ECOPHARMACOVIGILANCE IN PRACTICE: DESIGN OF AN INTERVENTION - THE DRUG DISPOSAL FLOW DIAGRAM

by

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DECLARATION

I, YVONNE YIRENKYIWAA ESSEKU, declare that this submission is my own work towards the MPhil and that to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any degree of the University, except where due acknowledgement has been made in the text.

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DEDICATION

I dedicate this work to my friend and husband, Harold.

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I thank the Almighty God for His grace, guidance and strength and the ability to undertake this course and dissertation. All I am, have been and ever hope to be are in Him.

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STATUTES

ABBREVIATIONS AND ACRONYMS

API	Active Pharmaceutical Ingredients
CCMC	Chemicals Control and Management Centre
DA	District Assembly
DDFD	Drug Disposal Flow Diagram
EDC	Endocrine Disrupting Contaminants
EHSD	Environmental Health and Sanitation Department
EMP	Environmental Management Plan
EPA	Environmental Protection Agency
EPV	Ecopharmacovigilance
FDA	Food and Drugs Authority
GNDP	Ghana National Drug Programme
MLGRD	Ministry of Local Government and Rural Development
MMDA	Metropolitan, Municipal and District Assembly
PC	Pharmacy Council
PPCP	Pharmaceutical and Personal Care Product
PHC	Population and Housing Census
PIE	Pharmaceutical in the Environment
PV	Pharmacovigilance
STG	Standard Treatment Guidelines
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UN-DESA	United Nations Department of Economic and Social Affairs
UNDP	United Nations Development Program
UNEP	United Nations Environment Programme
UNOCHA	United Nations Office for the Coordination of Humanitarian Affairs
WCED	World Commission on Environment and Development
WHO	World Health Organization
WWTP	Waste Water Treatment Plant

ABSTRACT

Ecopharmacovigilance has been said to describe the science and activities associated with the detection, evaluation, understanding and prevention of adverse effects of pharmaceuticals in the environment. Disposal practices utilised by consumers and players in the pharmaceutical value in dealing with unused and expired products contribute to having pharmaceuticals and personal care products (PPCPs) in water sources and other environmental media. A number of strategies have been implemented in different parts of the world to tackle the presence and persistence of pharmaceuticals in the environment. In order to effectively implement successful strategies in any setting, the context of the community in which the strategy is to be implemented is important. This study explores the disposal methods used, assesses the role of regulation on disposal practices and seeks to introduce a new tool, which incorporates the relevant context, to be utilised in the implementation of EPV in Ghana. The study found that there are gaps in the legislation governing the disposal of pharmaceuticals; the methods used for disposal result in pharmaceuticals in the environment; and the Drug Disposal Flow Diagram is a cost effective method of tackling the problem of pharmaceuticals in the environment.

CHAPTER 1.

INTRODUCTION

1.1 Background

1.1.1 The Environment and Health

All living organisms need a healthy environment in order to survive. This is because living organisms interact actively with their environment as they undertake their lifesustaining processes. Some of the significant interactions of human beings, and other living organisms, with the environment include taking up food and water from the environment, taking in oxygen-rich air and bringing out carbon-dioxide and releasing waste products into the environment – with the expectation that the environment will adequately handle such waste. Where the environment is strong and dynamic enough to support the needs of the organism, the organism will have a better quality of life. On the other hand, where the environment, as a result of insult inflicted from various quarters, cannot support the needs of that organism, the quality of life will be reduced. The environment in which human beings and other organisms live will, therefore, have a direct impact on their quality of life.

A number of factors impact the ability of the environment to support life to an optimum level: massive population growth, climate change and human-made pollution (Royal Society of Chemistry, 2007). The factor of human-made pollution has to do with the human activities that have the effect of introducing pollutants into the environment whether or not the introduction is on purpose. This is directly linked with the population growth, as increased numbers of human will directly increase the activities

that introduce pollutants into the environment. When pollutants enter the environment, they affect both the quality and quantity of resources that are available for consumption. The quality is affected by the mere presence of pollutants, whereas the quantity is affected because the polluted resources are no longer available for use for the intended purpose. Thus, the life supported by the polluted environment is negatively affected by the reduction in available resources such as air, water and land. Pollution may be as a result of both clearly negative practices such as poor sanitation as well as intrinsically positive practices such as the use of pharmaceuticals and other chemicals to improve the quality of life of the members of the community.

1.1.2 Pharmacovigilance and Ecopharmacovigilance

In using medicines, prescribers, dispensers, other health care providers and the users alike seek some particular effects which may be to give relief from symptoms of some condition, shorten the duration of an episode or condition, or prevent the condition altogether. Medicines may, however, also have some unintended or unwanted effects in addition to the required effects when consumed. Pharmacovigilance (PV) is the study of these unintended and unwanted effects. PV is defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO, 2002). There are also instances where some of these effects (unwanted or unexpected) may occur in the environment after elimination of the product by the consumer or as a result of direct dumping of unused pharmaceuticals in the environment. These unintended effects in the environment have led to a new aspect of PV known as ecopharmacovigilance (EPV). EPV has been said to "describe the science and activities associated with the detection, evaluation, understanding and

prevention of adverse effects of pharmaceuticals in the environment" (Holm, et al., 2013). The relevance of EPV (Velo, 2007) and how it affects the health and wellbeing of humans and the environment (Boxall, 2004) have been discussed.

1.1.2.1 Endocrine Disrupting Compounds (EDCs)

One significant source of environmental contaminants, and a focus of global research, is a group of compounds identified as endocrine disrupting chemicals (EDCs). An endocrine disruptor has been defined as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)population" (International Programme on Chemical Safety, 2002, p. 1). EDCs are made up of a range of classes of chemical products: "natural and synthetic hormones, plant constituents, pesticides, compounds used in the plastics industry and in consumer products and other industrial by-products and pollutants" (International Programme on Chemical Safety, 2002). EDCs interfere with the endocrine (hormone) system of humans and other animals. Some of the ways in which EDCs pose threats to living organisms include alteration of behaviour, fertility and other developmental functions.

A number of studies have shown a significant effect of EDCs on fish populations in exposed water bodies (Christiansen, et al., 2002), (Briggs, 2000), (Edmunds, et al., 2000). Researchers reported of large proportions of male fish in populations becoming either completely or functionally feminised. In some research findings, the fish populations became one hundred percent (100%) female upon exposure to some hormones (Christiansen, et al., 2002) and other chemicals such as DDT (Edmunds, et al., 2000) in their aquatic environments. EDCs have also been implicated in the induction of the formation of cancers in humans although direct causal links and

mechanisms of action have been difficult to establish (International Programme on Chemical Safety, 2002). These effects indicate that the impacts of EDCs are potentially severe and explain the international focus on such research issues.

1.1.2.2 Pharmaceuticals and Personal Care Products

One group of products that has been identified as having endocrine disrupting activity are pharmaceuticals and personal care products (PPCPs). PPCPs are an integral part of life. These products, in various formulations, are used to improve quality of everyday life. Medicines are essential for the maintenance of health and soaps and shampoos are essential for the maintenance of good hygiene. The role of medicines in the diagnosis, prevention and treatment of diseases is an important one in maintaining the health of any society. These medicines may be prescribed or used on the advice of a health care provider. Some persons may also use medicines without any such advice but rather because of past experiences with such medicines for the treatment of some condition. There are also those who take medicines prescribed for others or take medicines on the advice of persons who may not have any technical knowledge of the medicines.

The consumption of medicines for the treatment of disease conditions can be directly related to the disease patterns in the area under consideration. There are, however, some medicines that may be consumed, not for the treatment of disease conditions but for their effect on the quality of life or for the purpose of preventing some condition. Such medicines will therefore have no relation with the disease patterns and yet may bring about significant PV and EPV issues. There are also medicines that may not be consumed in very high quantities in the population generally but which may have very

significant environmental harm. Such medicines then become very important when discussing matters on EPV.

Members of the public acquire pharmaceutical products for different reasons including for the treatment and management of medical conditions. Pharmaceuticals may be used in institutional settings as well as in the home. Pharmaceuticals may also be used for the management of conditions in animals (veterinary use). When pharmaceutical products are consumed, they are metabolised and eliminated through faeces and urine into the environment (Sakrabani & Boxall, 2007). They may also enter the environment when they are deposited directly into the environment by consumers who want to dispose of excess supplies they may have (Abruquah, et al., 2013).

1.1.3 Legislation, Regulation and EPV

The regulation of public services is governed by legislation. In Ghana, the Environmental Health and Sanitation Directorate (EHSD) is responsible for the formulation of policy for sanitation and hygiene. These policies govern the disposal of all waste generated in the country including domestic and industrial waste. The implementation of these policies is undertaken primarily by the metropolitan, municipal and district assemblies (MMDAs) with input from other agencies such as the Environmental Protection Agency (EPA). The Food and Drugs Authority (FDA) is responsible for the disposal of PPCPs, the regulation of which it undertakes in collaboration with MMDAs and, in some instances, the EPA. For each of these agencies, their participation is dictated by the legislations governing their activities. These legislations will, therefore, have a direct impact on whether or not the disposal activities undertaken are focused on ensuring a healthy environment.

1.1.4 Disposal Practices and PPCPs

The methods used for the disposal of waste generally, and PPCPs in particular, will have a direct bearing on the presence, persistence and effects that these products have on the environment. Where waste is disposed of properly and effectively, PPCPs which are disposed of will not end up having any negative environmental effects. Effective specialised disposal of PPCPs will also prevent them from getting into the environment. On the other hand, where PPCPs are not properly handled, they will end up in the environment and cause various harmful effects.

A large percentage of household liquid and solid waste in Ghana is not collected and disposed of effectively. The liquid waste is allowed to mix up with the grey water in the normal drainage system and solid waste is disposed of in un-engineered dump sites. In the two largest cities in Ghana, Accra and Kumasi, less than 15% of septage generated is effectively treated (MLGRD, 2010), and these account for the highest levels of collection and treatment. With respect to solid waste disposal, there are currently four (4) engineered landfills in Ghana. These are located in Tema in the Greater Accra Region, Kumasi in the Ashanti Region, Sekondi-Takoradi in the Western Region and Tamale in the Northern Region. These landfills have the capacity to take up about 23% of the solid waste generated in those regions. The rest of the solid waste generated across the country end up in dump sites that are not engineered or in surrounding areas without being collected for safe disposal.

There is a lack of adequate household latrines in many low income communities (Ghana Statistical Service, 2012). This situation means that residents in these areas resort to communal and public toilets. This contributes to increased volumes of septage that is discharged untreated into water courses and streams (MLGRD, 2010).

In addition, a lack of public toilet facilities, particularly in the business and commercial areas of the city, results in people urinating directly into drains or in open spaces. The urine that goes into the drains flows directly into the river systems while those in open spaces may leach into the soil or become part of the run-off when the rains come down. The excreted medicines therefore become part of the river systems. The unchanged medicines or their active metabolites may then be able to have some effects, both short term and long term, on the flora and fauna in the river systems which drain the city and in the surroundings of the areas where they are directly discharged.

The disposal of unused and unwanted medicines also contributes to the presence of PPCPs in various environmental media. The official methods of disposal of unused medicines, as overseen by the FDA are not environmentally friendly resulting in medicines getting direct access to receiving water systems (Esseku, 2014). Again, as a result of the policies in place for the disposal of unused medicines, there are, arguably, large quantities of unused medicines with members of the general public (Esseku, 2014) which are likely to be disposed of in environmentally harmful ways (Abruquah, et al., 2013).

1.2 Statement of the Problem

PPCPs have been identified in different environmental media in various parts of the world. Some have been found to persist for significant periods of time in various environmental media, while others do not. In some parts of the world, there have been research activities to investigate the presence, persistence and effects of PPCPs in environmental media. There is, however, a dearth of knowledge with respect to the presence and persistence of pharmaceuticals in the environment and ecosystems in Ghana (Esseku & Dodoo, 2013).

Although PPCPs may exist in minute quantities, long-term release of them may result in significant environmental concentrations particularly in the sediments of receiving waters. On the other hand, long term exposure of humans and other organisms to the sub-therapeutic doses could result in major health concerns (Daughton & Ruhoy, 2011). There is, currently, little understanding of the disposal practices of players in the pharmaceutical value chain and how these practices impact the presence and persistence of pharmaceuticals in the environment.

Wastewater samples analysed in advanced research laboratories have sited amoxicillin as well as other antibiotics and pointed out their possible relation to antibiotic resistance. Since PPCPs may not be completely removed during the wastewater treatment process, these compounds may be discharged into streams and land application sites, and eventually contaminate the aquatic environment or persist in surface water, groundwater, and soil. If these compounds persist in the effluent, the choice of wastewater treatment and water reuse alternatives needs to be considered carefully to minimize exposure to humans, or treatment processes must be improved to protect humans and the environment.

Some interventions have been implemented in various parts of the world aimed at curbing the effects of the presence and persistence of pharmaceuticals in various environmental media. There is the need to introduce and implement effective strategies in other countries, Ghana included. Such interventions should be cost effective, especially in resource limited countries. In order to ensure such cost effectiveness, the strategies implemented should utilise a holistic approach and take into consideration assessment of the context within which the strategies are to be

implemented. Such contextual assessment required effective tools should also be reproducible and sustainable.

1.3 Objectives

The objectives of this work are:

1. To investigate the role of regulatory bodies in the disposal of pharmaceuticals and the methods used during supervised disposal and, consequently, minimising the effects of the medicaments and their active metabolites in the environment.
2. To investigate the disposal practices of community pharmacies as custodians of pharmaceuticals in the community and experts in the use of pharmaceuticals.
3. To investigate the disposal practices of consumers with respect to their unused and expired medicines.
4. To develop a tool for the assessment and evaluation of impact of identified disposal practices and proposed implementation strategies.

1.4 Justification of Study

As a result of the importance of the state of health and wellbeing of any population to its very survival, PPCPs are widely used all over the world, and Ghana and Africa are no exceptions to this phenomenon. When PPCPs are used, the chemical components, whether in the original form or as metabolites, end up in the environment either by direct dumping into the environment or through elimination by those who have consumed the products. Although there has been a lot of research in other parts of the world looking at the presence and persistence of PPCPs in the environment, their effects, and ways of controlling the input, persistence and effects, very little of such research has taken place in Africa in general and Ghana in particular. In various parts

of the world, various strategies have been implemented to combat these challenges. Some of these strategies may be useful for implementation in Africa. There is, however, a need for an assessment of the cost effectiveness of these strategies when being implemented in different settings. To this end, there is the need:

1. To look into the role of regulatory bodies in the disposal of pharmaceuticals and the methods used during supervised disposal and, consequently, minimising the effects of the medicaments and their active metabolites in the environment;

2. To investigate the disposal practices of community pharmacies as custodians of pharmaceuticals in the community and experts in the use of pharmaceuticals.

3. To investigate the disposal practices of consumers with respect to their unused and expired medicines

4. To develop a tool for the assessment and evaluation of impact of identified disposal practices.

There is currently evidence that PPCPs enter various environmental media through a number of routes including elimination by humans and animals after consumption and environmentally unfriendly methods of disposal of unused products. The research will look into the various methods of disposal of pharmaceuticals. There will be an investigation of how regulatory bodies involved in the disposal of pharmaceuticals carry out that responsibility, with particular interest in the impact on the environment. The research will involve a survey to assess the disposal practices of consumers in Ghana with respect to their unused and expired medicines. There will also be a survey to assess the disposal practices in place in community pharmacies with respect to their unused and expired medicines. The information gathered will be utilised in the

development of an assessment tool to guide the implementation of policies and strategies aimed at controlling the effects of pharmaceuticals in the environment.

This research will add to knowledge on how consumers dispose of their unused and expired medicines as well as the disposal practices of community pharmacies. There will also be added knowledge on the methods of disposal used by the regulatory bodies when it comes to waste generally and pharmaceuticals in particular. This added knowledge will inform policy on strategies to reduce the presence and persistence of PPCPs in the environment. It will also add to an understanding of the role of regulation in reducing the quantities and consequently effects of PPCPs in the Ghanaian environment. The study will further influence practice on handling of pharmaceuticals. The work will propose an assessment tool for evaluating disposal practices and their effects on the environment. The tool, therefore, informs the effective introduction of policies and strategies aimed at controlling pharmaceuticals in environmental media.

1.5 Scope of the Study

This research looks at a number of aspects of the presence of PPCPs in environmental media. One aspect is the impact of consumer disposal practices on the presence and persistence of pharmaceuticals in the environment. Exit surveys are utilised to gather information on the various ways in which members of the public deal with any medicines for which they no longer have any use for them or which may have expired while in their custody. The research also looks at how pharmacies as institutions dispose of unused and expired medicines, whether from their stocks or returned by clients.

Another aspect of the work is to look at how effective regulation can positively impact the environment with respect to the quantities of PPCPs that end up in the environment. In this regard, interviews are conducted with regulatory authorities involved in various aspects of disposal, environmental management and waste water treatment. The work does not undertake a comparative study of disposal practices between rural and urban dwellers. Nor does it attempt to sample disposal practices from various parts of the country to investigate patterns for disposal in those parts of the country.

1.6 Organization of Thesis

The thesis is organized as follows:

Chapter 1 - Introduction: This chapter presents a general overview of the environment, PPCPs and their disposal. The chapter also gives the statement of the problem and presents the objectives of the research. It also provides justification for the study and discusses the approach to and the scope of the study.

Chapter 2 – Literature Review: This chapter gives a comprehensive look at prior research and publications looking at the role of the environment in the developmental schemes of human societies as well as the input, presence and effect of pharmaceuticals in the environment. It further looks at research and publications on the persistence of pharmaceuticals in environmental media and the assessment of PPCPs in environmental media. The chapter also looks at publications on disposal practices with respect to solid waste, liquid waste and unused medicines.

Chapter 3 – Methodology: This chapter sets out details of how the research was undertaken. It presents the steps taken in developing the questionnaires and interview

guides for the various regulatory agencies. It also sets out the methodology of assessing the disposal practices of participants in the pharmaceutical delivery chain.

The chapter also presents the limitations of the study.

Chapters 4 – Results and Discussion: This chapter presents and discusses the results obtained in the research. It looks at the methods of disposal currently in place for the regulated disposal of PPCPs. The chapter further presents and discusses the ways in which the individuals surveyed deal with their unwanted and unused medicines as well as the disposal practices of community pharmacies. There is a discussion on how regulation can effectively reduce the quantities of medicines that remain unused and require disposal. There is also a presentation of the Drug Disposal Flow Diagram, a proposed tool for assessing and evaluating disposal practices and their impact on the environment. The chapter then presents the results of interviews of officers of regulatory bodies on the handling and disposal of medicines.

