

# AMGEN SOUTH AFRICA (PTY) LTD

## POPIA & PAIA INFORMATION MANUAL (Private Body)

Prepared in terms of section 51 of the Promotion of Access to Information Act 2 of 2000 (PAIA), read with the Protection of Personal Information Act 4 of 2013 (POPIA) and the Amended POPIA Regulations (17 April 2025). This manual is reviewed annually or when legislative changes occur.

Term / Acronym	Definition
<b>Act / Law</b>	POPIA (Act 4 of 2013) and PAIA (Act 2 of 2000).
<b>Company / We / Us</b>	Amgen South Africa (Pty) Ltd, a private company incorporated in South Africa Registration Number: 2011/112148/07 which acts as the Marketing Authorisation Holder (MAH) for certain medicines registered with SAHPRA and is responsible for their importation and marketing in South Africa.
<b>Data Subject</b>	The person to whom Personal information relates.
<b>Information Officer (IO)</b>	The person as defined in PAIA and POPIA who is appointed as the Information Officer and is responsible for compliance with PAIA and POPIA. The Information Officer may delegate certain responsibilities to one or more <b>Deputy Information Officers (DIOs)</b> , provided that such delegation is authorised and registered with the Information Regulator.
<b>Operator</b>	A third party that processes Personal information on behalf of us in terms of a written contract, in accordance with the purposes and means determined by Amgen as the responsible party.
<b>Personal information (PI)</b>	Any information about an identifiable natural person (and where applicable, juristic person).
<b>Special PI</b>	A subcategory of personal information that includes information about a data subject's: religious or philosophical beliefs, race or ethnic origin, trade union membership, political opinions, health or biometric information, sex life or sexual orientation, and criminal behaviour (including alleged offences and proceedings).
<b>Processing</b>	Any operation involving PI (collecting, using, storing, sharing, etc.).

## **Purpose of this Manual**

This manual helps the public to:

- See what records we make automatically available.
- Understand how to request access to other records under PAIA.
- Understand our POPIA practices – what PI we process, for what purposes, lawful bases, recipients, cross-border transfers, retention and security.
- Find contact details for our IO/DIO and how to lodge objections, corrections, deletions or complaints.

## **Key Contacts**

### **Information Officer**

Name: Preshan Naicker

Position: Snr Quality Manager/Information Officer

Tel: 011 100 5300

Email: [pnaicker@amgen.com](mailto:pnaicker@amgen.com) or [privacy@amgen.com](mailto:privacy@amgen.com)

Physical and postal address: Building 4, Healthcare Park, Woodlands Drive, Woodmead, Johannesburg, Gauteng, 2191

### **Information Regulator (South Africa):**

Website: <https://info regulator.org.za>

Email (Complaints): [complaints.IR@info regulator.org.za](mailto:complaints.IR@info regulator.org.za)

Email (General Enquiries): [enquiries@info regulator.org.za](mailto:enquiries@info regulator.org.za)

Tel: 010 023 5200

Physical Address: JD House, 27 Siemens Street Braamfontein, Johannesburg, 2001

## **Guide on Using PAIA**

A public guide explaining the Promotion of Access to Information Act (PAIA) and relevant rights under the Protection of Personal Information Act (POPIA) is available from the Information Regulator in all official languages, including Braille. A copy may be requested from our Information Officer or accessed directly from the Regulator's website.

PAIA request and complaint forms (Forms 1 to 5) are also available on the Regulator's website. We will provide printed or electronic copies upon request.

In accordance with Section 51(1)(d) of the Promotion of Access to Information Act (PAIA), the following categories of records are held by Amgen South Africa (Pty) Ltd. Access to records is subject to a request in terms of PAIA and evaluation under the applicable provisions of the Act.

Access to any of these records may be refused based on the grounds set out in Chapter 4 of PAIA, including where the records are confidential, legally privileged, or contain protected personal or commercial information.

