Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2018-013

17 SEP 2018

SUBJECT: Risk Management Plan (RMP) for Drug Establishments

1. BACKGROUND/RATIONALE

Republic Act (R.A.) No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" was issued to (a) enhance FDA's regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments and the registration and monitoring of health products, and (b) ensure FDA's monitoring and regulatory coverage over establishments and products under its jurisdictions (such as drug establishments and their drug products).

As provided under Book I, Article VII, Section 4 (h) of the Implementing Rules and Regulations of R.A. No. 9711, FDA has the power to mandate, order, review, and implement a Risk Management Plan (RMP) on any health product for conformance with FDA standards. Also, Book I, Article II, A, Section 2 (l) requires all concerned to implement RMPs which is a requirement for the issuance of appropriate authorization. More recently, Administrative Order No. 2014-0034, "Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorizations, and Administrative Order No. 2016-0003, "Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA)", formally mandates all drug establishments to have an RMP.

RMP is defined as a set of health product vigilance activities and interventions designed to identify, characterize, prevent or minimize risks to health products, and the assessment of effectiveness of those interventions. The implementation of an RMP as a requirement for drug establishments shall result in the coordinated and economical applications of resources to minimize, monitor, and control the probability and/or impact of risks to drug products with respect to their safety, efficacy, and quality.

2. OBJECTIVE

The objective of this FDA Circular is to provide guidance on the preparation of an RMP as part of the FDA's requirements for the issuance of a License to Operate (LTO).

3. SCOPE

This FDA Circular shall apply to all drug establishments, namely but not limited to(1) Distributors, (2) Drugstores/ Pharmacies/ Boticas including hospital and institutional pharmacies, (3), Retail Outlet for Non-Prescription Drugs (RONPDs), (4)

Sponsors, and Contract Research Organizations (CROs). However, manufacturers are required to comply with the standards of Pharmaceutical Inspection Co-Operation Scheme (PIC/S).

4. GUIDELINES

4.1. *Framework for RMP for Establishments*

All RMP for establishments must contain the following minimum sections: (1) Introduction, (2) Risk Identification, (3) Risk Minimization, (4) Risk Communication, and (5) Risk Monitoring and Management Evaluation.

4.1.1 Introduction

(a) Internal Environment. The internal environment of the drug establishment must be described in this section, as it sets the basis on how risks are viewed and addressed. The following information must be included in this section:

- A brief description of the establishment, its objectives, mission and vision;
- A brief description/illustration of the organization - the different departments/divisions, head officers (and their respective functions and responsibilities/duties;
- The risk management officer/team, where applicable;
- Other attached establishments/institutions critical to the functioning of the establishment and their relation to the drug establishment, functions and responsibilities/duties; and,
- Contact information of responsible officers during and beyond office hours.

(b) Risk Management Approach. A brief description of the overall risk management approach of the drug establishment must be provided in this section: the risk management processes, the personnel involved, the periodic reporting and monthly procedures to be performed, among others.

(c) Risk Management Objectives. Once the internal environment has been established, the specific objectives of the RMP should be set. In general, the objectives set must be to ensure the safety, efficacy, and quality of the drug products the establishment engage with in order to protect public health.

(d) Data Lock Point. The timeframe to which the RMP is expected to be valid should be indicated in this section.

4.1.2 Risk Identification

Risk identification consists of the identification and assessment of risks that may adversely affect the set objectives stated. In the preparation of risk identification, the following must be prepared:

(a) Risk universe containing all identified risks;
(b) Assessment of the risks based on their (i) significance and (ii) likelihood of occurrence made using accepted risk management tools to enable establishments to identify priority risks to manage within a given data lock point; and,
(c) Tabulated summary risk register containing:
    i. The priority risks;
    ii. The specific objectives under which the priority risks belongs; and,
    iii. Naming convention for each priority risk

For risks not currently known, planned activities must be set by the drug establishment to identify them.

4.1.3 Risk Minimization

For each priority risk, the appropriate risk minimization plans should be prepared. These plans may include policies and procedures to ensure the identified risks are prevented and/or minimized to an acceptable level. These risk minimization activities are classified into (a) routine risk minimization and (b) additional risk minimization.

Routine risk minimization activities are those planned activities conducted by the drug establishment regularly to minimize risks. Additional risk minimization activities are those planned activities conducted by the drug establishment when routine risk minimization activities are not sufficient to manage a risk, or should a significant risk occur.

