FOOD AND DRUGS AUTHORITY

STAKEHOLDER COMMUNICATION POLICY

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1. INTRODUCTION

The Food and Drugs Authority (FDA) is the governmental agency responsible for Food and Drugs regulation in Ghana. The Authority operates under the control and supervision of the Ministry of Health.

The FDA is mandated under the Public Health Act, Act 851, 2012 – Part 6, 7 & 8 to control the manufacture, importation, exportation, distribution, use and advertisement of food, drugs, cosmetics, household chemical substances, medical devices, tobacco and tobacco products, blood and blood products as well as the conduct of clinical trials protocols.
The FDA recognizes that effective and timely communication is key to carrying out its mandates of ensuring public health and safety with respect to the products under its purview locally manufactured, imported, exported, distributed, sold, or used in Ghana.

This document describes a strategic approach for effective communication of FDA information, advice and guidance across a broad range of health issues arising from FDA activities.

It also provides information, advice, and guidance to decision-makers (key audiences) to prompt action that will protect the health of individuals, families, communities and nations.

This guideline is hereby promulgated for information, guidance and strict compliance by all concerned.

2. SCOPE

To provide information, advice, and guidance to stakeholders (including decision makers) for prompt action that will protect public health and safety.

3. GLOSSARY

"**Stakeholder**"
Person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity of the FDA.

4. GENERAL

The communication of information plays a strategic role within the food and medicine regulatory environment. Effective communication supports the development of positive relationships with the stakeholder community and can also be utilized to influence attitudes and behaviours within the wider environment.

Management is committed to practice professional communications principles – using well written, high-quality communications that clearly articulate the message, are timely, and respect the time and privacy of recipients.

This document describes FDA's plan of action on effective stakeholder engagement

- **Who are our stakeholders?**
- **Why do we need to communicate with them?**
- **What do we wish to communicate with our stakeholders?**
- **When should we communicate?**
- **What are the best mechanisms for effective communication?**
- **Challenges to effective communication?**

5. Who are our stakeholders?

A stakeholder may be defined as an individual or group that can influence, or be influenced by FDA's actions.

The principal stakeholder groupings for a food and medicine regulatory agency are the general public, health care professionals, the pharmaceutical industry, national government, other regulators (internal or external), other non-regulators, media together with the staff (internal communication).

Stakeholder analysis is an important element in the establishment of a communication strategy. In order to communicate effectively we need to clearly identify **what we want to say, whom we wish to convey the information to, how to send the information and what action we wish to achieve from the communication**. It is

important that FDA present information that is accurate, meaningful and actionable to its stakeholders.

This document acknowledges the differences between the various stakeholders and the appropriateness of the communication to the groups involved.

Different stakeholders require different considerations:-

Pharmaceutical industry

- Timely
- Confidentiality
- Commercial Sensitivity

General public / Media

- Language - clarity, concise, non-sensational, non-trivial
- Timely
- Actions clearly defined
- Contacts provided

Healthcare professionals / Healthcare Professional Regulatory Bodies

- Accurate Target identification
- Timely access to information
- Clear recommendations for action
- Contacts provided
- Follow-up by FDA

Regulators internal/external / WHO

- Confidentiality
- Pre-publication discussion
- Agreed timeline for discussion; agreement and action
- Co-ordinated response
- Publication (when needed)
- Post-publication discussion (when needed)

Non-regulators/NGOs

- Confidentiality agreements
- Information sharing

National government (MOH)

- Accurate information
- Meaningful language
- Context consideration (background information)

Security Agencies

- Accurate information
- Meaningful language
- Context consideration (background information)

Staff (*internal communication***)**

1. Confidentiality
2. Relevant staff involved in pre-action discussion

3. Clear understanding of issues
4. Consistent messages from the organization
5. Circulation/Notification of information

FDA maintains a stakeholder register which describes identified stakeholders and their effect and impact on FDA activities.