### **Categories of Records Held**

#### **Corporate and Governance Records**

- Company registration and statutory documents
- Internal policies and procedures
- Regulatory submissions and licenses

#### **Financial and Tax Records**

- Annual financial statements
- Tax submissions and compliance records

#### **Human Resources Records**

- Employment-related records
- Training and development documentation

#### **Legal and Contractual Records**

- Agreements with third parties and service providers
- Legal correspondence and compliance files

#### **Operational and Product Records**

- Product safety, quality and recall records
- Pharmacovigilance and adverse event reports
- Sales, marketing and customer engagement documentation

#### **Information Technology and Security Records**

- System access, data protection, and incident management documentation

#### **Note:**

Access to these records is not automatic and is subject to the formal PAIA process. A request must be submitted using **PAIA Form 2**, and Amgen South Africa will assess the request in line with the Act. Some records may be partially or fully withheld if they fall under the exemption grounds in PAIA.

## **Personal Information We Process**

### **Data subjects**

- Patients/consumers (e.g., participants in clinical trials, pharmacovigilance reporters)
- Healthcare professionals (HCPs) and other business contacts
- Our employees/contractors
- Job applicants
- Suppliers, distributors, logistics partners, and their staff
- Users of our websites and digital services

### **Categories of PI (including Special PI)**

- Identity and contact details (e.g., name, address, telephone, email)
- Professional information (e.g., job title, affiliation for HCPs, role)
- Health/medical information (for patients/clinical trial participants)
- Sensitive data (e.g., biometric or health related, as applicable)
- Product safety /- pharmacovigilance - related information
- Contractual / vendor relationship data
- Online / digital service usage data (web-users)

### **Purposes & Lawful Bases**

- **Pharmacovigilance and Product Safety**  
To collect and evaluate safety and quality data, including adverse event and product complaint reporting, in compliance with legal obligations.
- **Regulatory Submissions and Compliance**  
To support health authority submissions and ensure ongoing compliance with applicable medical, safety and regulatory laws.
- **Clinical Trials and Research**  
To support the planning, conduct, management, and analysis of clinical trials in line with applicable ethics and data protection regulations.
- **Medical and Scientific Communications**  
To engage with healthcare professionals (HCPs) and researchers on Amgen's products and therapeutic areas, and to disseminate medical education and product information.
- **Human Resources and Employment Management**  
To manage employment relationships, including recruitment, payroll, benefits, training, health and safety, and diversity and inclusion initiatives.
- **Vendor and Supplier Management**  
To administer contracts, process payments, and perform due diligence and supplier oversight.
- **Sales and Marketing Activities**  
To manage commercial relationships, communicate product offerings, perform market research, and monitor product usage trends, in line with local marketing laws.
- **Legal, Financial, and Administrative Operations**

To meet internal audit, tax, record-keeping, insurance, litigation, and fraud prevention obligations.

- **IT, Security and Infrastructure**

To maintain and monitor Amgen's IT systems, ensure cybersecurity, and protect business and personal data from unauthorized access or disclosure.

### **Sources of PI**

Amgen South Africa (Pty) Ltd obtains personal information from a variety of sources during its lawful business operations. These sources include:

- **Directly from the data subject** (e.g., when individuals provide information via forms, applications, or direct interactions)
- **Healthcare professionals** (e.g., reporting adverse events or participating in scientific engagement)
- **Clinical trial sites and investigators** (e.g., for research participant data)
- **Third-party service providers** (e.g., vendors, contractors, consultants)
- **Regulatory and government authorities** (e.g., safety reports, licensing)
- **Other Amgen group companies and affiliates** (e.g., for shared business or compliance functions)
- **Publicly available sources** (e.g., professional registers, company websites, industry directories)
- **Digital interactions** (e.g., website usage, cookies, virtual platforms)

### **Recipients / Categories of Recipients**

Amgen South Africa (Pty) Ltd may share personal information, where necessary and appropriate, with the following categories of recipients for the purposes outlined in this manual, in compliance with applicable data protection laws:

