Bioderm THERAPEUTICS

Our Stakeholder interactions

Our Guide for in-field Activity

Our Guide for in-field Activity

Index.

Our Guide for in-field Activity

Our Stakeholder Interactions Guide

Bioderm Therapeutics is committed to conducting its field activities and customer interactions in compliance with South African laws, regulations, and ethical standards. This policy ensures that all company representatives, including sales and marketing personnel, adhere to the highest legal and ethical standards when engaging with healthcare professionals (HCPs), customers, and stakeholders.

Purpose

This policy provides guidance on the applicable legal and regulatory framework governing interactions with HCPs, healthcare organizations, patients, and other stakeholders in South Africa. It aims to ensure compliance with the Medicines and Related Substances Act, the National Health Act, the Protection of Personal Information Act (POPIA), and the South African Marketing Code Authority (MCA) guidelines.

Scope

This policy applies to all Bioderm Therapeutics employees, contractors, and third-party representatives engaged in field activities and customer interactions.

Our Guide for in-field Activity

Governing Field Activities.

Medicines and Related Substances Act

- Prohibits the sale, supply, or promotion of medicines in a manner that is misleading or outside of approved uses.
- Requires adherence to registration and licensing requirements for medicines promoted or sold.

National Health Act

- Regulates interactions with public healthcare facilities and professionals.
- Ensures that engagements do not interfere with the delivery of patient care or create conflicts of interest.

Protection of Personal Information Act (POPIA)

- Governs the collection, storage, and processing of personal information related to HCPs and patients.
- Requires transparency in data collection, ensuring that personal information is handled lawfully and with consent.

Competition Act

- Prohibits anti-competitive practices, including price-fixing, collusion, or any practice that unfairly restricts competition in the pharmaceutical industry.
- Ensures fair trade practices in negotiations with customers and suppliers.

Our Guide for in-field Activity

Prevention and Combating of Corrupt Activities Act

- Prohibits any form of bribery or inducement in interactions with HCPs, healthcare institutions, and government officials.
- Requires full disclosure of transfers of value to HCPs and healthcare organizations.

Marketing Code Authority (MCA) Guidelines

- Regulates promotional activities to ensure truthful, evidence-based, and ethical marketing of pharmaceutical products.
- Prohibits the offering of undue incentives to HCPs in exchange for product recommendations or prescriptions.

South African Health Products Regulatory Authority (SAHPRA) Regulations on Promotional Labeling and Advertising

- SAHPRA regulates all promotional labeling and advertising of medicines to ensure accuracy, balance, and compliance with approved indications.
- All promotional materials must:
  - Align with the approved package insert and not exaggerate claims about efficacy or safety.
  - Avoid misleading comparisons with other products.
  - Clearly indicate risk factors, contraindications, and potential adverse effects.
  - Be free from endorsements by celebrities or non-expert individuals.
- Direct-to-consumer advertising of prescription medicines is strictly prohibited.
- Any advertising or promotional campaigns must be pre-approved by SAHPRA where required.
- Compliance with SAHPRA's guidelines is essential to prevent regulatory sanctions and maintain industry integrity.

Our Guide for in-field Activity

Guidelines for Customer and HCP Interactions.

Promotional Activities

- All promotional interactions must be factual, evidence-based, and aligned with regulatory approvals.
- Representatives must not promote products for unapproved or off-label uses.
- Materials must be reviewed and approved by the compliance team before use in the field.
- Representatives must ensure that any claims made are supported by verifiable scientific data.

Sponsorships and Educational Support

- Bioderm Therapeutics may provide sponsorships for medical education programs, provided they are independent and not intended to influence HCP prescribing behaviour.
- All sponsorships and grants must be approved in advance and disclosed where required.
- Travel and accommodation support for HCPs must comply with MCA guidelines and should not be considered as an inducement.

Consulting and Speaker Engagements

- HCPs may be engaged for consulting services or as speakers only when there is a legitimate business need.
- A formal written agreement must be in place, clearly outlining the scope of work, deliverables, and fair market value (FMV) compensation.
- Payments must reflect the actual service provided and not be used to influence prescribing behaviour.
- Records of engagements must be maintained for compliance review.

Our Guide for in-field Activity

Product Samples and Donations

- Product samples may only be provided in compliance with the Medicines and Related Substances Act and MCA guidelines.
- Samples must be for patient benefit and not for resale or personal use by HCPs.
- Records of sample distribution must be maintained, ensuring traceability and compliance with reporting requirements.

