

**NATIONAL BIOPRODUCTS INSTITUTE**  
**(Association incorporated under section 21)**  
**(Registration No. 1994/002044/08)**  
**(Registered under the Non-Profit Organisations Act. Reg No. 020-898-NPO)**

**MANUAL PREPARED IN ACCORDANCE WITH SECTION 51 OF THE PROMOTION OF  
ACCESS TO INFORMATION ACT, ACT 2 OF 2000 (“THE ACT”)**

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**SECTION A: Introduction to National Bioproducts Institute (“NBI”)**

The NBI is a private, autonomous, association incorporated under section 21 ("not for profit"), non-governmental organisation. NBI is also registered as a Non-Profit Organisation.

**Mission Statement**

NBI strives to improve the quality of life of patients requiring plasma-derived medicinal products, diagnostic products and services. This will be achieved by:

- Providing quality, safe and effective biological products and services
- Complying with internal, national and international standards and requirements
- Using a cost-effective, efficient and competitive approach
- Supplying to customers in RSA, SADC and other identified countries in a competitive manner
- Financially supporting SANBS and creating value for all stakeholders

The mission will be achieved through competent and committed employees and the correct application of appropriate technology in an environmentally and socially responsible manner.

**Core Business**

NBI's core business is to manufacture pharmaceutical products from human plasma, using a process of protein fractionation. The majority of this plasma (> 95%) is obtained from our associate company, the South African National Blood Service (SANBS). The products made are distributed throughout South Africa, and where surpluses exist, to the Southern African Development Community (SADC) and other developing countries. NBI together with SANBS strives to achieve the Department of Health's goal of ensuring the self-sufficiency of blood, blood products and plasma-derived medicinal products for all patients in South Africa. To this end, NBI endeavours to provide products and services from South African resources using plasma from healthy, voluntary, non-remunerated donors. By purchasing plasma from the Blood Transfusion Services in South Africa, NBI is able to financially contribute to maintaining an excellent standard of blood transfusion to South African patients.

## **SECTION B: Particulars in terms of Section 51**

### **1. Contact Details**

<b>Name</b>	National Bioproducts Institute (Association incorporated under Section 21)
<b>Registration No.:</b>	1994/002044/08
<b>Non Profit Organisation No.</b>	020-898-NPO
<b>Postal Address</b>	Private Bag X9043, Pinetown, 3600
<b>Physical Address</b>	10 Eden Road, Pinetown, 3610
<b>Telephone:</b>	+ 27 031 719 6789
<b>Facsimile</b>	+ 27 031 708 5614
<b>Website</b>	<a href="http://www.nbi-kzn.org.za">www.nbi-kzn.org.za</a>
<b>Head of Body</b>	Mr SC Coffey
<b>Email Address of Head of Body</b>	<a href="mailto:coffeys@ecr.sanbs.org.za">coffeys@ecr.sanbs.org.za</a>

The following persons are duly authorised by the Head of NBI to act as Information Officers in terms of the Act:

**Mrs A Parusnath - Information Officer -** [parusnatha@nbi-kzn.org.za](mailto:parusnatha@nbi-kzn.org.za)

**Mr D Armstrong - Deputy Information Officer -** [armstrongd@nbi-kzn.org.za](mailto:armstrongd@nbi-kzn.org.za)

### **2. The Section 10 Guide on how to use the Act**

The guide will be made available by the South African Human Rights Commission (“SAHRC”) at Private Bag X2700, Houghton, 2041; telephone +27 11 4848300; fax +27 11 484 1360; website [www.sahrc.org.za](http://www.sahrc.org.za); E-mail [PAIA@sahrc.org.za](mailto:PAIA@sahrc.org.za). The guide will also be available for inspection, inter alia, at NBI’s offices, all post offices and Magistrates’ Courts.