- Regulatory authorities and health agencies (e.g., SAHPRA and other global authorities) for safety monitoring, reporting, and compliance
- Amgen group companies and affiliates (including those outside South Africa) for internal reporting, shared services, scientific collaboration, and operational support
- Clinical research partners and investigators, including ethics committees, contract research organisations (CROs), and academic institutions for clinical trial management and oversight

- Service providers and third-party vendors acting on Amgen's behalf under written agreements, including IT providers, logistics providers, consultants, auditors, and legal or professional advisers
- Healthcare professionals and institutions, where required for scientific exchange, adverse event follow-up, or access to patient support programmes
- Law enforcement agencies, courts, or other government bodies, where disclosure is required by law or regulation
- Business partners, distributors, or licensees, where necessary for marketing authorisation, supply chain management, or support of Amgen products

### **Cross-Border (Transborder) PI Transfers**

Amgen South Africa (Pty) Ltd may transfer personal information to Amgen Inc. and other Amgen affiliates or authorised service providers located outside of South Africa, including in the United States, the European Union, and other countries where we operate.

All such transfers are conducted in accordance with applicable data protection laws, including the Protection of Personal Information Act (POPIA), and are safeguarded by one or more of the following mechanisms:

- Amgen's approved Binding Corporate Rules (BCRs) for intra-group transfers;
- Standard Contractual Clauses (SCCs) or other approved legal transfer mechanisms;
- Transfers necessary for the performance of a contract or for compliance with legal obligations;
- Transfers subject to appropriate safeguards and with due regard to the data subject's rights.

Amgen ensures that all recipients of personal information provide a level of protection that is substantially similar to POPIA and that such data is processed only for authorised and documented purposes.

More information about Amgen's global privacy practices, including our Binding Corporate Rules, is available at: [www.amgen.com/bcr](http://www.amgen.com/bcr).

### **Security Safeguards**

Amgen South Africa (Pty) Ltd is committed to protecting personal information against loss, misuse, unauthorised access, disclosure, alteration, or destruction. In accordance with Section 19 of the Protection of Personal Information Act (POPIA), we implement appropriate, reasonable technical and organisational measures to ensure the integrity and confidentiality of personal information under our control.

These measures include, but are not limited to:

- **Access Controls**  
Personal information is accessible only to authorised personnel on a need-to-know basis.
- **Encryption and Secure Transmission**  
Where appropriate, data is encrypted during storage and transmission using industry-standard protocols.
- **Authentication and Password Protection**  
Systems and databases are protected through authentication tools and strong password policies.
- **Security Policies and Training**  
All personnel are trained on data protection responsibilities and Amgen's internal privacy and cybersecurity policies.
- **Regular Security Audits and Risk Assessments**  
Amgen conducts ongoing assessments to identify and mitigate data protection risks and ensure compliance.
- **Incident Response Procedures**  
In the event of a data breach or security incident, Amgen has an established response plan to assess, contain, report, and remediate as required under POPIA and internal policies.
- **Vendor Due Diligence**  
Third-party service providers are contractually obligated to apply equivalent security safeguards and are subject to ongoing oversight.

Amgen ensures that these safeguards are reviewed regularly considering changing technology, emerging risks, and applicable legal requirements.

### **Retention of Records**

We retain PI only as long as necessary for the purpose collected and to meet legal/regulatory, quality and pharmacovigilance obligations. PV and quality records are retained to meet SAHPRA and regulatory life-cycle expectations. Retention periods are set out in our internal Records Retention Schedule.

### **How to Exercise POPIA Rights**

In terms of the Protection of Personal Information Act (POPIA), data subjects have the right to access and control their personal information held by Amgen South Africa (Pty) Ltd.

Data subjects may exercise the following rights:

- **Access** – Request access to personal information we hold about you.
- **Correction** – Request that incorrect, outdated, or incomplete information be corrected.