Chapter 5 – Conclusion and Recommendations: This chapter summarises the research, looking at the presence of PPCPs in the environment, existing disposal practices and how regulation can improve the quality of the environment with respect to presence of PPCPs in the environment. The chapter further summarises the potential contribution of the Drug Disposal Flow Diagram to EPV and provides recommendations on possible utilisation of the tool. The chapter also gives recommendations in the areas of policy governing the practices of health care professionals, the disposal of waste in general and pharmaceuticals in particular and the handling of pharmaceuticals and gives suggestions for further research.

CHAPTER 2. LITERATURE REVIEW

The Rio Declaration, which emanated from the United Nations Conference on Environment and Development (UNCED) in 1992 emphasised the significance of the quality of the environment in the sustenance, development and survival of the human race. The document urges countries to ensure sustainable development by considering the environmental implications of their development strategies. Developmental projects must therefore be carried out in ways that regenerate the environment (UNCED, 1992), securing the ability of future generations to also develop. Thus, there is the need to curb environmental pollution and preserve the integrity of the environment. Environmental pollution takes various forms and has diverse effects on the air, soil and water sources.

Pollution of the water supply systems may be due to the presence of chemicals and other toxins in those systems; and these chemicals and toxins are introduced as a result of human activity. In recent years, PPCPs have been found to be a major contributor to pollution of environmental media, particularly water (Boxall, 2004) (Boxall, 2007). The role of PPCPs in polluting water supply systems is even more relevant when the endocrine disrupting capabilities of these products are taken into consideration. This characteristic makes them able to affect the physiologic and functional capabilities of some organisms which get exposed to them. In discussing the quality of water sources, therefore, PPCPs, their effects (both potential and actual) and means of controlling them, become cogent.

2.1 Environment and Development

Brundtland (1987) defines environment as "where we live" and development as "what we all do in attempting to improve our lot within that abode" (p. 7). The environment and development that takes place within that environment are therefore inextricably linked. As the Brundtland Commission (1987) put it "many forms of development erode environmental resources ... and environmental degradation can undermine economic development" (p. 13). There is, therefore, the need to make development sustainable so as to ensure that resources remain available for the use of future generations even as present generations meet their developmental needs (WCED, 1987). The two-way relation between environment and development is aptly captured by the World Bank (1992) in its 1992 World Development Report as follows:

> "First, environmental quality – water that is safe and plentiful and air that is healthy - is itself part of the improvement in welfare that development attempts to bring. If the benefits from rising incomes are offset by the costs imposed on health and the quality of life by pollution, this cannot be called development. Second, environmental damage can undermine future productivity. Soils that are degraded, aquifers that are depleted, and ecosystems that are destroyed in the name of raising incomes today can jeopardize the prospects of earning income tomorrow" (The World Bank, 1992, p. 1).

Since the publication of *Our Common Future* by Brundtland Commission under the auspices of the UN in 1987, a number of changes have taken place which affect both environmental quality and economic development. There has been a massive growth in population (4-fold) and economic output (40-fold) resulting in an increase in resource consumption which has now been assessed to be unsustainable (UN-DESA,

2012). According to the UN-DESA (2012), this level of unsustainable consumption and pollution has resulted in deforestation, loss of biodiversity with the current rate of species extinction above levels which are safe for human survival in the long term. It is with these challenges in mind that the United Nations Conference on Sustainable Development (Rio+20) was organised to look at how to achieve sustainable development by the use of green economy and better international cooperation (UN, 2015).

At the end of Rio+20, the leaders of the world recognised that "changing unsustainable and promoting sustainable patterns of consumption and production, and protecting and managing the natural resource base of economic and social development" were among the overarching requirements for sustainable development (UN, 2012). One of the key commitments made at the summit was to do with the protection of the environment, in light of the central role the environment plays in a green economy, and therefore, sustainable development. Prevention and control of environmental degradation, in all its forms is therefore, crucial to sustainable development.

2.2 Pharmaceuticals and the Environment

Pharmaceuticals, like various other chemicals, have been identified as being present in various environmental media (Boxall, 2004) (Velo, 2008). A number of pharmaceuticals have also been identified as being endocrine disrupting in nature. This has generated interest in how these pharmaceuticals behave in the environment. Of particular interest are the possible effects they may have on the health of humans, other organisms and the ecosystems in which these pharmaceuticals are (Davis, et al., 2006) (Boxall, 2007) (Christiansen, et al., 2002) (Wu, et al., 2011).

2.2.1 Agricultural Systems

As interest in pharmaceuticals in environmental media generally increases, there is a corresponding increase in research looking at the effects of pharmaceuticals in these media. Wu *et al* (2011) review publications of research into the uptake of pharmaceuticals by agriculturally relevant plants. They look at various studies on agricultural plants grown in hydroponic and soil systems (Wu, et al., 2011). Pharmaceuticals were administered into the systems (hydroponic and soil) in which the plants were grown. Various parts of plants (and in some cases, whole plants) were harvested and tested for the presence and concentration of the administered pharmaceuticals. The article reviews two studies on the uptake of pharmaceuticals from hydroponic systems and four studies on the uptake from soil.

The two studies on uptake from hydroponic systems show that the pharmaceuticals were generally taken up from the water although for some pharmaceuticals certain conditions had to be present for the uptake to take place. The studies found that with some plants and some pharmaceuticals, the uptake is very fast reaching equilibrium within four (4) hours; whereas some pharmaceuticals took as long as 51 days before being detected after exposure. On the actual uptake of pharmaceuticals, measurements showed significant differences in concentrations in various parts of the plants: the concentrations of the chemicals, while significant in the roots, were not high, though present, in the stems, leaves and seeds.

Research results on uptake from soils were not as clear cut as those from hydroponic systems. Studies reviewed looked at uptake of human and veterinary pharmaceuticals – four studies in all. Some pharmaceuticals were identified in the plant parts while others were not. In cases where the soil was spiked with pharmaceuticals only once,

the older plants had less concentration than the younger ones; on the other hand, when the contamination was continuous, the concentrations were similar. In all instances where the chemicals were present in the roots or root peels, the results were similar to those in the hydroponic systems – translocation to other parts of the plants was present but limited. In spite of variations in the rate of uptake and translocation of pharmaceuticals, the article shows that these chemicals are taken up by plants. Therefore these products potentially re-enter the terrestrial environment after disposal by being re-introduced into the food chain by plants.

2.2.2 Alligators in Fresh Water Bodies

Guillette Jr. *et al* (2000) look at a number of research studies into the effects of endocrine disrupting contaminants (EDCs) such as pesticides on various physiological characteristics of the American alligator in some Florida fresh water bodies (Guillette Jr, et al., 2000). They also undertake some field studies to investigate the extent to which EDCs alter certain features of the alligators investigated. The test lake (Lake Apopka) was selected because it had been a site of massive pesticide spill 40 years earlier, resulting in fewer eggs and lower survival rates of hatchlings and juvenile alligators over the years; the control lake (Lake Woodruff) had not been exposed in the spill.

In the review, the article compiles various endocrine disrupting effects that have been identified by various researchers in laboratory and field research, showing that a number of chemicals have the effect of altering both endocrine and physiologic characteristics of the American alligator. These alterations mean that certain organs that produce hormones needed for survival and reproduction do not develop properly. The effects were significant in male alligators where the genital sizes reduced with

exposure to the offending chemicals (Guillette, et al., 1996b). In some laboratory work reviewed by Guillette *et al*, they find that although some chemicals such as *trans*Nonachlor, acting alone may have a particular effect – sex reversal (where male alligators became female), exposure of the reptiles to a mixture of those chemicals with others e.g. *p,p'*-DDE resulted in effects that were different – there was no sex reversal despite high contamination levels with *trans*-Nonachlor. They also find that the effects changed when concentrations of the chemicals were changed and when other environmental conditions such as temperature were altered. This means that the effects of the presence of chemicals in the environmental media will be very difficult to predict if the concentrations of chemicals entering the environment are not controlled and monitored.

2.2.3 Other Effects

Other effects of the presence of pharmaceuticals and other chemicals in the environment have been identified: feminisation of fish as a result of aquatic bodies being exposed to various human hormones (Christiansen, et al., 2002) (Briggs, 2000) (Edmunds, et al., 2000); and the near collapse of south east Asian vulture populations as a result of exposure to the anti-inflammatory agent Diclofenac that had been administered to cattle for pain relief shortly before the death of the cattle (Roach, 2004; Randolph, 2011) are notable. There are studies which suggest that resistance to medications by microorganisms may be acquired from the environment (Borjesson, et al., 2009) (Szczepanowski, et al., 2009) (Holm, et al., 2013).

2.3 Entry of Pharmaceuticals into Environmental Media

When pharmaceuticals are consumed, they may have some unintended effects. The study of unintended effects of pharmaceuticals is known as pharmacovigilance (PV), which has been defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems (WHO, 2002). In recent years, ecopharmacovigilance (EPV), which looks at how pharmaceuticals affect the health and well-being of the environment and ecosystems (Boxall, 2004) has been defined formally as the science and activities associated with the detection, evaluation, understanding and prevention of adverse effects of pharmaceuticals in the environment (Holm, et al., 2013).

There are various ways by which pharmaceuticals get into the environment. The production of pharmaceuticals results in washings-off which contain some active pharmaceutical ingredients (APIs). These APIs may enter the environment as discharges from waste water treatment plants (WWTPs) or via direct discharge into where there are no functional WWTPs. When pharmaceuticals are consumed, they may be discharged (as unchanged compounds, inactivated compounds or active metabolites) into waste water treatment systems or directly into the drainage system without treatment. Pharmaceuticals may also be released into the soil after consumption by humans and animals alike or may be discharged into environmental media from institutions and drug manufacturing concerns. Another source of pharmaceuticals in environmental media is from veterinary and agricultural use. The introduction may be as a result of direct introduction by elimination processes and indirectly by reapplication of manure and mulch in agricultural practices. No matter the means by which pharmaceuticals enter the environment, these activities have the

effect of getting the chemicals into the human food chain and into underground water tables beyond the reach of cleansing (WCED, 1987). The various ways in which PPCPs enter the environment are summarised in Figure 2-1 below.

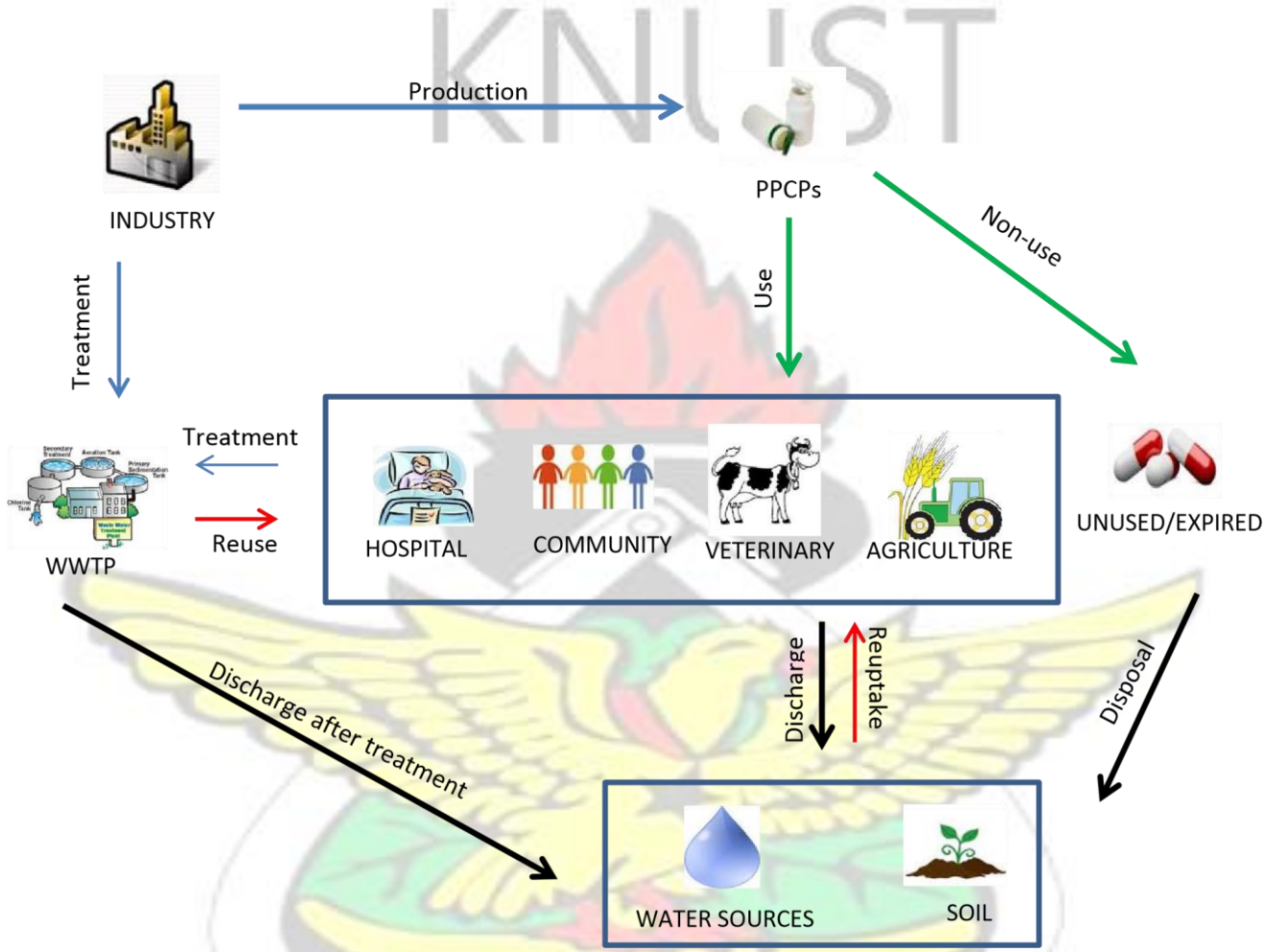

Figure 2-1: Schematic of movement of pharmaceuticals

2.4 Persistence in Environmental Media

Pharmaceuticals in the environment undergo various attenuation processes such as photo-degradation, dilution, adsorption by solids and aerobic and anaerobic breakdown (Sakrabani & Boxall, 2007). However, some pharmaceuticals and chemicals tend to persist in the environment in their original form or as metabolites.

Nilsen *et al* test sediment samples collected from the Columbia River, Willamette River, the Tualatin River and several small urban creeks for the presence of pharmaceuticals. Glassmeyer *et al* in investigating the use of chemical analytes as waste water tracers found pharmaceuticals and other chemicals in the effluent of waste water treatment plants. In another research, a veterinary pharmaceutical was traced through lagoons, ground water and runoff on the farms under investigation (Watanabe, et al., 2008). Davis *et al* (2006) also investigate the presence of pharmaceuticals in the soil and runoff from land treated with a mixture of pharmaceuticals. Table 2-1 shows the results of these studies in tabular form.

Table 2-1: Summary of results on investigations of various media for persisting pharmaceuticals Source: Author

Research Work	Medium Investigated	Location of Medium	Status with respect to Pharmaceuticals/chemicals
Watanabe, et al, 2008	Flush lanes, Lagoons, ground water,	California, USA	1 veterinary pharmaceutical
Davis, et al, 2006	Runoff, soil exposed to pharmaceuticals	Colorado, USA	All pharmaceuticals detected in runoff and soil after exposure
Nilsen, et al.	River bodies and tributaries	Columbia River, USA	20 pharmaceuticals detected
Glassmeyer, et al.	Waste water treatment effluent	WWTPs, USA	78 chemicals (of which 17 were pharmaceuticals) detected

2.4.1 Water Treatment Systems

In the work done by Nilsen *et al*, pharmaceuticals were present in both the upstream and downstream samples. The methods used in analysis had been previously published as capable of analysing these compounds in solid media (Kinney, et al., 2006a)

(Kinney, et al., 2006b). The samples were taken from upstream and downstream of WWTPs which discharge the treated water into the water bodies investigated. This indicates the inability of the WWTPs to effectively remove the pharmaceuticals being investigated. The implication is of major concern because the WWTPs act as point sources for the introduction of pharmaceuticals into the receiving water bodies of the plants.

The role of WWTPs as a significant point source of pharmaceuticals in the environment is emphasised by the work done by Glassmeyer *et al*. Glassmeyer *et al* take samples upstream and two points downstream of WWTPs as well as at the point at which the plants discharge into the aquatic environment and test for the presence of pharmaceuticals in the samples taken. The study by Glassmeyer *et al* show the greatest concentration of pharmaceuticals and other chemicals in the effluent samples of WWTPs as compared with upstream and downstream sources. This is the situation for all chemicals that were not removed during the treatment process. The treatment plants, in addition to not being able to remove some chemicals and pharmaceuticals from the treated waste water, appear to concentrate the chemicals and pharmaceuticals in the effluent. In instances where there are inadequate or no treatment plants for waste water, the situation becomes even more precarious. In such instances, all pharmaceuticals, whether in the active state or as metabolites, that are released directly into the environment remain in that state and affect all organisms to which they may come into contact.

2.4.2 Water Bodies and Surrounding Soil

Watanabe *et al* (2008) trace the route of a veterinary pharmaceutical along the path the product will normally travel once introduced into the environment by lactating cows

that consume them: from the flush lanes to lagoons and thence into the surrounding ground water. They take samples from all these points and test them for the presence of monensin, an antimicrobial product used for dairy cattle. In this study, all flush lane and lagoon water samples as well as samples from ground water immediately surrounding the dairy areas contained monensin. Monensin therefore persists in the aquatic environment and the immediate soil surroundings (Watanabe, et al., 2008). This antibiotic used in dairy production may therefore impact on microorganisms in the aquatic environment including producing resistance in certain microorganisms (Boxall, 2007). It must be noted, however, that in the study, monensin was absent from the fields of the same dairy farms to which manure had been applied, showing that monensin may not effectively persist in the soil. The researchers suggest that this absence could be due to sorption by soil particles and breakdown under anaerobic conditions.

2.4.3 Runoff from Contaminated Soils

Davis *et al* (2006) investigate the presence of pharmaceuticals in the runoff from soil that had been treated with pharmaceuticals. In their study, they treat selected plots of land with a mixture of pharmaceuticals, simulate rainfall, take runoff samples and test the runoff samples for the presence of the pharmaceuticals. The runoff samples collected from treated soil contained all the pharmaceuticals used. The study was to examine the worst case scenario. The pharmaceuticals were, therefore, applied shortly before the rainfall event. Thus, there may not have been sufficient time for any attenuation to have taken place as could happen in real life. Despite this, the study shows that pharmaceuticals which get into the soil can contribute to contamination of surface water.

2.4.4 Leachate from Landfills

Shield (2011) compiles a number of investigations conducted into the presence and persistence of pharmaceuticals in various environmental media in her backgrounder. In her paper, Shield (2011) reviews a number of research investigations into the presence of pharmaceuticals in various surface water sources. The pharmaceuticals identified in these sources belong to varied pharmacological groups (Shield, 2011), suggesting that the types of pharmaceuticals that persist in the aquatic media are not limited to a particular pharmacological group. The paper also reviews investigations into the presence of pharmaceuticals in drinking water. The investigations show that where the drinking water is sourced from pristine watersheds protected from human activities, there are no pharmaceuticals in the drinking water, whereas other sources show the presence of pharmaceuticals albeit in very low concentrations. Although the concentrations found in drinking water are far below therapeutic doses, there is no knowing the effects of long term exposure to such low quantities of pharmaceuticals through drinking water.