For identified risks with no recommended minimization activities, appropriate justification must be provided.

4.1.4 Risk Communication

The drug establishment should establish a communication system to ensure that identified risks that warrant appropriate communication (1) internally, (2) to FDA, (3) to healthcare professionals and consumers, and/or (4) other stakeholders such as the Department of Health (DOH) and the Local Government Unit (LGU) are properly communicated. The system must clearly specify the situations/criteria wherein risk communication must be done, as well as the means for communicating.

In addition, the drug establishment should also describe its internal reporting procedures to ensure that all important risks are communicated to its management and the FDA.

4.1.5 Risk Monitoring and Management Evaluation

Risk management systems should be reviewed periodically. Policies and procedures to that effect should be in place, specifying the frequency of evaluation.

In addition, once a risk occurred, the RMP should also be reviewed. Review of the implementation of the different planned activities must be done.

For situations warranting revision of the RMP, these must also be described.

The format described above is attached as Annex A. Existing RMPs of licensed establishments are acceptable so long as they are equivalent with those described above. Sample RMP for drug distributors and retailers are attached as Annex B and C, respectively.

4.2.*Review of RMP*

The RMP must always be available for inspection at any time the drug establishment is open for business. RMP shall be reviewed by FDA in the event that a trigger (i.e., situations wherein the quality, safety and efficacy of a product has been compromised) has occurred.

Upfront submission is not required, except for manufacturers wherein the RMP is part of the Site Master File (SMF).

5. REPEALING CLAUSE/SEPARABILITY CLAUSE

Provisions in previous circulars and memoranda that are inconsistent with this Circular are hereby withdrawn, repealed, and/or revoked accordingly.

If any provision in this FDA Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this FDA Circular shall not be affected.

6. EFFECTIVITY

This Circular shall take effect immediately.

NELA CHARADE G. PUNO, RPh
Director General

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Annex A

Risk Management Plan Format

Sec. A Introduction
1. ~~Internal Environment~~
2. Risk Management Approach
3. Risk Management Objectives
4. Data Lock Point

Sec. B Risk Identification
1. Risk Universe
2. Risk Assessment
3. Summary Risk Register
4. Unknown Risks

Sec. C Risk Minimization
1. Routine Risk Minimization
2. Additional Risk Minimization
3. Justification for Identified Risks without Minimization Activities

Sec. D Risk Communication
1. Internal Communication
2. Communication to FDA
3. Communication to Consumers and Healthcare Professionals
4. Communication to Other Stakeholders

Sec. E Risk Monitoring and Management Evaluation
1. Routine Evaluation
2. Additional Evaluation

Annex B

Sample Risk Management Plan for Drug Distributors

Sec. A: Introduction

1. Internal Environment

ABC Pharma Inc., is a licensed drug distributor-importer with license number LTO-123456 located at Alabang, Muntinlupa city.

ABC Pharma Inc. is owned by Juan dela Cruz.

ABC Pharma Inc., is licensed to import raw materials, active ingredients and/or finished products for wholesale distribution to other local FDA-licensed drug establishments.

The following are my responsibilities as an importer:

- My establishment is open for business hours only under the supervision of my PRC registered pharmacist
- The approved and valid License to Operate is displayed in a conspicuous place of the establishment
- Comply with regulatory standards of FDA, in particular good distribution and storage practices
- Ensure that I conduct business with legal entities/licensed establishments
- Ensure the products we distribute and/or sell are registered or to be registered with FDA prior to distribution or sale;

As a Marketing Authorization Holder, the following are my responsibilities with regard to my products:

- Ensure that current Good Manufacturing Practice Guidelines is applied in full in the manufacture of my products
- Ensure that the formulation per dosage form is in agreement with the master formula and with the batch manufacturing record forms
- Ensure that the manufacturing procedure is exactly as specified in the master formula and batch manufacturing records
- Ensure that each batch of all finished and starting materials is tested or certified against the full specifications and fully complied with before it is released for manufacturing/distribution purposes
- Ensure that all APIs are obtained from legally authorized and qualified sources
- Assume primary responsibility and/or stewardship over the product in case of liability, adverse events, and/or other public health & safety issues

Attached is the organizational chart of the establishment, including the Risk Management Team.

In case of emergency, the following are the contact information of the members of the Risk Management Team

- A
- B
- C

2. Risk Management Approach

As a general rule, the team meets every 3rd week of the last month of the quarter to

conduct its periodic review of risk management. Minutes and attendance are taken. The SOP (SOP #1234) for the risk management review is attached.

