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SAHPRA Stakeholder Engagement Framework

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1. Background and Introduction

In order to execute its mandate as a health products regulator, the South African Health Products Regulatory Authority (SAHPRA) will engage with stakeholders on an ongoing basis. The stakeholders are individuals and organisations who have an interest in or are influenced by its work and the work of its partners who are in some way or other connected to SAHPRA's purpose. Partners, on the other hand, are individuals or organisations who assist, support and collaborate with the regulator but are not directly influenced or affected by the work of the regulator. The term "partners" refers to international partners such as the World Health Organisation (WHO), regional regulatory frameworks (NEPAD, African Medicines Regulatory Harmonisation (AMRH) and other health product regulators on the African continent and beyond including Recognised Regulatory Authorities (RRA)with whom SAHPRA has an MoU. As a Section 3A public entity, SAHPRA recognises that it is primarily accountable to the South African public who will therefore be prioritised as the primary stakeholder of health products regulation.

The specific mandates and requirements of public and stakeholder engagement are reflected in various sections of the Medicines and Related Substances Act (Act 101 of 1965 as amended). Section 34 of the Act[1] restricts the divulgence of specific information obtained by the Authority primarily in the interests of protecting the intellectual property of applicants. However, section 22B of the Act provides the Authority with clear guidance on the circumstances under which any type of information can be disclosed.

"22B Publication of information relating to medicines, Scheduled substances, medical devices or IVDs.—
(1) Notwithstanding the provisions of section 34 the Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, Scheduled substance, medical device or IVD.
(2) The Director General may publish the information referred to in section (1) or release it to the public in a manner which he or she thinks fit."

As a Section 3A public entity, SAHPRA's rules of engagement with stakeholders will be defined by key legislation which protects the rights of all South Africans. In particular, the provisions of the Promotion of Access to Information Act (PAIA) (Act 2 of 2000) ensures that the public has the right to request information and documents from the Authority while the Protection of Personal Information (POPI) Act (Act 4 of 2013) ensures that South Africans enjoy the protection of personal information that may be processed by the Authority in its routine activities.

Since its inception, SAHPRA has prioritised the active engagement of its stakeholders, recognising it as a critical activity in achieving its core function of regulating health products

[1] Section 34 of the Act states: "34. Preservation of secrecy - No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer."

in South Africa. As SAHPRA evolves, it will develop and grow its scope of communication and stakeholder engagement.

1.1. Scope and Objectives

The objectives of this Stakeholder Engagement Framework are to:

1) Describe the core values and approaches that will govern the management of SAHPRA's stakeholder relations;
2) Describe the key stakeholder groups that need to be engaged;
3) Explain the key approaches and tools that will be employed to communicate with stakeholders;
4) Declare the key barriers to effective communication in an effort to mitigate or minimise the risks of these occurring; and
5) Increase transparency on the communication infrastructure within SAHPRA and how SAHPRA engages with stakeholders.

This Framework will inform and support SAHPRA's strategic plans, performance plans and capacity development agenda. It will also inform and support the creation of guidance documents and other tools that will serve to guide and support the SAHPRA Board and its staff in planning, designing undertaking and assessing various stakeholder engagement activities.

SAHPRA recognises that the diverse nature of the work of the Authority will require effective engagement with several stakeholders and their representative groups.

The purpose of the Stakeholder Engagement Framework is not to address the management of relations with the media, the general public, individual pharmaceutical companies and service providers. The engagement with these stakeholders will be addressed in a guideline document. The focus is on managing relations with internal and external stakeholder groups and setting out the tools for engagement.

1.2. Applying SAHPRA's Core Values and Principles to Communication

Care

Underpinning all SAHPRA interactions is our care for patients, animals, society and the environment. All communication is conducted in a manner that respects the expertise, viewpoints and needs of the relevant SAHPRA stakeholders, while ensuring that at the heart of all our communication is the health and safety of patients, animals and the public. The Authority recognises the importance of two-way communication and active listening and will develop platforms of stakeholder engagement that support mutual learning. Respecting the diversity of its stakeholders and their needs and preferences, the Authority will endeavour to develop approaches to communication that would support these needs and preferences wherever possible.

The Framework aims to identify relevant stakeholders and to facilitate easy and meaningful engagement.