Shield (2011) also reviews studies that have identified pharmaceuticals in fish tissue. The tissues investigated were from fish from streams and rivers which act as receiving water bodies for municipal waste water treatment plants and sewage treatment plants.

The tissues examined show the presence of pharmaceuticals to which the fish have been exposed from their habitat. Her compilation also reviews investigations into the presence of pharmaceuticals in leachate from various landfills and their surrounding environment. Once again, the pharmaceuticals identified belong to different pharmacological groups. Some of the landfills investigated had been closed for decades before the investigation showing that some of the pharmaceuticals had

persisted in the environment for very long periods of time. This finding is particularly important for emerging economies where engineered landfills are not the norm. Table 2-2 below gives a tabular representation of a summary of the reports of landfills and surrounding environments distilled from "Pharmaceuticals in the Environment" (Shield, 2011).

Table 2-2: Summary of findings from landfills and surroundings Source: Author

Research Work	Medium Investigated	Location of Medium	Status with respect to Pharmaceuticals/chemicals
Behr, Stahler, & Pistell, 2010	Landfill Leachate	Maine, USA	47 pharmaceuticals detected
Barnes, et al., 2004	Groundwater down gradient from a closed landfill	WWTPs, USA	76 pharmaceuticals and other organic contaminants detected
Buszka, Yeskis, Kolpin, Furlong, Saugg, & Meyer, 2009	Four wells down gradient of landfill	Indiana, USA	Several pharmaceuticals and metabolites

2.5 Disposal Practices and PPCPs in the Environment

2.5.1 Liquid Waste

Liquid waste includes human excreta, animal manure and domestic and commercial wastewaters (MLGRD, 2010). Human excreta in the form of septage are collected from septic tanks and "discharged untreated into many water courses and streams" (MLGRD, 2010) with less than 15% of septage generated in Accra and Kumasi being treated. Grey water is waste water that results from washing items in the home and bathing. Water used for bathing will contain traces of medications excreted through

sweat and topical medications that have been washed off after application. It is also likely to contain medications which may be eliminated through the urine. This category of liquid waste is usually disposed of in the street, in open drains and in gutters. According to the national Population and Housing Census (PHC) of 2010 (Ghana Statistical Service, 2012), about 35% of households throw their grey water onto the compound of their homes, about 28% onto the street outside their homes and about 19% into open drains. Only 11% of households use plumbing systems. It must be noted that these plumbing systems end up in drains which are discharged into river systems and other receiving waters without treatment.

The disposal of human excreta is influenced by the toilet facilities used by people when moving their bowels. According to the PHC, the percentage of households that use public toilet facilities is currently at 34.6%. Such a high percentage of users of public toilet facilities means the public toilet facilities fill up faster and have to be emptied quicker. This creates a problem as the excreta so taken from the public toilet facilities are discharged untreated into water bodies and streams (MLGRD, 2010).

2.5.2 Solid Waste

Solid waste includes all solid waste material, litter, street sweepings, drain cleaning, dead animals and other waste materials (MLGRD, 2010). The Environmental Sanitation Policy of 2010 indicates that 76% of households rely on improper waste collection and disposal methods with less than 5% using house-to-house collection. This conflicts with the 2010 population and housing census report which sets the proportion of households using collection methods at 14.4% which is still a very low percentage. The Census report (Ghana Statistical Service, 2012) also indicates that an average of about 38% of households dump their solid waste into open spaces and a

further 9% dispose of their waste indiscriminately, about 11% of households burn their solid waste and a further 3% bury their waste.

The figures put out by the Ghana Statistical Service show an improvement over those given by the Ministry of Local Government and Rural Development. The improved figures, however, still show a major challenge with respect to the disposal of waste by households – over 60% of households use methods that introduce contaminants directly into the soil without any form of treatment whatsoever. This means that about 60% of all unused or expired medications disposed of in the waste will end up being put directly into the soil.

2.5.3 Unused medicines

Not much work has been done with respect to the linkages between disposal practices and the presence and persistence of pharmaceuticals in the environment in Africa. In Ghana, one significant study on disposal of medications is that done by Abruquah et al (2013). The study looks at the way residents of Konongo-Odumasi in the Ashanti Region of Ghana dispose of their unwanted medication and the possible impact of improper disposal on the environment. The researchers use judgment sampling and interviewed 500 residents. They find that 38% of respondents buried their unwanted medications in the ground, 29% added them to the household trash and disposed of them accordingly, 7% burned them and 4% flushed them down the toilet; only 1% of the respondents said they returned their medications to the pharmacy if they thought they did not need them anymore (Abruquah, et al., 2013). This means that up to 45% of respondents deposit their unused pharmaceuticals directly in the environment without any attenuation whatsoever.

Household trash is normally collected by municipal authorities and disposed of in dump sites. With the exception of the landfills used by the Tema, Kumasi, Tamale and Sekondi-Takoradi Metropolitan authorities, all the landfills used by other district authorities are not engineered. Thus, the 29% of the respondents interviewed by Abruquah et al who indicated that they put their unused medicines in the household trash have those medicines ending up in the soil. This means up to 74% of respondents put their unwanted medications directly into the environment. This form of dumping means that in almost all these instances, the pharmaceuticals will be present in the soil and water systems in higher concentrations than they would be if going through WWTPs: the worst case scenario (Davis, et al., 2006) may therefore be applicable. Abruquah et al compare these disposal practices with practices in other parts of the world and find significant differences in the patterns of disposal. The differences in disposal patterns means that there is the need to identify the ways and routes by which pharmaceuticals and other chemicals enter particular environmental media to ensure that remedial measures put in place are effective.

A study has also been undertaken on the disposal of unused medicines under the supervision of the Food and Drugs Authority (FDA) of Ghana (Esseku, 2014). The research was a case study which examines the official methods of disposal of unused medicines and how the methods used can impact water resources in the country. The study utlilised semi-structured interviews of personnel involved in the disposal of medicines and chemicals in general, and the Disposal of Unused/Unwanted Medicines Project (DUMP) in particular. This project was initiated by the Cocoa Clinic of Ghana in response to an identified need for a safe method of disposing of unused medicines among the clientele of the clinic. The study shows that there are gaps in the legislative

framework for the disposal of medicines both at the level of the regulator and at the level of participants in the pharmaceutical value chain. These gaps result in significantly large quantities of medicines being disposed of indiscriminately by individuals as well as organisations. This is because these individuals and organisations end up with unused and expired medicines at their disposal which need to be disposed of. They are, however, not required by any legal provision to utilise the supervised methods of disposal, and utilising those methods implies incurring expenditure. These individuals and organisations, therefore, tend to use methods that end up polluting the environment. Another significant finding of the study is that the methods that are used for the regulated disposal of unused medicines that have been received from members of the public are not environmentally friendly. Thus the medicines end up polluting various environmental media – air, soil and water resources.

CHAPTER 3. METHODOLOGY

The research was undertaken by combining a number of different investigative methods. Desk reviews were conducted to assess the legal framework governing the treatment and disposal of the active ingredients and products of PPCPs. The various legislative and policy documents were reviewed to give an overview of the framework currently in place. A survey was conducted to investigate how unused and expired PPCPs are disposed of in community pharmacies. Another survey was conducted to assess how consumers handle their unused and expired medicines. It also looked at the experiences of consumers when they interact with prescribers and dispensers. Key informant interviews were conducted to gather information on the role of regulatory authorities in the disposal of waste generally and PPCPs in particular. The interviews

also sought information on the methods of disposal generally used by players in the pharmaceutical value chain.

3.1 Surveys

Surveys are observational studies in which no parameters are altered. The purpose of using an observational study such as a survey is to take a snapshot of the situation in time. A survey will give information on what is happening at the material time when the survey is conducted. For the purposes of this study, two different sets of surveys were conducted targeted at consumers and community pharmacies. The surveys used in the study sought information on the ways in which PPCPs are disposed of by pharmacies and consumers. The surveys also sought information on the interactions between prescribers and dispensers on the one part, and consumers on the other, when consumers seek medical help. Again, the surveys were utilised in assessing the completeness and adequacy of the information given during these interactions. Although surveys will normally not provide information on cause and effect, they may be used to draw correlations between some characteristics and practices.

3.1.1 Questionnaire Development

Two different sets of questionnaire were developed for the different sets of surveys to be conducted. The questionnaire for the survey targeting community pharmacies was designed to be completed by pharmacists present in or responsible for the facilities. The aim was primarily to gather information on how these facilities handle and dispose of unused and expired PPCPs. The sources of these unconsumed PPCPs were not investigated but the steps taken by the facility as an institution was the focus of

investigation. Appendix A is a sample of the questionnaire used for community pharmacies.

The surveys targeted at consumers were of two types: one targeted consumers who had interacted with prescribers, and the other, those who had interacted with dispensers. The questionnaires investigating the interactions with prescribers looked at prescriber attitude towards previously prescribed but as yet unconsumed medications. The questionnaires also sought to interrogate the prescriber attitude towards pre-existing health conditions for which consumers may be taking other medications. Information on prescription forms were also gathered to assess for completeness and adequacy to ensure that dispensers are able to give the correct medications to ensure the rational and responsible use of medicines. The questionnaire also gathered information on the consumers' attitude toward compliance with their prescribed medications and how they handled any medications that may have expired or remained unused. Appendix B is a sample of the questionnaire used to investigate prescribing encounters.

The questionnaire investigating dispensing experiences was aimed at gathering information on how clear the communication and interactions were during dispensing. It sought to assess whether dispensing personnel enquired about other medications consumers may be on, and what the consumers were to do with such medications. Also the questionnaire was designed to investigate the completeness and clarity of labels put on dispensed medication. The questionnaire further investigated how consumers complied with the dispensed medications and how they handled their unused, unwanted or expired medications. Appendix C is a sample of the questionnaire used to investigate dispensing encounters.

3.1.2 Sampling and Administration of Questionnaires

In administering the questionnaires, only a sample of the population was interviewed. In any study involving sampling, the results obtained from the sample are likely to be extrapolated to represent the whole population (Levin, 2005). There is therefore the need to remove bias during the design of the study to ensure that the results of the sample selected are a true reflection of the whole population. In order to ensure that the associations observed and estimates made are accurate, there is the need to minimise confounding. This can be done by randomisation of the sample. To ensure the minimisation of bias in the questionnaires administered to individuals, respondents were selected according to a previously predetermined method before getting to the site where the questionnaires were administered.

3.1.2.1 Community Pharmacies

The questionnaires to community pharmacies were administered in two (2) regions - Greater Accra and Ashanti - as representative of the whole country. This is because all pharmacies are required to meet minimum standards by the Pharmacy Council of Ghana (Pharmacy Council, 2015). Conditions will therefore not vary widely across the country and pharmacies in the two regions will be fairly representative of pharmacies across the whole country. Pharmacists in the community pharmacies were given the opportunity to accept or decline to participate in the survey. This was done by giving them participant consent forms which they read and indicated their choice. Appendix D is a sample of the consent form given to pharmacists. Those who accepted to participate in the survey were then given the questionnaires to answer.

3.1.2.2 Individual Respondents

The questionnaires to consumers were administered to individuals who had interacted with prescribers or dispensers. The individuals were interviewed in three (3) regions - Greater Accra, Ashanti and Northern. In all the sites, the study was conducted as an exit survey, interviewing consumers as they exited the various facilities. The questionnaires investigating prescriber encounters were administered to clients exiting hospital and clinic facilities and those investigating dispensing encounters to those exiting community pharmacies. The questionnaires were administered by systematic sampling. The first interviewee is identified on arrival to the site, and subsequently, every third client who is willing to participate in the study was interviewed. The regions in which the questionnaires were administered were selected to be representative of the whole country – the northern, middle and southern belts.

In order to ensure that informed consent was given, the clients were given consent forms which were signed before administration of questionnaire. Where the client is unable to read, the consent form was read and explained, and the client asked to append his or her mark, if they opted to participate in the survey, before the interview was conducted. Appendix E shows the consent form given to clients before administration of questionnaires.

3.2 Interviews

Key informant interviews were conducted to garner information on the policies and practices in place for the disposal of waste in general and unused and expired medicines in particular. The Food and Drugs Authority (FDA) is responsible for implementation of the Public Health Act, 2012 (Act 851) which, among other things,

is responsible for implementation of regulation governing food and drugs in Ghana. A representative of FDA was therefore interviewed to look at the policies and practices in place for disposal of PPCPs. The Environmental Protection Agency (EPA) is responsible for ensuring the health of the environment in the country. In view of the fact that this research looks at the effect of the presence of PPCPs in the environment, a representative of EPA was interviewed to look at the methods used for the disposal of medicinal products and how they affect the environment. The Environmental Health and Sanitation Directorate (EHSD) is responsible for the disposal of both solid and liquid waste. This made it relevant to interview a representative of the EHSD to ascertain the policies and practices in place for the disposal of both solid and liquid waste. The Pharmacy Council of Ghana (PC) has as its mandate securing in the public interest, the highest standards of the practice of pharmacy. This means the Council regulates the practice of pharmacy in Ghana. The practice of pharmacy deals essentially with medicines, and thus is relevant when looking at the disposal practices in place for pharmacies. To this end, a representative of the PC was interviewed.

3.2.1 Interview Guides

In undertaking this study, interview guides were prepared to facilitate discussions with key informers. The guides utilised open-ended questions to allow for comment and explanation as needed. Different guides were designed for the different key informers paying attention to the role of the particular interviewee institution. Appendix F shows details of the discussion guide used in the interview with the FDA, Appendix G shows details of the discussion guide used in the interview with the EPA and Appendix H shows details of the discussion guide used in the interview with the EHSD. Appendix J shows the interview guide used in the interview with the PC.

3.2.2 Interview – Food and Drugs Authority

The Head of the Drug Enforcement Department of the FDA, Mr. Thomas Amedzro, was interviewed for the FDA. The interview took place at the FDA Head Office on the 8th May, 2015 at 1:10 pm. The interview was to ascertain the legal framework governing PPCPs in Ghana as well as the role of the FDA with respect to the manufacturing, importation, distribution and disposal of PPCPs. The interview discussed in particular, how effluents and unused products from participants in the value chain of PPCPs are handled. The discussion also looked at some of the strategies in place for ensuring compliance with any laid down rules. The interview also discussed the role of FDA in the disposal of unused PPCPs from households and private health facilities.

The different sources from which unused and expired medicines are obtained by the Authority for disposal as well as how often such products were obtained were also discussed during the interview. The interview further sought a detailed account of the disposal process and whether or not there are any special measures taken in the process of disposal to deal with or mitigate any environmental outcomes resulting from the methods of disposal used. There was also the issue of costs related to disposal and how those costs are defrayed: this was also discussed during the interview.

The cross-cutting nature of the issue of disposal of medicines meant that there was the need to ascertain whether or not there was any collaboration with other national agencies with respect to the disposal of medicines. Another matter of significance is that of the effects of indiscriminate and unregulated disposal of medicines on the environment and the society. The interview therefore sought an elaboration on the

dangers of such practices from the perspective of the regulator, and the measures put in place, if any, to tackle those effects.

3.2.3 Interview – Environmental Protection Agency

Dr. Charles Kwesi Koomson, a Senior Programme Officer at the Chemical Control and Management Centre of the Environmental Protection Agency was interviewed at the EPA Head Office on the 31st January, 2014 at 10:20am. The purpose of the interview was to ascertain what regulations and practices with respect to the disposal of medicines there are in Ghana and how those regulations and practices apply to the EPA. In particular, the interview sought to investigate any regulations relating to the disposal of medicines that may apply to the EPA and the practice of how medicines are disposed of in Ghana. The interview also sought information on the perspectives the Agency with respect to the disposal of unused medicines and the role of the Agency with respect to the disposal of medicines.

In view of the different effects various medicines and chemicals will have on the environment, the interview sought to ascertain whether or not the medicines and chemicals disposed of by the Agency are categorised in any way before disposal. The interview also sought to ascertain the measures, if any, that have been put in place to deal with the environmental outcomes that may arise as a result of the methods used for the disposal of medicines and chemicals, what dangers there may be as a result of indiscriminate and unregulated disposal of medicines and the measures, if any, which have been put in place to counter those effects. The interview further sought to ascertain the levels of collaboration the agency has with other public agencies when it comes to the disposal of medicines.

3.2.4 Interview – Environmental Health and Sanitation Division

Ms Bertha Darteh, the Capacity Building Co-ordinator of the Environmental Health and Sanitation Division was interviewed at the Project Co-ordinating Unit of the Ministry of Local Government. The interview took place on the 12th May, 2015 at 3:00 pm. The purpose of the interview was to ascertain the role of the EHSD in the disposal of solid and liquid municipal waste in general and PPCPs in particular. Specifically, the interview discussed the policy and legal framework governing the treatment and disposal of waste in Ghana as well as the practices relating to disposal. The interview also discussed guidelines in place for the disposal of waste which may contain APIs of PPCPs.

With respect to liquid waste, the interview discussed the numbers of waste water treatment plants (WWTPs) with a direct focus on their capacity, levels of functionality and effectiveness in treating liquid waste. The interview also discussed how any excesses not accommodated by WWTPs are handled nationwide. On solid waste, the interview discussed the numbers, capacity, functionality and effectiveness of engineered landfills in Ghana. There was also discussion on how leachate from these landfills is treated as well as how the excesses not accommodated by the designated dump sites are handled.

3.2.5 Interview – Pharmacy Council

Mr. Joseph Nyoagbe, the Registrar of the Pharmacy Council (PC) of Ghana was interviewed at the Headquarters of the Council. The interview took place on the 11th of May, 2015 at 3:20 pm. The purpose of the interview was to ascertain the role of the PC in the regulation of pharmaceutical service delivery. During the interview,

discussions focused on the legal framework for the delivery of pharmaceutical services as well as the regulations and guidelines in place for the delivery of those services. Another issue discussed during the interview is the existence or otherwise of standards to be adhered to in the delivery of pharmaceutical services. In addition, there were discussions on the supervisory activities undertaken by Council to ensure that its directives are adhered to. The interview further discussed to policy position of the Council with respect to the disposal of APIs.

3.3 Review of Existing Legal Framework

The existing legal framework governing the disposal of waste generally and medicines in particular was reviewed. The Environmental Sanitation Policy of 2010 is the document that governs environmental sanitation in Ghana. It sets out the targets and expectations of implemented strategies and identifies the various bodies responsible for different aspects of environmental sanitation in Ghana. It provides a general framework in which activities aimed at securing environmental sanitation may be carried out. The Policy was reviewed to give a broad understanding of the general direction of the nation with respect to sanitation and to assess the strategies and methods put in place for the disposal of PPCPs.

