

# KEY ONCOLOGICS (PTY) LTD

(Registration Number: 1995/013825/07)

Manual in terms of section 51 of the  
Promotion of  
Access to Information Act, 2 of 2000

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## 1. CONTACT PARTICULARS:

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## 2. INTRODUCTION:

Key Oncologics (Pty) Ltd is a pharmaceutical company which carries on the business of importing and distribution of oncology medication. Key Oncologics (Pty) Ltd operates in the healthcare sector and are healthcare professionals registered under the Pharmacy Act 53 of 1974 and are subjected to the rules and regulations of the South African Pharmacy Council.

This manual serves to inform members of the public of the categories of information held by the company, and which may subject to the grounds of refusal listed in the Access to Information Act, 2 of 2000 ('the Act'), be disclosed after evaluation of an access application being made in terms of the Act.

## 3. GUIDE IN TERMS OF SECTION 10 OF THE ACT:

- 3.1 Section 50 of the Act provides that a requester may be provided access to records of a private body, if the record is required for the exercise or protection of any rights. If a public body lodges a request, to access to a record of a private body for the exercise or protection of any rights, other than its rights, it must be acting in the public interest.
- 3.2 Requests in terms of the Act shall be made in accordance with the prescribed procedures, at the rates provided. The forms and tariffs are dealt with in paragraphs 6 and 7 of the Act.
- 3.3 Requesters are referred to the 'Guide on how to use the Promotion of Access to Information Act 2 of 2000' in terms of Section 10 of the Act which has been compiled by the South African Human Rights Commission (SAHRC), and to be updated and published by the Information Regulator from time to time.

#### **4. INFORMATION AVAILABLE IN TERMS OF OTHER LEGISLATION:**

- Basic Conditions of Employment Act 75 of 1997
- Broad-based Black Economic Empowerment Act 53 of 2003
- Companies Act 71 of 2008
- Consumer Protection Act 68 of 2008
- Competition Act 89 of 1998
- Compensation for Occupational Injuries and Health Diseases Act 130 of 1993
- Copyright Act 98 of 1978
- Credit Agreements Amendment Act 79 of 1995
- Currency and Exchanges Act 9 of 1933
- Customs and Excise Act 91 of 1964
- Electronic Communications and Transactions Act 25 of 2002
- Employment Equity Act 55 of 1998
- Finance Act 2 of 2012
- Financial Intelligence Centre Act 38 of 2001
- Health Professions Act 56 of 1974
- Income Tax Act 58 of 1962
- Intellectual Property Laws Amendments Act 28 of 2013
- Labour Relations Act 66 of 1995
- Medical Schemes Act 131 of 1998
- Medicines and Related Substances Control Act 101 of 1965
- National Credit Act 34 of 2005
- National Health Act 61 of 2003
- Occupational Health and Safety Act 85 of 1993
- Pharmacy Act 53 of 1974
- Prevention of Organised Crime Act 121 of 1998
- Promotion of Access to Information Act 2 of 2000
- Protection of Personal Information Act 4 of 2013
- Skills Development Levies Act 9 of 1999
- Skills Development Act 97 of 1998
- Tax Administration Act 28 of 2011

- Uncertificated Securities Tax Act 31 of 1998
- Unemployment Contributions Act 4 of 2002
- Unemployment Insurance Act 63 of 2001
- Value Added Tax Act 89 of 1991

Legislation provides that private bodies may allow certain persons access to specified records upon request. Information is available in terms of the above legislation to the persons or entities specified in such legislation, as well as the specific protections offered by such laws. As legislation changes may occur and new laws can stipulate new requirements, which may extend or limit the scope of access by persons specified in such entities, this list should not be construed as being a final and complete list.

## **5. INFORMATION AUTOMATICALLY AVAILABLE:**

The following categories of information are automatically available for public inspection, printing and photocopying. It is not necessary to request this information in terms of the Act and it may be obtained by accessing the Key Oncologics (Pty) Ltd website or contacting the Information Officer:

5.1 [www.keyoncologics.co.za](http://www.keyoncologics.co.za)

5.2 Single Exit Price (SEP) lists are available on the Department of Health's website ([www.mpr.gov.za](http://www.mpr.gov.za)).

Section 21 product price lists are only made available to Health Care Professionals on special request.

5.3 Pamphlets \ brochures for products are only available to Health Care Professionals

5.4 In terms of the requirements of the Medicines and Related Substance Control Act (Act 101 of 1965), Key Oncologics (Pty) Ltd is prohibited to market products to the general public. Key Oncologics (Pty) Ltd is only allowed to hand out pamphlets and brochures to registered Healthcare Professionals. The materials may only contain information regarding the product, the nature thereof and specific information relating to the use of the product and treatment regimens.

