

Expect more.

DBN ENVIRONMENTAL AND SOCIAL MANAGEMENT GUIDANCE FOR PHARMACIES

Contents

a)	Version Control
1.	DEFINITIONS, TERMS & ABBREVIATIONS4
2.	INTRODUCTION4
	3. SCOPE4
4.	INTENT4
5.	BACKGROUND TO THE SECTOR4
6.	KEY EOHSS RISKS
	6.1. Clinical Waste and Sharps5
	<i>6.1.1. Mitigation measures</i> 5
	6.2. Deliveries
	6.3. Dispensing & Provision of Advice5
	<i>6.3.1. Mitigation measures</i> 5
	6.4. Drug Disposal6
	6.4.1. Mitigation measures6
	6.5. Energy Consumption6
	or Linegy consumption
	6.6. Exposure to Hazardous Drugs and Other Substances
	6.6. Exposure to Hazardous Drugs and Other Substances
	6.6. Exposure to Hazardous Drugs and Other Substances
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7
	 6.6. Exposure to Hazardous Drugs and Other Substances
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7 6.8. Manual Handling and Repetitive Injury 7 6.8.1. Mitigation measures 7
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7 6.8. Manual Handling and Repetitive Injury 7 6.8.1. Mitigation measures 7 6.9. Packaging Waste 7
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7 6.8. Manual Handling and Repetitive Injury 7 6.8.1. Mitigation measures 7 6.9. Packaging Waste 7 6.9.1. Mitigation measures 8
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7 6.8. Manual Handling and Repetitive Injury 7 6.8.1. Mitigation measures 7 6.9. Packaging Waste 7 6.9.1. Mitigation measures 8 6.10. Water and Wastewater 8
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7 6.8. Manual Handling and Repetitive Injury 7 6.8.1. Mitigation measures 7 6.9. Packaging Waste 7 6.10. Water and Wastewater 8 6.10.1. Mitigation measures 8 6.10.1. Mitigation measures 8
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7 6.8. Manual Handling and Repetitive Injury 7 6.8.1. Mitigation measures 7 6.9. Packaging Waste 7 6.9.1. Mitigation measures 8 6.10. Water and Wastewater 8 6.10.1. Mitigation measures 8 6.10.1. Mitigation measures 8 6.10.1. Mitigation measures 8 6.11. Violence and Lone Working 8
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7 6.8. Manual Handling and Repetitive Injury 7 6.8.1. Mitigation measures 7 6.9. Packaging Waste 7 6.10. Water and Wastewater 8 6.10. Water and Wastewater 8 6.11. Violence and Lone Working 8 6.11.1. Mitigation measures 8 6.11.1. Mitigation measures 8
	6.6. Exposure to Hazardous Drugs and Other Substances 6 6.6.1. Mitigation measures 7 6.7. Financial Implications 7 6.8. Manual Handling and Repetitive Injury 7 6.8.1. Mitigation measures 7 6.9. Packaging Waste 7 6.9. Packaging Waste 7 6.10. Water and Wastewater 8 6.10.1. Mitigation measures 8 6.11. Violence and Lone Working 8 6.12. Illicit Drug Manufacturing 8

a) Version Control

Date	Version	Change Description	Author/Editor
07/09/2016	0.01	Initial Draft	Manager: Environment & Social Development
28/02/2018	0.02	DBN Logo and update as per 07 April 2017 Kreditanstalt für Wiederaufbau (KfW) Development Bank Gap Assessment of the Development Bank of Namibia's (DBN) Environmental & Social Management System (ESMS)	

The table below serves to track the key revisions made to this document for change control purposes.

CFC's	Chlorofluorocarbons
DBN	Development Bank of Namibia
EOHS&S	Environmental, Occupational Health and Safety and Social
HSE	Health, Safety and Environmental
ESMP	Environmental and Social Management Plan
HCFC's	Hydro chlorofluorocarbons
PPE	Personal Protective Equipment

1. DEFINITIONS, TERMS & ABBREVIATIONS

2. INTRODUCTION

This guideline is designed to be used by the Development Bank of Namibia (DBN) clients to understand the nature of environmental, occupational health and safety and social (EOHS&S) risks associated with existing or planned operations in this sector and suggested actions for businesses to manage these EOHS&S risks.

It also provides guidance for clients on potential due diligence questions to discuss with management to understand how their business is managing these EOHS&S risks. This guideline focuses on material EOHS&S risks; it is not an exhaustive list of EOHS&S risks. In managing EOHS&S risks, all businesses should be compliant with relevant EOHS&S laws and regulations and best practices.

This guideline focuses on pharmacy operations with reference to the International Finance Corporation's Environmental, Health and Safety (EHS) General Guidelines. The EHS Guidelines are technical reference documents with general and industry-specific examples of Good International Industry Practice (GIIP).