The Public Health Act, 2012 (Act 851) governs the handling and disposal of PPCPs. The review was undertaken to assess the effectiveness of the provisions to that Act dealing with the disposal of unused PPCPs vis-à-vis EPV. The Environmental Protection Agency Act, 1994 (Act 490) governs the functions and activities of the EPA which is responsible for ensuring the general health of the environment. The Act was reviewed to assess the role and powers of the EPA with respect to the disposal of chemical substances that could have some impact on the environment. The Local

Government Act 1992 (Act 462) sets out the mandate of the various local governance agencies in Ghana. The disposal of household and industrial waste falls within the ambit of these agencies. Act 462 was reviewed to assess how these agencies, in carrying out their mandate, may be contributing to the presence of PPCPs in environmental media.

3.4 Design and Development of Drug Disposal Flow Diagram

The information gathered from the surveys, interviews and review of relevant documents was used to design and develop a model DDFD. The DDFD was designed by identifying the various points in the disposal process at which PPCPs could be introduced into the environment – the process chain. The various sources of contributors to PPCPs which need disposal such as industry, community pharmacy and community consumption are also identified based on the information gathered. The percentages contributed by the sources at the various points of introduction are assessed and used to construct a matrix. The matrix is finally utilised in the development of the DDFD.

3.5 Limitations to the Study

The study gathers information from regulators, community pharmacies and consumers with respect to the disposal practices currently in place for PPCPs. The information so gathered is utilised in designing a new tool, the Drug Disposal Flow Diagram (DDFD) for the assessment of disposal practices and their effects on the environment. The tool gives a pictorial representation of the levels of contamination that result from the various practices for disposing of waste and unused and expired medicinal products. The study does not include interviews of representatives of some

participants in the pharmaceutical supply chain such as manufacturing industries and wholesalers. Information for these sections of the pharmaceutical value chain are obtained from the interviews with the regulatory institutions. This work may be scaled up to give a more comprehensive look at the true state of the impact disposal on the environment.

CHAPTER 4. RESULTS AND DISCUSSION

The results of the study are presented largely in the narrative, with certain findings captured in tabular and graphical form. The narrative form allows for the presentation of steps in the procedures related to the disposal of medicines to be presented in chronology. It also allows explanations and perspectives of key informants to be captured. The narrative method is used when discussing the general findings of the various surveys carried out. The method is also used in discussing some pertinent comments given by some interviewees. The legal framework within which the various activities involved in disposal of PPCPs are undertaken is also discussed in the narrative form, as are the disposal methods used for PPCPs at various levels of use, i.e. production, distribution and consumption. Summaries of findings from the surveys are presented in tabular and graphical form as appropriate. The use of the new assessment tool, the DDFD, is also presented in tabular and graphical forms as appropriate. This allows for pictorial presentations which make for ease of comprehension as well as facilitating the comparison of figures.

The information gathered from the interview with Food and Drugs Authority was analysed to evaluate the procedure and methods used in the disposal of PPCPs and how such procedures and methods may affect the quality of the environment in general and water sources in particular. The information gathered also informed analyses on ways

of disposing of medicines which take into account the current constraints of the FDA and still preserves the quality of the environment. Analysis of the information gathered was also used to assess the understanding of officials with respect to the potential effects of inappropriate disposal of medicines and the steps (if any) taken to mitigate those effects. The information obtained from the EHSD was analysed to assess the quantity and quality of facilities for the disposal of waste in the country as well as the procedures involved. Analysis of the information also looked at any focus there may be on the impact of PPCPs on the environment vis-à-vis the methods of disposal currently in place for the disposal of waste.

Analysis of the information obtained from the EPA was used to evaluate the potential effects of the methods of disposal used for chemicals generally. The information was also used to assess the understanding of the officials with respect to the potential impact of inappropriate disposal methods. Information from the PC was analysed to assess the activities of the Council that impact the handling and disposal of unused and expired medicines. Analysis also ascertained the understanding of the Council with respect to how the activities engaged in during the delivery of pharmaceutical care may impact the health of the environment. The results of the study are analysed under the following headings: (i) Regulation of Disposal of PPCPs; (ii) Disposal of Waste; (iii) Disposal of Unused Medicines and (iv) Drug Disposal Flow Diagrams and EPV.

4.1 Regulation of Disposal of PPCPs

The disposal of waste in general, and PPCPs in particular, is regulated by a number of agencies in Ghana. The Environmental Health and Sanitation Directorate (EHSD) is responsible for policy development for environmental sanitation and hygiene. There is currently an Environmental Sanitation Policy (MLGRD, 2010) in place for the

maintenance of environmental sanitation in Ghana. The implementation of policies developed by the EHSD is undertaken by the Metropolitan, Municipal and District Assemblies (MMDAs). The activities undertaken by the MMDAs are, however, governed by the Local Government Act, 1993 (Act 462). The FDA is responsible for providing and enforcing standards that govern medicines, among other things. The functions and powers of the FDA are set out in the Public Health Act, 2012 (Act 851) which governs the activities of the FDA. The EPA is responsible for securing the environmental integrity of the nation and is governed by the Environmental Protection Agency Act, 1994 (Act 490). The activities undertaken by these agencies in the performance of their functions and execution of their responsibilities are greatly influenced by the requirements of the laws governing the work they do. The results of the study are, therefore, analysed within the context of this legal framework.

4.1.1 Public Health Act, 2012 (Act 851)

The Public Health Act was passed in 2012 to revise and consolidate the law relating public health, to prevent disease, promote, safeguard, maintain and protect the health of humans and animals and to provide for related matters (Government Printer, 2012). It is in this enactment that the regulatory provisions governing the manufacture, importation, exportation, registration, sale and supply of PPCPs may be found. The object of the FDA, established by this Act, is the provision and enforcement of standards for the sale of PPCPs (Government Printer, 2012). Any standards relating to the manufacture, importation, exportation, registration, sale and supply of PPCPs are therefore to be developed and enforced by the Authority. The Act also provides for the disposal of regulated products. By Act 851, the disposal of PPCPs in Ghana is

to be undertaken by the FDA as provided for under section 132 titled *Closure of premises and safe disposal of unwholesome regulated products*:

(1) The Authority shall, order the closure of any premises where articles regulated by this Part are manufactured, stored, prepared or sold, if the Authority has reason to believe that the articles are exposed to the risk of contamination or deterioration, and the Authority may make a further order appropriate in the circumstances.

(2) The Authority shall supervise the safe disposal of an unwholesome regulated product at a fee determined by the Authority.

(3) A person shall not dispose of an unwholesome regulated product without the supervision of the Authority.

(4) A person who contravenes subsection (3) shall pay a fine of not more than five thousand penalty units to the Authority.

The provisions relating to the disposal of medicines, therefore, are in respect of unwholesome products from closed premises, the destruction of adulterated drugs and the disposal of seized medicines. Even if the provision regarding unwholesome products were interpreted as including expired medicines, Act 851 appears to envisage that such products would be present in premises where they are "manufactured, stored, prepared or sold", to wit commercial facilities and supply points. The Act does not envisage that "unwholesome" medicines may be present in private homes, or if it does, the Act does not provide for such medicines.

The Act does not provide for PPCPs which may remain unused, whether with manufacturers, suppliers or wholesalers. Where manufacturers, suppliers or wholesalers have medicines which remain unused, and those products are not

categorised as unwholesome, they appear to be under no legal obligation to dispose of them in any prescribed way. Manufacturers and suppliers are also under no legal obligation to dispose of their unused products under the supervision of the FDA as prescribed under section 132 unless those products are categorised as unwholesome. The section under which the provision appears may be taken into consideration when categorising products as unwholesome or otherwise. In that light, therefore, the categorisation as unwholesome or otherwise comes to play when the premises where products are manufactured, stored, prepared or sold are closed or to be closed. In instances where no issue relating to closure has arisen, disposal of products with manufacturers, wholesalers and distributors remain at the discretion of these institutions even though the practice for these institutions is to dispose of their products under the supervision of the FDA (Amedzro, 2015).

Consumers of PPCPs may stop using them for any number of reasons including change of prescription, the incidence of adverse effects or resolution of symptoms of the condition being treated. When PPCPs are stopped, consumers will have these products in their possession and have to dispose of them. There are, however, no legal provisions governing how such products are to be disposed of. There is also no provision governing the disposal of PPCPs which may expire while with the consumer. This lacuna in the law means that when it comes to the disposal of such products, they are handled in the same way as adulterated and unwholesome products from site where they are manufactured, stored, prepared or sold. This may appear not to affect the methods used for disposal; however, it directly affects the procedures that would be followed by individuals in attempts to dispose of their unused and expired medicines. Disposal under the supervision of the FDA has cost implications for the persons

involved in disposing of the medicines as provided for in section 132 (2). This is ascertained as being the practice, with organisations paying to have their products disposed of under the supervision of the FDA (Amedzro, 2015). These conditions are likely to have the effect to deterring private persons from going through the procedures laid down by the FDA for disposal of PPCPs. These individuals may, therefore, end up disposing of these unused medicines in ways that do not take environmental effects into consideration and, therefore, have detrimental consequences on the environment.

Some mandates may be exercised in the issuance or legislative instrument, bye laws and various types of regulations. Act 851 provides in section 148 for the issuance of guidelines by the FDA "for the destruction of an adulterated food or drug" and "for...the seizure and disposal of products regulated under this Part". The Act, therefore, makes provision for adulterated products and products that may be seized for any number of reasons. It does not, however, appear to envisage that unadulterated products such as unused medicines may need to be disposed of. Again, where the products have not been seized, the Act does not provide for the disposal or destruction of such products. Further, the Act does not require the adherence to procedures and methods that protect the quality of the environment in general or preserve of quality of water resources in particular in the preparation or enforcement of these guidelines. Whether or not the guidelines developed take steps to preserve the environmental quality or promote sustainable development will, therefore, be dependent on the officers responsible for the preparation of those guidelines and their understanding of environmental issues and the contribution that disposal methods have on environmental quality and sustainability.

4.1.2 Environmental Protection Agency Act, 1994 (Act 490)

The establishment, functions and responsibilities of the EPA are provided for in the Environmental Protection Agency Act, 1994 (Act 490). Among its functions set out in section 2, the EPA is "to secure by itself or in collaboration with any other person or body the control and prevention of discharge of waste into the environment and the protection and improvement of the quality of the environment" and "to prescribe standards and guidelines relating to the pollution of air, water, land and any other forms of environmental pollution including the discharge of waste and the control of toxic substances". Although these provisions do not deal directly with the disposal of medicines, in the absence of clearer provisions, the EPA became responsible for advising other agencies such as the FDA on the proper disposal of medicines so as to reduce and control harm to the environment. The passage of the Public Health Act vested the total responsibility for the disposal of PPCPs in the FDA. The practice currently in place is for the FDA to seek advice for the EPA when they perceive that the disposal of some product, whether because of the content or the quantity, may pose some threat to the environment.

4.1.3 Local Government Act, 1993 (Act 462)

The Local Government Act was passed to establish and regulate the local government system and provide for related matters. The Act sets out the functions and powers of the District Assembly (DA). Among the functions set out, DAs are to provide, under section 8 (3) (d) "municipal works and services in the district". Such municipal works and services include the provision of waste management services (Darteh, 2015). Although all DAs across the country provide waste management services, there is no particular emphasis on the disposal of medicines. In the collection and disposal of

waste, therefore, medicines which may be received from community members are disposed of together with other household waste (Darteh, 2015).

Act 462 provides as follows under section 79 titled *By-laws by District Assembly*:

(1) A District Assembly may make by-laws for the purpose of a function conferred on it by or under this Act or any other enactment.

(2) A District Assembly may in the by-laws

a. Specify as penalty a fine not exceeding two hundred penalty units or a term of imprisonment not exceeding six months or to both the fine and the imprisonment;

b. Specify a further penalty not exceeding one penalty unit for each day on which the offence is continued after written notice of the conviction has been served on the offender in the case of a continuing offence; and c. Make provision for the payment of the fees or charges which the District Assembly thinks fit.

(3) The by-laws made by a District Assembly shall be read and construed subject to this Act and any other enactment.

A DA may, under this enactment, provide for the collection and disposal of waste within the district. The assembly is also empowered to prescribe penalties for noncompliance with the provisions of the by-laws. Under these provisions, all DAs are sufficiently empowered to ensure the proper disposal of both solid and liquid waste by members of their various jurisdictions. Currently, however, about 90% of households do not use plumbing works and therefore have no form of control over the liquid waste generated. Such liquid waste is disposed of in the areas surrounding the

households (Ghana Statistical Service, 2012). Thus any PPCPs present in such waste is deposited in the environment as part of grey water or become part of the run off after rains. In addition, up to 65% of households do not have toilets (Ghana Statistical Service, 2012). This situation means that there is very little management of the disposal of human excreta, with the direct implication that when PPCPs or their active metabolites are eliminated after consumption, there is little control of where they end up in the environment.

The provisions of Act 462 may also be construed as sufficiently empowering DAs to provide regulations on the disposal of unused and expired medicines within their jurisdictions. The regulations could be developed for both community members and organisations within their jurisdictions that deal with medicines. Such regulations may also be extended to cover other health related waste products that are not covered by Act 851 or any other enactment.

Act 462 further provides for model by-laws which may be made by the Minister where there is the need for a uniform provision concerning a particular matter. Matters involving the disposal of unused, unwanted and expired PPCPs may properly fall within the category which requires the passage of model by-laws. Section 81 provides as follows:

> (1) Where the Minister is satisfied that uniform provision may reasonably be made in respect of a matter for which by-laws may be made under this Act, the Minister may, by legislative instrument, make model by-laws in respect of that matter.
>
> (2) Where model by-laws are not expressed to apply throughout the Republic, they shall apply within the areas of authority of the District Assemblies

specified by the Minister by notice published in the Gazette, and subject to the modifications or omissions that the Minister may in a particular case consider expedient, any other by-laws relating to the subject-matter of the model by-laws shall to that extent cease to have effect within those areas.

4.2 Disposal of Waste

The disposal of waste is a means by which pharmaceuticals may end up in various environmental media. This is because if waste is not disposed of in ways that take environmental issues into consideration, any chemicals present in the waste will end up being dumped directly into environmental media without any form of attenuation. The methods of waste disposal are, therefore, relevant to EPV. The waste that is generated by the carrying on of daily activities need to be disposed of on a regular basis. The waste may be liquid or solid. Liquid waste includes all the elimination products after consumption of medicines such as faeces, urine and sweat from bathing water. Products which have been applied topically may also be washed and disposed of as household liquid waste. Liquid waste will ideally be treated in a WWTP where treatment will, ostensibly, be to ensure that the effluent will not have any harmful effect on the environment. The effluent after treatment in WWTPs will be discharged into receiving water bodies.

The ideal case for solid waste is that the waste is dumped in engineered landfills which provide for containment of the waste. The leachate from the landfills are channelled appropriately, treated and discharged as would liquid waste. Solid waste will contain the solid products which are no longer useful and will include, as the case may be, pharmaceuticals which are being disposed of. Although solid and semi-solid dosage forms are obvious candidates, liquid dosage forms may find themselves disposed of

with the solid waste because of their containers or because the persons disposing of them cannot come up with a better method of disposal.

4.2.1 Disposal of Liquid Waste

Liquid waste, which includes human excreta, liquid waste products from household and commercial activities and animal excreta (MLGRD, 2010) is supposed to be treated at WWTPs. When medicines are taken into the body, they may be metabolised by the body into active or inactive metabolites. Some medicines remain unchanged and end up being eliminated without any metabolism. Medicines that are eliminated through faeces will be disposed of by way of the disposal of normal human excreta. Medicines that are excreted through urine will be disposed of partly with faeces and partly in bath water. Medicines excreted through sweat will be washed off during bathing. Most products applied for topical purposes will also be washed off during bathing although some, on absorption, may be eliminated in the same manner as other medicines taken into the body.

According to Ms Bertha Darteh of the EHSD, only about 1% of the WWTPs in the country are currently functioning, with no measures in place to handle the overflow. Currently, an estimated 150 to 200 vacuum trucks, with capacities ranging from 5 – 15 cubic metres each, discharge human excreta directly into the sea each day from the Greater Accra Metropolitan area alone (Darteh, 2015). This means an estimated amount of 1750 m^3 of raw faeces is dumped daily, and 638,750 m^3 annually into the sea untreated. Appendix K shows the calculation by which this figure is arrived at. This situation is repeated across the whole country, and in places without water bodies to be utilised for dumping, the faeces are dumped on unused tracks of land. The human excreta disposed of in this way contains huge amounts of consumed pharmaceuticals

which may have been metabolised to both inactive and active metabolites or may have been eliminated from the body unchanged. Another source of pharmaceuticals to faeces disposed of by vacuum trucks is the fact that some consumers pour their unused and expired medicines into the toilet. Such products end up directly in the septic tanks which are emptied and discharged untreated into water bodies and on unused tracks of land. Those that end up in WWTPs are also largely untreated.

Water from bathing also contributes pharmaceuticals into the environment. Topical medicines are applied on the surface of the body and may be intended to have effect on the applied area. The applied medicine may also be intended to be absorbed into the body for pharmacological activity. The part which is absorbed may be metabolised but will be eliminated from the body. The part which ends up being washed off during bathing is disposed of as liquid waste from households. Methods of disposal of household liquids are varied (Ghana Statistical Service, 2012) - disposed of in the street, poured out into open drains and in gutters. All these methods of disposal directly introduce compounds into the washed water into the environment.

4.2.2 Disposal of Solid Waste

Solid waste has been defined to include all solid waste material, litter, street sweepings, drain cleaning, dead animals and other waste materials (MLGRD, 2010). According to the results from the national census, over 60% of households dispose of their solid waste using methods that introduce contaminants directly into the soil - dumping into open spaces, disposing of waste indiscriminately, burning and burying their waste (Ghana Statistical Service, 2012). By that report, less than an average of 15% of households countrywide have their waste collected for disposal at designated landfills, although there are significant regional variations (Ghana Statistical Service, 2012). Ms

Darteh of the EHSD indicated that there are currently only 4 engineered landfills in the country. These are located in Tamale, Tema, Kumasi and Sekondi-Takoradi.

These landfills are used, on average, for about 15% of solid waste produced in those areas, leaving the rest of the waste to be disposed of in ways that are environmentally unfriendly. On the other hand, the waste that is collected in regions without engineered landfills are dumped in designated areas. The leachate from these sites seep directly into the soil below and contaminate ground water. As Shield (2011) reports, leachate from dump sites can be detected in surrounding soil even decades after decommissioning those sites. Where the dumped waste contains API or their metabolites, they are likely to contaminate ground water and soil in the short, medium and long terms.