Hospitality and Entertainment

- Hospitality must be modest and directly related to scientific or educational discussions.
- Entertainment of HCPs (such as recreational activities or leisure trips) is strictly prohibited.
- Any meals or refreshments provided must be reasonable in value and secondary to the professional engagement.

Transparency and Reporting

- All interactions with HCPs must be documented and recorded in accordance with compliance requirements.
- Transfers of value, including sponsorships, honoraria, and educational grants, must be reported as required by law.
- Bioderm Therapeutics will conduct periodic audits to ensure adherence to this policy.

Our Guide for in-field Activity

Reporting Adverse Events and Other Product Safety Information

- Employees and representatives must report any adverse events related to Bioderm Therapeutics products within 24 hours of becoming aware of the event.
- Reports should include product details, patient information (with consent and confidentiality maintained), and a description of the event.
- Adverse events must be reported to the Pharmacovigilance Department or designated compliance officer.
- If an HCP or customer reports a potential adverse event, representatives must not make medical judgments or recommendations but should document and escalate the report immediately.
- Bioderm Therapeutics will maintain a system for tracking, analyzing, and reporting adverse events to SAHPRA as required.
- Any safety concerns that require urgent action must be communicated promptly to regulatory authorities and healthcare providers where applicable.

Our Guide for in-field Activity

Product Safety Information includes any information about the safety, quality, or performance of Bioderm products received from any source, which includes any non-prescription or prescription drug, medical device or combination. There are four categories of Product Safety Information, listed below:

Factor	Description	Examples
1. Adverse Events	• Any untoward medical occurrence in a subject, patient, or consumer administered a Bioderm product • All reports of Adverse Events should be forwarded, regardless of the seriousness of the event, whether or not there is a causal relationship with the Bioderm product, and regardless of the event being mentioned in the product label/instructions	• Abnormal test findings • Clinically significant signs and symptoms • Changes in physical examination findings • Progression/worsening of underlying disease • Lack of efficacy for a Bioderm product • Drug abuse or dependency • Death
2. Unexpected Therapeutic Effect	A beneficial therapeutic effect of a product aside from the use for which it was given	Patient takes a product for high cholesterol and notices decreased insomnia

Our Guide for in-field Activity

Factor	Description	Examples
3. Product / Medical Device Complaints	• *Product Complaint:* any written, electronic, or oral communication that alleges deficiencies related to the quality or physical properties, condition, package insert, and/or packaging of a product • *Medical Device Complaint*: any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, instructions for use, or performance of a medical device, including any medical device constituent part of a combination product, and/or Bioderm-sponsored medical software products that are regulated as medical devices, such as mobile apps, website functionality, etc.	• Blister pack arrived empty • Vial is leaking liquid • Syringe is jammed • Product is/may be counterfeit
4. Circumstances That May Lead To Adverse Events	Certain situations should also be forwarded whether or not there are any associated adverse events, including: • Drug misuse • Extravasation • Drug overdose • Exposure during pregnancy, breastfeeding • Medication errors • Occupational exposure • Off-label use	Occupational Exposure: A hospital maintenance worker accidentally splashes a Bioderm medicinal solution in his eye while cleaning up • Off-label use: Product X is prescribed for a child with hypertension when Product X is approved for adult use only

Our Guide for in-field Activity

Compliance and enforcement

- Employees must complete annual compliance training on regulatory requirements and ethical standards.
- Managers must ensure that their teams fully understand and adhere to compliance obligations.
- Regular internal audits will be conducted to assess adherence to compliance standards.
- Any suspected breaches of compliance must be reported to the Compliance Officer or through the company's anonymous reporting system.
- Non-compliance with this policy may result in disciplinary action, including termination of employment, fines, or legal consequences.
- Bioderm Therapeutics is committed to a culture of compliance, and employees are encouraged to seek guidance whenever uncertain about regulatory requirements.

What Should You Speak Up About?

- Employees are expected to report any concerns related to:
- Unethical or Illegal Conduct – Fraud, corruption, bribery, or financial misconduct.Discrimination or Harassment – Any form of workplace discrimination, bullying, or harassment.
- Health & Safety Violations – Unsafe work conditions, lack of protective equipment, or environmental hazards.
- Data Privacy Breaches – Unauthorized access to patient, customer, or employee data (POPIA compliance).
- Regulatory & Compliance Violations – Non-compliance with SAHPRA, MCA, or Competition Act guidelines.