3. SCOPE

This guidance is applicable to all the Development Bank of Namibia's (DBN) clients/customers who intends to or have set up operations in this sector category and, extends to their assets, facilities, operations, projects and activities, including activities undertaken by any contractor on behalf of the Company, business units and managed operations including corporate/administration offices and other facilities located off site.

4. INTENT

The intent of this guidance note is to assist prospective clients to develop a thorough Environmental and Social Management Plan (ESMP) for their activities and merely act as a guidance and is not comprehensive nor exhaustive.

5. BACKGROUND TO THE SECTOR

A retail pharmacist works according to legal and ethical guidelines such as the Pharmacy Act No 9 of 2004, Pharmacy Professions Act, 1993 and Government Gazette No. 4000, Notice 51 of 27 February 2008, to ensure the correct and safe supply of medical products to the public. They are involved in maintaining and improving people's health by providing advice and information, and supplying prescription medicines. Retail pharmacists also sell over-the-counter medical products and instruct clients on the use of medicines and medical appliances. Some pharmacists also offer specialist health check services, such as blood pressure monitoring and medical screening.

Retail pharmacies usually consist of a retail storefront with a dispensary to the rear where medications are stored and dispensed. The dispensary is subject to pharmacy legislation; with requirements for storage conditions, compulsory texts, equipment, etc., specified in legislation.

All pharmacies are required to have a pharmacist on-duty at all times when open and/or it is also a requirement that the owner of a pharmacy must be a registered pharmacist. Some supermarkets now include a pharmacy as a department of their store and many pharmacies sell a diverse arrangement of additional items such as cosmetics, toiletries, office supplies, vitamins, alternative medicines, food supplements, confectionary, and snack foods in addition to medicines and prescriptions.

6. KEY EOHSS RISKS

Below are the material EOHSS risks associated with this sector and key measures to manage them. Where gaps are found in the management of key EOHSS risks, the DBN E&S risk management measures may form part of a corrective E&S action plan agreed with clients.

6.1. Clinical Waste and Sharps

Clinical wastes (waste contaminated with potentially infected bodily fluids), including sharps (needles etc.) may be produced within the pharmacy, e.g. from the treatment of minor wounds, emergency diabetes shots and epinephrine injections for bee sting treatments etc.

6.1.1. Mitigation measures

- Clinical wastes and sharps should be stored in designated waste containers to await safe disposal through an authorised waste disposal service.
- Provide secure segregated waste containers for hazardous and clinical waste and sharps.

6.2. Deliveries

Congestion and disturbance to neighbouring businesses and residents from delivery vehicles may result in complaints.

6.3. Dispensing & Provision of Advice

Many drugs can have severe side effects if they are taken in incorrect quantities or are not suitable for a particular patient. If these are prescribed medicines, the prescribing doctor should have verified the suitability and specified the way in which the medicines are to be taken.

6.3.1. Mitigation measures

• The pharmacist must ensure there is no dispensing error and the doctor's instructions are correctly transcribed onto the medicines.

- The pharmacy must have procedures in place to check the correct prescription is dispensed and the patient is aware of any specific requirements or contra-indications related to taking the medicines whether prescribed or sold over the counter.
- As trained healthcare professionals, pharmacists can play a key role in verifying the quality of prescribing carried out by doctors within the community; they are in a position to spot and query potential discrepancies in prescribing practice.

6.4. Drug Disposal

Nearly all medicines have an expiry date after which they should not be used. Pharmacies may also have obsolete and unwanted medicines returned by customers. It is good community relations for pharmacies to accept expired or unneeded medicines from the public to ensure that these are safely removed from circulation.

6.4.1. Mitigation measures

- All medicines should be disposed of in a safe and appropriate manner according to the guidance for that medicine but this is frequently by incineration.
- Medicines should not be disposed of in the sewerage system as the active ingredients may not be removed by water treatment and would enter the environment where they can cause harm to wildlife and humans.
- Medicines awaiting destruction must be clearly marked in order to minimise the risk of errors and inadvertent supply to patients.
- Drugs classed as hazardous should be stored separately from non-hazardous drugs. Hazardous drugs are those that are toxic, carcinogenic, mutagenic or toxic for reproduction
- Operate a take-back scheme for unwanted and expired medicines to prevent inappropriate disposal.
- Ensure that access to hazardous medicines is only available to authorised persons.
- Ensure detailed records are maintained of the dispensing of prescription controlled drugs.
- Provide advice to customers and patients on the safe and environmentally friendly disposal of medicines and clinical waste.

6.5. Energy Consumption

Retail pharmacies are relatively low users of energy. The main energy uses are:

- Refrigeration units for the preservation of certain medicines;
- Heating;
- Lighting

The refrigeration units may use ozone depleting refrigerants, such as Chlorofluorocarbons (CFCs) and Hydro chlorofluorocarbons (HCFCs), the production of which are being phased out under the Montreal Protocol.