Ethical Conduct

The Authority will strive towards ensuring that all stakeholder engagements are underpinned by openness, honesty, scientific integrity and fairness. This means that information communicated about medicines will be as accurate and up to date as possible. Creating a culture of openness and transparency in decision-making has become a central focus of regulatory work around the world and will form the essence of SAHPRA's communication activities. The Authority will hold itself accountable to its primary stakeholder – the South African public – for all interactions, ensuring that communications are conducted with the aim of adding value and building knowledge towards executing its core mandate. In pursuance of this aim, the Authority will cultivate a professional environment where all contributions are valued, everyone is treated consistently and fairly, diverse viewpoints are heard and capitalised on and conflicts are resolved effectively.

Unity of Purpose

All communications will be underpinned by the core function of the Authority, which is to protect and improve public health and animal health by ensuring the safety, efficacy, performance and quality of health products throughout South Africa. This will require that all employees and stakeholders are made aware of policies, guidelines and procedures that support the core principles and values of the Authority.

While all SAHPRA's engagements will be driven by its strategic priorities, it will also consider stakeholders' objectives, environment, expertise and level of influence. When there is a shared vision of success, a more focused meaningful engagement is possible. Through communication planning and management of expectations, a more collaborative, trusting relationship with stakeholders becomes possible.

Service Excellence

Effective and timely communication is at the heart of regulatory service excellence. The Authority will strive towards cultivating a culture of extroversion and local responsiveness. This translates to building trust and good relationships with stakeholders by understanding them and their needs and by responding quickly and providing appropriate solutions that are underpinned by the core mission and values of the organisation. The Authority will continually measure its performance against its own targets and benchmarking against other regulators, while monitoring challenges and opportunities for growth. SAHPRA will strive to ensure that the information it communicates on the safety, efficacy and quality of health products is consistently accurate and reliable.

SAHPRA will furthermore strive to engage all relevant stakeholders from the start and agree on when and how to engage them. This will require clear explanations of the engagement process and timelines and, where feasible and appropriate, include negotiation with stakeholders on procedures and timelines for regulatory actions and dialogues in the form of scheduled meetings and response times for information requests or feedback. SAHPRA will transparently explain its decision-making process but is not obliged to provide

individualised feedback to stakeholders on the reasons for failing to accepting their recommendations on policies, guidelines or procedures under review.

Transformation
Respecting the national commitment to transformation towards a free, fair and just society, the Authority will strive to reach those people and organisations who contribute to, influence, or are affected by its work. This includes those that may be harder to reach, in the case of language, race, poverty, culture, age or mobility barriers.
We aim to provide all our stakeholders with the information they need to participate in a meaningful way.

To adapt to change timeously and positively, address setbacks and ambiguity and align its thinking and approach to changing situations, the Authority will seek to influence and support the global regulatory network in which it operates while accepting support from the global regulatory network, including but not limited to recognized regulatory authorities. It will do so by promoting and implementing harmonisation and reliance practices that would ultimately ensure local responsiveness to the evolving needs of our country and the health of all who live within its borders.

Innovation
The Authority will embrace the use of innovative approaches and technologies that will support excellence in its core business, including the development of locally relevant platforms that support the two-way engagement of stakeholders. Interactions with stakeholders and public trust will be monitored through various means, including surveys, to identify areas of improvement in stakeholder engagement and the fulfilment of key regulatory functions. The Authority will keep abreast of developments and environmental changes in order to improve its effectiveness while responding to or preventing any problems that may arise. Through resource planning and the development of its annual performance plan, the Authority will aim to be responsive to the evolving environment and public health needs, with the aim of improving public health and patient outcomes.

Independence and Integrity
By maintaining a culture of professionalism, integrity, honesty and scientific rigour, the Authority will strive towards maintaining public trust and independence in the accomplishment of its mandate. Part of this culture includes acknowledgment of uncertainty, challenges and threats and opportunities for improvement. The SAHPRA Code of Conduct for all staff, consultants, committee members and Board Members will be applied actively in order to ensure the proper functioning of the Authority in carrying out its mandate.

2. Identifying and Communicating with our Stakeholders and Partners

The following provides an overview of who the Authority recognises as its key target audience and how it will communicate with these various stakeholder groups. The approaches will evolve over time as the Authority expands its capacity and work.

2.1 Internal Stakeholders

The Staff of the Authority: Engagement will be pursued through various means, including regular staff meetings, the intranet, website and various other management forums across the Authority, by means of a comprehensive and simple approach to ensure that communication within the Authority is efficient and appropriate.

The SAHPRA Board: A programme of engagement between the Board, its committees and executive management will be key to ensuring that the strategic plans are executed and the Board is able to respond to any queries, including media queries.