3. Risk Management Objectives

Our general risk management objective is to ensure the safety, efficacy, and quality of drug products, and ensure compliance with regulatory requirements Specifically:

- Ensure compliance to regulatory action
- Ensure compliance to GSP
- Ensure compliance to ethical business practices

Objective Category			
Objective name	**Particulars**	**KRA**	**KPI**
Compliance to regulatory action	Compliance to product recalls	Full compliance; immediate removal from retailers	Up to date list of advisories; complete documentation on recalls
Compliance to GSP	Compliance to Cold-chain	Products stored and maintained in correct temp	Consistent temperature on monitoring charts
Cmpliance to ethical business practices	Ensure compliance to MCPs	Good performance of detailmen	Less than 2 complaints/ reports received

4. Data Lock Point

With the recently promulgation of the MCPs, our data lock point is six months. Within 2 months of the end of the data lock point, we commit to revise the RMP

Sec. B: Risk Identification

1. Risk Universe

Compliance to regulatory action		
Recall	**Submission of CAPA**	**Reporting to Inspector**
Lack of time to check		
Poor internet connection		
Clients demanding for product		
Difficulty in coordinating with retailers		
Poor distribution records (for example, highest risk)		

GSP
Cold-chain
Irregular checking
Lack of SOPs
Malfunctioning monitoring equipment
Power-outage(for example, highest risk)
Malfunctioning refrigerator

Business Ethics

Promotion	Advertising	Conventions
No time to review promotional materials		
Misleading promotional designs		
Low technical skills of and/or unethical detailmen (for example, highest risk)		
Pressure from physicians		
Pressure from global		

2. Risk Assessment

Delphi method was used to assess the risks identified in the risk universe and prioritize them.

3. Summary Risk Register

Naming Convention	Priority Risk	Risk Management Objective
Distribution Records Risk	Incomplete/poorly managed records will hamper the process of recall	Compliance to regulatory action
Power-outage Risk	Power-outage will result into fluctuation in the temperature within the warehouse, and the shutting-down of cold rooms/walk-in freezers	Compliance to GSP
Detailmen Promotion Risk	Low technical skills of and/or unethical detailmen - poor training will result to low technical skills and/or unethical detailmen	compliance to ethical business practices

4. Unknown Risks

The risk management team, as part of the periodic review, will also address risks not previously identified following SOP 5678.

Sec. C: Risk Minimization

Priority Risk	Routine Risk Minimization	Additional Risk Minimization
Distribution Records Risk	Ensure all relevant information is complete in the records	Special project to complete existing records/problematic records
Power-outage Risk	Regularly view power interruption schedule	Additional back-up generator
Detailmen Promotion Risk	Regular maintenance of generator	Warning/ sanction + re-training/ orientation following SOP 1214515
	Re-training after 1 year	

Sec. D: Risk Communication

Distribution Records Risk		
Criteria	**Communication Content**	**Medium**
Recall from FDA	Inform records management team to review distribution records immediately	Phone
Voluntary Recall	Inform records management team to review distribution records immediately	Phone

Power Outage Risk		
Criteria	**Communication Content**	**Medium**
Continued power-outage	Provide information to management/maintenance regarding the risks to quality and their preparation	Phone

Detailmen Training Risk		
Criteria	**Communication Content**	**Medium**
Reporting of Physician of unethical/misleading promotional practices	Memo as warning the detailmen of the complaint received	Formal Letter
Monitoring of BOP-PRC	Memo as warning the detailmen of the complaint received	Formal Letter
Monitoring of FDA	Memo as warning the detailmen of the complaint received	Formal Letter

Sec. E: Risk Monitoring and Management Evaluation

The RMP will be reviewed and revised at the end of the data lock point. Review shall follow SOP 124345

RMP shall be reviewed in instances the identified risks occur which needed additional risk management.

Annex C

Sample Risk Management Plan for Drugstores

Sec. A: Introduction

1. Internal Environment

DEF Drugs is a licensed drugstore with license number LTO-123456 located at Alabang, Muntinlupa city.

DEF Drugs is owned by Juan dela Cruz.

DEF Drugs is licensed to sell registered drug products, including temperature sensitive products, specifically vaccines to the general public on a retail basis.