4.2.3 Disposal of Industrial Waste

The EPA is responsible for the disposal of industrial and medical waste. According to Dr. Koomson of the Chemicals Control and Management Centre (CCMC) of the Agency, guidelines for the disposal of hazardous materials are currently in the draft stages. Dr Koomson stated that the categorisation of medical waste by the EPA did not include pharmaceuticals, but rather covered biological waste and hazardous chemicals that may be used in the delivery of health care. In that regard, the disposal of medicines is not viewed by the EPA as being within their ambit. However, prior to the passage of the Public Health Act, the EPA was actively involved in the disposal of pharmaceuticals by organisations. Thus organisations were expected to deal with both the EPA and the FDA if they required supervised disposal of pharmaceuticals. The CCMC, currently, collaborates with the FDA and District Assemblies on the disposal of medical waste (Koomson, 2014). The Centre also provides technical support to the

FDA upon request (Amedzro, 2015).

4.3 Disposal of Unused Medicines

4.3.1 Disposal of Unused Medicines under the Supervision of FDA

4.3.1.1 Procedure – *Interview with FDA*

The process for disposing of medicines is triggered by the receipt of an official letter by the FDA from an organisation that it, the organisation, has some medicines that it requires to be disposed of (Amedzro, 2015). The process may also be triggered by an order from a court of competent jurisdiction that some particular quantity or batch of medicines is to be disposed of. The FDA may also, of its own accord, commence the process to dispose of products where those products have been seized or identified as adulterated. According to Dr. Koomson of the EPA, prior to the passage of Act 851, such an organisation would also have had to inform the EPA by letter with pictures of such an intention or need.

The organisation seeking to dispose of medicines may be a hospital, a wholesale outlet, a retail outlet or a manufacturing company where the products to be disposed of are pharmaceuticals. It may also be an organisation that has been ordered by a court of competent jurisdiction to dispose of certain quantities of products. The products to be disposed of may be expired, unused, unwanted or damaged PPCPs; they may also be active pharmaceutical ingredients (APIs) from manufacturing outlets. The letter to the FDA will normally indicate the quantity and type(s) of products to be disposed of.

The FDA then carries out an onsite inspection and audit of the medicines to ascertain the types and quantities to be disposed of. This assessment will determine the disposal method(s) to be used as well the fees to be paid by the organisation in question and the

sites of disposal. The payment of disposal fee, which is calculated per the number of tonnes to be disposed of, does not apply to government agencies. This fee means that organisations which are not bound by law to have their disposal supervised by the FDA find other means to dispose of their unwanted or unused PPCPs. The same will apply where some organisations have only small quantities to be disposed of, since the fees are calculated in tonnage and will be a deterrent for utilising FDA supervision voluntarily. The methods of disposal utilised in such instances tend to be detrimental to the health of the environment and may be harmful for human, animal and plant health.

Dr. Koomson stated that, prior to the passage of Act 851, the EPA would have been involved in the onsite inspection and audit of products to be disposed of and would advise on the appropriate means of disposal. Currently, the EPA is consulted where there is uncertainty as to the best method to use for disposal. Where there is also a fear that the products to be disposed of could have grave effects on the environment by reason of their chemical nature or the volumes involved, the EPA is consulted to give advice on the best course of action to take. The role of the EPA, after the passage of Act 851, is now advisory rather than dealing with implementation.

On the date set for disposal, the FDA supervises the packing of the medicines for disposal, leads the vehicle to the disposal site and carries out the disposal of the medicines using the method of disposal determined beforehand. A representative of the organisation initiating the process is present during the period of the disposal. The FDA then certifies that the quantities of products stated in the audit have indeed been destroyed on behalf of the organisations. Again, before the passage of Act 851, an EPA official would be present during the period of disposal (Koomson, 2014). PPCPs

for disposal are kept on the premises and under the supervision of the organisation which requires the disposal until the set date for disposal. The conditions for storage are therefore as provided by the organisation in question. There are currently no guidelines in place with respect to the storage conditions of medicines slated for disposal.

4.3.1.2 Methods of Disposal – *Interview with FDA*

There are currently four (4) ways by which the FDA carries out the disposal of medicines. The medicines may be crushed and buried. With this method, the products are placed in the identified excavated spot, the medicines are crushed and the pit is covered over with earth. Another method is burning. Here, the products are sent to the disposal site, doused with fuel and set on fire. The third method used by the FDA for the disposal of medicines is by emptying liquid formulations into municipal drains. Solid formulations are not handled in this manner. The fourth method is by incineration. With this method, since the FDA has no incinerators, the incinerators used are those owned by other organisations. Incineration is used for the disposal of vaccines, oncogenic medicines and steroids. All other solid products are disposed of by crushing and burying or by burning and liquid products go down the municipal drainage system. Medicines for disposal are not sorted out according to pharmacological action at the time of disposal at the various dump sites or into the drainage system. This means that medicines which interact may end up together and therefore induce some unpredicted effects in the environmental media into which they are deposited.

The sites for disposal are not owned or managed by the FDA. They are owned and managed by metropolitan, municipal and district assemblies (MMDAs). The

Authority is, therefore, unable to ensure that the sites are handled in such a way as to assure the optimum health of the surrounding environment. The fact that the disposal sites are owned and operated by the MMDAs also means organisations initiating the disposal pay a site fee for the use of the disposal site. This fee is for the management of the site and is paid by all organisations requiring the disposal of medicines, whether public or private. The payment of the site fee is another deterrent for organisations which are not required by law to dispose of their unused or unwanted PPCPs under the supervision of the FDA. This is confirmed by the surveys conducted in community pharmacies.

The FDA uses dump sites in Kpone, Abokobi and Nsawam for the disposal of medicines. The Kpone and Abokobi dump sites are used for crushing and burying and the Nsawam site, which is significantly removed from human population, is used for burning of products. The Nsawam site is also used for crushing and burying as the need arises. The distance of the Nsawam site from human population is aimed at reducing the exposure of the residents of the Nsawam township to the fumes from the burning of medicines, as such fumes may be toxic to the human population. The sites for crushing and burying are chosen having consideration of the level of the water table. Thus dumping sites are located in areas where the water table is low so as to reduce the probability of contamination of ground water by the pharmaceuticals that have been buried.

The FDA does not have a schedule for the disposal of medicines. Instead, as and when the need arises, as organisations indicate a need to have the medicines or APIs to be disposed of, the FDA organises the disposal. The sites therefore come into use as and

when needed rather than based on any schedule. Figure 4-1 shows a summary of the process of disposal supervised by the FDA.

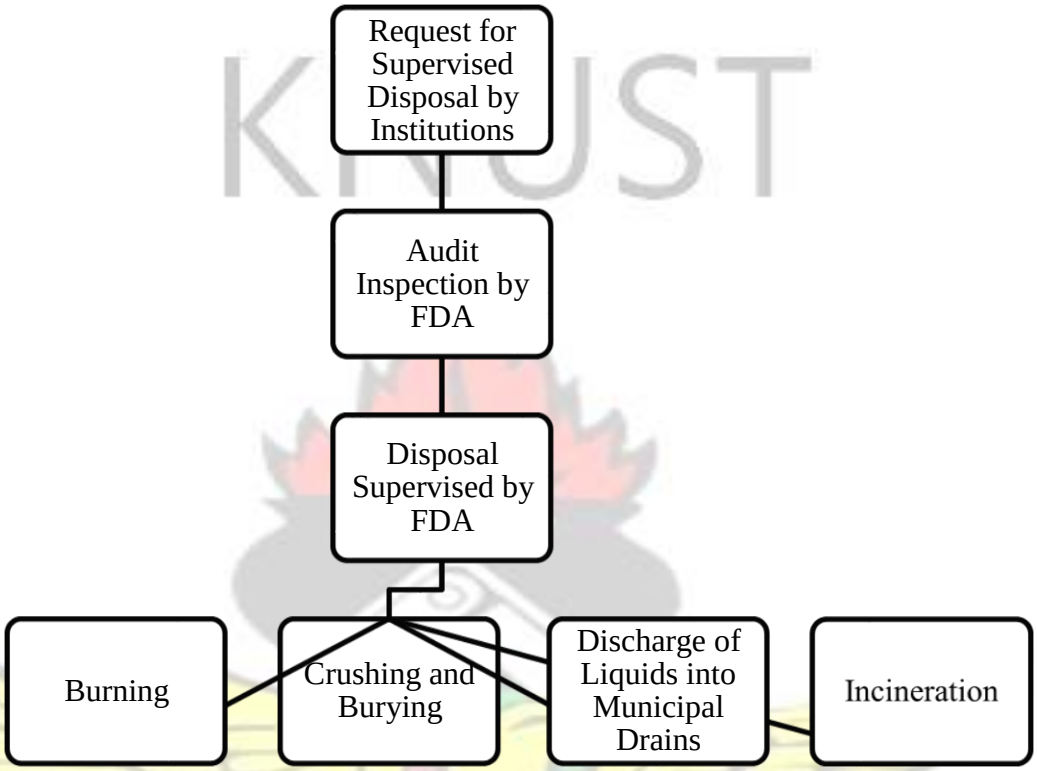

Figure 4-1: Supervised Disposal of Unused/Expired Medicines by FDA

4.3.2 Unsupervised Disposal of Unused and Expired Medicines

4.3.2.1 Community Pharmacies

Community pharmacies play a crucial role in the delivery of healthcare. The licence issued by the PC in respect of community pharmacies means that these facilities are able to supply all categories of medicines to members of the public for use in their homes or in the clinical setting. The requirement of the presence of a pharmacist, a professional trained to be an expert on medicines, during all opening hours of the community pharmacy (Pharmacy Council, 2015) means that the facility becomes a

place for obtaining reliable information about medicines. Although there are regional and geographic disparities with respect to access to pharmaceutical services, in communities where these facilities are present, they become the first point of call for most members of the community who need health care. Further, the community pharmacy also becomes the reference centre for members of the community who need any information with respect to their medicines.

Using the questionnaire in Appendix A, thirty (30) community pharmacies were surveyed with respect to their methods of disposal or unused and expired medicines. Of the facilities interviewed, one had never had expired medicines because it was new. The rest had all had expired medicines which required disposal. However, the survey showed that about 66% had disposed of medicines since establishment as shown in Figure 4-2.

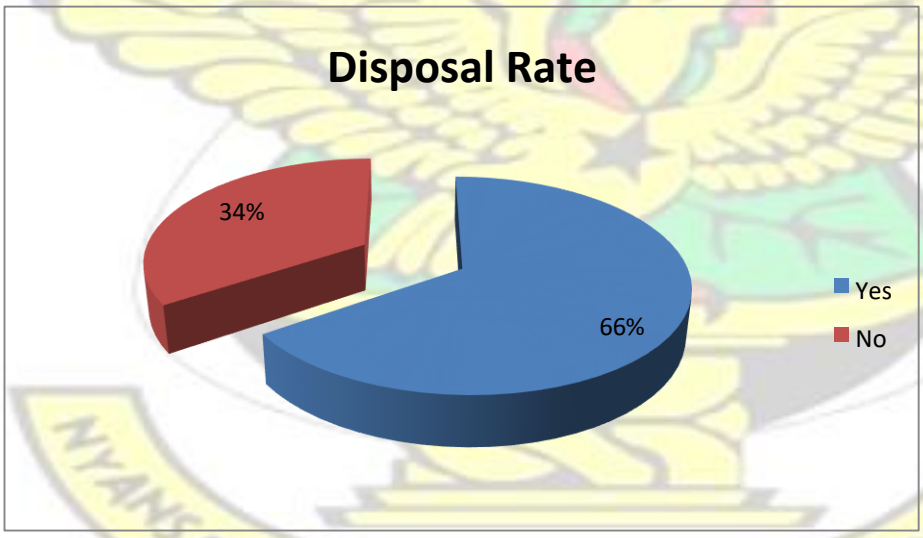

Figure 4-2: Disposal of Pharmaceuticals among Community Pharmacies

The results show that there are some community pharmacies (34% of respondents) which do not dispose of their expired medicines. The reasons for non-disposal are varied including no knowledge of what to do with the expired medicines or still

developing modalities on how these expired products should be handled. A few were keeping them so they could eventually write them off their books without losing twice over – having the products expire and paying taxes on those products.

These responses from the pharmacists show that there is the need for education on the proper disposal of medicines. There is clearly a lack of understanding of how disposal under the supervision of FDA may help the business of the pharmacy. Where the FDA supervises the disposal, the certificate issued by the authority is used by the relevant organisations to defray their tax obligations in respect of the medicines destroyed. On the other hand, the fact that a significant number of facilities still have expired medicines mean there is the opportunity to deal with those ones properly. It is possible for these unused and expired products to be mobilised by means of exemptions from payment of fees and education. The mobilised products can then be disposed of in ways that give some form of protection to the environment.

The facilities that indicated having disposed of pharmaceutical products reported different methods of disposal. Figure 4-3 shows the various methods employed by community pharmacies in the disposal of their expired products. From these results, almost 40% of solid dosage forms, more than 26% of all liquid dosage forms and over 50% of all semi-solid products are disposed of in the trash and therefore end up at dump sites. This accounts for the most commonly used method overall. Disposal in the trash is the method used by most facilities for disposing of their solid and semisolid dosage forms. The most commonly used method of disposing of liquid dosage form is to pour down the drain. In such instances, the contents go down the drain, but the containers in which they are stored, which may still have some residue, are disposed of in the trash. A few respondents were not sure of how what methods were used for

disposal. This is because there were higher authorities such as owners of the facilities or the headquarters of the organisations that was responsible for the disposal of unused or expired medicines. These were captured under "Other" in Figure 4-3.

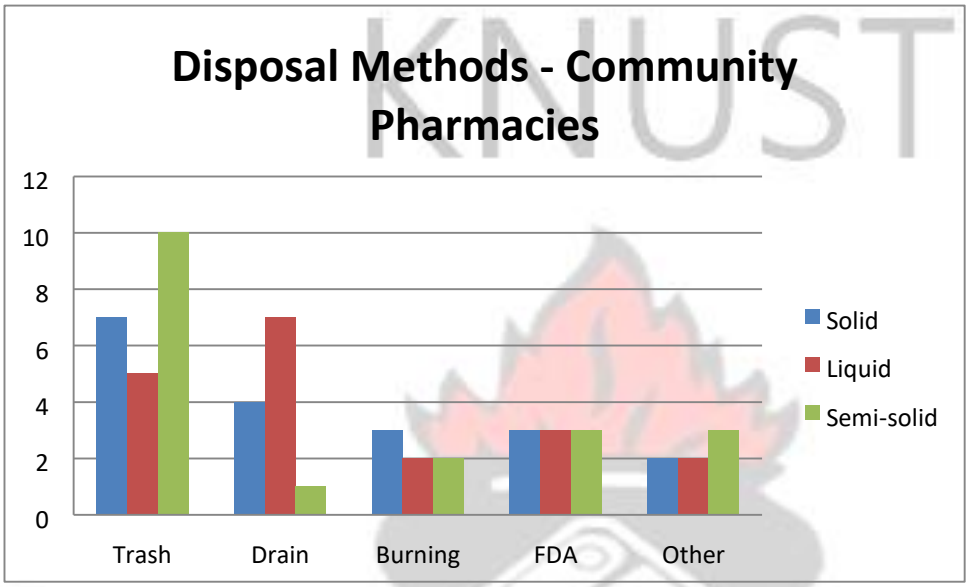

Figure 4-3: Disposal Methods used by Community Pharmacies

4.3.2.2 Consumers

Individuals who seek health care in various facilities invariably receive medications where pharmacotherapy is indicated for resolving their needs. The expectation of health care professionals when medicines are prescribed and dispensed to consumers is that they will comply with the dosage regimen prescribed. Flowing from that is an expectation that all medications dispensed will be consumed. There are instances, however, when medications are stopped by prescribers. In other instances, the patients stop taking their medications for various reasons without the intervention of a health care professional. Some of the reasons given by respondents for not completing their medications include stopping because they no longer feel uncomfortable and that they simply don't like taking medicines. The survey showed that 47% of respondents do

not normally complete their medications. Figure 4-4 shows the reasons respondents gave for not completing their medications.

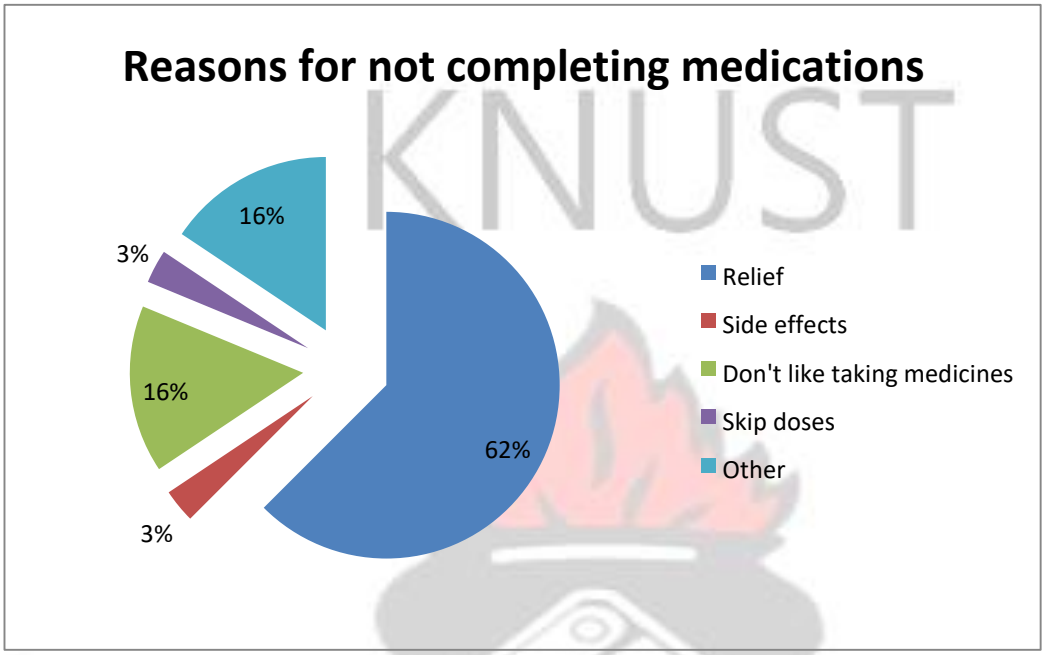

Figure 4-4: Reasons why consumers do not complete their medications

The survey also showed that even those who would not consider themselves as not completing medications may, from time to time, have medications in their custody which may end up being unused. At the time of the survey, 51% of respondents stated that they had medicines from a previous visit to a health professional which they had not completed. These medicines are likely to end up being disposed of as unused or unwanted as subsequent visits to health care facilities bring new medications which have to be taken. Another 48% had medicines which they keep for use in cases of emergencies. Medicines kept for emergencies may or may not be used as their use depends on the expected emergency arising. Where they remain unused, they will require disposal at some point in time.