6. Why do we need to communicate?

Protection of public health and safety is the basis for all of the FDAss communication with its stakeholders. Whether the information being conveyed is pertinent to the urgent recall of a substandard or falsified (SF) product, or the sharing of new prescribing information – both situations are grounded in the FDA's key functions as a protector of public health and safety.

Some important reasons to communicate include the development of trust, social responsibility, market transparency and professional ethics all of which support the overall goal of protecting public health and safety.

It is therefore appropriate that the FDA who is responsible for the registration, licensing, inspection, surveillance and clinical trial protocols be actively involved in the dissemination of information with regards to its regulated products. The principle of 'trust' should be established and stakeholders should feel confident that the regulator is the appropriate source of up-to-date, quality information.

It is necessary to replace traditional views of 'need to know' basis with a more open and transparent approach. This approach must recognize the right of individuals/ organizations to accurate, meaningful and helpful information in respect of FDA regulated products.

Information sharing across the regulatory community has become the lifeblood of decision-making - the result of communicating with the wider stakeholder network.

In summary, the reasons for communicating with stakeholders are:-

- Protection of public health and safety through: -
    - Rapid communication of appropriate, accurate, information to a clearly identified audience
- Information sharing – 'Information is power'
- Informed decision making
- Creating awareness about the role of the regulator
- Influencing the regulatory and wider environment
- Improved relationship with stakeholders
- Noted as 'accurate information' provider

Strategic Approach for dealing with Stakeholders:

- Improved stakeholders' consultation to provide input into the planning and policymaking of the FDA.
- Knowing the needs and expectations of stakeholders before selecting the methods for communication.
- Establishing a dialogue with the stakeholders to ensure the Authority is aware of issues of importance to the stakeholders.
- Making the affected stakeholders aware of the Authority's policies and decisions through the consultative process, and offering them the opportunity to ask questions and give their opinion to promote trust.

7. What information do we wish to communicate with our stakeholder(s)?

To ensure that we are communicating successfully, we examine the stakeholders' considerations and design our communication content and mechanisms accordingly.

A matrix that supports the classification of communications within the regulatory network is provided in Figure 1.

Examples of specific information to be communicated may include but not limited to:

- Rapid Alerts (Pharmacovigilance)
- Rapid Alerts (Quality Defects)
- Product Recalls
- Press Releases – SF medical products, banned products etc.
- 'Dear Healthcare Professional' letters
- Media briefings/interviews
- Newsletters
- Annual Reports
- Letters/emails to stakeholders
- Interactive Web Based Information/social media.
- Meetings
- Shared information within the organization (all the above)

Figure 1

	General Information	Specific Information	Commercially Sensitive Information	Health Care Professional - Information	Regulatory Sensitive Data
General Public / Media	X				
Pharmaceutical Industry			X	X	
Regulatory Network			X		X

	General Information	Specific Information	Commercially Sensitive Information	Health Care Professional - Information	Regulatory Sensitive Data
Non Regulatory Network				X	X
Health Care Professionals				X	
National Government		X			X
Staff - Internal	X	X	X	X	X

8. When should we communicate with our stakeholders?

Communication timing can be loosely broken down into: -

- Proactive Communication
- Reactive Communication

9. What are the most appropriate mechanisms for effective communication?

A communication model that supports a number of mechanisms for sharing and disseminating information will be considered. Communication methods will be strategically linked to the target audience. The difference in stakeholders will determine the method in which they receive or access information. FDA will ensure that methods identified will facilitate two-way communication.

Advance in modern technology now provide opportunities to reach large numbers of people rapidly. This significant advantage will be routinely employed where appropriate.

A number of the current mechanisms used to communicate with stakeholders are listed hereunder:

- Formal and informal dialogue e.g. meetings with or without a report
- Structured meetings e.g. Stakeholder meetings
- Workshops
- Social media
- Professional media
- Professional groups
- Email
- Web Site(s)
- Radio/Television
- Video presentations
- Education materials (flyers, leaflets, posters, brochures..)

