee has been paid.
- (b) You will be *notified of* the amount required to be paid as the request fee.
- (c) The fee payable for access to a record depends *on* the form *in which* access is required and the reasonable time *required* to search for and prepare a record.
- (d) If you qualify for exemption *of* the payment *of* any fee, please state the reason for exemption.

Reason for exemption from payment of fees:

F. Form of access to record

If you are prevented by a disability to read, view or listen to the record in the form of access provided for in 1 to 4 hereunder, state your disability and indicate in which form the record is required.

Disability:	Form in which record is required:
Mark the appropriate box with an X.	
NOTES:	
(a) Compliance with your request in the specified form may depend on the form in which the record is available.	
(b) Access in the form requested may be refused in certain circumstances. In such a case you will be informed if access will be granted in another form.	
(c) The fee payable for access for the record, if any, will be determined partly by the form in which access is requested.	

1. If the record is in written or printed form:			
Copy of record*		inspection of record	
2. If record consists of visual images this includes photographs, slides, video recordings, computer-generated images, sketches, etc.)			
transcription of the images		of the copy of images images*	the view

3. If record consists of recorded words or information which can be reproduced in sound:				
listen to the soundtrack audio cassette		transcription of soundtrack* written or printed document		
4. If record is held on computer or in an electronic or machine-readable form:				
printed copy of record*		printed copy of information derived from the record"		copy in computer readable form* (stiffy or compact disc)
*If you requested a copy or transcription of a record (above), do you wish the copy or transcription to be posted to you? Postage is payable.			YES	NO

G. Particulars of right to be exercised or protected

If the provided space is inadequate, please continue on a separate folio and attach it to this form. The requester must sign all the additional folios.

1. Indicate which right is to be exercised or protected:
2. Explain why the record requested is required for the exercise or protection of the aforementioned right:

H. Notice of decision regarding request for access

You will be notified in writing whether your request has been approved/denied. If you wish to be informed in another manner, please specify the manner and provide the necessary particulars to enable compliance with your request.

How would you prefer to be informed of the decision regarding your request for access to the record?

Signed at _____ this _____ day of _____ 20____.

SIGNATURE OF REQUESTER / PERSON ON WHOSE BEHALF REQUEST IS MADE