## **6. RECORDS HELD BY KEY ONCOLOGICS (PTY) LTD AND CATEGORIES OF RELATED DATA SUBJECTS:**

Key Oncologics (Pty) Ltd retains records in the categories listed below. The list is provided to clarify the activities of Key Oncologics (Pty) Ltd.

**Internal records relating to day-to-day business**, which includes business founding and incorporation documents (memorandum of incorporation, director appointments, other documents such as director, auditor, secretary appointment or termination), share register and other statutory registers, public officer, minutes and policies; annual and other reports; operational records, policies and procedures; contracts; licences, trademarks and other intellectual property records; production, sales and marketing records; pricing records; other internal policies and procedures; internal correspondence; statutory records; records relating to partnerships, joint ventures and co-marketing agreements; etc.

**Key Oncologics (Pty) Ltd Financial Records** which includes Annual Financial Statements; Tax Returns; Accounting Records; Banking Records; Bank Statements; Electronic Banking Records; Asset Register; Rental Agreements; and Invoices.

**Income Tax Records** which include: PAYE Records, Documents issued to employees for income tax purposes, Records of payments made to SARS on behalf of employees; All other statutory compliances including VAT, Skills Development Levies, UIF and Workmen's Compensation.

**Personnel records**, which includes records relating to temporary employees, fixed term employees, part-time employees, permanent employees, contractors, partners, directors, executive directors, non-executive directors. Includes personal files and similar records; third party records relating to their personnel; employment contracts; conditions of employment; workplace policies; disciplinary records; termination records; minutes of staff meetings; performance management records and systems and all employment-related records and correspondence.

**Safety, Health and Environment (SHE) records** which include SHE policy and mandatory SHE Records.

**Regulatory and Quality Assurance** Licensing with the South African Health Products Regulatory Authority ("SAHPRA"), Registration with the South African Pharmacy Council and Quality Manual. Customer/client/patient records, which includes customer/client/patient lists; agreements, consents, needs assessments; financial and accounts information; research information; evaluation records; profiling; and similar information.

**Supplier and service provider records**, which includes supplier registrations; contracts; service level agreements; confidentiality agreements and non-disclosure agreements, quality agreements; communications; logs; delivery records; commissioned work; and similar information, some of which might be provided to us by such suppliers and providers under service- and other contacts. Scientific and technical records, which includes manuals, product registrations, product dossiers, product research approvals, product information (including but not limited to product package inserts) and related documents; pharmacovigilance and other consumer/provider records and reports; scientific records and scientific articles and research papers; lectures; health professionals council / statutory body records; approvals and licenses, registrations and associated conditions and requirements; trade association and trade association group membership information and similar business and industry information.

**Third party information**, which may be available but only on the conditions as set out in the mutual agreements with such parties.



**Communication and IT records**, which includes hard copies and electronic communications, logs; electronic and cached information; software and software licensing; programming work; websites and electronic programmes.

**Environment and market information** which includes information obtained, publicly available information as well as confidential and/or commissioned information which pertains to the specific sector and market of the business and factors that affect the business, professional and healthcare environment.

**Please Note:**

*In the health sector, personal, health and patient information are protected by legislation such as the Protection of Personal Information Act, the National Health Act and HPCSA ethical rules, and disclosure can only take place, if at all, within these and other frameworks.*

*The fact that the Company list a record type does not necessarily mean that the Company will disclose such record(s), and all access is subject to the evaluation processes outlined herein, which will be exercised in accordance with the requirements of the Act. Information in our possession may belong to third party entities, such as our holding company; our suppliers, clients and consumers; patients/consumers; and our trade associations. In such case we might not be able to provide the requested information.*

**7. THE PURPOSE OF THE PROCESSING OF INFORMATION:**

Key Oncologics (Pty) Ltd processes information for the following purposes:

- 7.1 Conducting clinical trials
- 7.2 Research and development
- 7.3 Advisory Boards
- 7.4 Motivation for funding of products and devices
- 7.5 Conferences and symposia
- 7.6 Continued Professional Developments
- 7.7 Social Ethics meetings
- 7.8 Reporting to authorities
- 7.9 Reporting to the holding company
- 7.10 Reporting of Adverse Events
- 7.11 Patient Associations

**8. CATEGORIES OF RECIPIENTS WITH WHOM INFORMATION MAY BE SHARED:**

Key Oncologics (Pty) Ltd may share personal information with:

- 8.1 Affiliates and associated entities



- 8.2 Legal and Financial Advisors
- 8.3 Holding Company
- 8.4 Principal Company
- 8.5 Industry authorities, (SAMED and MCA)
- 8.6 Government authorities, (SAHPRA, DoH, SAPC.)
- 8.7 SARS
- 8.8 Department of Employment and Labour Department
- 8.9 Advisory boards
- 8.10 Medical schemes