6.6. Exposure to Hazardous Drugs and Other Substances

Pharmacist may be exposed to hazardous drugs and other substances in the air and on work surfaces, particularly if they are involved in drug compounding (i.e. the preparation of custom ordered medications).

Hazardous exposure to workers may occur through inhalation of dust created during: pill dispensing, hand manipulation; operation of a tablet encapsulation machine; and by performing sieving and granulation operations, particularly when appropriate engineering controls are not applied.

Dermal absorption may occur when preparing creams, liquids, gels, and moisturizers. Improper handling of these medications may contaminate the work environment and may produce adverse health effects, both acute and chronic, in exposed workers.

6.6.1. Mitigation measures

- Train individuals in the hazards of exposure to ingredients during the compounding and handling of medications.
- Implement procedures to reduce direct skin contact; reduce exposure via inhalation; and minimize the possibility of chemicals being brought home on workers' clothing.
- Provision of personal protective equipment (PPE) that is fit for the task to prevent injury and maintain hygiene standards.
- Staff should be trained in the correct selection, use and maintenance of PPE;

6.7. Financial Implications

The financial implications on a viable business of a dispensing error that results in an adverse health outcome or the sale of contaminated products could be significant. Financial impacts may arise form compensation claims, loss of reputation and/or loss of contracts.

Significant upgrades in hygiene and quality control standards may be required in order to reduce the risk of dispensing error or contamination and to satisfy national and international standards;

- Capital investment may be required to achieve compliance with environmental, health, safety and hygiene standards;
- Specific national or international legislation, e.g. controlled drugs, packaging and waste disposal may require modification to facilities and processes or require additional capital investment;
- Injures may lead to increased payroll costs to replace workers;
- Fines, penalties and third party claims may be incurred for non-compliance with environment, health and safety regulations.

6.8. Manual Handling and Repetitive Injury

Lifting, repetitive work and posture injuries occur as a result of lifting and carrying heavy or awkward shaped items, height of work surfaces and prolonged standing. Particular care should be taken when retrieving objects from very low or high shelves. Repetitive tasks can lead to musculoskeletal injuries.

6.8.1. Mitigation measures

• Organise dispensary so that frequently accessed products are stored at a convenient height to avoid excessive bending and stretching.

6.9. Packaging Waste

The most significant waste stream in terms of volume is likely to be waste arising from the packaging used to protect products during transport to the store, e.g. cardboard, plastic film, polystyrene and wooden pallets. The different waste types should be stored separately to facilitate recycling.

6.9.1. Mitigation measures

- Provide separate waste containers for each type of waste to enable efficient recycling.
- Contact suppliers to explore ways to reduce packaging waste.

6.10. Water and Wastewater

Wastewater discharged from retail pharmacies arise from sanitary uses and cleaning.

6.10.1. Mitigation measures

• Care should be taken that spilled medicines are not discharged to the sewer.

6.11. Violence and Lone Working

Pharmacies will have drugs on the premises that are desirable to illegal drug users. They are therefore vulnerable to robbery and theft.

Retail pharmacies usually operate a rota system to ensure that at least one pharmacy in an area is open at all times. This could mean that employees are working alone at night and could therefore be particularly at risk from attack or accident.

6.11.1. Mitigation measures

Consider improving security precautions to provide greater protection for workers where workplace violence is a problem, e.g.

- Install Plexiglas in the payment window
- Provide better visibility and lighting in the pharmacy area
- Provide training for staff in recognising and managing hostile behaviour
- Implement security devices such as panic buttons, surveillance cameras, alarm systems, and security guards

6.12. Illicit Drug Manufacturing

Pseudoephedrine and ephedrine decongestants found in many over-the-counter products can be easily extracted to make the drug methylamphetamine and methamphetamines. Pharmacists should be vigilant to suspiciously high demand for over-the-counter decongestants which, contains the pseudoephedrine and ephedrine agents.

6.12.1. Mitigation measures

- In dealing with requests where they may have suspicions, pharmacists should use their professional judgement and discretion in deciding whether a genuine clinical need exists and that the medicine is appropriate for the patient
- Report suspiciously high demand for the over-the-counter decongestants, which contains the pseudoephedrine and ephedrine agents
- Requests for these products should be referred to the pharmacist, particularly if the request might appear to suggest that it is not for a genuine therapeutic reason

The DBN will look at the following during loan application and monitoring after disbursement;

- Perform a complete tour of the facility, accompanied by someone knowledgeable about all the activities there.
- Confirm organisational responsibilities and systems for environment, occupational health, safety and social matters and that these systems cover both employees employed directly and sub-contractors.
- During the initial site visit, the issues will vary according to the size of operation and the level of environment, health and safety management already introduced. While visiting the site it is important to discuss and review the following:

Topic	Issue to Review
Organisational responsibili	• Confirm organisational responsibilities and systems for environment, occupational health and safety.
Management Plans	• Review the operational procedures and management plans available regarding the control of risks. As a minimum any business should have the following in place.
	• Environmental, Occupational Health & Safety management systems which include operational procedures that are communicated, implemented and regularly reviewed (i.e. "live" systems that are used in practice, not just kept as an office manual)
	• Monitoring programmes to monitor environmental, occupational health & safety, and hygiene risks
	Improvement objectives, targets and project plans
	• A training plan for personnel to include environmental and occupational health and safety issues
	• Emergency plans for environment, occupation & community health occupational health & safety, and safety incidents and site security
	• Demonstrable involvement of senior management in environment, occupational health & safety management and leadership.
Environment, Health and	• Confirm organisational responsibilities and systems for environment, health and safety;
Safety	• What is the standard of "housekeeping" on the premises? Do areas look clean and tidy?
	• Check the condition of storage facilities for medicines; Are they kept at the correct temperature and humidity conditions?
	• Observe drug dispensing procedures. Are staff wearing appropriate PPE for the task they are performing? Is customer understanding of potential side-effects and contra-indications checked?
	Check signage on the premises:
	• Does it convey the health and safety risks?
	Are fire exits clearly marked?
	 Is fire-fighting and first aid equipment available?
	• Check the age and condition of equipment, look for signs of wear and tear, degradation, leaks and breaks;
	• Check that waste storage areas are clean of debris, clearly signed and that waste containers are covered to prevent waste escaping, for example, check that waste containers have lids or are stored in an area with a roof;

	• Check that concrete weater starses is used for herendous weater and for aliginal weater and sharper if appropriate
	• Check that separate waste storage is used for hazardous waste and for clinical waste and sharps if appropriate;
	• Check that waste disposal takes place on a regular basis;
	• Check security arrangements for protection of workers and prevention of unauthorised access to controlled drugs;
	• Check that the business has a system of inventory control to ensure that all medicines are accounted for and the details required by national regulations are recorded;
	• Does the organisation/pharmacist have insurance in place to cover dispensing error/the recall of contaminated products? Have there been any recent product recall incidents?
	• Have the premises been inspected recently (within the past 2 years) by the regulatory authorities for health, safety and the environment?
	• Have there been any recent (within the last three years) incidents on site such as serious injuries or dispensing errors? Are there insurances in place to cover such incidents?
	• Does the business plan have line items for Environment, Health, Safety and Hygiene improvements?
	Check the conditions and duration of validity for all permits and registrations
Social, Labour and Community	• Check that labour standards, contracting and remuneration are in line with national law and are consistent with the average for the sector;
	• Check that hours worked, including overtime, are recorded and staff should receive written details of hours worked and payment received;
	• Check that wages and working hours are consistent with the average for the sector and national standards;
	• Has the Company received inspections from the local labour inspectorate in the previous three years? Have these resulted in any penalties, fines, major recommendations or corrective action plans?
	• Does the organisation have a grievance mechanism which allows employees to raise workplace concerns?
	• Are employees free to form, or join, a worker's organisation of their choosing?
	• Take note/ask questions relating to any activities that address the improvements listed in the mitigation measures section of this document.
	• Operational procedures to manage environmental, health and safety risks;
	 Monitoring programmes;
	 Improvement objectives, targets and project plans;
	 Training for personnel;
	 Regular inspections, checks and audits with records to demonstrate achievement of the required level of performance against legal requirements and improvement action;
	• Emergency plans for environment, health and safety accidents;
	• Management review/demonstrated involvement in environment, health and safety management.

7. **REVIEW**

The principles contained in this guidance will be reviewed on an annual basis to facilitate improvement.

8. GENERAL REFERENCES FOR STANDARD METHODS

- Cassell DK 2007, Pharmacists at risk: Pharmacists must learn how to ensure their own safety with pharmacies a common target for theft, Drug Topics Nov 5, 2007
- National Institute for Occupational Safety and Health (NIOSH) 2004, Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, NIOSH Publication No. 2004-165, <u>http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf</u>
- Royal Pharmaceutical Society of Great Britain 2005, The Hazardous Waste (England And Wales) Regulations 2005: Interim Guidance for Community Pharmacists for England and Wales and Information for Scotland
- Royal Pharmaceutical Society of Great Britain 2007, Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales, http://www.rpsgb.org/pdfs/cdsafedestructionguid.pdf
- U.S. Department of Labour, Occupational Safety and Health Administration 2001, Potential Health Hazards Associated with the Process of Compounding Medications from Pharmaceutical Grade Ingredients, Technical Information Bulletin, TIB 01-12-21