When it comes to how individuals dispose of their unused, unwanted and expired medicines, respondents indicated that the main method utilised was putting them in the trash. This method did not change significantly whether the dosage form was solid, liquid or semi-solid. In addition to this method, some also buried them, burned them or poured them down the drain. A few respondents were not sure of how medicines were disposed of as they were not responsible for disposal. Those are captured as "Other" in Figure 4-5. Figure 4-5 shows the disposal practices of the consumers interviewed.

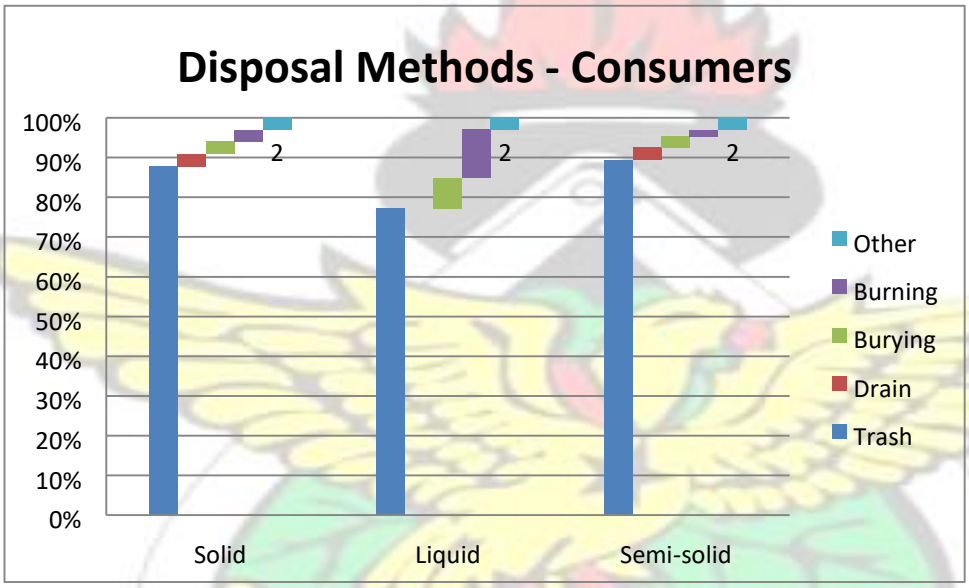

Figure 4-5: Disposal Practices of Consumers

4.3.3 Effect of the Presence and Persistence of Pharmaceuticals on Water Resources and Ecosystems

Various effects have been recorded as resulting from the exposure of living organisms to PPCPs in their environment. Some of the recorded effects are observed in the laboratory whereas others have been seen in the natural environment. Some effects

have been observed in the organisms directly exposed to the pharmaceuticals; while other effects have been observed in organisms that depend on those exposed. There are, also, some effects that are envisaged as a result of the understanding of biological systems. These potential and observed effects raise concerns regarding the inadvertent exposure to PPCPs.

4.3.3.1 Pharmaceuticals and Water Resources

The current method for disposing of liquid medicines is by discharging the contents into municipal drains. This method means that the receiving waters of these drains become the direct dumping sites for the pharmaceuticals. The medicines enter the drains in the active forms. The drains empty into streams and rivers and ultimately into the sea. The water bodies in question, therefore, get contaminated with these pharmaceuticals reducing the quality of the water supply. It further exposes organisms in these water bodies to direct contact with pharmaceuticals.

Pharmaceuticals, after disposal, are able to enter surface and ground water sources even if not directly placed there. In these water sources, the pharmaceuticals become contaminants. In rivers and streams, they are able to get accumulated in the tissue of aquatic animals. They may become toxic to these aquatic animals or to animals higher up the food chain that may consume the tissues of these organisms. Human hormones and some pesticides can affect the reproductive health of fish, alligators and other aquatic organisms which may be sensitive to them. The pharmaceuticals in water sources may also affect plants: they may be toxic to the plants, killing them. They may also be taken up by these plants and reintroduced into the terrestrial environment.

4.3.3.2 Pharmaceuticals and Ecosystems

Pharmaceuticals have been known to have very major unintended effects. The near collapse of the Southeast Asian vulture populations is one classic case of how pharmaceuticals can affect ecosystems. The vultures died after consuming the flesh of cattle that had been treated with Diclofenac near the time of death. The Diclofenac stayed in the tissues of the cattle and poisoned the vultures that consumed the flesh of the dead cattle. The consumption of tissues which may have significant concentrations of pharmaceuticals as a result of accumulation may therefore have serious consequences both on humans and other organisms higher up the food chain. It must be pointed out that the Diclofenac did not have any recorded negative effects on the cattle. It is, therefore, possible for animals lower down the food chain, such as fish, when exposed to pharmaceuticals in their habitat, to show no signs of toxicity. Plants exposed to pharmaceuticals in their habitat, may also show no signs of toxicity and yet accumulate the toxins in their tissues. On the other hand, animals up the food chain, on consuming these food sources, may find themselves poisoned by them.

Another dramatic effect on ecosystems is that relating to the feminisation of male fish on exposure to female human hormones. In some instances, there was 100% feminisation. This will mean that there will be no reproduction, as there will be only females in that particular water system; the fish population will collapse and all other organisms that live on the fish, higher up the food chain may also have their populations collapsing. The exposure of producers (plants) and primary consumers (animals lower down the food chain) to pharmaceuticals, therefore, potentially, put all other consumers in that particular food chain at risk.

4.3.4 Potential Impact of Poor Disposal of Medicines

During the interviews, Mr. Amedzro of the FDA and Dr. Koomson of the EPA indicated that improper disposal of pharmaceuticals will have negative implications for both the environment and the populations close to where the disposal takes place. It is this understanding that has led to burning being carried out in sites which have been identified as being significantly removed from human populations. The dump sites are also areas which have been identified as having low water tables. This is to reduce to the barest minimum, the possibility of contamination of ground water by the pharmaceuticals buried in those sites.

The study, however, revealed that there is no policy in place to deal with potential long term impacts which result from these methods of disposal. The current procedure of burning medicines at sites which are identified as not close to human habitation, for instance, does not take into consideration the fact that the fumes released into the atmosphere can travel great distances carried along by the wind. The fumes can also affect nearby vegetation as the vegetation in question become exposed to chemicals that may be present in the fumes. Although inhabitants of neighbouring communities may not smell the fumes because they are not concentrated, long term exposure to even small doses of the chemicals present in these fumes may impact the health of those exposed. The situation may well be similar to long term exposure of residents of industrialised countries to air pollutants. These pollutants have been identified as being harmful to human health as well as damaging the natural environment. Locating burning sites in areas which are not close to human habitation may therefore not be an effective way of preserving quality of life and the environment. Acquisition of better facilities such as incinerators for the FDA will afford the burning of pharmaceuticals

in a controlled manner which also minimises the potential of exposure of humans or other life forms to these fumes.

4.3.4.1 Surface Water

There are potentially other effects resulting from open burning of medicinal products. Surface water sources, for instance, may be affected. Any chemicals which may be present in the fumes after burning these medicines have the potential to dissolve into surface water bodies such as streams, rivers and even the ocean. They may be dissolved in rain or fog which may then enter these surface water sources. The doses at which the medicines enter these water bodies may be small, but the long term exposure of aquatic animals and humans who use those water sources constantly may be significant. Bearing in mind that the medicines are not sorted out at the time of disposal, the potential for chemical reactions to take place between different compounds, with the application of heat, to produce other compounds whose effects that may not be understood cannot be overlooked.

As contaminants of water sources, pharmaceuticals can also affect humans and other organisms that may not live in the water bodies but depend on their water supply for survival. Contaminated water sources will be unhealthy for human and animal consumption. Although consumption at this level of contamination exposes the consumers to sub-therapeutic doses, some pharmaceuticals have effect on liver enzymes, and these effects may be present even at sub-therapeutic doses. Liver enzymes are involved in the metabolisms of various drugs, chemicals and other compounds that get consumed. The enzymes may break the medicines down and therefore stop the action of the medicine and prevent toxicity, or convert inactive compounds into their active forms. Consumption of these contaminants means, then,

that the pro-drugs may become ineffective and active medications may become toxic even at ordinarily safe doses.

In addition to the potential effect of some pharmaceuticals on liver enzymes, the long term exposure to low doses of various combinations of pharmaceuticals is a matter for concern. Pharmaceuticals have various levels of interactions with other chemicals, various foods and some physiological conditions. The inadvertent exposure to these products means that the potential and actual interactions cannot be envisaged when patients are being counselled on the potential interactions of taking some particular medication. This means no remedial measures can be put in place to avert any interactions. Indeed, when interactions arise, it may be impossible to ascertain the causative agent leading to a failure in proper resolution of the problem. Another possible consequence of the inadvertent consumption is the creation of depots in some tissues, such as fatty tissues, in the body which will then release the medications over long periods of time. Such sustained release of medications and other chemical compounds in the body may give rise to health complications in unsuspecting individuals.

Fish have been found to accumulate some pharmaceuticals in various tissues; alligators have shown lower survival rates and reduced phalanges on exposure to different kinds of chemicals; male fish have been shown to experience feminisation on exposure to human female hormones. In addition to these, there is the potential and yet to be investigated effect of humans as they become exposed to small doses of medicines in their daily activities and expose their liver to the constant stress of dealing with subtherapeutic doses of medicines. Although the detected doses are usually small, the long term exposure could result in major health effects. Contamination of surface

water sources means that these water sources, over the long run, will no longer be available for use by the local populations defeating the strive for development. Also, since surface water sources are the source of livelihood for some local populations, contamination of these water sources will mean a loss of livelihood of these populations.

Another matter which is not addressed by the procedures in place for the disposal of medicines is that of the uptake of medicines by plants. Plants tend to concentrate pharmaceuticals present in aquatic environments as well as in the soil in various parts of the plant (Wu, et al., 2011). The import of this is that there is a clear danger of plants in swamps to become sources of the reintroduction of pharmaceuticals into the terrestrial environment. This is in addition to the fact that some human pharmaceuticals have been identified as being toxic to some plants (Wu, et al., 2011). Some plants may therefore be killed by exposure to some pharmaceuticals and others will re-introduce them into the terrestrial environment for consumption by humans and other organisms higher up the food chain.

The exposure of some fish to human hormones in their aquatic environment has resulted in the feminisation of male fish (Christiansen, et al., 2002). The exposure of alligators to some EDSs also resulted in the reduction in phallus sizes as well as reproductive and physiological capabilities (Guillette, et al., 1996b). These changes point to an even more ominous potential effect of the exposure of humans to pharmaceuticals in their water sources – the gradual and probably imperceptible feminisation of male humans, reduction in phallus sizes for human males, or the reduction in reproductive capability. The levels of pharmaceuticals that have been

identified are sub-therapeutic, but consistent exposure over long periods of time may result in the development by males of female features.

4.3.4.2 Ground Water

The sites for dumping – sites used for crushing and burying of medicines – have been identified as places with very low water tables. This is an attempt at avoiding contamination of groundwater by the pharmaceuticals so dumped. The presumption here is that crushing and burying medicines high above the water table will prevent contamination of the groundwater by medicines buried. However, Shield (2011) reports of the presence of pharmaceuticals in groundwater samples 300m from a landfill site which had been closed twenty-one (21) years earlier. The pharmaceuticals, therefore, persist in the soil for long periods of time and leach deeper and deeper into the soil. They are, therefore, able, in time, to reach the water table no matter how low. Dumping in un-engineered dump sites, no matter how high above the water table, may therefore only postpone the problem – pollution of ground water resources. In the future, then, the ground water supplies may not be able to meet the needs of the populations as the supplies become more and more contaminated as a result of exposure to medicines.

4.3.4.3 Impact on Health and Healthcare Delivery

One concern the world over with respect to health and health care delivery in recent years is that of anti-microbial resistance. WHO has identified infections caused by microorganisms which are resistant to appropriate medications to be responsible for higher costs of treatment as a result of the need to use stronger medications; ineffectiveness in the well-established standard therapies; and the spread of difficult to

treat conditions (WHO, 2013). Although there are as yet no studies, to the author's knowledge, to confirm that the resistance is acquired as a result of exposure to medications in the environment, there is a realistic possibility – and this has been put out by other authors (Holm, et al., 2013) - that exposure to antibiotics could develop resistance in the microorganisms so exposed. This possibility is realistic because the doses in the environment are much lower than therapeutic doses, thus exposing the microorganisms to the medications without being sufficient to destroy them as would have been in therapeutic doses. The long term exposure may, therefore, induce the development of resistance in the microorganisms.

4.4 Drug Disposal Flow Diagrams and EPV

With the increased interest in the presence and persistence of pharmaceuticals in the environment, a number of interventions have been introduced in various parts of the world to improve the quality of environmental media. These strategies have been aimed at the various routes by which pharmaceuticals enter the environment. They are therefore to reduce the input of pharmaceuticals into environmental media. With the background of the ubiquitous nature of pharmaceuticals, there is the need for strategies to be implemented across the globe. In order for the strategies to be successful when implemented in other areas, there is the need for a contextual analysis of the new setting for implementation. The Drug Disposal Flow Diagram (DDFD) is a new tool designed to assess the context within which strategies may be introduced for the purpose of implementing EPV. The DDFD is a pictorial diagram showing the disposal of PPCPs. It provides the opportunity to assess what strategies would be most effective.

4.4.1 Implemented Strategies

In order to reduce the introduction of pharmaceuticals into the environment, and thereby mitigate the effect, some strategies have been implemented in different parts of the world. Some implemented strategies include take back schemes, take back events and, more recently, environmental management plans (EMPs). Take back schemes and events have been utilized to receive large amounts of unused and expired medicines from consumers. These activities ensure that the medicines will be disposed of in ways that protect environmental integrity as the disposal of unused medicines does not become the responsibility of individuals. Again the methods used for disposal will the determined to be effective in ensuring that the medicines so disposed of do not end up contaminating the environment. EMPs are required on the introduction of new medicines into a country. The environmental impact is assessed and the plans are put in place for mitigation.

These strategies may be introduced in other parts of the world to help in implementing EPV. In order for these strategies to be successful upon scale-up, however, the context within which the strategies are to be introduced is important. For instance, in undertaking take back schemes and events, it is necessary to ensure that they will effectively tackle the problem in a cost effective manner. There should also be effective disposal methods in place to deal with the medicines that are taken back. Such methods may include incineration of received products. Liquid products may be treated in WWTPs which are designed to remove pharmaceuticals. Where there is the need for dumping into landfills, these landfills will be engineered and the leachate received for treatment in appropriately designed WWTPs.

Where EMPs are introduced, persons introducing new products into a particular country are required to undertake assessments of the impacts those products are expected to have on the environment. The introducers are then required to identify and implement strategies aimed at mitigating those effects. In implementing the strategies, there are reporting requirements to be followed. Again, activities undertaken have to be inspected and supervised by regulatory bodies. In order to ascertain effectiveness of the EMPs there is the need for effective monitoring and evaluation systems. Also, regulatory and monitoring bodies must be equipped with the proper skill set in order to effectively supervise the EMPs. Where these systems are non-existent or ineffective, therefore, EMPs will not be an effective tool in EPV.

4.4.2 About Drug Disposal Flow Diagrams

The need to implement new strategies within a well understood context requires the assessment of the context in question. The Drug Disposal Flow Diagram (DDFD) is a new tool for the effective assessment of the community or country within which EPV strategies are to be introduced. The tool assesses the disposal practices of players within the pharmaceutical chain system – manufacturers, distributors, retailers and consumers. The information obtained from the various participants is used to prepare a matrix. The matrix is used to calculate the percentages that are handled in environmentally friendly manner and the percentages not properly handled. The results from the matrix are then fed into the DDFD which provides a pictorial illustration of how medicines are disposed of. This presentation gives an indication of the methods that will give the most cost effective impact. The DDFD provides policy makers with information on which areas to target and assess the impact of implemented strategies.

4.4.2.1 Design

The design of the DDFD requires an identification of the various disposal practices at different levels of the pharmaceutical value chain. This is because at different levels of the pharmaceutical value chain, there may be the need to dispose of PPCPs. The different levels of the value chain are responsible different processes in the pharmaceutical industry. In designing this model, these processes together have been named the process chain for pharmaceuticals. Figure 4-6 shows the process chain used in the model DDFD.

Figure 4-6: The process chain of Pharmaceuticals

Source: Author's Construct

The process chain gives an indication of the players in the value chain. The various players in each step of the process chain are identified. This is necessary to ensure an effective investigation of the relative contributions of these players to the presence and persistence of PPCPs in relevant environmental media. Generation within the process chains deals with the source from which the PPCP enters the environment rather than the manufacturer of the products in question. In this regard, five sources of generation were identified as industry, hospital, community pharmacy, household and animal consumption. This is important for the quantification of the relative contributions of the players to the presence or persistence of PPCPs in the environment. The collection part of the process chain represents the quantities that are collected for treatment or disposal. Based on the information gathered from the interviews and surveys,

percentages are estimated as being safely and unsafely collected, transported, treated and reused.

4.4.2.2 Matrix development

The matrix for the DDFD is developed to quantify of the safety level of the methods used for collection, disposal and treatment. The information obtained from the various aspects of the study were analysed to and used to calculated percentages that represent the safety levels with respect to the various processes in the value chain. As the target for all production of PPCPs is consumption, primarily by humans and to a smaller extent in agricultural or veterinary use, the combination is assigned 90% of generation. Human community consumption is assigned 55%, hospital and other institutional use is assigned 25% and 10% is assigned to generation from animals. Industry is assigned 8%. This is informed by the fact of the production process results in the generation PPCPs which will have to be disposed of. Community pharmacies as a group are assigned 2% since the amounts generated for production will be, primarily, medications that would have expired. From the information gathered from different parts of the study, percentages are assigned to the different participant as their contributions to the different aspects of the process chain. This information is used to develop the matrix for the DDFD. Table 4-1 is the matrix developed from putting in the information from the study.

Table 4-1: Drug Disposal Flow Diagram (DDFD) Matrix

Source: Author

Type of System		of which safely collected	not safely collected	of which safely delivered	not safely delivered	of which safely treated	not safely treated	Safe: 4%
Industry	8%	100%	0%	100%	0%	20%	80%	
		8.00%	0.00%	8.00%	0.00%	1.60%	6.40%	2%
Hospital	25%	25%	75%	75%	25%	20%	80%	
		6.25%	18.75%	4.69%	1.56%	0.94%	3.75%	1%
Community Pharmacy	2%	10%	90%	100%	0%	20%	80%	
		0.20%	1.80%	0.20%	0.00%	0.04%	0.16%	0%
Household	55%	50%	50%	70%	30%	5%	95%	
		27.50%	27.50%	19.25%	8.25%	0.96%	18.29%	1%
Animal Consumption	10%	10%	90%	100%	0%	20%	80%	
		1.00%	9%	1.00%	0.00%	0.20%	0.80%	0%

Unsafe: **96%**	**57%**	**10%**	**29%**
	Local area & drainage	Drainage system	Receiving waters

4.4.2.3 The model Drug Disposal Flow Diagram

The DDFD for a particular country or region is designed by putting the information from the matrix into a pictorial format. This format allows the situational analyses to be displayed for easy understanding. In the model DDFD, medicine-filled arrows were utilised to show the deposit of pharmaceuticals into environmental media by the various ineffective methods used. This culminates in a red figure indicating the percentage of pharmaceuticals deposited in the environment without attenuation. To portray the appropriate methods of collection, treatment, disposal and reuptake or reuse, the green arrows are used to show that those methods are environmentally friendly. These arrows point to green figures indicating the value percentage of pharmaceuticals disposed of properly. Figure 4-7: Model Drug Disposal Flow Diagram shows the model DDFD based on the information gathered during this study.