The following are my responsibilities as an drugstore (petition form):

- My establishment is open for business hours only under the supervision of my PRC registered pharmacist
- The approved and valid License to Operate is displayed in a conspicuous place of the establishment
- Comply with regulatory standards of FDA, in particular good distribution and storage practices
- Ensure that I conduct business with legal entities/licensed establishments
- Ensure the products we distribute and/or sell are registered or to be registered with FDA prior to sale;

Attached is the organizational chart of the establishment.
In case of emergency, the following are the contact information of the members of the Risk Management Officer

- A
- B
- C

2. Risk Management Approach

The risk management officer regularly meets the team and facilitates the meeting every 1st week of June to conduct its periodic review of risk management. Minutes and attendance are taken. The SOP (SOP #1234) for the risk management review is attached.

3. Risk Management Objectives

As a licensed drugstore, our general risk management objective is to ensure the safety, efficacy, and quality of drug products, and ensure compliance with regulatory requirements. Specifically:

- Regular updating to advisories and policies
- Ensure compliance to regulatory action
- Ensure compliance to GSP

Objective Category			
Objective name	**Particulars**	**KRA**	**KPI**
Update to advisories and policies	Up to date review of issued advisories	Full compliance	Up to date list of advisories

	pertaining to safety of drug products		
	Up to date review of laws affecting drugstores	Full compliance	Up to date list of policies and SOPs
Compliance to regulatory action	Compliance to product recalls	Full compliance; immediate removal from shelf	Up to date list of advisories; documentation on returns
Compliance to GSP	Compliance to Cold-chain	Products stored and maintained in correct temp	Consistent temperature on monitoring charts
	Compliance to room temperature monitoring		

4. Data Lock Point

Since most objectives are done routinely, the data lock point is set 2 months before the expiration of the validity of the LTO.

Sec. B: Risk Identification

1. Risk Universe

Up to Date Advisories and Policies	
FDA Advisories	**AO, FDA Circulars, Memos, Memorandum Circulars**
Lack of time to check	
Lack of time to meet and discuss	
Lack of time to change SOPs	
Poor internet connection	
Malfunctioning computer	
Difficulty in interpreting(for example, highest risk)	

Compliance to regulatory action		
Recall	**Submission of CAPA**	**Reporting to Inspector**
Lack of time to check(for example, highest risk)		
Poor internet connection		
Malfunctioning computer		
Clients demanding for product to be dispensed		
Disapproval of Owner		

GSP		
Cold-chain	**Room-temperature products**	**Lock and Key Products**
Irregularly checking		
Lack of SOPs		
Malfunctioning monitoring equipment		
Power-outage(for example, highest risk)		
Malfunctioning refrigerator		

2. Risk Assessment

Delphi method was used to assess the risks identified in the risk universe and prioritize them.

3. Summary Risk Register

Naming Convention	Priority Risk	Risk Management Objective
Interpretation Risk	Low technical skills/poor understanding of the Advisory to comply	Up to date advisories and policies
Time Management Risk	Poor time management of staff resulting to neglect in checking the FDA website for recalls	Compliance to regulatory action
Power-outage Risk	Power-outage will result into fluctuation in the temperature within the store, and the shutting-down of refrigerator	Compliance to GSP

4. Unknown Risks

The risk management officer, in coordination with the store staff, as part of the periodic review, will also address risks not previously identified following SOP 5678.

Sec. C: Risk Minimization

Priority Risk	Routine Risk Minimization	Additional Risk Minimization
Interpretation Risk	Conduct regular discussion with staff and owner	Consult with local chapter or national association
		Consult with FDA
Time Management - Risk	Allot specific time for checking FDA Website	No additional risk minimization required
	Conduct regular discussion with staff and owner (presentation of new policies) and removal from shelf	
Power-outage Risk	Regularly view power interruption schedule	Continued power-outage: transfer products
	Preparation of contingency (Cooler/generator)	

Sec. D: Risk Communication

Time Management Risk		
Criteria	**Communication Content**	**Medium**
Supplier has not contacted the store on products recalled	Follow-up supplier	Phone

Power Outage Risk		
Criteria	**Communication Content**	**Medium**

Continued power-outage	Provide information on owner regarding the possibility of poor quality meds	Phone
	Contact supplier for any assistance	Phone

Sec. E: Risk Monitoring and Management Evaluation

The RMP will be reviewed and revised at the end of the data lock point. Review shall follow SOP 124345

RMP shall be reviewed in instances the identified risks occur which needed additional risk management.