Technical Support Committees: Technical support committees comprising experts in various areas of regulatory activities such as clinical evaluation of medicines, pharmaceutical and analytical review of dossiers, pharmacovigilance, biologics, medical devices and complementary medicines, will be established to support the work of in-house staff. There will be regular meetings held between the committees and staff members as well as one-on-one interactions, including training and mentorship between staff members and technical experts. In addition to regular meetings, support committees will be kept up to date of any changes through appropriate communication using means such as e-mail, the intranet or posting notifications of changes on the SAHPRA website.

2.2. External Stakeholders and Partners

The General Public: A host of communication tools will be used to engage with target audiences within the South African public. Platforms and procedures aimed at canvassing information on patient experiences around specific issues will be developed in an effort to strengthen the voice of patients in the regulatory decision-making process. This will include the website, internet, social media, radio and print advertisements as well as regulatory documents such as patient information leaflets and public health advisories that will support the safe and effective use of medicines. Where necessary, non-governmental groups such as advocacy groups, patient support groups and consumer groups will be engaged to assist with decision-making around the perceived and real merits and risks associated with marketed health products. Concerns raised by these groups may assist the Authority in identifying public health messages that need to be prioritised.

Health Products Industry: Manufacturers, distributors, wholesalers, researchers and contract research organisations (CROs) in the field of human and veterinary medicines, medical devices and radiation equipment and radionuclides comprise the health products industry. In addition to communication of regulatory decisions pertaining to their respective products, the Authority will need to inform, consult with and sometimes involve and collaborate with individual and representative groups of the health products industry on specific issues. In addition to routine correspondence, and the posting of regulatory guidance documents on the website, regular pre-arranged meetings with industry, special

consultative meetings, workshops, conferences and round-table discussions will be utilised to exchange views, promote dialogue, enhance understanding, improve communication and provide efficient, targeted and timely information in a proactive manner to support transparency and accountability in regulatory decision-making while ensuring that independence in decision-making is preserved.

The Minister of Health, other Ministries, the Director-General (DG) of Health and Parliament and Government (National and Provincial): The SAHPRA Board has a mandate to report to the Minister of Health and Parliament on the status and function of the Authority. This will be in the form of various Board reports as well as regular meetings between the SAHPRA Board and the Minister and DG of Health. In addition, partnership with the National Department of Health is pivotal in supporting public health. Meetings and other forums between SAHPRA management and staff and specific units within the National Department of Health will be needed to ensure that shared functions, including vigilance, are harmonised and managed collaboratively. Other ministries, including the Ministry of Trade and Industry, Treasury, and the Ministry of Agriculture, will need to be engaged on matters of drug policy. SAHPRA will regularly report to Parliament on the execution of its mandate as well as respond to any questions raised by Parliament in an accurate and timely manner.

Health Professionals and Health Professional Organisations: Supporting health care professionals by facilitating their safe and effective use of quality medicines is a fundamental function of the Authority. Obtaining information from health care professionals on the performance of health products requires that mechanisms for reporting product quality complaints, inappropriate advertising, suspected adverse reactions and events and other problems are easily accessible to these important stakeholders. Moreover, provision of feedback and up-to-date information on licensed health products will be a critical communication function of the Authority.

Academia and Research Institutions: Universities and other organisations involved in research and policy initiatives are important stakeholders. South African universities have a history of supporting post-marketing surveillance initiatives, conducting clinical trials and developing educational programmes aimed at supporting the regulatory body and its work. Academic and research institutions are influenced by the regulatory guidelines and priorities relating to the conduct of clinical trials and post-marketing surveillance. In addition, the role of academic institutions should be developed further to facilitate capacity building of regulatory expertise as the science of regulation rapidly evolves. Most important, academic institutions need to be up-to-date with regulatory decisions and trends to ensure that their curriculums are used to optimise the safe and effective use of health products by health professionals.

Media: The media have a key role to play in supporting the communication between the Authority and the general public as well as international community. All media communications will be centrally co-ordinated through the communications department of the Authority who will facilitate press conferences, interviews, press releases, newsletters, media briefings and communication of regulatory decisions.

International Organisations: In order to ensure that the Authority remains relevant and contemporary and is respected nationally and globally, partnerships and liaison with various international agencies will be essential. International agencies such as WHO, the Pharmaceutical Inspection Co-Operation Scheme (PIC/s) the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Children's Fund (UNICEF), the World Alliance for Patient Safety and other national regulatory agencies in Africa and beyond will be engaged through participation in international forums such as joint working groups, consortiums, as well as through the website, newsletter and media relations.