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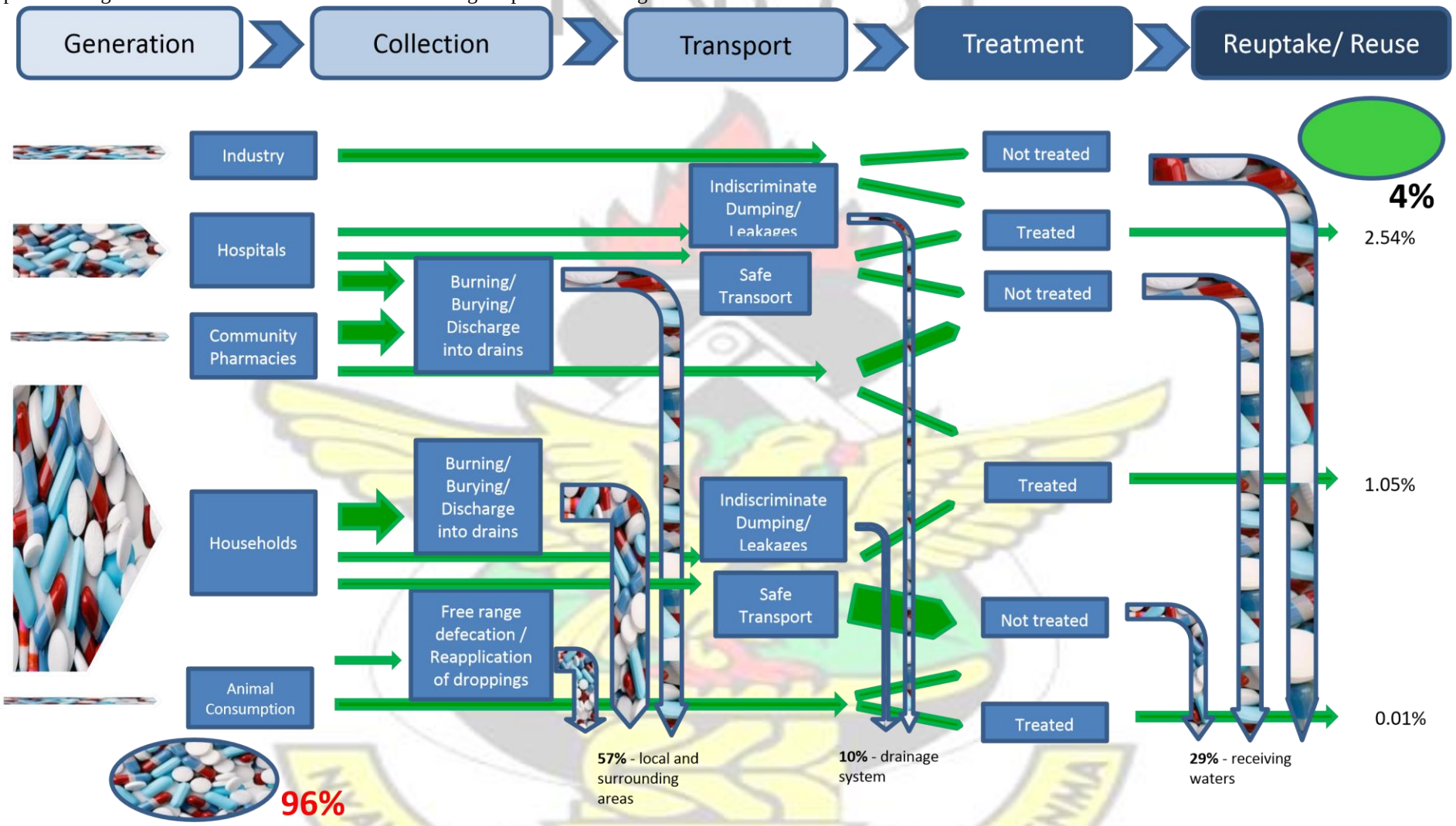

Figure 4-7: Model Drug Disposal Flow Diagram

Source: Author's Construct

4.4.3 Utilisation of DDFDs in EPV

The DDFD incorporates the assessment of the context within which EPV strategies are to be implemented. Such assessment allows for investigation into the effectiveness of a strategy in a particular setting. The tool also ensures any strategies that are designed and implemented are cost effective. In that regard, the tool highlights areas that require focused intervention to achieve maximum impact. In the model diagram, for instance, it gives information as to most effective ways of targeting the issues. The model DDFD shows that only 4% of PPCPs are safely handled when it comes to disposal. An estimated 57% of disposed of PPCPs end up in the local areas close to where they are generated. This means that methods that are targeted at receiving from such areas, such as take back schemes and events would be effective in minimising the quantities that get into the environment. Whether the strategy is a take back scheme or method would be dependent on how accessible take back points are and how appropriately the received PPCPs can be at the receiving centre prior to disposal. The diagram further indicates that 29% of PPCPs end up directly in receiving waters. This could be controlled by education of the populace to reduce disposal of unused and expired PPCPs into drains. Industries could also be supported to install and use WWTPs that effectively remove PPCPs during the treatment cycle.

A further 10% contaminates drainage systems exposing various organisms to the PPCPs that may be present therein. This percentage could be dealt with by education of the population on the proper ways of handling municipal waste generally and PPCPs in particular. This means that focussing on these areas will yield the best outcomes with

respect to EPV. The nature of the tool also allows for sustainability. This aspect can be effected by undertaking investigations into the prevailing practices from time to time. The results can be developed into flow diagrams that show how effective implemented strategies have been and what else to do to even further improve the situation.

CHAPTER 5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Summary of Findings

There are various ways by which pharmaceuticals enter the environment. Some of the human activities by which pharmaceuticals enter the environment include the disposal of liquid and solid waste in general and the disposal of unused, unwanted and expired medicines in general. This study was undertaken on the assumption that when medicines are disposed of without environmental considerations, the pharmaceuticals will end up in various environmental media, and ultimately contaminate water resources and affect ecosystems. This section summarises the findings of the study.

5.1.1 Entry of Pharmaceuticals into the Environment

There is currently a set of legal provisions that cover the disposal of unwholesome and adulterated medicines, hazardous waste and other waste products related to pharmaceuticals and other chemicals: the Public Health Act, 2012 (Act 851) and Environmental Protection Agency Act, 1994 (Act 490). The legal framework in place does not cover unused, unwanted, undamaged or expired medicines. Although the current practice is for manufacturers, wholesalers and distributors to get FDA supervision when disposing of their expired products, there is no legal requirement for their unused products that have not been classified as adulterated to be disposed of under the supervision of the FDA. The law does not also provide for the disposal of unused and expired medicines which may be with members of the public and for which there will be the need for disposal. These categories of medicines are therefore largely unregulated when it comes

to their disposal. Individuals and private institutions that may have some quantities of medicines to dispose of which are not adulterated or seized will have to make payment both to the FDA and the managers of the dump sites before those medicines will be disposed of. This situation is likely to deter those who may want to voluntarily dispose of their unwanted medicines.

A number of methods are currently in place for the regulated disposal of medicines. Some of these methods incorporate some health and environmental considerations in execution: open burning of medicines in areas removed from human settlement to avoid exposure of the populations to fumes which contain chemicals; and crushing and burying medicines in sites which have been identified as having low water tables.

5.1.2 Potential Environmental Impact

The methods currently used for the regulated disposal of medicines, although put in place with environmental considerations in mind, are not sufficient to protect the environment from damage that could occur as a result of the presence or persistence of pharmaceuticals in the environment. The chemicals in the fumes of burned medicines can dissolve in surface water systems, contaminating those sources. Medicines which are discharged directly into municipal drainage systems also contaminate receiving waters and expose flora and fauna to those medicines.

The disposal of unused liquid medications into municipal sewage systems poses a danger for surface water sources. This is because all drainage systems open out into rivers and streams and ultimately into the sea. Discharging liquid medicines into drains means that

the receiving waters for those drains end up introducing the medicines directly into the water bodies.

Where medicines are dumped into the soil without any lining, the medicines leach into the soil and may be able to contaminate the soil at least for some period of time. Some medicines have been found to be able to persist in the soil and, over time, are able to pollute ground water sources. Potentially, therefore, the medicines are able to leach into the surrounding soil. This means that medicines that are persistent in the soil have the opportunity, over time, to reach groundwater sources. These methods of disposal, thus, have the potential to contaminate groundwater.

5.1.3 Unregulated Disposal

The study showed that although 34% of community pharmacies do not dispose of their expired products, 66% do. Of those who do dispose of their products, only 13% dispose of them under the supervision of the FDA. The remaining 87% utilise methods that introduce the pharmaceuticals directly into environmental media. This is because the methods used are not environmentally friendly. When medicines are disposed of in such unregulated and indiscriminate ways, they end up in various environmental media and result in various effects on both plants and animals.

5.1.4 Effects of Water Resources and Ecosystems

Medicines that enter the environment, almost invariably, get into the surface water or ground water sources. They contaminate the water supply reducing both quantity and

quality of water resources. They may also become a source of toxin for aquatic organisms with then become sources through which these pharmaceuticals get into the food chain and impact the ecosystem negatively.

5.1.5 The Drug Disposal Flow Diagram

The DDFD provides a method of assessment by which the impact of the methods of disposal used can be evaluated. The tool looks at the disposal methods of participants in the pharmaceutical value chain. It provides information on the most impactful methods used and therefore allows for re-evaluation of the impact of disposal with time. This tool, thus, gives a sustainable method for implementing EPV particularly in resource constrained settings where there is a clear need for cost effectiveness of implemented methods.

5.2 Conclusion

One significant way by which pharmaceuticals enter the environment is the process of disposal of waste generally and unused medicines in particular. The regulatory framework governing the disposal of medicines does not adequately provide for the disposal of unused, unwanted or expired medicines. These medicines are therefore largely disposed in ways that do not support sustainable development. The methods of disposal currently used for the regulated disposal of medicines to not provide sufficient protection for the environment. They provide some short term protection against exposure of populations to air pollution. The measures, however, do not provide long term protection against exposure to chemicals or long term pollution of surface and ground water sources.

The methods used by individuals and institutions that do not utilise the regulated disposal create a real challenge for both short term and long term exposure. The methods introduce pharmaceuticals directly into the environment by pouring down drains, open burning and burying in the ground. These methods result in the direct introduction of pharmaceuticals into the environment. There are currently relatively large amounts of various categories of medicines which remain unused after dispensing to members of the public. These medicines are likely to be disposed of indiscriminately, polluting the water sources and making unavailable for use in the future.

When pharmaceuticals pollute surface water and ground water sources, they make these water sources unavailable for use, reducing both the quantity and quality of water supply. The pharmaceuticals also become toxic to aquatic organisms, poisoning them and reducing their populations. Some of these organisms may also accumulate the pharmaceuticals in various tissues and expose organism higher up the food chain to the pharmaceuticals. Exposure to small doses of pharmaceuticals may cause microorganisms to develop resistance to these pharmaceuticals and make infections caused by these microorganisms more difficult to treat in the future.

The DDFD effectively assesses the methods of disposal that are in place. In the study, the DDFD showed that 57% of the contamination takes place in the local area and drainage where the medicines are. The receiving waters take up 29% of the contamination. Targeting these areas with effective disposal methods will, thus, be cost effective in tackling the challenge of pharmaceuticals in the environment.

5.3 Recommendations

5.3.1 Disposal of Unused Medicines

The legal framework as in place currently does not provide sufficient protection for the environment with regard to the effects of medicines that get introduced as a result of disposal. In order to ensure sustainable development, there is the need to review the legal framework to provide properly for the disposal of products other than adulterated medicines or seized products. There is the need to provide for the disposal of unused and unwanted medicines which may be in the possession of all participants in the pharmaceutical value chain as well as consumers.

The personnel in the various government agencies that are responsible for and involved in the disposal of pharmaceuticals need comprehensive understanding of how pharmaceuticals can impact the environment. To this end, it is recommended that they undergo training which equips them with an in-depth understanding of the potential and actual effects of the pharmaceuticals on various pharmaceutical media. Such training could be incorporated into their orientation programmes that go with joining the relevant departments.

The procedures in place for the disposal of medicines do not provide sufficient protection to the environment. There is the need to ensure that all dump sites are engineered so as to prevent pharmaceuticals from leaching through the soil into the groundwater. The leachate collected from these landfills can then been treated to remove pharmaceuticals before being allowed to enter receiving waters. The practice of open burning should be

replaced with incineration to ensure that there is no chance of pollution of the environment by fumes from these open burning processes.

The disposal of liquid medicines directly into drains means that the medicines flow directly into receiving waters where they can cause all sorts of damage to aquatic organisms. These receiving waters also become the primary sources of water consumption for residents downstream. There is the need to ensure that liquid medicines are treated in WWTPs which are designed to remove pharmaceuticals before subsequent disposal into the receiving waters. There could also be specialised methods of incinerating these products to prevent the pollution of receiving waters.

5.3.2 Implementation of the Drug Disposal Flow Diagram

This study has shown that the clear majority of members of the public have unused and expired medicines in their possession. These medicines are almost always disposed of in ways that introduce them directly into the environment without any attenuation. The DDFD provides a method of evaluating the disposal practices and their impact on the environment. Utilising this tool at the national level will better inform policy on the most cost effective methods to be used when implementing EPV. The tool also provides a sustainable means of evaluating progress that may have been made in the implementation process. It will, therefore, help assess lessons learned and improve future methods of disposal.

5.4 Suggestions for Further Study

5.4.1 Presence and Persistence of Pharmaceuticals

Although investigations have been undertaken in other parts of the world to look into the actual responses of plants and animals to the presence of pharmaceuticals in their environment, very little has been done in Ghana in that regard.

a. There is the need for investigation into the types of pharmaceuticals that are present and persist in various environmental media in the country. Such research will influence policy on the ways of handling various types of medicines with particular focus on the ones that are found to be present and persistent.
b. There is also the need for comprehensive research into the effects of the presence and persistence of pharmaceuticals on various organisms.
c. There is a further need to look into how agriculturally relevant plants that are native to Ghana and Africa in general respond to the presence of pharmaceuticals in various environmental media.

5.4.2 DDFDs and Policy Design

The DDFD designed in this study is a model. In order to effectively utilise the information in effective policy design, there is the need for further research. Such research will provide give a clearer picture of the disposal of pharmaceuticals in the environment.

a. There is the need to extend of the interviews to include other practitioners in the pharmaceutical value chain. This will provide a clearer picture with respect to the disposal of PPCPs in the country.
b. There is also the need to increase the number of respondents interviewed during the administration of the questionnaires. such an increase will lead to inferential analyses of the practices undertaken by individuals in the disposal of their unused products. This will further provide relevant information on how to reduce and control the occurrence on PPCPs in water sources and other environmental media.
c. There is also the need to investigate the consumption levels in the veterinary sector to understand consumption patterns in animals.

The DDFD can then be designed with the information obtained from the upscaling. The diagram obtained may then be utilised in the preparation of policy directive and the design and implementation strategies in response to EPV challenges.

5.4.3 Health Delivery Practices

The disposal of products that remain unused with members of the public constitute a significant portion of the PPCPs found in the environment. Consumers usually obtain medications from health care outlets, whether medical or pharmaceutical. The quantities that are dispensed and used may be a reflection of the level of interaction between health care professionals and the consumers. There is the need for investigations into prescribing and dispensing practices to ascertain whether or not these practices can be improved to reduce the amounts of medicines left unused by attendants to various health care delivery

outlets.

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APPENDICES

Appendix A

Questionnaire to pharmacies on the handling and disposal of expired and unused medicines

PLEASE TICK IN THE APPROPRIATE BOX

Location Details

1. **Name of District:**
2. **Designation of District:**

   □ Metropolitan

   □ Municipal

   □ District
3. **Name of Area/Locality:**

4. **Designation of Area/Locality:**

□ Residential

□ Commercial

□ Industrial

5. **Description of Area/Locality:**

□ Rural

□ Urban

□ Peri-urban

RESPONDENT DETAILS 6.

Gender:

□ Male

□ Female

7. **Age:** ……..

8. **How many years have you been practicing as a pharmacist? …….**

EXPIRED AND UNUSED MEDICINES

9. **Have you ever had any expired or unused medicines in your facility?**

□ yes

□ no

10. **Have you ever disposed of unused and expired medicines from your facility?**

□ yes go to 11

□ no go to 22

DISPOSAL OF CLASS A AND CLASS B MEDICINES

Please indicate how unused or expired Class A and Class B medicines are disposed of in your pharmacy, whether they are received from your clients or they are from your stocks.

11. **Solid dosage forms such as tablets and capsules.**

□ thrown in the rubbish

□ thrown in the drain

□ buried in the ground

□ burnt

□ handed over to FDA for disposal

□ other (please specify)……..

12. **Liquid dosage forms such as syrups and suspensions.**

□ thrown in the rubbish

□ thrown in the drain

□ buried in the ground

□ burnt

□ handed over to FDA for disposal

□ other (please specify) ……..

13. **Semi-solid dosage forms such as creams and ointment.**

□ thrown in the rubbish

□ thrown in the drain

□ buried in the ground

□ burnt

□ handed over to FDA for disposal

□ other (please specify) ……..

DISPOSAL OF OTC MEDICINES

Please indicate how unused or expired OTCs are disposed of in your pharmacy, whether they are received from your clients or they are from your stocks.

14. **Solid dosage forms such as tablets and capsules.**

□ thrown in the rubbish

□ thrown in the drain

□ buried in the ground

□ burnt

□ handed over to FDA for disposal

□ other (please specify) ……..

15. **Liquid dosage forms such as syrups and suspensions.**

□ thrown in the rubbish

□ thrown in the drain

□ buried in the ground

□ burnt

□ handed over to FDA for disposal

□ other (please specify)……..

16. **Semi-solid dosage forms such as creams and ointment.**

□ thrown in the rubbish

□ thrown in the drain

□ buried in the ground

□ burnt

□ handed over to FDA for disposal

□ other (please specify) ……..

17. **If you do not hand over your expired medicines to FDA for disposal, will you be ready to incur some expenditure to ensure an environmentally friendly method of disposal of your medicines?**

□ yes

□ no

18. **If you answered yes to question 17, how much would you consider a reasonable annual fee for environmentally friendly disposal?……..**

19. **If you answered no to question 17, why not?**

.....