- **Deletion** – Request deletion of personal information that is inaccurate, irrelevant, or excessive.
- **Objection** – Object to the processing of personal information under certain circumstances.
- **Withdrawal of Consent** – Withdraw consent where processing is based on prior consent.
- **Lodging a Complaint** – Lodge a complaint with Amgen or the Information Regulator if you believe your data rights have been infringed.

### **How to Submit a Request**

Requests may be submitted to our Information Officer via:

Email: [privacy@amgen.com](mailto:privacy@amgen.com) or Via the [FORM](#)

Postal Address:

Information Officer

Amgen South Africa (Pty) Ltd

Building 4, Healthcare Park, Woodlands Drive,

Woodmead, Johannesburg, 2191

You may also use the prescribed Form 1 (Objection to Processing) or Form 2 (Request for Access), available from the Information Regulator’s website at [www.inforegulator.org.za](http://www.inforegulator.org.za), or on request from our office.

### **Response Timelines**

We will acknowledge and respond to valid requests within 30 calendar days, in line with the POPIA Regulations. Where necessary, this period may be lawfully extended. If a request is refused, reasons will be provided and you will be informed of your right to lodge a complaint.

### **Operator (Processor) Management**

Amgen South Africa (Pty) Ltd engages third-party service providers (“operators”) who process personal information on our behalf in the course of providing contracted services. In accordance with Section 21 of the Protection of Personal Information Act (POPIA), Amgen ensures that operators uphold equivalent data protection standards by implementing the following measures:

- **Written Operator Agreements**  
All operators are engaged under written contracts that clearly define:
  - The scope and purpose of processing
  - Confidentiality and security obligations
  - Breach notification requirements
  - Restrictions on sub-processing without prior written approval
  - Responsibilities for assisting Amgen with data subject rights
  - Secure deletion or return of personal information at the end of the engagement

- Security and Privacy Due Diligence

Operators undergo security and privacy assessments during onboarding and are subject to periodic risk-based reviews to ensure ongoing compliance with Amgen's standards.

- Cross-Border Processing Controls

Where operators process or transfer personal information outside South Africa, such transfers are carried out only under Amgen's documented instructions and in compliance with POPIA Section 72, using appropriate safeguards (e.g., Standard Contractual Clauses or Amgen's Binding Corporate Rules).

Amgen holds operators accountable for maintaining the confidentiality, integrity, and availability of personal information throughout the processing lifecycle.

**Availability of this Manual**

This manual is available free of charge on [www.amgen.com/dp](http://www.amgen.com/dp) and at our registered office during normal business hours. On request we can provide a copy by email.

## **ANNEX:**

### **FEES IN RESPECT OF RECORDS REQUESTED FROM PRIVATE BODIES**

#### **Fees Payable for PAIA Requests**

In terms of the **PAIA Regulations**, the following fees may be charged when a request for access to records is made:

##### **1. Request Fee**

- A requester, other than a personal requester, is required to pay a **request fee of R50.00** before the request is processed.

##### **2. Reproduction Fees**

Fees for making copies or reproductions of records (per A4 page or part thereof):

<b>Format</b>	<b>Fee (ZAR)</b>
Photocopy of a paper record	R1.10
Printed copy from an electronic record	R0.75
Copy on a stiffer disc	R7.50
Copy on a compact disc (CD)	R70.00
Transcription of visual images (A4 page)	R40.00
Copy of visual images	R60.00
Transcription of audio (A4 page)	R20.00
Copy of an audio record	R30.00

##### **3. Access Fee**

An additional **access fee** may be charged if the request is granted, to cover the cost of searching, preparing, and arranging access to the records.

##### **4. Postage**

Where applicable, **postage or courier costs** may also be charged.

Requesters will be informed in writing of the fees payable and may be required to pay a deposit if the search and preparation time is expected to exceed six hours.

**REVISION HISTORY**

<b>DATE</b>	<b>VERSION NO.</b>	<b>CHANGE SUMMARY</b>
29 OCT 2025	1.0	New version created