Donors and Other Partners: Regulatory agencies cannot function without the support and collaboration of partners such as WHO and its network of collaborating centres, regional collaborative forums such as Zazibona, as well as donor agencies. There is growing appreciation internationally of the need to develop robust models of reliance and data sharing. This has given rise to the launch and growth of multi-national regional platforms and investment by donors in regulatory re-engineering projects which improve regulatory information and communication technologies and promote collaboration with key partners. Investing time and resources in building our partnerships is ultimately aimed at supporting SAHPRA's mandate, which includes ensuring that the needs of our key stakeholder, the public, are met.

3. Approaches to Communicating with Stakeholders

Effective communication relies on the use of an appropriate engagement method or combination of methods for each situation. The selection of the most appropriate method/s depends on the situation itself (purpose of engagement, roles and responsibilities and issue/s being considered), and on the available time, skills and resources. Table 1 outlines the four key approaches of engagement that will be employed by the Authority in its commitment to stakeholders.

Table 1: Key Stakeholder Engagement Approaches with Examples

Approach	Level of engagement	Examples of engagement
Inform	One-way communication to inform and/or educate stakeholders	Announcements, policy and guidance documents, press releases, newsletters, and guidelines
Consult	To gain information and feedback from stakeholders – usually in written format.	Requests for comment on draft policies and guidelines, and surveys
Involve	Direct interactions with stakeholders – with two-way/multi-way communication, usually with the intention of both parties learning from the interaction	Stakeholder meetings/workshops, public hearings, and conferences
Collaborate/participate	Direct interactions, with bi-directional or multi-directional	Technical expert groups/committees, focus

	communication. Learning, negotiation and decision-making occur with all stakeholders involved. Stakeholders work together and take action	groups, multi-country initiatives (e.g. ZAZIBONA), joint projects, and partnerships

In addition to these there are three lower levels of engagement that the Authority may utilise as deemed appropriate. These include:
a) ***Remaining passive:*** There is no active communication in this interaction but the information is noted, e.g. protests, letters, media, websites and pressure from advocacy groups.
b) ***Monitoring***: Stakeholder views will be monitored through rumour surveillance, media tracking or following social media for vigilance purposes.
c) ***Transacting***: This engagement takes place in the confines of a contractual relationship where one partner directs the objectives and provides funding (e.g. consultancies employed by the Authority or donor funding). In this case there is limited bi-directional communication, as the terms of the contract are agreed to and the fulfilment of the contract is monitored.

These three approaches are suitable as initial steps in building a relationship of trust with stakeholders in order to facilitate a more interactive and effective engagement in due course.

4. Tools of Communication

A host of communication tools will be utilised to support effective stakeholder engagement, both internally and externally. The types of tools used and the extent to which they are used will expand as the communication capacity and resources within the Authority grow. These will include:

- the SAHPRA website
- media relations (e.g. press releases, press briefings, press conferences, articles)
- newsletters and digital magazines
- advertising (e.g. print, radio, television and social media)
- information leaflets (multilingual formats)
- videos and other multimedia
- mobile phone apps
- conferences and seminars
- internet and intranet
- face-to-face meetings, round table discussions and workshops, accompanied by timely minutes
- focus group discussions
- annual reports to relevant stakeholders (e.g. Parliamentary/Ministerial reports and proceedings)
- Surveys, including communication of survey results where relevant

5. Working Principles of Communication

The Authority's approach to how we communicate will be guided by the following working principles:

- Consistency of timely messaging will be maintained throughout the Authority – all internal and external communications will be centrally co-ordinated through the Communications Department.
- Well-conducted meetings with stakeholders will be held – all meetings will have an agenda, clearly stipulating the objectives of the meeting and properly minuted with a clear action plan, which will be distributed in a timely manner to relevant stakeholder attendees and more broadly if appropriate.
- A communication liaison will be allocated within each of the programmes within SAHPRA. This liaison will be the contact point with the Communications Department.
- Liaison staff and the Communications Department will meet regularly to ensure a flow of information throughout the organisation and to co-ordinate the communications requirements of each programme and sub-programme.
- All print and design materials will be produced centrally by the Communications Department to agreed print and design standards in line with brand requirements. Templates will be developed to assist with this process.
- All communications materials produced by the Authority will be in simple English. Every effort will be made to ensure that all important communications will be available in as many official languages as possible reflecting the diversity of languages spoken in our country.
- Permission for use of the Authority's name or logo by a third party may only be given by the Communications Department.
- One template is to be used for all presentations by the Authority.
- All media queries should be forwarded to the Communications Department for appropriate response. In order to ensure consistency of messages, no employee will provide any information about the Authority or relating to its work to members of the media without the prior permission or involvement of the Communications Department. No employee of the Authority will conduct an interview with members of the media without the involvement of the Communications Department.