## **9. PLANNED TRANS-BORDER FLOW OF INFORMATION:**

Key Oncologics (Pty) Ltd plans trans-border flow of information for the following:

- 9.1 Clinical trial information
- 9.2 Adverse Event Reporting
- 9.3 Financial reporting information
- 9.4 Training records
- 9.5 Employment Records

## **10. SUITABILITY OF INFORMATION SECURITY MEASURES:**

Personal Information held by Key Oncologics (Pty) Ltd is stored as follows:

### **10.1 Physically held records:**

- 10.1.1 Lockable cabinets in all offices
- 10.1.2 Lockable offices
- 10.1.3 CCTV security cameras on the premises
- 10.1.4 Off-site 24-hour monitored smoke detectors
- 10.1.5 Off-site 24-hour monitored armed response alarm system
- 10.1.6 24-hour guards, access control to facility with armed response
- 10.1.7 Biometric fingerprint access control to the office buildings
- 10.1.8 Fire resistant lockable cabinets for archives

### **10.2 Electronically held Information:**

- 10.2.1 All software is password protected / restricted and only the relevant personnel have access to applicable systems. Personnel do not share computers, workstations, profiles or passwords.
- 10.2.2 Network Attached Storage with biometric fingerprint access
- 10.2.3 Locked server room for hosting, internet services and telephony
- 10.2.4 Fire resistant safe where weekly backups are stored
- 10.2.5 Encryption, firewalls, and antivirus



## 11. REQUEST PROCEDURE:

A person who wants access to the records must complete the necessary request forms, attached as **Attachment 1, (Request Form)**, that is also available at the offices of Key Oncologics (Pty) Ltd or at [www.keyoncologics.co.za](http://www.keyoncologics.co.za), or can be accessed on [www.sahrc.org.za](http://www.sahrc.org.za) or on the website of the Department of Justice at [http://www.justice.gov.za/forms/paia/J752\\_paia\\_Form%20C.pdf](http://www.justice.gov.za/forms/paia/J752_paia_Form%20C.pdf)

The completed request form must be sent to the address or fax number provided in this manual and marked for the attention of the Information Officer.

### 11.1 When a record is requested, the following will apply:

- The Request Form must be correctly completed and must include the rights that the requester wishes to protect or exercise by requesting the information and the reason for requesting access to the information:
  - Type or print in BLOCK LETTERS an answer to every question.
  - If a question does not apply, state "N/A" in response to that question.
  - If there is nothing to disclose in reply to a particular question state "NIL" in response to that question.
  - If there is insufficient space on the printed form, additional information may be provided in an additional attached folio.
  - When the use of an additional folio is required, precede each answer with the applicable title.
- Proof of identity is required to authenticate the identity of the requester, in addition to the Access Request Form; requesters will be required to supply a certified copy of their identity document or a valid passport document.
- If the requester is representing of another person, the Request Form must contain the contact details and signature of the person on whose behalf the request is made, authorising the request on his/her behalf, we may require further proof to verify the validity of the authority;
- The requester must state in which format (inspection of copy, paper copy, electronic copy, transcript, etc.) s/he wants to access the information;
- If the record is part of another record, the requester will only be given access to the part(s) that pertains to the information s/he wants or is entitled to, and not the remainder of the record.

### 11.2 Payment of fees

Payment details can be obtained from the Information Officer indicated above and can be made either via a direct deposit, by electronic fund transfer or by postal order (no credit card payments are accepted). Proof of payment must be supplied. The following applies to request other than personal requests:

- An initial request fee of R50.00, excluding VAT, is payable on submission of the request. This fee is not applicable to Personal Requesters, referring to any person seeking access to records that contain their personal information, who are exempt from paying such fee; (**“request fee”**).
- If the preparation of the record requested requires more than the prescribed 6 (six) hours, a deposit of not more than one third of the access fee which would be payable if the access was granted, shall be payable.
- The requestor may lodge an application with a court against the tender/payment of the request fee and/or deposit.
- Records may be withheld until applicable fees have been paid.

If the request for access is successful an access fee may be required for the search, reproduction and/or preparation of the record(s) and will be calculated based on the Prescribed Fees as set out in **Attachment 2** hereto. The latest fee structure is available on the website of the SAHRC at [www.sahrc.org.za](http://www.sahrc.org.za).

### 11.3 Notification

The Information Officer will within 30 (thirty) days from receipt of a valid request decide whether or not to grant the request and provide notice of such decision with reasons thereof, (if required).

This 30 (thirty) day period may be extended for a further period of not more than 30 (thirty) days, if the request is for a large volume of information, or the request requires a search for information held at different storage premises and the information cannot reasonably be obtained within the original 30 (thirty) day period. The requester will be notified in writing should an extension be sought.