- Lectures
- Surveys

10. Challenges to effective communication?

The FDA exists in a growing regulatory environment made up of many partners, to which decisions are more regularly reached through a centralized process thus making effective and timely communication difficult. Ensuring a consistent message across all partners has also proved difficult – with stakeholders receiving mixed messages from different partners.

This communication strategy has been developed to support information sharing in a consistent, understandable and timely manner.

Anything that acts against this policy can be an obstacle to good communication and efforts would be made to recognize and avoid the pitfalls listed below:

- Poor use of, or inappropriate language for the target audience
- Non user-friendly terminology
- Legal issues/obstacles
- Lack of timeline
- Confidentiality agreements
- Commercial sensitivities
- Reluctance to communicate or share information
- Inability to obtain the necessary information to communicate or share
- Information overload; too much information.
- Defensiveness; distorted perceptions, bias
- Cultural barriers
- Language barrier
- Interference
- Inconsistency of approach; different messages from multiple sources
- Poor or incomplete data; inadequate information
- Lack of empathy or understanding of the stakeholder perspective

In order to determine how well our communication strategy is effective we will endeavor to ensure the following:

That all communication is:

- clear
- concise
- has a clearly defined action plan
- targets appropriate audience
- allows constructive feedback; follow-up to determine effectiveness
- calling for action
- proactive rather than reactive

- follows agreed timeline

11. Main Conclusions

Communication with stakeholders is an essential aspect of the Authority's routine operations, with well-developed communication routines and competence in using different methods to communicate with different stakeholder groups. Knowledge about stakeholder's opinions, expectations and needs are collected and understood by the Authority.

The development of strategies to support effective internal and external communication is essential to the successful future of the Authority. The Authority therefore continually develops competency in this area and ensures that resources are available to support this strategic activity within the organization.

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Stakeholder Register

Name of Stakeholder	Degree to which Stakeholder is Impacted by FDA	Level of Stakeholder's Influence/Impact on FDA Outcomes	Level of Involvement in FDA	Preferred Method of Communication (e.g. Meeting, Email, Status Report)	Result of Stakeholder Analysis
Ministry of Health	High	High	High	Meeting, Letters, Email, Status Retport	Manage Closely (HP+HI)
FDA Board of Directors	High	High	High	Meeting, Email, Status Retport	Manage Closely (HP+HI)
Technical Advisory Committee	High	High	High	Meeting, Letters, Email, Status Retport	Manage Closely (HP+HI)
Staff - Internal	High	High	High	Memos, Meeting, Email, Status Retport	Manage Closely (HP+HI)
Regulatory Network	Medium	Medium	Medium	Letters, Email, Status Reports	Keep Informed (LP-HI)
Public/Media	High	High	Medium	Meeting, Letters, Email, Status Retport	Manage Closely (HP+HI)
Patient Groups	Medium	Medium	Low	Meeting, Letters, Rapid Alerts	Keep Informed (LP-HI)
Healthcare Professional Association	High	Medium	Medium	Meeting, Letters, Rapid Alerts	Keep Informed (LP-HI)
Healthcare Professional Regulatory Bodies	High	Medium	Medium	Meeting, Letters	Keep Informed (LP-HI)
Public Health Program	High	High	High	Meeting, Letters, Rapid Alerts	Manage Closely (HP+HI)
Research Institutions	Medium	Medium	Medium	Meeting, Letters, Rapid Alerts	Keep Informed (LP-HI)

L= Low, H=HighI= interest, P=

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Security Agencies	Medium	Medium	Low	Meeting, Letters, Emails, Rapid Alerts	Keep Informed (LP-HI)
NGOs	Medium	Medium	Medium	Meeting, Letters, Emails, Rapid Alerts	Keep Informed (LP-HI)
Pharmaceutical Industry	High	High	Medium	Meeting, Letters, Rapid Alerts	Manage Closely (HP+HI)

L= Low, H=HighI= interest, P=