.....

DISPOSAL BY FDA

20. **Does your pharmacy incur any expenditure you hand over any medicines to FDA for disposal?**

□ disposal fee to the FDA.

□ transportation fee.

□ site fee at the land fill site.

□ other (please specify) …….

□ no, my facility does not incur in expenditure for disposal

21. **How does FDA dispose of unused or expired medicines?**

□ by crushing and burying medicines at land fill sites.

□ by open burning at land fill or other designated sites.

□ by incineration.

□ by pouring down the drain.

□ by flushing down the toilet

□ I do not know

□ other (please specify) …….

NON-DISPOSAL

22. **Why have you never disposed of expired or unused medicines from your facility?** □ We do not currently have a laid down procedure for the disposal of expired or unused medicines.

    □ we are not aware of the appropriate procedure for the disposal of expired medicines.

    □ we are yet to dispose of expired medicines.

    □ other (please specify) ……..

23. **How do you intend to dispose of any expired or unused medicines in your facility?**

    □ by putting them in the rubbish.

    □ by pouring them down the drain.

    □ by pouring them in the toilet.

    □ by burying them.

    □ by burning them.

    □ by handing them over to the FDA for disposal

    □ other (please specify) …….

24. **Will you be ready to incur some expenditure to ensure an environmentally friendly method of disposal of your medicines?**

    □ yes

    □ no

25. **If you answered yes to question 24, how much would you consider a reasonable annual fee for environmentally friendly disposal?**

    ……..

26. **If you answered no to question 24, why not?**

    .....

THANK YOU FOR YOUR TIME AND EFFORT.

Appendix B

Questionnaire to Consumers on Prescribing Practices and Handling of Unconsumed Medicines

Location Details

1. **Name of District:**
2. **Designation of District:**

    □ Metropolitan

□ Municipal

□ District

3. **Name of Area/Locality:**
4. **Designation of Area/Locality:**

□ Residential

□ Commercial

□ Industrial

5. **Description of Area/Locality:**

□ Rural

□ Urban

□ Peri-urban

Respondent Details

6. **Highest qualification:**

□ No educational qualification

□ JHS

□ SHS

□ "O" level

□ "A" level

□ Diploma

□ HND

□ Bachelors

□ Masters

□ PhD

□ Other (please specify).....

7. **Gender:**

□ Male

□ Female

8. **Age:** ……
9. **Where do you normally go to first when you are not feeling well?**

□ Hospital

□ Community pharmacy

□ Chemical seller

□ Herbal shop

Prescribing Encounters

10. **In your last encounter with a prescriber, what was the problem?**

    □ a recent illness **please move to questions 11 - 18**

    □ a chronic illness **please move to questions 19-23**

Recent Illness

11. **Allergic reactions are reactions that people get when they take some medicines or some type of food. These reactions include itching, runny nose, skin rashes etc. Did the prescriber have discussions with you on any allergic reactions you may have?**

    □ yes

    □ no

12. **Do you, in fact, have any allergic reactions?**

    □ yes

    □ no

13. **Did you discuss any other conditions you have apart from the one for which you went to see the prescriber?**

    □ yes

    □ no

14. **Did the prescriber find out from you if you were on any other medications?**

    □ yes

    □ no

15. **Were you, in fact, in any other medications?**

    □ yes

    □ no

16. **Were you told of the reason(s) you were being given the new medications?**

    □ yes

    □ no

17. **Did the prescriber inform you of the name(s) of the medications he/she was prescribing for you?**

    □ yes

    □no

18. **If yes, did he/she find out if you have taken those medications before?**

    □ yes

    □no

    Chronic Illness

19. **Did the prescriber have discussions with on whether you were able to take your previous medication as directed?**

    □ yes

    □ no

20. **Did you take your medications according to the instructions given?**

    □ yes

    □ no

21. **Did you have discussions on whether or not you had completed your previous medications?**

    □ yes

    □ no

22. **Did you, in fact, complete your previous medications?**

    □ yes

    □ no

23. **What action was taken with respect to your medications**

    □ Medications topped up

    □ Medications reviewed

    □ Medications replaced

24. **Did you get a prescription from the doctor?**

    □ yes

    □ no

25. **If yes, could you please show me the prescription?**

    Please identify the features present on the prescription (to be completed by interviewer)

    □ Name of Patient

    □ Age of Patient

    □ Weight of patient

    □ Names of medications

□ Dosage form of medications

□ Strength of medications

□ Dosage regimen of medications

□ Duration for which the medication is to be taken

□ Name of Prescriber

□ Signature of Prescriber

□ Contact of Prescriber

Medications

26. **Some people cannot take all their medication. Are you normally able to take all your medications?**

□ yes

□ no

27. **If you answered "no" to 26, what are the possible reasons why you are not able to take all your medications?**

□ After you get relief, I stop taking it until I feel uncomfortable again.

□ I try to use the medicine as long as possible, so I increase the interval between the doses.

□ the side effects of some medicines are so unbearable, I stop taking them.

□ I do not like taking medicines

□ I have a lot of medicines you take and so sometimes, I skip some of them

□ other (please specify) ……..

28. **Do you currently have any medications from a previous visit to a hospital or pharmacy?**

□ yes

□ no

29. **Do you have any medications stored for emergency use?**

□ yes

□ no

30. **Who is responsible for handling medicines in your home? .....**

31. **How do you normally deal with medications that are not consumed and are not expired?**

□ I pass them on to friends and family who may need it

□ I keep them to use another day

32. **How do you normally deal with medications which are tablets, capsules, etc that are not consumed and are expired?**

□ I throw them in the rubbish

□ I throw them in the drain

□ I bury them in the ground

□ I burn them

□ other (please specify) ……..

33. **How do you normally deal with medications which are syrups, suspensions, etc that are not consumed and are expired?**

□ I throw them in the rubbish

□ I flush them down the toilet

□ I pour down the drain

□ I pour on the ground

□ I bury them in the ground

□ I burn them

□ other (please specify) ……

34. **How do you normally deal with medications which are creams, ointments, etc that are not consumed and are expired?**

□ I throw them in the rubbish

□ I throw them in the drain

□ I bury them in the ground

□ I burn them

□ other (please specify) ……..

Thank you for your time and effort.

Appendix C

Questionnaire to Consumers on Dispensing Practices and Handling of Unconsumed and Expired Medicines

Location Details

1. **Name of District:**
2. **Designation of District:**

□ Metropolitan

□ Municipal

□ District

3. **Name of Area/Locality:**
4. **Designation of Area/Locality:**

□ Residential

□ Commercial

□ Industrial

5. **Description of Area/Locality:**

□ Rural

□ Urban

□ Peri-urban

Respondent Details

6. **Highest educational qualification:**

□ No educational qualification

□ JHS

□ SHS

□ "O" level

□ "A" level

□ Diploma

□ HND

□ Bachelors

□ Masters

□ PhD

□ Other (please specify).....

7. **Gender:**

□ Male

□ Female

8. **Age:** ……
9. **Where do you normally go to first when you are not feeling well?**

□ Hospital

□ Community pharmacy

□ Chemical seller

□ Herbal shop

Dispensing Encounters

10. **Where do you normally get your medications from?**

□ hospital/clinic pharmacy

□ community pharmacy

□ chemical seller

11. **During your last trip to the pharmacy, were you questioned about other medications you are taking?**

□ yes

□ no

12. **Did the staff in the pharmacy communicate with you in a language you understand?**

□ yes

□ no

13. **Were you given instructions on how you are to take the medications?**

□ yes

□ no

14. **Were you given the exact amount of medications for the period of time you are to take the medication?**

□ yes, I received the exact quantity

□ no, I received less than the exact quantity because I did not have sufficient funds

□ no, I received less because the facility did not have sufficient quantities

□ no, I received more than the exact quantity because they were not ready to supply the exact amount

□ no, I did not receive the exact quantity but they did not give me any reason.

15. **Were you given information on when to stop taking your medications?**

□ yes, when I feel better

□ yes, when the medication gets finished

□ yes, if I get any side effects

□ no, I was not told when to stop

16. **When will you stop taking the medications?**

□ when I feel better

□ when the medication gets finished

□ if I get any side effects

17. **Could you please show me the dispensed medication you received?**

Please identify the features present on the label of the dispensed medication (to be completed by interviewer)

□ Name of Patient

□ Name of medicine dispensed

□ Strength of active ingredient

□ Quantity of product dispensed

□ Complete dosage regimen in written and/ or graphic form

□ Duration of use

□ Name and address of dispensing facility and dispenser

□ Special instructions where applicable

□ Date of dispensing

18. **Did you get all the medications that were prescribed for you?**

□ yes

□ no

19. **If you answered "no" to 18, where did you get the remainder of your medications?**

□ from another pharmacy

□ from a chemical seller's facility

Medications

20. **Some people cannot take all their medication. Are you normally able to take all your medications?**

□ yes

□ no

21. **If you answered "no" to 20, what are the possible reasons why you are not able to take all your medications?**

□ After I get relief, I stop taking it until you feel uncomfortable again.

□ I try to use the medicine as long as possible, so I increase the interval between the doses.

□ the side effects of some medicines are so unbearable, I stop taking them.

□ I do not like taking medicines

□ I have a lot of medicines I take and so sometimes, I skip some of them

□ other (please specify) ……..

22. **Do you currently have any medications from a previous visit to a hospital or pharmacy?**

□ yes

□ no

23. **Do you have any medications stored up for emergency use?**

□ yes

□ no

24. **Who is responsible for handling medicines in your home?.....**

25. **How do you normally deal with medications that are not consumed and are not expired?**

□ I pass them on to friends and family who may need it

□ I keep them to use another day

□ I never have any; I complete all my medications

26. **How do you normally deal with medications which are tablets, capsules, etc that are not consumed and are expired?**

□ thrown in the rubbish

□ thrown in the drain

□ buried in the ground

□ burnt

□ other (please specify) ……..

27. **How do you normally deal with medications which are syrups, suspensions, etc that are not consumed and are expired?**

□ thrown in the rubbish

□ flushed down the toilet

□ poured down the drain

□ poured on the ground

□ other (please specify) ……

28. **How do you normally deal with medications which are creams, ointments, etc that are not consumed and are expired?**

□ thrown in the rubbish

□ thrown in the drain

□ buried in the ground

□ burnt

□ other (please specify) ……..

Thank you for your time and effort.

Appendix D

Participant Consent Form for Questionnaire on Prescribing and Dispensing Practices

Dear Participant,

This survey is conducted by Yvonne Yirenkyiwaa Esseku as part of her MPhil/PhD Pharmacology programme. We would like to interview you for about 20 minutes on matters concerning:

- How you handle returned and expired medicines in your facility.
- How you dispose of medicines which have expired in your facility.

This information is to help in understanding of the disposal of medicines.

All information you provide is confidential and will only be used for this research and not be shared with any other person. We will not put your name, address and other personal identification information on the questionnaire. In order to contact you again if we need further clarification of any information, a code will be put on the questionnaire.

Please note that you may stop the survey at any time and you are also free to refuse to answer any question. If you have any questions about this survey, you may ask me or contact Yvonne Yirenkyiwaa Esseku on 0208159943.

When you sign this form, it means you understand what will be expected of you and that you are willing to participate in this survey.

This consent form was read by:

□ Respondent

□ Interviewer

Decision of Respondent:

□ Agreed and signed

□ Refused

Respondent: .....

Interviewer: ..... Date: .....

Appendix E

Participant Consent Form for Questionnaire on Prescribing and Dispensing Practices and excess Pharmaceuticals

Dear Participant,

This survey is conducted by Yvonne Yirenkyiwaa Esseku as part of her MPhil/PhD programme. We would like to interview you for about 20 minutes on matters concerning:

- Your encounters with prescribers,
- Your encounters with dispensers,
- How you handle unconsumed medicines.

This information is to help in understanding how people get and use medicines.

All information you provide is confidential and will only be used for this research and not be shared with any other person. We will not put your name, address and other personal identification information on the questionnaire. In order to contact you again if we need further clarification of any information, a code will be put on the questionnaire.

Please note that you may stop the survey at any time and you are also free to refuse to answer any question. If you have any questions about this survey, you may ask me or contact Yvonne Yirenkyiwaa Esseku on 0208159943.

When you sign this form, it means you understand what will be expected of you and that you are willing to participate in this survey.

This consent form was read by:

□ Respondent

□ Interviewer

Decision of Respondent:

□ Agreed and signed

□ Refused

Respondent: .....

Interviewer: ..... Date: .....

Appendix F

Discussion Guide for FDA on the environmental effects of Chemicals and APIs used in Pharmaceuticals and Personal Care Products Interviewee Details

Venue:

Date:

Time:

Name of officer interviewed:

Position of officer in institution and relation to the collection of unused medicines:

Legal framework for pharmaceuticals and personal care products

What is the legal framework governing the regulation of the pharmaceutical industry in Ghana?

What is the legal framework governing the regulation of the personal care product industry in Ghana?

Manufacturing

What is the role of the FDA in the regulation of the manufacturing sector of the pharmaceutical and personal care industry?

How is the effluent from manufacturing concerns handled?

Are manufacturing concerns required to treat the discharge resulting from washing during manufacturing? Is there a form of monitoring system in place?

Are there any guidelines for environmental risk assessment with respect to chemicals and APIs used in the manufacturing sector for pharmaceuticals and personal care products? Please give details.

Importation

What is the role of FDA in the regulation of imported pharmaceuticals in Ghana?

Are there any guidelines for environmental risk assessment with respect to imported pharmaceuticals and personal care products? Please give details if applicable.

Disposal of unconsumed medicines

What is the role of FDA with respect to the disposal of unconsumed medicines in Ghana? Please explain with regards to

1. Importers/manufacturers
2. Wholesalers/distributers
3. Hospitals/pharmacies
4. Consumers/households

How are unused and expired medicines generally disposed of in the country? Please describe in detail.

What are the different sources from which FDA disposes of unused and expired medicines?

How often does the FDA supervise the disposal of unused or expired medicines?

Are there any special measures to deal with any environmental outcomes which may arise from the disposal methods used?

Does the authority collaborate with other agencies with respect to the disposal of medicine? If yes, please explain the collaboration.

Appendix G

Discussion Guide for the Environmental Protection Agency on the Treatment and Disposal of Pharmaceuticals and Personal Care Products

Interviewee Details Venue:

Date:

Time:

Name of officer interviewed:

Position of officer in institution and relation to the disposal of medicines:

Questions for Discussion

What is the legal framework governing the treatment and disposal of pharmaceuticals and personal care products in Ghana?

How are expired and unused medicines and personal care products generally disposed of in the country?

How are effluents from PPCP manufacturing concerns dealt with?

Are there any guidelines for environmental risk assessment with respect to chemicals and APIs used in the manufacturing sector for pharmaceuticals and personal care products? Please give details.

Are there any treatment plants in place designed for taking out Active ingredients of PPCPs?

What is the role of the Agency when it comes to the disposal of PPCPs from the following?

Manufacturers / importers

- Wholesalers and distributors
- Retailers
- Consumers – institutions and individuals

Are there any guidelines for the handling of APIs for disposal?

How are unused medicines stored by the institution? Special storage facilities? Please describe the relevant features of such facilities, if any.

Does the institution receive unexpired medicines? If so, how are those medicines dealt with?

How long are unused PPCPs usually kept before disposal?

How are PPCPs and chemical medical waste disposed of? Please describe in detail.

Are there any special measures to deal with actual or potential environmental outcomes which may arise from the disposal methods used?

What are the cost implications? How are the costs of disposal defrayed?

Does the Agency collaborate with other national agencies with respect to the disposal of PPCPs?

What are the dangers of indiscriminate and unregulated disposal of PPCPs to the environment and the society?

Are there any measures put in place to tackle the effects of indiscriminate and unregulated disposal of PPCPs?

Appendix H

Discussion Guide for EHSD on the disposal and treatment of solid and liquid waste vis-a-vis excreted pharmaceuticals

Interviewee Details Venue:

Date:

Time:

Name of officer interviewed:

Position of officer in institution and relation to the collection of unused medicines:

Questions for Discussion

What is the legal framework governing the disposal of solid and liquid waste in Ghana?

What are the national guidelines on the treatment of liquid and solid waste in Ghana?

Do these guidelines provide for the elimination of active ingredients in pharmaceuticals and personal care products which may be present in the waste to be treated? Please explain.

Liquid Waste

How many WWTPs are currently functioning in the country? Please comment on their current condition in terms of state of repair and proportion liquid waste treated by these plants.

Is the Department involved in the operation of the WWTPs? To what extent?

What percentage of liquid waste produced in Ghana is effectively treated in the functioning WWTPs?

How are the excesses not accommodated in these WWTPs taken care of?

Is the effluent of WWTPs tested for the presence of pharmaceuticals or any other chemicals before being discharged into receiving water bodies? Please explain.

Is there a strategy in place for dealing black water which may be present in drains? Please explain.

Solid Waste

How many engineered landfills are currently functioning in the country? Please comment on their current condition in terms of state of repair and proportion solid waste treated by these plants.

Is the Department involved in the operation of landfills? To what extent?

What percentage of solid waste produced in Ghana is effectively treated in the functioning engineered landfills?

How are the excesses not accommodated in these landfills taken care of?

Is the effluent of engineered landfills tested for the presence of pharmaceuticals or any other chemicals before being discharged into receiving water bodies? Please explain.

Appendix J

Discussion Guide for Pharmacy Council on the environmental effects of Chemicals and APIs used in Pharmaceuticals and Personal Care Products

Interviewee Details

Venue:

Date:

Time:

Name of officer interviewed:

Position of officer in institution and relation to the collection of unused medicines:

The Role of Pharmacy Council in the delivery of pharmaceutical service

What is the legal framework governing the delivery of pharmaceutical care delivery?

What is the procedure if a person desires to provide pharmaceutical care services?

What does the delivery of pharmaceutical care service entail?

Are there any minimum requirements for establishing a facility for delivery of pharmaceutical service? Please give as much detail as possible.

Are there any monitoring and evaluation plans in place for ensuring that the standards are adhered to? Please explain in detail.

Does Pharmacy Council have any role in the disposal of unused and expired medicines and other personal care products? Please explain.

Is there a policy position on the potential and actual effects of pharmaceuticals in the environment whether or not consumed? Please explain.

Appendix K

Calculation of Amounts of Pharmaceuticals Discharged into the Sea, River Bodies and Unused Land Patches

Capacity of Vacuum Trucks discharging: 5 – 15 m^3

Number of vacuum trucks discharging daily: 150 – 200 No.

Working average of trucks: 10 m^3

Average number of trucks discharging daily: 175 No.

Average quantities discharged daily:

10 X 175 = 1750 m^3

Average quantities discharged annually:

1750 m^3 X 365 = 638,750 m^3