### **3. Information available in accordance with other Legislation**

National Bioproducts Institute keeps records in accordance with the following legislation, all of which are available, subject to such legislation and the Act. This is not an exhaustive list:

Pharmacy Act 54 of 1974, Medicines and Related Substances Control Act 101 of 1965, Human Tissue Act 65 of 1983, Health Act 63 of 1977, Medical Schemes Act 131 of 1998, Companies Act 61 of 1973, Non Profit Organisations Act 17 of 2000, Pensions Funds Act 24 of 1956, Income Tax Act 58 of 1962, Unemployment Insurance Act 63 of 2001, Value Added Tax Act 89 of 1991, Credit Agreements Act 75 of 1980, Currency and Exchanges Act 9 of 1933, Debtor Collectors Act 114 of 1998, Finance Act 35 of 2000, Financial Services Board Act 97 of 1990, Financial Relations Act 65 of 1976, Harmful Business Practices Act 23 of 1999, Insurance Act 27 of 1943, Trade Marks Act 194 of 1993, Customs and Excise Act 91 of 1964, Compensation for Occupational Injuries and Diseases Act 130 of 1993, Occupational Health and Safety Act 85 of 1993, Genetically Modified Organisms Act 15 of 1997, International Air Transportation Association Act Environmental Conversation Act 73 of 1989, Environmental Conversation Act 73 of 1989, National Environmental Management Act 107 of 1998, Labour Relations Act 66 of 1995, Basic Conditions of Employment Act 75 of 1997, Skills Development Act 9 of 1999, Hazardous Substances Act 15 of 1973, Constitution of Republic of South Africa Act 108 of 1996, Employment Equity Act 55 of 1998 and the Skills Development Levies Act 9 of 1999.

#### **4. Subjects and Categories of Records held by the Natal Bioproducts Institute**

The company holds records in the categories listed below. Please note that the requester is not automatically allowed access to these records and access may be refused in accordance with Section 62 to 69 of the Act.

- 4.1 Companies Secretarial and Legal Records**  
Memorandum and Articles of Association, Annual Financial Statements, Records relating to appointment of directors, auditors, secretary, Statutory registers and records, Minute book of directors' resolutions, Contracts and agreements.
- 4.2 Finance and Related Records**  
Tax returns, Accounting records, Banking and related records, Stock records and Asset Registers, Annual Financial Statements.
- 4.3 Operational Documents and Records**  
Policies and Systems, Standard Operating Procedures, Application documents for registration in terms of Medicines and Related Substances Control Act 101 of 1965, Customer Information, Customer Complaint and Adverse Drug Event monitoring reports, Material Management Documentation, Sales and Distribution Documentation, Product investigations, including incident and deviation monitoring, Testing protocols and results, Batch Manufacturing Documentation, Audit Documentation, Vendor Management Documentation.
- 4.4 Personnel Documents and Records**  
Personal records provided by personnel (including permanent and temporary) including, but not be limited to:- List of employees, employee benefits, other information relating to employees.
- 4.5 Safety and Medical Records**  
Medical Testing Records, Injured on Duty Forms.
- 4.6 Information Technology Records**  
Licences, Software programs and applications, Computer generated databases and backups, SAP system and related Documentation.
- 4.7 Library Services**  
Books, Journal Articles
- 4.8 Research**  
Laboratory Log Books, Clinical Trial Protocols

#### **5 NOTICE(S) IN TERMS OF SECTION 52(2) OF THE ACT**

At this stage no notice(s) has/have been published

#### **6 THE REQUEST PROCEDURES**

##### **Form of request:**

- The requester must use the prescribed form to make a request for access to a record. This must be made to the information officers identified above at the address, fax number or electronic mail address specified above.
- The requester must provide sufficient detail on the request form to enable the officer of the NBI to identify the record and the requester. The requester should also indicate which form of access is required. The requester should also indicate if any other manner is to be used to inform the requester and state the necessary particulars to be so informed.
- The requester must identify the right that is sought to be exercised or to be protected and provide an explanation of why the requested record is required for the exercise or protection of that right.
- If a request is made on behalf of another person, the requester must then submit proof of the capacity in which the requester is making the request to the satisfaction of the Information Officer concerned.

**Fees:** The fees payable are as set out in the Regulations to the Act. Further information in this regard is available from the Information officers or alternatively on the South African Department of Justice Website at [www.doj.gov.za](http://www.doj.gov.za).

## **6. AVAILABILITY OF THE MANUAL**

Copies of this manual are available for inspection, free of charge, at the offices of NBI Copies are also available from the South African Human Rights Commission and electronically off the World Wide Web at [www.nbi-kzn.org.za](http://www.nbi-kzn.org.za)

## **7. PRESCRIBED FEES AND PRESCRIBED FORMS**

The fees prescribed and the forms that have to be completed are available on request from the NBI offices. In addition, please note that they are also electronically available on the World Wide Web at [www.nbi-kzn.org.za](http://www.nbi-kzn.org.za).

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