### 11.4 Grounds for refusal of access to records

All requests will be evaluated against the provisions of the Act. The Act allows the Information Officer to refuse access on grounds stipulated in the Act. Access to confidential information, or trade- or commercial secrets of a business is not allowed. The main grounds for refusal of a request for information are:

- 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 Key Oncologics (Pty) Ltd or a third party, if the record contains:
  - Trade secrets;
  - Financial, commercial, scientific or technical information which disclosure could likely cause harm to the financial or commercial interests of that party;
  - Information disclosed by a third party to Key Oncologics (Pty) Ltd if the disclosure could put that third party to a disadvantage in negotiations or commercial competition;

- Mandatory protection of confidential information of Key Oncologics (Pty) Ltd and/or third parties if it is protected in terms of any agreement – the provisions of the Act to apply in relation to the rights of the relevant third parties;
- Mandatory protection of the safety of individuals and the protection of property;
- Mandatory protection of records which could be regarded as privileged in legal proceedings;

### 11.5 Appeal against refusal to grant access

If a requester is aggrieved by the refusal of the Information Officer to grant a request for a record, the requester may, upon notification of the Information Officer's decision (or upon his or her deemed refusal in terms of Section 58 of the Act), apply to court for appropriate relief within the prescribed time frames as prescribed by the Act.

## 12. AVAILABILITY OF THE MANUAL:

This manual is published in terms of Section 51 of the Act and provides the members of the public the categories of information held by Key Oncologics (Pty) Ltd, and which may, subject to the grounds of refusal listed in the Act, be disclosed after evaluation of access application made in terms of the Act.

A copy of this manual is available to the public for inspection on the Key Oncologics (Pty) Ltd website at [www.keyoncologics.co.za](http://www.keyoncologics.co.za). The manual is further available for viewing as a hard copy at the office of the Compliance Officer at our offices situated at the address listed under Contact Particulars above.

A copy of this manual will also be available from the South African Human Rights Commission ("SAHRC") at the addresses and/or telephone numbers as published by the Commission or once the relevant and applicable provision of the Protection of Personal Information Act, 2013 ("POPI Act") come into effect, from the Information Regulator: <http://www.justice.gov.za/infoereg/about.html>

This manual will be reviewed / updated every two years and will be available to the Information Regulator and any person upon request and payment of prescribed amount.

## 13. HISTORY OF UPDATES:

VERSION	EFFECTIVE DATE	REASON FOR UPDATE
01	25/02/2020	New Manual
02	01/07/2021	Routine Update



**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: .....

Telephone number: ..... Fax 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: .....

**D. 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. **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 to the record, if any, will be determined partly by the form in which access is requested.

<b>1. If the record is in written or printed form:</b>				
	copy of record*		inspection of record	
<b>2. If record consists of visual images</b> (this includes photographs, slides, video recordings, computer-generated images, sketches, etc.):				
	view the images		copy of the images*	transcription of the images*
<b>3. If record consists of recorded words or information which can be reproduced in sound:</b>				
	listen to the soundtrack (audio cassette)		transcription of soundtrack* (written or printed document)	
<b>4. If record is held on computer or in an electronic or machine-readable form:</b>				
	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? <b>Postage is payable.</b>				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 \_\_\_\_\_ on this \_\_\_\_\_ day of \_\_\_\_\_ 2 \_\_\_\_\_

\_\_\_\_\_  
SIGNATURE OF REQUESTER/  
PERSON ON WHOSE BEHALF REQUEST IS MADE

## **PRESCRIBED FEES**

(Section 54(7) of the Promotion of Access to Information, Act No. 2 of 2000) [Regulation 11(3)]

(a)	For every photocopy of an A4-size page or part thereof	R 1.27
(b)	For every printed copy of an A4-size page or part thereof held on a computer or in an electronic or machine-readable form	R 0.86
(c)	For a copy in a computer-readable form on compact disc	R 80.50
(d)	(i) For a transcription of visual images, for an A4-size page or part thereof	R 46.00
	(ii) For a copy of visual images	R 69.00
(e)	(i) For a transcription of an audio record, for an A4-size page or part thereof	R 23.00
	(ii) For a copy of an audio record	R 34.50
(f)	To search for and prepare the record for disclosure or part thereof for each hour or part thereof reasonably required for such search and preparation	R 34.50
(g)	Six hours of searching to be exceeded before a deposit is payable	
(h)	One third of the access fee is payable as a deposit by the requester	
(i)	The actual postage fee is payable when a copy of a record must be posted to a requester	

**PLEASE NOTE THAT ALL PRICES LISTED ARE INCLUSIVE OF VALUED-ADDED TAX**