6. Barriers to Communication

Unclear objectives: The purpose of the engagement should be clear and commonly understood and agreed upon by all parties prior to initiation of engagement. In some instances, the stakeholders may need to be involved in defining the purpose of the engagement. Failure to do so can compromise the efficiency of these engagements and could result in misunderstanding and mistrust.

Differing capacities of stakeholders: Certain important stakeholder groups may lack the capacity required to engage the Authority on specific issues. This can mean that their critical voices are excluded from consideration during the decision-making process, despite the opportunity provided to them to contribute. The Authority may need to find different, innovative and locally relevant approaches to engaging these groups and may also need to support initiatives that will enhance their capacity to contribute.

Insufficient skills in the team: SAHPRA will need to build capacity in this area of its work over time. As such, the types of stakeholder engagement activities offered and the tools employed will evolve and grow over time. The Authority will continually assess its capacity for providing effective communication that promotes the achievements of its mandate.

Unfocused dialogue: Issues that are not critical to the objectives of a specific initiative can arise during interactions with stakeholders. Stakeholders may raise such ad hoc issues, which may not be directly pertinent and could therefore distract from the aim of obtaining relevant input, which could derail the engagement process. Issues that are peripheral to the key objectives of the engagement need to be set aside and managed separately. It is important that these issues are not ignored, but also appropriately dealt with. Therefore, a clearly considered plan for addressing these issues will need to be developed.

Failure to review and evaluate: Lack of ongoing review and evaluation of the communication activities will hamper improvements in this critical activity of the Authority and will adversely affect relationships with key stakeholders. Therefore, the detailed strategic plan will include elements of periodic and ongoing review that will be adjusted as needed.

Protection and access to information: While personal and proprietary information submitted to the Authority is to be protected as stipulated in the Act, the intention is not to compromise access to information about health products that is in the public's interest. Requests for information must be made in accordance with the requirements of PAIA. Personal information obtained in the normal course of the functioning of the Authority (for example through adverse drug reaction reports and patient and provider information in Section 21 applications) must be properly protected in accordance with the POPI Act.

7. Communication Infrastructure within SAHPRA

The Director of Communications will work closely with the Communications Committee, CEO, CRO and other senior executives to oversee the communications strategy of SAHPRA. Each regulatory unit will have a communications liaison officer who will serve as the liaison point between the relevant technical unit and the Communications Department. The Director of Communications will work with the employment relations officer within the human resources (HR) management services to ensure effective internal communications between various departments, the executive and the Board. The Board Secretary will serve as the communications liaison officer between the Board and the Director of Communications.

8. Measures of Successful Communication

Monitoring and evaluation of the Authority's communication activities are vital in ensuring that SAHPRA's communication strategy has a positive impact on the public's trust in SAHPRA, thereby improving public health through improved stakeholder relations. It also ensures that the resources are targeted to have optimal impact on public health and that the Authority's strategic objectives are being met. This Stakeholder Engagement Framework

is a dynamic and evolving document, responding to the ever-changing environment and public health needs.

Relationships with key stakeholders will be monitored by the Communications Department through various approaches such as surveys, focus groups and direct feedback. Regular reports will be provided to the Communications Committee of the Board on interactions and relations with each stakeholder group.

9. References

1. Australian Government Department of Health. Stakeholder Engagement Framework. http://www.health.gov.au/internet/main/publishing.nsf/Content/stake-frame (accessed 15 October 2018).
2. European Medicines Agency (EMA). European Medicines Agency (EMA) stakeholder relations management framework. EMA/48651/2016. https://www.ema.europa.eu/documents/other/european-medicines-agency-ema-stakeholder-relations-management-framework_en.pdf (accessed 15 October 2018).
3. Health Information and Quality Authority. Communications and Stakeholder Engagement Strategy 2013-2015. July 2013. https://www.hiqa.ie/system/files/Communications-Stakeholder-Engagement-Strategy-2015.pdf (accessed 15 October 2018).
4. Medicines and Related Substances Act, (No. 101 of 1965 as amended). https://www.sahpra.org.za/documents/959cb9e1Test.pdf (accessed 21 March 2019).
5. The Protection of Personal Information Act (No. 4 of 2013). https://www.saica.co.za/Portals/0/Technical/LegalAndGovernance/37067_26_11_Act4of2013ProtectionOfPersonalInfor_correct.pdf (accessed 21 March 2019).
6. Framework for interaction between the European Medicines Agency (EMA) and industry stakeholders. EMA/591272/2014. https://www.ema.europa.eu/en/documents/other/framework-interaction-between-european-medicines-agency-industry-stakeholders_en.pdf